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COMMISSION ON LABORATORY ACCREDITATION

Laboratory Accreditation Program

HEMATOLOGY - COAGULATION CHECKLIST

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HEMATOLOGY - COAGULATION

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SUMMARY OF CHANGES
HEMATOLOGY - COAGULATION Checklist
9/27/2007 Edition

The following questions have been added, revised, or deleted in this edition of the checklist, or in the two editions immediately previous to this one.

If this checklist was created for a reapplication, on-site inspection or self-evaluation it has been customized based on the laboratory's activity menu. The listing below is comprehensive; therefore some of the questions included may not appear in the customized checklist. Such questions are not applicable to the testing performed by the laboratory.

Note: For revised checklist questions, a comparison of the previous and current text may be found on the CAP website. Click on Laboratory Accreditation, Checklists, and then click the column marked Changes for the particular checklist of interest.

NEW Checklist Questions

<u>Question</u>	<u>Effective Date</u>
HEM.05075	09/27/2007
HEM.21575	09/27/2007
HEM.35347	09/27/2007
HEM.35759	09/27/2007
HEM.35762	09/27/2007
HEM.35765	09/27/2007
HEM.35768	09/27/2007
HEM.35822	09/27/2007
HEM.35892	09/27/2007
HEM.35895	09/27/2007
HEM.35898	09/27/2007
HEM.35901	09/27/2007
HEM.35909	09/27/2007
HEM.35910	09/27/2007
HEM.35911	09/27/2007
HEM.35912	09/27/2007
HEM.35913	09/27/2007
HEM.35914	09/27/2007
HEM.35915	09/27/2007
HEM.35916	09/27/2007
HEM.35918	09/27/2007
HEM.35919	09/27/2007
HEM.35920	09/27/2007
HEM.35921	09/27/2007
HEM.35922	09/27/2007
HEM.35923	09/27/2007
HEM.35924	09/27/2007

HEM.17385	10/31/2006
HEM.18038	10/31/2006
HEM.18691	10/31/2006
HEM.19344	10/31/2006
HEM.23453	10/31/2006
HEM.23476	10/31/2006
HEM.23787	10/31/2006
HEM.37905	10/31/2006
HEM.37910	10/31/2006
HEM.37915	10/31/2006
HEM.37923	10/31/2006
HEM.37925	10/31/2006
HEM.37930	10/31/2006
HEM.37935	10/31/2006
HEM.38003	10/31/2006
HEM.38004	10/31/2006
HEM.38005	10/31/2006
HEM.38006	10/31/2006
HEM.38007	10/31/2006
HEM.38008	10/31/2006
HEM.13466	04/06/2006
HEM.16732	04/06/2006
HEM.20143	04/06/2006
HEM.20146	04/06/2006

REVISED Checklist Questions

<u>Question</u>	<u>Effective Date</u>
HEM.10185	09/27/2007
HEM.34400	09/27/2007
HEM.35832	09/27/2007
HEM.23360	10/31/2006
HEM.34687	10/31/2006
HEM.34798	10/31/2006
HEM.35100	10/31/2006
HEM.37960	10/31/2006
HEM.37991	10/31/2006
HEM.38002	10/31/2006
HEM.21000	04/06/2006
HEM.23430	04/06/2006
HEM.35851	04/06/2006

DELETED Checklist Questions

<u>Question</u>	<u>Effective Date</u>
HEM.10200	09/27/2007
HEM.22666	10/31/2006
HEM.37187	10/31/2006
HEM.20250	04/06/2006
HEM.20300	04/06/2006
HEM.20350	04/06/2006
HEM.34150	04/06/2006

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CONTINUING EDUCATION INFORMATION

Beginning January 2008, you may earn continuing education credits (CME/CE) by completing an online Inspection Preparation activity that includes review of this checklist.

Prior to reviewing the checklist, log on to the CAP Web site at www.cap.org <<http://www.cap.org>>, click the Education Programs tab, then select Laboratory Accreditation Program (LAP) Education Activities, and Inspection Preparation for complete instructions and enrollment information.

IMPORTANT: The contents of the Laboratory General Checklist are applicable to the Hematology and Coagulation section of the laboratory.

NOTE: This Checklist now includes Body Fluid tests (Clinical Microscopy), as well as sections on semen analysis, previously located in the Urinalysis Checklist.

INSPECTION TECHNIQUES – KEY POINTS

I. READ – OBSERVE – ASK – the three methods of eliciting information during the inspection process. These three methods may be used throughout the day in no particular order. Plan the inspection in a way that allows adequate time for all three components.

READ = Review of Records and Documents

Document review verifies that procedures and manuals are complete, current, available to staff, accurate and reviewed, and describe good laboratory practice. Make notes of any questions you may have, or processes you would like to observe as you read the documentation.

OBSERVE – ASK = Direct Observation and Asking Questions

Observing and asking questions accomplish the following:

1. Verifies that the actual practice matches the written policy or procedure
2. Ensures that the laboratory processes are appropriate for the testing performed

3. Ensures that outcomes for any problem areas, such as PT failures and issues/problems identified through the quality management process, have been adequately investigated and resolved
4. Ensures that previously cited deficiencies have been corrected

Use the following techniques:

- **Observe laboratory practices** – look at what the laboratory is actually doing. Compare the written policy/procedure to what you actually observe in the laboratory to ensure the written policy/procedure accurately reflects laboratory practice. Note if practice deviates from the documented policies/procedures.
- **Ask open ended, probing questions** – these are starting points that will allow you to obtain large amounts of information, and help you clarify your understanding of the documentation you've seen and observations you've made. This eliminates the need to ask every single checklist question, as the dialogue between you and the laboratory may address multiple checklist questions.
 - Ask open-ended questions that start with phrases such as “show me how...” or “tell me about ...” or “what would you do if...”. By asking questions that are open-ended, or by posing a hypothetical problem, you will avoid “cookbook” answers. For example, ask “Could you show me the specimen transport policy and show me how you ensure optimum specimen quality?” This will help you to determine how well the technical staff is trained, whether or not they are adhering to the lab's procedures and policies, and give you a feel for the general level of performance of the laboratory.
 - Ask follow-up questions for clarification. Generally, it is best not to ask the checklist questions verbatim. For example, instead of asking the checklist question “Is there documentation of corrective action when control results exceed defined tolerance limits?” ask, “What would you do if the SD or CV doubles one month?” A follow-up probing question could be, “What would you do if you could not identify an obvious cause for the change in SD or CV?”

II. Evaluate Selected Specimens and Tests in Detail

For the Laboratory General Checklist: Follow a specimen through the laboratory. By following a specimen from collection to test result, you can cover multiple checklist questions in the Laboratory General checklist: questions on the specimen collection manual; phlebotomy; verbal orders; identification of patients and specimens; accessioning; and result reporting, including appropriate reference ranges, retention of test records, maintaining confidentiality of patient data, and proper handling of critical results and revisions to reports.

For the individual laboratory sections: Consult the laboratory's activity menu and focus on tests that potentially have the greatest impact on patient care. Examples of such tests include HIV antibodies, hepatitis B surface antigen, urine drugs of abuse, quantitative beta-hCG, cultures of blood or CSF, acid-fast cultures, prothrombin time and INR reporting, and compatibility testing and unexpected antibody detection. Other potentially high-impact tests may be identified by looking at very high or low volume tests in the particular laboratory, or problems identified by reviewing the Variant Proficiency Testing Performance Report.

To evaluate preanalytic and postanalytic issues: Choose a representative specimen and “follow” the specimen through the laboratory or section of the laboratory, reviewing appropriate records in the preanalytic and postanalytic categories.

To evaluate analytic processes: Choose 2 or 3 analytes and perform a comprehensive review of records, including procedure manuals, quality control and proficiency testing records, instrument maintenance records and method performance validations for the last 2 years, selecting timeframes at the beginning, mid-point, and end of this timeframe. Compare instrument print-outs to patient reports and proficiency testing results to ensure accurate data entry. If problems are identified, choose additional tests or months to review.

III. Verify that proficiency testing problem have been resolved: From the inspector’s packet, review the Variant PT Performance Report that identifies, by analyte, all of the PT scores below 100%. Correlate any PT problems to QC or maintenance records from the same time period. Be thorough when reviewing these representative records, selecting data from the beginning, middle and end of the period since the last on-site inspection.

IV. Review correction of previous deficiencies: Review the list of deficiencies from the previous on-site inspection provided in the inspector’s packet. Ensure that they have been appropriately addressed.

Certain requirements in this checklist are now different for waived tests, versus nonwaived tests. Please refer to the checklist sections on Quality Management and Quality Control; and Reagents. The current list of tests waived under CLIA-88 may be found at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm>.

LABORATORY SAFETY

The inspector should review relevant questions from the Safety section of the Laboratory General checklist, to assure that the hematology laboratory is in compliance. Please elaborate upon the location and the details of each deficiency in the Inspector's Summation Report.

PROFICIENCY TESTING

Definitions:

Proficiency testing (PT) is defined as determination of laboratory testing performance by means of interlaboratory comparisons, in which a PT program periodically sends multiple specimens to members of a group of laboratories for analysis and/or identification; the program then compares each laboratory’s results with those of other laboratories in the group and/or with an assigned value... (adapted from Clinical Laboratory Standards Institute Harmonized Terminology Database; available at <http://www.nccls.org/>).

Alternative assessment is defined as determination of laboratory testing performance by means other than PT--for example, split-sample testing, testing by a different method, *etc.*

****NEW**** **09/27/2007**

HEM.05075 **Phase I** **N/A** **YES** **NO**

Does the laboratory’s current CAP Activity Menu accurately reflect the testing performed?

NOTE: An accurate Activity Menu is required to properly assess a laboratory’s compliance with proficiency testing requirements. The accuracy of the Activity Menu can be assessed by inquiry of responsible individuals, and by examination of the laboratory’s test requisition(s), computer order screens, procedure manuals, or patient reports. All tests performed by the laboratory should be listed on the Activity Menu, and visa versa.

If tests are identified that are not included on the laboratory’s test menu, the inspector should contact the CAP (800-323-4040) for instructions.

Please note that unusual or esoteric tests performed in the laboratory section may not be specifically listed on the laboratory's activity menu but may be identified on the activity menu as a miscellaneous code. Further information may be found with the laboratory's instrumentation list. Some activities are also included on the Master Activity Menu using more generic groupings or panels instead of listing the individual tests. The Master Activity Menu represents only those analytes that are directly measured. Calculations are not included.

COMMENTARY:

N/A

REFERENCE: Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 2004(Oct 1): 985 [42CFR493.51].

HEM.10150 **Phase II** **N/A** **YES** **NO**

Does the laboratory participate in the appropriate required CAP Surveys or another proficiency testing (PT) program accepted by CAP for the patient testing performed?

NOTE: The list of analytes for which CAP requires proficiency testing is available on the CAP website [<http://www.cap.org/>] or by phoning 800-323-4040 (or 847-832-7000), option 1. A laboratory's participation in proficiency testing must include all analytes on this list for which it performs patient testing. Participation in proficiency testing may be through CAP Surveys or another proficiency testing provider accepted by CAP. Laboratories will not be penalized if they are unable to participate in an oversubscribed program. If unable to participate, however, the laboratory must implement an alternative assessment procedure for the affected analytes. For regulated analytes, if the CAP and CAP-accepted PT programs are oversubscribed, CMS requires the laboratory to attempt to enroll in another CMS-approved PT program.

For purposes of photomicrograph identification in CAP Surveys, it is strongly recommended that the current CAP Surveys Hematology Glossary (Blood Identification section) be readily available to the bench technologist in the section.

COMMENTARY:

N/A

REFERENCES: 1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 1992(Feb 28):7146 [42CFR493.801]; 2) Westgard JO, *et al*. Laboratory precision performance. State of the art versus operating specifications that assure the analytical quality required by clinical laboratory improvement amendments proficiency testing. *Arch Pathol Lab Med*. 1996;120:621-625; 3) Cembrowski GS, *et al*. Pump up your PT IQ. *Med Lab Observ*. 1996;28:46-51; 4) Streichman S, *et al*. External quality assessment scheme for hematological laboratories in Israel. *Lab Hematol*. 1996;2:99-105; 5) Roussi J, *et al*. Lupus anticoagulants: first French interlaboratory etalonorme survey. *Am J Clin Pathol*. 1996;105:788-793; 6) Lafferty J, *et al*. Proficiency testing of hemoglobinopathy techniques in Ontario laboratories. *Am J Clin Pathol*. 1997;107:567-575; 7) NCCLS. *Continuous Quality Improvement: Integrating Five Key Quality System Components; Approved Guideline—Second Edition*. NCCLS document GP22-A2 (ISBN 1-56238-552-6). NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2004; 8) Jennings I, *et al*. Potentially clinically important inaccuracies in testing for the lupus anticoagulant: an analysis of results from three surveys of the UK National External Quality Assessment Scheme (NEQAS) for blood coagulation. *Thromb Haemost*. 1997;77:934-973; 9) England JM, *et al*. Guidelines for organisation and management of external quality assessment using proficiency testing. Expert Panel on Cytometry of the International Council for Standardization in Haematology. *Int J Haematol*. 1998;68:45-52; 10) College of American Pathologists, Commission on Laboratory Accreditation. Standards for laboratory accreditation; standard III. Northfield, IL: CAP, 1998; 11) Brien WF, *et al*. Calculation vs calibration curve for INR determination. Results of an interlaboratory proficiency scheme. *Am J Clin Pathol*. 1999;111:193-201; 12) Cunningham MT, *et al*. A method for proficiency testing of small peer groups in the College of American Pathologists coagulation surveys. *Arch Pathol Lab Med*. 1999;123:199-205; 13) College of American Pathologists. Surveys hematology glossary. Northfield, IL: CAP, 1999:1-26.

HEM.10160**Phase II****N/A YES NO**

For tests for which CAP does not require PT, does the laboratory at least semiannually 1) participate in external PT, or 2) exercise an alternative performance assessment system for determining the reliability of analytic testing?

NOTE: Appropriate alternative performance assessment procedures may include: split sample analysis with reference or other laboratories, split samples with an established in-house method, assayed material, regional pools, clinical validation by chart review, or other suitable and documented means. It is the responsibility of the laboratory director to define such alternative performance assessment procedures, as applicable, in accordance with good clinical and scientific laboratory practice. Participation in ungraded/educational proficiency testing programs also satisfies this checklist question.

Semiannual alternative assessment must be performed on tests for which PT is not available.

The list of analytes for which CAP requires proficiency testing is available on the CAP website [<http://www.cap.org/>] or by phoning 800-323-4040 (or 847-832-7000), option 1.

COMMENTARY:

N/A

REFERENCES: 1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 2003(Jan 24):7184 [42CFR493.1236(c)(1)]; 2) Shahangian S, *et al*. A system to monitor a portion of the total testing process in medical clinics and laboratories. Feasibility of a split-specimen design. *Arch Pathol Lab Med*. 1998;122:503-511; 3) NCCLS. *Assessment of Laboratory Tests When Proficiency Testing is Not Available; Approved Guideline*. NCCLS document GP29-A (ISBN 1-56238-479-1). NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2002.

HEM.10170**Phase II****N/A YES NO**

Does the laboratory integrate all proficiency testing samples within the routine laboratory workload, and are those samples analyzed by personnel who routinely test patient samples, using the same primary method systems as for patient samples?

NOTE: Replicate analysis of proficiency samples is acceptable only if patient specimens are routinely analyzed in the same manner. With respect to morphologic examinations (identification of cell types and microorganisms; review of electrophoretic patterns, etc.), group review and consensus identifications are permitted only for unknown samples that would ordinarily be reviewed by more than one person in an actual patient sample.

If the laboratory uses multiple methods for an analyte, proficiency samples should be analyzed by the primary method. The educational purposes of proficiency testing are best served by a rotation that

allows all technologists to be involved in the proficiency testing program. Proficiency testing records must be retained and can be an important part of the competency and continuing education documentation in the personnel files of the individuals. In the specific case of blood film photomicrographs, reported identifications must be made by a single individual who normally performs such identifications in patient samples. Responsibility for identifications should be rotated over time among all staff that render morphologic assessments in clinical samples. Group review and consensus identifications are permitted only for those unknown samples that would ordinarily be reviewed by more than one person in an actual patient sample. When external proficiency testing materials are not available, the semi-annual alternative performance assessment process should also be integrated within the routine workload, if practical.

COMMENTARY:

N/A

REFERENCES: 1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 1992(Feb 28):7146 [42CFR493.801(b)]; 2) Shahangian S, *et al*. Toward optimal PT use. *Med Lab Observ*. 2000;32(4):32-43.

****REVISED**** **09/27/2007**

HEM.10185 **Phase II** **N/A YES NO**

Is there ongoing evaluation of PT and alternative assessment results, with prompt corrective action taken for unacceptable results?

NOTE: Compliance with this item can be examined by selecting a sample of PT evaluation results and alternative assessment records. Special attention should be devoted to unacceptable results. Compliance requires that all of the following are true:

1. *There is documented evidence of ongoing review of all PT reports and alternative assessment results by the laboratory director or the director's designee. Reviews should be completed within one month of the date reports and results become available to the laboratory.*
2. *All "unacceptable" PT results and alternative assessment test result have been investigated.*
3. *Corrective action has been initiated for all unacceptable PT and alternative assessment results. Corrective action is appropriate to the nature and magnitude of the problem; it might consist of staff education, instrument recalibration, change in procedures, institution of new clerical checks, discontinuation of patient testing for the analyte or discipline in question, or other appropriate measures.*
4. *Primary records related to PT and alternative assessment testing are retained for two years (unless a longer retention period is required elsewhere in this checklist for specific analytes or disciplines). These include all instrument tapes, work cards,*

computer printouts, evaluation reports, evidence of review, and documentation of follow-up/corrective action.

COMMENTARY:

N/A

REFERENCES: 1) Ehrmeyer SS, *et al.* Use of alternative rules (other than the 1-2s) for evaluating interlaboratory performance data. *Clin Chem.* 1988;34:250-256; 2) Klee GG, Forsman RW. A user's classification of problems identified by proficiency testing surveys. *Arch Pathol Lab Med.* 1988;112:371-373; 3) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 1992(Feb 28):7173 [42CFR493.1407(e)(4)(iv)]; 4) Clinical and Laboratory Standards Institute (CLSI). *Using Proficiency Testing to Improve the Clinical Laboratory; Approved Guideline—Second Edition.* CLSI document GP27-A2 (ISBN 1-56238-632-8). Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2007; 5) Shahangian S, *et al.* Toward optimal PT use. *Med Lab Observ.* 2000;32(4):32-43; 6) Zaki Z, *et al.* Self-improvement by participant interpretation of proficiency testing data from events with 2 to 5 samples. *Clin Chem.* 2000;46:A70.

****NEW****

04/06/2006

HEM.13466

Phase II

N/A YES NO

Is there a policy that prohibits interlaboratory communication about proficiency testing samples until after the deadline for submission of data to the proficiency testing provider?

COMMENTARY:

N/A

REFERENCES: 1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 1992(Feb 28):7146 [42CFR493.801(b)(3)]; 2) Bierig JR. Comparing PT results can put a lab's CLIA license on the line. Northfield, IL: College of American Pathologists *CAP Today.* 2002;16(2):84-87.

****NEW****

04/06/2006

HEM.16732

Phase II

N/A YES NO

Is there a policy that prohibits referral of proficiency testing specimens to another laboratory?

NOTE: *Under CLIA-88 regulations, there is a strict prohibition against referring proficiency testing specimens to another laboratory. In other words, the laboratory may not refer a proficiency testing*

NOTE: The QM/QC program in the hematology laboratory must be clearly defined and documented. The program must ensure quality throughout the preanalytic, analytic, and post-analytic (reporting) phases of testing, including patient identification and preparation; specimen collection, identification, preservation, transportation, and processing; and accurate, timely result reporting. The program must be capable of detecting problems in the laboratory's systems, and identifying opportunities for system improvement. The laboratory must be able to develop plans of corrective/preventive action based on data from its QM system.

All QM questions in the Laboratory General Checklist pertain to the hematology laboratory.

COMMENTARY:

N/A

REFERENCES: 1) NCCLS. *Application of a Quality Management System Model for Laboratory Services; Approved Guideline—Third Edition*. NCCLS document GP26-A3 (ISBN 1-56238-553-4). NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2004; 2) NCCLS. *A Quality Management System Model for Health Care; Approved Guideline—Second Edition*. NCCLS document HS1-A2 (ISBN 1-56238-554-2). NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2004.

HEM.20020

Phase II

N/A YES NO

Is there a documented procedure(s) describing methods for patient identification, patient preparation, specimen collection and labeling, specimen preservation, and conditions for transportation, and storage before testing, consistent with good laboratory practice?

COMMENTARY:

N/A

REFERENCES: 1) Boos MS, *et al*. Temperature- and storage-dependent changes in hematologic variables and peripheral blood morphology. *Am J Clin Pathol*. 1998;110:537; 2) Wood BL, *et al*. Refrigerated storage improves the stability of the complete blood cell count and automated differential. *Am J Clin Pathol*. 1999;112:687-695; 3) Jense R, Fritsma GA. Preanalytical variables in the coagulation laboratory. *Advance/Laboratory*. 2000;9(7):90-94.

HEM.20035

Phase II

N/A YES NO

Are tolerance limits (numeric and/or non-numeric) fully defined and documented for all hematology and coagulation control procedures?

NOTE: The goal is to have scientifically valid, logical "action limits" for quality control procedures that promptly alert the technologist of the need for immediate evaluation of the particular assay, including initiation of corrective action, before release of patient results.

COMMENTARY:

N/A

HEM.20050

Phase II

N/A YES NO

For numeric QC data, are Gaussian or other quality control statistics (e.g., SD and CV) calculated at specified intervals to define analytic imprecision?

NOTE: For CBC data where stabilized whole blood is not used for quality control, such statistics may be generated from previous patient samples using the standard deviation of duplicate pairs.

COMMENTARY:

N/A

REFERENCES: 1) Mukherjee KL. Introductory mathematics for the clinical laboratory. Chicago, IL: American Society of Clinical Pathology, 1979:81-94; 2) Barnett RN. Clinical laboratory statistics, 2nd ed. Boston, MA: Little, Brown, 1979; 3) Weisbrodt IM. Statistics for the clinical laboratory. Philadelphia, PA: JB Lippincott, 1985; 4) Matthews DF, Farewell VT. Understanding and using medical statistics. New York, NY: Karger, 1988; 5) Cembrowski GS, *et al.* An optimized quality control procedure for hematology analyzers with the use of retained patient specimens. *Am J Clin Pathol.* 1988;89:203-210; 6) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2003(Jan 24):7146 [42CFR493. 1256(d)(10)(i)]; 7) Ross JW, Lawson NS. Analytic goals, concentrations relationships, and the state of the art for clinical laboratory precision. *Arch Pathol Lab Med.* 1995;119:495-513; 8) NCCLS. *Laboratory Statistics—Standard Deviation; A Report.* NCCLS document EP13-R (ISBN 1-56238-277-2). NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087, 1995; 9) Clinical and Laboratory Standards Institute (CLSI). *Statistical Quality Control for Quantitative Measurement Procedures: Principles and Definitions; Approved Guideline—Third Edition.* CLSI document C24-A3 (ISBN 1-56238-613-1). Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2006.

HEM.20070

Phase II

N/A YES NO

Does the laboratory have an action protocol when data from precision statistics change significantly from previous data?

NOTE: As an example, if the laboratory's normal-level commercial control usually yields a monthly CV of 2% for WBC, but the most recent month shows a 4% CV, then something has caused increased

imprecision, and investigation with documentation is required. Similarly, if the monthly SD for MCV by moving averages is typically around 1.8 fL, but now is at 3.1 fL, the laboratory must find a cause for this shift and take action, if indicated. Finally, if commercially sponsored interlaboratory QC data for the same control lot and instrument model show SD/CV values markedly smaller or larger than the peer group, an explanation is required.

COMMENTARY:

N/A

HEM.20120 Phase II

N/A YES NO

Are control specimens tested in the same manner and by the same personnel as patient samples?

It is implicit in quality control (QC) that control specimens are tested in the same manner as patient/client specimens. Moreover, QC specimens must be analyzed by personnel who routinely perform patient/client testing - this does not imply that each operator must perform QC daily, so long as each instrument and/or test system has QC performed at required frequencies, and all analysts participate in QC on a regular basis. To the extent possible, all steps of the testing process must be controlled, recognizing that pre-analytic and post-analytic variables may differ from those encountered with patient/clients.

COMMENTARY:

N/A

REFERENCE: Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 2003(Jan 24):7166 [42CFR493.1256(d)(8)].

HEM.20140 Phase II

N/A YES NO

Are the results of controls verified for acceptability before reporting results?

NOTE: It is implicit in QC logic that patient test results are not reported when controls do not yield acceptable results. When an unacceptable QC result is obtained, patient/client test results obtained since the last acceptable test run must be re-evaluated to determine if there is a significant clinical difference in patient/client results.

COMMENTARY:

N/A

REFERENCE: Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 2003(Jan 24):7166 [42CFR493.1256(f)], and 2003(Oct 1):1046[42CFR493.1282(b)(2)].

****NEW****

04/06/2006

HEM.20143

Phase II

N/A YES NO

Is there documentation of corrective action when control results exceed defined acceptability limits?

NOTE: Patient test results obtained in an analytically unacceptable test run or since the last acceptable test run must be re-evaluated to determine if there is a significant clinical difference in patient/client results. Re-evaluation may or may not include re-testing patient samples, depending on the circumstances.

Even if patient samples are no longer available, test results can be re-evaluated to search for evidence of an out-of-control condition that might have affected patient results. For example, evaluation could include comparison of patient means for the run in question to historical patient means, and/or review of selected patient results against previous results to see if there are consistent biases (all results higher or lower currently than previously) for the test(s) in question).

COMMENTARY:

N/A

REFERENCE: Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 2003(Oct 1):1046[42CFR493.1282(b)(2)].

****NEW****

04/06/2006

HEM.20146

Phase II

N/A YES NO

Are quality control data reviewed and assessed at least monthly by the laboratory director or designee?

COMMENTARY:

N/A

NOTE: The CAP does NOT require supervisory review of all test results before or after reporting to patient records. Rather, this question is intended to address only that situation defined under CLIA-88 for "high complexity testing" performed by trained high school graduates qualified under 42CFR493.1489(b)(5) when a qualified general supervisor is not present.

COMMENTARY:

N/A

REFERENCE: Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 1992(Feb 28):7182 [42CFR493.1463(a)(3) and 42CFR493.1463(c)]: 7183 [42CFR493.1489(b)(1) and 42CFR493.1489(b)(5)].

PROCEDURE MANUAL

The procedure manual should be used by personnel at the workbench and should include: test principle, clinical significance, specimen type, required reagents, test calibration, quality control, procedural steps, calculations, reference intervals, and interpretation of results. The manual should address relevant pre-analytic and post-analytic considerations, as well as the analytic activities of the laboratory. The specific style and format of procedure manuals are at the discretion of the laboratory director.

The inspection team should review the procedure manual in detail to understand the laboratory's standard operating procedures, ensure that all significant information and instructions are included, and that actual practice matches the contents of the procedure manuals.

****REVISED**** **04/06/2006**

HEM.21000 **Phase II** **N/A YES NO**

Is a complete procedure manual available at the workbench or in the work area?

NOTE 1: The use of inserts provided by manufacturers is not acceptable in place of a procedure manual. However, such inserts may be used as part of a procedure description, if the insert accurately and precisely describes the procedure as performed in the laboratory. Any variation from this printed or electronic procedure must be detailed in the procedure manual. In all cases, appropriate reviews must occur.

NOTE 2: A manufacturer's procedure manual for an instrument/reagent system may be acceptable as a component of the overall departmental procedures. Any modification to or deviation from the procedure manual must be clearly documented.

NOTE 3: Card files or similar systems that summarize key information are acceptable for use as quick reference at the workbench provided that:

- a. A complete manual is available for reference*
- b. The card file or similar system corresponds to the complete manual and is subject to document control*

NOTE 4: Electronic (computerized) manuals are fully acceptable. There is no requirement for paper copies to be available for the routine operation of the laboratory, so long as the electronic versions are readily available to all personnel. However, procedures must be available to laboratory personnel when the electronic versions are inaccessible (e.g., during laboratory information system or network downtime); thus, the laboratory must maintain either paper copies or electronic copies on CD or other media that can be accessed via designated computers. All procedures, in either electronic or paper form, must be readily available for review by the inspector at the time of the CAP inspection.

Electronic versions of procedures must be subjected to proper document control (i.e., only authorized persons may make changes, changes are dated/signed (manual or electronic), and there is documentation of annual review). Documentation of review of electronic procedures may be accomplished by including statements such as “reviewed by [name of reviewer] on [date of review]” in the electronic record. Alternatively, paper review sheets may be used to document review of electronic procedures. Documentation of review by a secure electronic signature is NOT required.

COMMENTARY:

N/A

REFERENCES: 1) van Leeuwen AM. 6 steps to building an efficiency tool. *Advance/Laboratory*. 1999;8(6):88-91; 2) Borkowski A, et al. Intranet-based quality improvement documentation at the Veterans Affairs Maryland health care system. *Mod. Pathol.* 2001;14:1-5; 3) Clinical and Laboratory Standards Institute (CLSI). *Laboratory Documents: Development and Control; Approved Guideline—Fifth Edition*. CLSI document GP2-A5 (ISBN 1-56238-600-X). Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2006.

HEM.21070

Phase II

N/A YES NO

Is there documentation of at least annual review of all policies and procedures in the hematology laboratory section by the current laboratory director or designee?

NOTE: The director must ensure that the collection of policies and technical protocols is complete, current, and has been thoroughly reviewed by a knowledgeable person. Technical approaches must be scientifically valid and clinically relevant. To minimize the burden on the laboratory and reviewer(s), it is suggested that a schedule be developed whereby roughly 1/12 of all procedures are reviewed

monthly. Paper/electronic signature review must be at the level of each procedure, or as multiple signatures on a listing of named procedures. A single signature on a Title Page or Index of all procedures is not sufficient documentation that each procedure has been carefully reviewed. Signature or initials on each page of a procedure is not required.

COMMENTARY:

N/A

REFERENCES: 1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 1992(Feb 28):7173 [42CFR493.1407(e)(13)]; 2) Borkowski A, *et al*. Intranet-based quality improvement documentation at the Veterans Affairs Maryland health care system. *Mod. Pathol*. 2001;14:1-5.

HEM.21075

Phase II

N/A YES NO

Does the director (or a designee who meets CAP director qualifications) review and approve all new policies and procedures, as well as substantial changes to existing documents, before implementation?

NOTE: Current practice must match the policy and procedure documents.

COMMENTARY:

N/A

REFERENCES: 1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 2003(Jan 24):7164 [42CFR493.1251(d)]; 2) Borkowski A, *et al*. Intranet-based quality improvement documentation at the Veterans Affairs Maryland health care system. *Mod. Pathol*. 2001;14:1-5.

HEM.21080

Phase II

N/A YES NO

Does the laboratory have a system documenting that all personnel are knowledgeable about the contents of procedure manuals (including changes) relevant to the scope of their testing activities?

NOTE: This does not specifically require annual procedure sign-off by testing personnel. The form of this system is at the discretion of the laboratory director.

COMMENTARY:

N/A

clumping. *Am J Clin Pathol.* 1984;82:132-133; 3) Rabinovitch A. Anticoagulants, platelets and instrument problems. *Am J Clin Pathol.* 1984;82:132; 4) NCCLS. *Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture; Approved Standard—Fifth Edition.* NCCLS document H3-A5 (ISBN 1-56238-515-1). NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2003; 5) NCCLS. *Procedures and Devices for the Collection of Diagnostic Capillary Blood Specimens; Approved Standard—Fifth Edition.* NCCLS document H4-A5 (ISBN 1-56238-538-0). NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2004; 6) NCCLS. *Tubes and Additives for Venous Blood Specimen Collection; Approved Standard—Fifth Edition.* NCCLS document H1-A5 (ISBN 1-56238-519-4). NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2003; 7) Broden PN. Anticoagulant and tube effect on selected blood cell parameters using Sysmex NE-series instruments. *Sysmex J Intl.* 1992;2:112-119; 8) Brunson D, *et al.* Comparing hematology anticoagulants: K₂EDTA vs K₃EDTA. *Lab Hematol.* 1995;1:112-119; 9) Boos MS, *et al.* Temperature- and storage-dependent changes in hematologic variable and peripheral blood morphology. *Am J Clin Pathol.* 1998;110:537; 10) Wood BL, *et al.* Refrigerated storage improves the stability of the complete blood cell count and automated differential. *Am J Clin Pathol.* 1999;112:687-695.

HEM.22070**Phase II****N/A YES NO**

Are there documented criteria for the rejection of unacceptable specimens and the special handling of sub-optimal specimens?

NOTE: This question does not imply that all "unsuitable" specimens are discarded or not analyzed. If, for example, a CBC is ordered and there is visible hemolysis, the hemoglobin concentration may still be valid, but other parameters are not. There must be a mechanism to notify clinical personnel responsible for patient care, and to note the condition of the sample on the report if the analytically valid incomplete test results are desired by the ordering physician. The laboratory should record that a dialogue was held with the physician, when such occurs.

COMMENTARY:

N/A

REFERENCES: 1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2003(Jan 24):7183 [42CFR493.1249(a) and (b)]; 2) Boos MS, *et al.* Temperature- and storage-dependent changes in hematologic variable and peripheral blood morphology. *Am J Clin Pathol.* 1998;110:537.

HEM.22100**Phase II****N/A YES NO**

Are samples collected in capillary tubes for microhematocrits or capillary/dilution systems obtained in duplicate whenever possible and adequately labeled with patient identification information throughout the analytic sequence?

NOTE: This applies to capillary tubes used for microhematocrit determinations as well as capillary/dilution systems used in proximity to the patient. Microspecimen containers such as those used for capillary blood CBC parameter determinations need not be collected in duplicate. Because of the risk of injury, the use of plain glass capillary tubes is strongly discouraged.

COMMENTARY:

N/A

HEM.22150

Phase II

N/A YES NO

Are CBC specimens checked for clots (visual, applicator sticks, or automated analyzer histogram inspection/flags) before reporting results?

NOTE: This may be done visually or with applicator sticks before testing. Additionally, microclots will often present themselves histographically on automated and semi-automated particle counters or by flagging, and the laboratory must become familiar with such patterns. Finally, platelet clumps or fibrin may be microscopically detected if a blood film is prepared on the same sample.

COMMENTARY:

N/A

HEM.22200

Phase II

N/A YES NO

Are CBC specimens checked for significant in vitro hemolysis and possible interfering lipemia before reporting results?

NOTE: Specimens for complete blood counts must be checked for in vitro hemolysis that may falsely lower the erythrocyte count and the hematocrit, as well as falsely increase the platelet concentration from erythrocyte stroma. Visibly red plasma in a tube of EDTA-anticoagulated settled or centrifuged blood should trigger an investigation of in vivo hemolysis (in which case the CBC data are valid) versus in vitro hemolysis (in which case some or all of the CBC data are not valid and should not be reported). Lipemia may adversely affect the hemoglobin concentration and the leukocyte count. This does not imply that every CBC specimen must be subjected to centrifugation with visual inspection of the plasma supernatant, particularly if this would significantly impair the laboratory's turnaround time. An acceptable alternative for high volume laboratories with automated instrumentation is to examine the numeric data for anomalous results (especially indices), as well as particle histogram inspection.

COMMENTARY:

N/A

REFERENCE: Cantero M, *et al.* Interference from lipemia in cell count by hematology. *Clin Chem.* 1996;42:987-988.

HEM.22625

Phase I

N/A YES NO

Has the laboratory clearly defined sample storage conditions and stability for all hematology parameters?

NOTE: The laboratory should define sample storage conditions and stability for all hematology parameters, as time- and temperature-dependent alterations can occur, creating spurious results.

COMMENTARY:

N/A

REFERENCES: 1) Boos MS, *et al.* Temperature- and storage-dependent changes in hematologic variable and peripheral blood morphology. *Am J Clin Pathol.* 1998;110:537; 2) Gulati GL, *et al.* Changes in automated complete blood cell count and differential leukocyte count results induced by storage of blood at room temperature. *Arch Pathol Lab Med.* 2002;126:336-342.

SPECIMEN COLLECTION AND HANDLING - COAGULATION

HEM.22707

Phase I

N/A YES NO

Is there a documented policy regarding clearing (flushing) of the volume of intravenous lines before drawing samples for hemostasis testing?

NOTE: Collection of blood for coagulation testing through intravenous lines that have been previously flushed with heparin should be avoided, if possible. If the blood must be drawn through an indwelling catheter, possible heparin contamination and specimen dilution should be considered. When obtaining specimens from indwelling lines that may contain heparin, the line should be flushed with 5 mL of saline, and the first 5 mL of blood or 6-times the line volume (dead space volume of the catheter) be drawn off and discarded before the coagulation tube is filled.

COMMENTARY:

N/A

REFERENCES: 1) Lew JKL, *et al.* Intra-arterial blood sampling for clotting studies. Effects of heparin contamination. *Anesthesia.* 1991;46:719-721; 2) Konopad E, *et al.* Comparison of PT and aPTT values drawn by venipuncture and arterial line using three discard volumes. *Am J Crit Care.*

1992;3:94-101; 3) Laxson CJ, Titler MG. Drawing coagulation studies from arterial lines; an integrative literature review. *Am J Critical Care*. 1994; 1:16-24; 4) Adcock DM, *et al*. Are discard tubes necessary in coagulation studies? *Lab Med*. 1997;28:530-533; 5) Brigden ML, *et al*. Prothrombin time determination. The lack of need for a discard tube and 24-hour stability. *Lab Med*. 1997;108:422-426; 6) NCCLS. *Collection, Transport, and Processing of Blood Specimens for Testing Plasma-Based Coagulation Assays; Approved Guideline—Fourth Edition*. NCCLS document H21-A4 (ISBN 1-56238-521-6). NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2003; 7) NCCLS. *Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture; Approved Standard—Fifth Edition*. NCCLS document H3-A5 (ISBN 1-56238-515-1). NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2003.

HEM.22748**Phase I****N/A YES NO****Are all coagulation specimens collected into 3.2% buffered sodium citrate?**

NOTE: Sodium citrate is effective as an anticoagulant due to its mild calcium-chelating properties. Of the 2 commercially available forms of citrate, 3.2% buffered sodium citrate (109 mmol/L of the dihydrate form of trisodium citrate $\text{Na}_3\text{C}_6\text{H}_5\text{O}_7 \cdot 2\text{H}_2\text{O}$) is the recommended anticoagulant for coagulation testing. The citrate concentration in 3.8% sodium citrate is higher and its use may result in falsely lengthened clotting times with calcium-dependent coagulation tests (i.e., PT and aPTT) with slightly underfilled samples and with samples with high hematocrits. If the laboratory does not adhere to recommendations for use of 3.2% buffered sodium citrate, it must have data on file to demonstrate that the alternative citrate concentration produces accurate and precise coagulation results. Coagulation testing cannot be performed in samples collected in EDTA due to the more potent calcium chelation. Heparinized tubes are not appropriate due to the inhibitory effect of heparin on multiple coagulation proteins.

COMMENTARY:

N/A

REFERENCES: 1) Adcock DM, *et al*. Effect of 3.2% vs 3.8% sodium citrate concentration on routine coagulation testing. *Am J Clin Pathol*. 1997;107:105-110; 2) Reneke, J *et al*. Prolonged prothrombin time and activated partial thromboplastin time due to underfilled specimen tubes with 109 mmol/L (3.2%) citrate anticoagulant. *Am J Clin Pathol*. 1998;109:754-757; 3) NCCLS. *Collection, Transport, and Processing of Blood Specimens for Testing Plasma-Based Coagulation Assays; Approved Guideline—Fourth Edition*. NCCLS document H21-A4 (ISBN 1-56238-521-6). NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2003.

HEM.22789**Phase I****N/A YES NO****Are there documented guidelines for rejection of under- or overfilled collection tubes?**

NOTE: The recommended proportion of blood to the sodium citrate anticoagulant volume is 9:1. Inadequate filling of the collection device will decrease this ratio, and may lead to inaccurate results for calcium-dependent clotting tests, such as the PT and aPTT. Conversely over-filling of the collection device will increase this ratio and may lead to clotted samples or inaccurate results.

COMMENTARY:

N/A

REFERENCES: 1) Peterson P, Gottfried EL. The effects of inaccurate blood sample volume on prothrombin time (PT) and activated partial thromboplastin time. *Thromb Haemost.* 1982;47:101-103; 2) Adcock DM, *et al.* Effect of 3.2% vs 3.8% sodium citrate concentration on routine coagulation testing. *Am J Clin Pathol.* 1997;107:105-110; 3) Reneke J, *et al.* Prolonged prothrombin time and activated partial thromboplastin time due to underfilled specimen tubes with 109 mmol/L (3.2%) citrate anticoagulant. *Am J Clin Pathol.* 1998;109:754-757; 4) NCCLS. *Collection, Transport, and Processing of Blood Specimens for Testing Plasma-Based Coagulation Assays; Approved Guideline—Fourth Edition.* NCCLS document H21-A4 (ISBN 1-56238-521-6). NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2003.

HEM.22830

Phase I

N/A YES NO

Are there documented guidelines for detection and special handling of specimens with elevated hematocrits?

NOTE: A hematocrit value >55% may lead to spurious coagulation results. The citrate anticoagulant distributes only in the plasma and not into the blood cells. For this reason, plasma citrate concentration will be increased if the patient's hematocrit is greater than 55%, leading to prolonged PT and aPTT results, as well as erroneous results for other calcium-dependent clotting tests such as clottable protein C/protein S. Accordingly, there should be a documented procedure for detection and special handling of polycythemic specimens. If possible, a new phlebotomy should be performed, using a reduced volume of sodium citrate, adjusted for the elevated hematocrit. Conversely, there are no current data to support a recommendation for adjusting the citrate concentration in the presence of severe anemia (hematocrit <20%).

COMMENTARY:

N/A

REFERENCES: 1) NCCLS. *Collection, Transport, and Processing of Blood Specimens for Testing Plasma-Based Coagulation Assays; Approved Guideline—Fourth Edition.* NCCLS document H21-A4 (ISBN 1-56238-521-6). NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2003; 2) Siegel JE, *et al.* Effect (or lack of it) of severe anemia on PT and APTT results. *Am J Clin Pathol.* 1998; 110:106-110; 3) Siegel JE, *et al.* Monitoring heparin therapy. APTT results from partial- vs full-draw tubes. *Am J Clin Pathol.* 1998;110:184-187.

HEM.22871**Phase II****N/A YES NO**

Are coagulation specimens checked for clots (visual, applicator sticks, or by analysis of testing results) before testing or reporting results?

NOTE: Coagulation specimens must be checked for clots of any size. Clotted specimens will have extremely low levels of fibrinogen and variably decreased levels of other coagulation proteins, so that results of the PT, aPTT, fibrinogen and other coagulation assays will be inaccurate or unobtainable. Checking for clots may be done with applicator sticks or by visual inspection of centrifuged plasma for small clots. This may also be performed by analysis of results (waveform analysis or delta checks). Additionally, when a clot is not detected during PT and aPTT testing and, where the fibrinogen level is <25 mg/dl, it should be suspected that the sample is actually serum. This may be important when coagulation specimens are received as centrifuged, frozen "plasma". Centrifuged plasma and serum cannot be distinguished by visual inspection alone. There should be a mechanism in place to identify these specimens appropriately and/or to reject the sample as a probable serum sample. Laboratories should be encouraged to work with their clients that perform sample processing to ensure that they practice appropriate specimen handling for coagulation specimens.

COMMENTARY:

N/A

REFERENCES: 1) NCCLS. Collection, Transport, and Processing of Blood Specimens for Testing Plasma-Based Coagulation Assays; Approved Guideline—Fourth Edition. NCCLS document H21-A4 (ISBN 1-56238-521-6). NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2003; 2) Arkin CF. Collection, handling, storage of coagulation specimens. *Advance/Lab.* 2002;11(1);33-38.

HEM.22912**Phase II****N/A YES NO**

Are coagulation tests promptly performed on fresh plasma, or is the platelet-poor plasma frozen until testing can be performed?

NOTE: After blood collection, there is progressive degradation of the labile coagulation factors V and VIII, leading to increasing prolongation of the aPTT and PT. The allowable time interval between specimen collection and sample testing depends on the temperature encountered during transport and storage of the specimen. Optimally, for specimens that are uncentrifuged or centrifuged with plasma remaining on top of the cells in an unopened tube kept at 2-4°C or 18-24°C, the following guidelines should be observed:

1. *Prothrombin time – 24 hours*
2. *aPTT – 4 hours*
3. *Other coagulation assays (e.g., thrombin time, protein C factor V and factor VIII) - 4 hours*

If testing cannot be performed within these times, platelet-poor plasma should be removed from the cells and frozen at -20°C for up to 2 weeks or at -70°C for up to 6 months. A frost-free freezer should not be used, because of warming cycles. If a laboratory has established an allowable time interval different than that detailed above, data must be available to verify that coagulation testing is valid in the time interval established.

COMMENTARY:

N/A

REFERENCES: 1) NCCLS. Collection, Transport, and Processing of Blood Specimens for Testing Plasma-Based Coagulation Assays; Approved Guideline—Fourth Edition. NCCLS document H21-A4 (ISBN 1-56238-521-6). NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2003; 2) Adcock DM, *et al.* The effect of time and temperature variables on routine coagulation tests. *Blood Coag Fibrinolysis*. 1998;9:463-470; 3) Neofotistos D, *et al.* Stability of plasma for add-on PT and aPTT tests. *Am J Clin Pathol*. 1998;109:758-763; 4) Davis KD, *et al.* Use of different thromboplastin reagents causes greater variability in international normalized ratio results than prolonged room temperature storage of specimens. *Arch Pathol Lab Med*. 1998;122:972-977.

HEM.22953**Phase II****N/A YES NO**

Are platelet functional studies (platelet aggregation or initial platelet function test) performed within an appropriate period after venipuncture?

NOTE: Following venipuncture, platelets continue to activate in vitro, so that platelet functionality becomes abnormal after a period of approximately 4 hours. The laboratory should ensure that platelet aggregation studies are completed within 4 hours from the time of phlebotomy, or erroneous results could be obtained.

COMMENTARY:

N/A

REFERENCE: Triplett DA, *et al.* Platelet function: laboratory evaluation and clinical application. Chicago, IL: American Society for Clinical Pathology, 1978.

RESULTS REPORTING - GENERAL

HEM.23000**Phase II****N/A YES NO**

Are reference intervals (normal ranges) established or verified by the laboratory for the population tested?

NOTE: Age- and sex-specific reference intervals (normal values) must be verified or established by laboratory. For example, a reference interval can be validated by testing samples from 20 healthy representative individuals; if no more than 2 results fall outside the proposed reference interval, that interval can be considered validated for the population studied (refer to CLSI guideline C28, referenced below). If a formal reference interval study is not possible or practical, then the laboratory should carefully evaluate the use of published data for its own reference intervals, and retain documentation of this evaluation.

COMMENTARY:

N/A

REFERENCES: 1) Fraser CG, *et al.* Biologic variation of common hematology laboratory quantities in the elderly. *Am J Clin Pathol.* 1989;92:465-470; 2) The reticulocytes: automatic counting, indication and interpretation. *Sysmex J Intl.* 1992;2:120-135; 3) Takamatsu N, *et al.* A study of the hematological reference ranges and changed with age using the automated hematology analyzer K-1000. *Sysmex J Intl.* 1992;2:136-145; 4) Hinchliffe RF. Reference values, In Lilleyman JS, Hann IM (eds). *Paediatric hematology.* Edinburgh, UK: Churchill-Livingstone, 1992:1-22; 5) Goyzueta FG, *et al.* Automated differential white blood cell counts in the young pediatric population. *Lab Med.* 1996;27:48-52; 6) Parry H, *et al.* Smoking, alcohol consumption, and leukocyte counts. *Am J Clin Pathol.* 1997;107:88-91; 7) Craver RD, *et al.* Hemoglobin A₂ levels in healthy persons, sickle cell disease, sickle cell trait, and beta-thalassemia by capillary isoelectric focusing. *Am J Clin Pathol.* 1997;107:88-91; 8) Brugnara C. Reference values in infancy and childhood, In Nathan DG, Orkin SH (eds). *Nathan and Oski's hematology of infancy and childhood*, 5th ed. Philadelphia, PA: WB Saunders, 1998:i-xxvii; 9) Walka MM, *et al.* Complete blood counts from umbilical cords of healthy term newborns by two automated cytometers. *Acta Haematol.* 1998;100:167-173; 10) NCCLS. *How to Define and Determine Reference Intervals in the Clinical Laboratory; Approved Guideline—Second Edition.* NCCLS document C28-A2 (ISBN 1-56238-406-6). NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898, USA 2000; 11) Brigden ML, Johnston M. A survey of aPTT reporting in Canadian medical laboratories. The need for increased standardization. *Am J Clin Pathol.* 2000;114:276-282; 12) Mezzena G, *et al.* Reference interval of D-dimer in pregnant women. *Clin Chem.* 2000;46:A130; 13) Trost DC, *et al.* Probability-based construction of reference ranges for ratios of log-Gaussian analytes: an example from automated leukocyte counts. *Am J Clin Pathol.* 2002;117:851-856.

HEM.23050**Phase II****N/A YES NO**

Where possible, are all patient results reported with accompanying reference intervals or interpretive ranges?

NOTE: The results of commercial quality control plasmas that may be used in coagulation assays are internal data for quality assurance purposes, and must NOT be externally reported; if reported with patient results, they may be confused as normal values.

The use of high and low flags (generally available with a computerized laboratory information system) is recommended.

Under some circumstances it may be appropriate to distribute lists or tables of reference intervals to all users and sites where reports are received. This system is usually fraught with difficulties, but if in place and rigidly controlled, it is acceptable.

COMMENTARY:

N/A

REFERENCES: 1) Brigden ML, Johnston M. A survey of aPTT reporting in Canadian medical laboratories. The need for increased standardization. *Am J Clin Pathol.* 2000;114:276-282; 2) Trost DC, *et al.* Probability-based construction of reference ranges for ratios of log-Gaussian analytes: an example from automated leukocyte counts. *Am J Clin Pathol.* 2002;117:851-856.

HEM.23100

Phase II

N/A YES NO

Are documented criteria established for immediate notification of a physician or other clinical personnel responsible for patient care when results of certain tests exceed critical limits important for prompt patient management decisions?

NOTE: These may be indicated either in the procedure manual and/or in a separate manual. The bench technologists must be familiar with critical limits for procedures that they perform.

COMMENTARY:

N/A

REFERENCES: 1) Kost GJ. Critical limits for urgent clinician notification at US medical centers. *JAMA.* 1990;263:704-707; 2) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2003(Jan 24):[42CFR493.1251(b)(13)]; 3) Steindel SJ, Heard NV. Critical values: data analysis and critique. Q-Probes 92-04. Northfield, IL: College of American Pathologists, 1992; 4) Kost GJ. Using critical limits to improve patient outcome. *Med Lab Observ.* 1993;25(3):22-27; 5) Ben-Ezra J. Serial mean platelet values and laboratory panic value callbacks. *Am J Clin Pathol.* 1998;110:538-539; 6) Dalton-Beninato K. Critical value notifications are never welcome news. *Lab Med.* 2000;31:319-323; 7) From P, *et al.* Effect of urgent clinician notification of low hemoglobin values. *Clin Chem.* 2001;47:63-66; 8) Howanitz PJ, *et al.* Laboratory critical values policies and procedures. A College of American Pathologists Q-probes study in 623 institutions. *Arch Pathol Lab Med.* 2000;126:663-669.

HEM.23120 Phase II**N/A YES NO****Is there documentation of prompt notification of the physician (or other clinical personnel responsible for patient care) of results of all critical results?**

NOTE: This documentation should include: date, time, responsible laboratory individual, person notified and test results. In addition, the laboratory should document any failure of attempts to notify the appropriate person of critical results, and document the action taken to prevent recurrence of this problem.

COMMENTARY:

N/A

REFERENCES: 1) Kost GJ. Critical limits for urgent clinician notification at US medical centers. *JAMA*. 1990;263:704-707; 2) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 2003(Jan 24):[42CFR493.1291(g)]; 3) Steindel SJ, Heard NV. Critical values: data analysis and critique. Q-Probes 92-04. Northfield, IL: College of American Pathologists, 1992; 4) Kost GJ. Using critical limits to improve patient outcome. *Med Lab Observ*. 1993;25(3):22-27; 5) Ben-Ezra J. Serial mean platelet values and laboratory panic value callbacks. *Am J Clin Pathol*. 1998;110:538-539; 6) Dalton-Beninato K. Critical value notifications are never welcome news. *Lab Med*. 2000;31:319-323; 7) Howanitz PJ, et al. Laboratory critical values policies and procedures. A College of American Pathologists Q-probes study in 623 institutions. *Arch Pathol Lab Med*. 2000;126:663-669.

HEM.23150 Phase II**N/A YES NO****Are routine and STAT results available within a reasonable time?**

NOTE: A reasonable time for routine daily service, assuming receipt or collection of specimen in the morning, is 4-8 hours. For common hematology and coagulation tests, emergency or STAT results that do not require special additional verification procedures should be reported within 1 hour after specimen receipt in the laboratory.

COMMENTARY:

N/A

REFERENCES: 1) Steindel SJ, Novis DA. Using outlier events to monitor test turnaround time. A College of American Pathologists Q-Probes study in 496 laboratories. *Arch Pathol Lab Med*. 1999;123:607-614; 2) Manor PG. Turnaround times in the laboratory: a review of the literature. *Clin Lab Sci*. 1999;12(2):85-89; 3) Novis DA, Dale JC. Morning rounds inpatient test availability. A College of American Pathologists Q-Probes study of 79 860 morning complete blood cell count and electrolyte test results in 367 institutions. *Arch Pathol Lab Med*. 2000;124:499-503; 4) Steindel SJ,

decreased levels of the vitamin K-dependent coagulation factors. This change in sensitivity will affect the calculation of the INR value.

The laboratory should be able to provide documentation that the calculation of the INR is correct and appropriate for the new ISI value. These changes should be implemented wherever the INR is calculated, whether by the coagulation instrument, laboratory information system, or manually.

It is critical to calculate and report appropriate INR values. Reporting erroneous INR values may lead to use of excessive or insufficient oral anticoagulant medication, which may result in bleeding or thrombotic complications in patients.

COMMENTARY:

N/A

REFERENCES: 1) NCCLS. One-stage prothrombin time (PT) test and activated partial thromboplastin time (aPTT) test; approved guideline H47-A. Wayne, PA: NCCLS, 1996; 2) Fairweather RB, *et al.* College of American Pathologists Conference XXXI on laboratory monitoring of oral anticoagulant therapy. *Arch Pathol Lab Med.* 1998;122:768-781; 3) Ansell J, *et al.* Managing oral anticoagulant therapy. *Chest* 2001;119:22s-38s.

****REVISED**** **10/31/2006**

HEM.23360 **Phase II** **N/A YES NO**

Is the appropriate geometric mean of the PT reference interval used in the INR calculation?

NOTE: The appropriate geometric mean of the PT reference interval must be used in the INR calculation, given by the formula:

$$INR = (PT \text{ of patient} / PT \text{ of geometric mean normal population})^{ISI}$$

The mean normal population value may change when the specimen collection process, instrument, reagent lot, or reagent changes.

The geometric and arithmetic means may not be identical and the geometric mean is the preferred value. When the distribution of values is distributed normally, the GM, the arithmetic mean, the median and the mode of the population being studied are identical theoretically. These values diverge from each other, however, as the population distribution becomes more skewed. The geometric mean is a more appropriate estimate of the average value than the arithmetic mean when the population of interest is lognormally distributed because the geometric mean takes skewing into account.

The geometric mean (GM) is the antilog of the arithmetic mean of the logarithms of the individual normal PT values of interest. Calculation of the geometric mean is indicated below; this calculation is available in many spreadsheet programs, such as Microsoft Excel.

$GM = \text{antilog} [(log(X1) + log(X2) + log(X3) + \dots + log(Xn))/n]$.

COMMENTARY:

N/A

REFERENCES: 1) NCCLS. One-stage prothrombin time (PT) test and activated partial thromboplastin time (aPTT) test; approved guideline H47-A. Wayne, PA: NCCLS, 1996 ; 2) Fairweather RB, *et al.* College of American Pathologists Conference XXXI on laboratory monitoring of oral anticoagulant therapy. *Arch Pathol Lab Med.* 1998;122:768-781; 3) Ansell J, *et al.* Managing oral anticoagulant therapy. *Chest* 2001;119:22s-38s; 4) Critchfield GC, Bennett ST. The influence of the reference mean prothrombin time on the international normalized ratio. *Am J Clin Pathol.* 1994 Dec;102(6):806-11.

****REVISED**** **04/06/2006**

HEM.23430 Phase II N/A YES NO

Are there checks of patient reports for correct INR calculations, patient values, and reference ranges under the following circumstances?

- 1. Change in lot or type of PT reagent**
- 2. Change in instrument**
- 3. Establishment of new PT reference range**
- 4. Change in INR calculation**
- 5. At defined intervals, in the absence of the above changes**

NOTE: It is suggested that the calculations be checked at the following INR values: 2.0 and 3.0. Patient reports should be checked at least once per year even in the absence of changes to the test system and calculations. This question applies whether the INR is calculated by the coagulation analyzer or by the laboratory information system.

COMMENTARY:

N/A

REFERENCES: 1) NCCLS. One-stage prothrombin time (PT) test and activated partial thromboplastin time (aPTT) test; approved guideline H47-A. Wayne, PA: NCCLS, 1996; 2) Fairweather RB, *et al.* College of American Pathologists Conference XXXI on laboratory monitoring of oral anticoagulant therapy. *Arch Pathol Lab Med.* 1998;122:768-781; 3) Ansell J, *et al.* Managing oral anticoagulant therapy. *Chest* 2001;119:22s-38s.

****NEW**** **10/31/2006****HEM.23453** **Phase I** **N/A YES NO****Is there documentation that the aPTT-based heparin therapeutic range is established and subsequently validated when appropriate?**

NOTE: The heparin-responsiveness of aPTT reagents may change from lot to lot and among different reagents used on different instrument platforms. For this reason, it is necessary to establish the heparin therapeutic range for the aPTT assay with each change of coagulation instrument and/or reagent type. The therapeutic range must be validated with each new lot of a given aPTT reagent.

COMMENTARY:

N/A

REFERENCES: 1) Rosborough TK. Comparison of anti-factor Xa heparin activity and activated partial thromboplastin time in 2,773 plasma samples from unfractionated heparin-treated patients. *Am J Clin Pathol.* 1997;108:662-668; 2) Olson JD, et al. College of American Pathologists conference XXXI on laboratory monitoring of anticoagulant therapy. Laboratory monitoring of unfractionated heparin therapy. *Arch Pathol Lab Med.* 1998;122:782-798; 3) Smythe MA, et al. Use of the activated partial thromboplastin time for heparin monitoring. *Am J Clin Pathol.* 2001;115:148-155; 4) Smythe MA, et al. Different heparin lots. Does it matter? *Arch Pathol Lab Med.* 2001;125:1458-1462; 5) Hirsh J, et al. Guide to anticoagulant therapy. Heparin: a statement for healthcare officials from the American Heart Association. *Circulation.* 2001 19:2994-3018; 6) Hirsh J, Raschke R. Heparin and low-molecular-weight heparin: the Seventh ACCP Conference on Antithrombotic and Thrombolytic Therapy. *Chest.* 2004 Sep;126(3 Suppl):188S-203S.

****NEW**** **10/31/2006****HEM.23476** **Phase I** **N/A YES NO****Is there documentation that the aPTT-based heparin therapeutic range is established and validated using an appropriate technique?**

NOTE: The aPTT is commonly used to monitor the anticoagulant effects of unfractionated heparin. The therapeutic range for heparin therapy should be established by using ex vivo plasma samples anticoagulated with 3.2% sodium citrate obtained from patients receiving current therapy with unfractionated heparin. This can be accomplished one of two ways. (1) The aPTT and heparin activity is measured for each sample and the aPTT range is calculated by comparison to heparin activity or (2) the aPTT of patient samples using the new lot or aPTT method is compared to the prior aPTT lot. It is recommended that the first method be used initially to establish the therapeutic range before starting patient testing with a new instrument or new reagent, while the second method can be used for validation of the therapeutic range with subsequent reagent lot changes. It is not best practice to use

plasma samples spiked with heparin in vitro to calculate the therapeutic range, as differences in heparin binding proteins in vitro may lead to overestimation of the therapeutic range.

COMMENTARY:

N/A

REFERENCES: 1) Rosborough TK. Comparison of anti-factor Xa heparin activity and activated partial thromboplastin time in 2,773 plasma samples from unfractionated heparin-treated patients. *Am J Clin Pathol.* 1997;108:662-668; 2) Olson JD, *et al.* College of American Pathologists conference XXXI on laboratory monitoring of anticoagulant therapy. Laboratory monitoring of unfractionated heparin therapy. *Arch Pathol Lab Med.* 1998;122:782-798; 3) Smythe MA, *et al.* Use of the activated partial thromboplastin time for heparin monitoring. *Am J Clin Pathol.* 2001;115:148-155; 4) Smythe MA, *et al.* Different heparin lots. Does it matter? *Arch Pathol Lab Med.* 2001;125:1458-1462; 5) Hirsh J, *et al.* Guide to anticoagulant therapy. Heparin: a statement for healthcare officials from the American Heart Association. *Circulation.* 2001 19:2994-3018; 6) Hirsh J, Raschke R, Heparin and low-molecular-weight heparin: the Seventh ACCP Conference on Antithrombotic and Thrombolytic Therapy. *Chest.* 2004 Sep;126(3 Suppl):188S-203S.

HEM.23500

Phase I

N/A YES NO

Are reference intervals for PT and aPTT current for the reagent or lot number, and have they been appropriately determined?

NOTE: Because of the variability between different types of PT and aPTT reagents, and even different lots of PT and aPTT reagents, there may be significant changes in the reference interval after a change of the type or lot of reagent. For this reason, the laboratory should establish or verify the reference interval with each change of lot or change in reagent.

COMMENTARY:

N/A

HEM.23575

Phase I

N/A YES NO

Are recommendations available to clinicians concerning which laboratory tests to use for monitoring heparin, low molecular weight heparin, direct thrombin inhibitors (e.g., lepirudin, bivalirudin, argatroban) and/or oral anticoagulant therapy, and the therapeutic range for the tests?

NOTE: For oral anticoagulant agents (e.g., warfarin), the prothrombin time (PT/INR) is recommended, although many other methods are still in use. In addition, more than a dozen methods are in use for monitoring heparin and low molecular weight heparin therapy. For unfractionated heparin the activated partial thromboplastin time (aPTT) and/or activated clotting time are commonly

used, but the heparin assay (factor Xa inhibition) may also be employed. For low molecular weight heparin or danaparoid, monitoring is often not necessary, but the heparin assay (Xa inhibition assay) may be used in certain circumstances, as the aPTT is generally insensitive to the effect of these agents. Direct thrombin inhibitors are becoming more widely utilized and these drugs are often monitored using the aPTT. The tests available should be applicable to the anticoagulant drugs available on the pharmacy formulary at the medical institution. The laboratory should work closely with the pharmacy or therapeutics committee to ensure that appropriate assays are available for the drugs in use by physicians, and that information is available on the test values that indicate that the anticoagulant is in a therapeutic range.

COMMENTARY:

N/A

REFERENCES: 1) Rosborough TK. Comparison of anti-factor Xa heparin activity and activated partial thromboplastin time in 2,773 plasma samples from unfractionated heparin-treated patients. *Am J Clin Pathol.* 1997;108:662-668; 2) Haraldsson HM, et al. Performance of prothrombin-proconvertin time as a monitoring test of oral anticoagulation therapy. *Am J Clin Pathol.* 1997;108:662-668; 3) Baker BE, et al. Inability of the activated partial thromboplastin time to predict heparin levels: time to reassess guidelines for heparin assays. *Arch Intern Med.* 1997;157:2475-2479; 4) Brigden, ML et al. INR reporting in Canadian medical laboratories. An update. *Am J Clin Pathol.* 1998;109:589-594; 5) Leech BF, Carter CJ. Falsely elevated INR results due to the sensitivity of a thromboplastin reagent to heparin. *Am J Clin Pathol.* 1998;109:764-768; 6) Fairweather RB, et al. College of American Pathologists conference XXXI on laboratory monitoring of oral anticoagulant therapy. *Arch Pathol Lab Med.* 1998;122:768-781; 7) Olson JD, et al. College of American Pathologists conference XXXI on laboratory monitoring of oral anticoagulant therapy. Laboratory monitoring of unfractionated heparin therapy. *Arch Pathol Lab Med.* 1998;122:782-798; 8) Lousberg TR, et al. Evaluation of excessive anticoagulation in a group model health maintenance organization. *Arch Intern Med.* 1998;158:528-534; 9) Davis KD, et al. Use of different thromboplastin reagents causes greater variability in international normalized ratio results than prolonged room temperature storage of specimens. *Arch Pathol Lab Med.* 1998;122:972-977; 10) Koerner SD, Fuller RE. Comparison of a portable capillary whole blood coagulation monitor and standard laboratory methods for determining international normalized ratio. *Mil Med.* 1998;163:820-825; 11) Laposata M, et al. College of American Pathologists conference XXXI on laboratory monitoring of low-molecular-weight heparin, danaparoid, hirudin and related compounds, and argatroban. *Arch Pathol Lab Med.* 1998;122:799-807; 12) Smythe MA, et al. Use of the activated partial thromboplastin time for heparin monitoring. *Am J Clin Pathol.* 2001;115:148-155; 13) Smythe MA, et al. Different heparin lots. Does it matter? *Arch Pathol Lab Med.* 2001;125:1458-1462; 14) Ansell J, et al. Managing oral anticoagulant therapy. *Chest.* 2001;119:22s-38s; 15) Hirsh J, et al. Heparin and low-molecular-weight heparin: Mechanisms of action, pharmacokinetics, dosing, monitoring, efficacy and safety. *Chest.* 2001; 119:64s-94s; 16) Hirsh J, et al. Guide to anticoagulant therapy. Heparin: a statement for healthcare officials from the American Heart Association. *Circulation.* 2001 19:2994-3018.

REAGENTS

****NEW**** **10/31/2006**

HEM.23787 Phase II N/A YES NO

For waived tests, does the laboratory follow manufacturer instructions for handling and storing reagents?

COMMENTARY:

N/A

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The remaining checklist questions in the REAGENTS section do not apply to waived tests.

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The verification of reagent performance is required and must be documented. Any of several methods may be appropriate, such as direct analysis with reference materials, parallel testing of old vs. new reagents, or checking against routine controls. The intent of the questions is for new reagents to be checked by an appropriate method and the results recorded before being placed in service.

HEM.24000 Phase II N/A YES NO

Are reagents and solutions properly labeled, as applicable and appropriate, with the following elements?

- 1. Content and quantity, concentration or titer**
- 2. Storage requirements**
- 3. Date prepared or reconstituted by the laboratory**
- 4. Expiration date**

NOTE: The above elements may be recorded in a log (paper or electronic), rather than on the containers themselves, providing that all containers are identified so as to be traceable to the appropriate data in the log. While useful for inventory management, labeling with "date received" is not routinely required. There is no requirement to routinely label individual containers with "date opened"; however, a new expiration date must be recorded if opening the container changes the expiration date, storage requirement, etc. The inspector will describe specific issues of non-compliance in the Inspector's Summation Report.

COMMENTARY:

N/A

HEM.24100 Phase II**N/A YES NO****Are all reagents used within their indicated expiration date?**

COMMENTARY:

N/A

REFERENCE: Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 2003(Jan 24):7164 [42CFR493.1252(d)].

HEM.24150 Phase II**N/A YES NO****Are reagents for functional clotting assays (e.g., PT, aPTT, fibrinogen) prepared, stored, and discarded as recommended by the manufacturer?**

COMMENTARY:

N/A

REFERENCE: NCCLS. One-stage prothrombin time (PT) test and activated partial thromboplastin time (aPTT) test; approved guideline H47-A. Wayne, PA: NCCLS, 1996.

HEM.24575 Phase II**N/A YES NO****Are new reagent lots and/or shipments checked against old reagent lots with patient samples or suitable reference material before or concurrently with being placed in service?**

NOTE: The laboratory must run and compare results of material of known value prior to and following changing/priming of new reagent lots or shipments. The comparison studies must be performed before or at the same time that new reagent lots are placed in service. The material of known value may include patient samples or control material. For qualitative tests, minimum cross-checking includes retesting at least one known positive and one known negative patient sample from the old reagent lot against the new reagent lot, ensuring that the same results are obtained with the new lot. Good clinical laboratory science includes patient-based comparisons in many situations, since it is patient results that are "controlled". A weakly positive control should also be used in systems where patient results are reported in that fashion.

Appropriate checks must be performed on inert materials to ensure that new lots do not interfere with the method (e.g., performance of background counts on diluents).

COMMENTARY:

N/A

INSTRUMENTS AND EQUIPMENT

A variety of instruments and equipment are used to support the performance of analytical procedures. All instruments and equipment should be properly operated, maintained, serviced, and monitored to ensure that malfunctions of these instruments and equipment do not adversely affect the analytical results. The inspection team should review the procedures for instrument/equipment operations, maintenance, and monitoring records to ensure that these devices are properly used. The procedures and schedules for instrument maintenance must be as thorough and as frequent as specified by the manufacturer.

HEM.25000**Phase II****N/A YES NO**

Is the temperature of water baths and/or heat blocks, refrigerators, and other temperature-dependent equipment checked appropriately?

NOTE: Temperature-dependent equipment containing reagents and patient specimens must be monitored daily, as equipment failures could affect accuracy of patient test results. Items such as water baths and heat blocks used for procedures need only be checked on days of patient testing.

COMMENTARY:

N/A

HEM.25150**Phase II****N/A YES NO**

Are pipettors and dilutors (fixed volume or adjustable) checked at specific defined intervals for accuracy and reproducibility, (gravimetric, colorimetric or other verification procedure), and results recorded?

NOTE: For analytic instruments with integral automatic pipettors, the accuracy and precision of the pipetting system should be checked periodically, unless that is not practical for the end-user laboratory. Manufacturers' recommendations should be followed.

COMMENTARY:

N/A

REFERENCES: 1) Curtis RH. Performance verification of manual action pipets. Part I. *Am Clin Lab.* 1994;12(7):8-9; 2) Curtis RH. Performance verification of manual action pipets. Part II. *Am Clin Lab.* 1994;12(9):16-17; 3) Perrier S, *et al.* Micro-pipette calibration using a ratiometric photometer-reagent system as compared to the gravimetric method. *Clin Chem.* 1995;41:S183; 4) Bray W. Software for the gravimetric calibration testing of pipets. *Am Clin Lab.* Oct 1995 (available on the internet at http://www.labtronics.com/pt_art.htm); 5) Johnson B. Calibration to dye for: Artel's new pipette calibration system. *Scientist.* 1999;13(12):14; 6) Connors M, Curtis R. Pipetting error: a real problem with a simple solution. Parts I and II. *Am Lab News.* 1999;31(13):20-22; 7) Skeen GA, Ashwood ER. Using spectrophotometry to evaluate volumetric devices. *Lab Med.* 2000;31:478-479.

HEM.25250**Phase II****N/A YES NO**

Is volumetric glassware of certified accuracy (Class A), or checked by the laboratory to verify accuracy?

NOTE: Volumetric glassware must be certified for accuracy (class A) or checked for accuracy before being placed in service.

COMMENTARY:

N/A

REFERENCES: 1) Curtis RH. Performance verification of manual action pipets. Part I. *Am Clin Lab.* 1994;12(7):8-9; 2) Curtis RH. Performance verification of manual action pipets. Part II. *Am Clin Lab.* 1994;12(9):16-17; 3) Perrier S, *et al.* Micro-pipette calibration using a ratiometric photometer-reagent system as compared to the gravimetric method. *Clin Chem.* 1995;41:S183; 4) Bray W. Software for the gravimetric calibration testing of pipets. *Am Clin Lab.* Oct 1995 (available on the internet at http://www.labtronics.com/pt_art.htm); 5) Kroll MH, *et al* (eds). Laboratory instrument evaluation, verification & maintenance manual, 5th edition. Northfield, IL: College of American Pathologists, 1999:126-127; 6) Johnson B. Calibration to dye for: Artel's new pipette calibration system. *Scientist.* 1999;13(12):14; 7) Connors M, Curtis R. Pipetting error: a real problem with a simple solution. Parts I and II. *Am Lab News.* 1999;31(13):20-22; 8) Skeen GA, Ashwood ER. Using spectrophotometry to evaluate volumetric devices. *Lab Med.* 2000;31:478-479.

HEM.25300**Phase II****N/A YES NO**

Are microscopes clean, adequate (*i.e.*, low, high dry and oil immersion lenses), optically aligned, and properly maintained with documentation of preventive maintenance?

NOTE: Koehler illumination must be maintained for optimal resolution. For manual platelet counting, a phase contrast microscope is recommended.

COMMENTARY:

N/A

REFERENCE: Vetter JP. Solving problems with illumination, focus, and detail in color photomicrography. *Lab Med.* 1997;28:719-723.

HEM.25350

Phase II

N/A YES NO

Are instrument maintenance, service and repair records (or copies) promptly available to, and usable by, the technical staff operating the equipment?

NOTE: Effective utilization of instruments by the technical staff depends upon the prompt availability of maintenance, repair, and service documentation (copies are acceptable). Laboratory personnel are responsible for the reliability and proper function of their instruments and must have access to this information. Off-site storage, such as with centralized medical maintenance or computer files, is not precluded if the inspector is satisfied that the records can be promptly retrieved.

COMMENTARY:

N/A

COMPLETE BLOOD COUNT (CBC) INSTRUMENTS

.....
CALIBRATION
.....

Several different methods may be used for calibration of an automated Complete Blood Count (CBC) instrument. The laboratory should have a document that describes in detail the procedures for calibration and calibration verification.

Calibration techniques include: A) the use of multiple analyzed fresh whole blood specimens, and B) the use of manufactured, stabilized preparations of red cells, white cells (or white cell surrogates) and platelets (or platelet surrogates). Typically, a laboratory uses one of these two approaches as their primary calibration technique, with the other for backup, or for verification of the primary method, or on an emergency basis.

REFERENCE: NCCLS. *Calibration and Quality Control of Automated Hematology Analyzers; Proposed Standard*. NCCLS document H38-P [ISBN 1-56238-398-1]. NCCLS, 940 West Valley Road, Wayne, Pennsylvania 19087, U.S.A 1999.

HEM.25550**Phase II****N/A YES NO**

Does the initial or primary instrument calibration include duplicate analysis of at least 10 fresh whole blood samples that have been analyzed by reference methods?

NOTE: The exact number of whole blood samples and number of replicates may not be as specified above for all instruments. Manufacturers' instructions should be followed.

COMMENTARY:

N/A

REFERENCES: 1) International Committee for Standardization in Haematology' Expert Panel of Haemoglobinometry. Recommendations for reference method for haemoglobinometry in human blood (ICSH standard 1986) and specifications for international haemoglobinocyanide reference preparation (3rd edition). *Clin Lab Haematol.* 1987;9:73-79; 2) Lewis SM, *et al.* Current concepts in haematology 3: blood count calibration. *J Clin Pathol.* 1991;144:881-884; 3) NCCLS. *Procedure for Determining Packed Cell Volume by the Microhematocrit Method; Approved Standard—Third Edition*. NCCLS document H7-A3 (ISBN 1-56238-413-9). NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898, USA 2000; 4) NCCLS. *Reference and Selected Procedures for the Quantitative Determination of Hemoglobin in Blood; Approved Standard—Third Edition*. NCCLS document H15-A3 (ISBN 1-56238-425-2). NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2000; 5) Dickerhoff R, von Ruecker A. Enumeration of platelets by multiparameter flow cytometric flow cytometry using platelet-specific antibodies and fluorescent reference particles. *Clin Lab Haematol.* 1995;17:163-172; 6) Houwen B, *et al.* The reference method for hemoglobin measurement revisited. *Lab Hematol.* 1996;2:86-93.

HEM.25570**Phase II****N/A YES NO**

Are criteria established for calibration verification?

NOTE: Criteria must be established for calibration verification. Criteria include:

1. *At complete changes of reagents (i.e., change in type of reagent from same vendor, or change to a different vendor)*
2. *When indicated by quality control data*
3. *After major maintenance or service*
4. *When recommended by the manufacturer*
5. *At least every six months*

1. Use of preserved or stabilized whole blood controls
2. "Moving average" monitoring
3. Retained patient specimens, or
4. Some combination of the above

For laboratories subject to CLIA-88, at least 2 different controls must be assayed and evaluated every 24 hours. For each QC procedure employed, the laboratory must have appropriate QC ranges. For example, expected recovery ranges for commercial control materials are NOT the same as between-run SD ranges, and are probably too wide for daily QC of a single instrument. The laboratory should calculate its own imprecision statistics for each instrument.

.....

Stabilized Controls

.....

HEM.25850

Phase II

N/A YES NO

Are 2 different stabilized control specimens analyzed and results recorded during each 24-hours of analyzer use?

NOTE: Stabilized control materials must be at 2 different analytic levels (i.e., "normal" and "high"). Three levels of control is a conceptual carryover from clinical chemistry, and does not apply to hematology particle counting. Dilute, "low-level" (e.g., leukopenic and thrombocytopenic) "oncology" controls are less informative indicators of calibration status, and are neither required nor recommended. For example, a 10% calibration bias will be numerically most apparent in a high-level control, less apparent in a normal-level control, and perhaps inapparent in a low-level control; it would be quite extraordinary for a low-level control to indicate a calibration problem that is not revealed by the other controls. There should be some relationship between the frequency of control runs and the numbers of patient specimens processed. If the frequency of commercial control use is less than 2 per 24 hours, one or more of the additional approaches to QC must be employed to produce a total of at least 2 different data points per 24 hours.

COMMENTARY:

N/A

REFERENCES: 1) Lott JA, *et al.* Synthetic materials for platelet quality control. *Am J Med Technol.* 1983;49:43-48; 2) Yacko M, *et al.* Multiple methods for platelet enumeration. Observation of a newly introduced bias. *Am J Clin Pathol.* 1987;87:109-112; 3) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2003(Jan 24):7168 42CFR493.1256(d)]; 4) Dotson MA. Methods to monitor and control systematic error. In: clinical hematology: principles, procedures, correlations, 2nd edition. Stiene-Martin EA, *et al.*, eds. Philadelphia, PA: Lippincott, 1998:579-590; 5) Fink NE, *et al.*

(stabilized control material or retained patient specimens) is employed. The latter is needed to detect random error and to avoid bias due to masking of drift by characteristics of the subpopulations within each individual batch.

Laboratories analyzing fewer than 100 CBC specimens daily (long term average) should not use moving averages as the primary method for process control, as this would not generate sufficient data within a day to be of value.

Depending on the particular instrument, there may be "on-board" moving average analyses for RBC indices only. In such cases, additional QC techniques are required for WBC, PLT, and WBC differential parameters. However, some laboratories have found the mathematical logic of moving averages, modified average of normals, etc, applicable to other CBC parameters, and some instruments have these capabilities built into their software. Or, such calculations may be performed with an associated computer.

HEM.25920**Phase II****N/A YES NO****Are control limits for moving averages appropriately sensitive?**

NOTE: There must be documentation of the method used to establish the moving average, the frequency of calculation (batch size), and a definition of the basis for selection of upper and lower limits. Control limits for moving averages must be appropriately sensitive such that significant calibration alterations are always detected. Recalibration is not required for minor calibration variations of no clinical consequence. In other words, there should be a high probability for error detection and a low probability for false rejection.

COMMENTARY:

N/A

REFERENCES: 1) Bull BS, *et al.* A study of various estimators for the derivation of quality control procedures from patient erythrocyte indices. *Am J Clin Pathol.* 1974;61:473-481; 2) Talamo TS, *et al.* Microcomputer assisted hematology quality control using a modified average of normals program. *Am J Clin Pathol.* 1981; 76:707-712; 3) Bull BS, Korpman RA. Autocalibration of hematology analyzers. *J Clin Lab Automation.* 1983;3:111-116; 4) Cembrowski GS, Westgard JO. Quality control of multichannel hematology analyzers: evaluation of Bull's algorithm. *Am J Clin Pathol.* 1985;83:337-345; 5) Bull BS, Hay KL. Are red blood cells indexes international? *Arch Pathol Lab Med.* 1985;109:604-606; 6) Levy WC, *et al.* Preserved blood versus patient data for quality control - Bull's algorithm revisited. *Am J Clin Pathol.* 1986;85:719-721; 7) Levy WC, *et al.* The incorporation of red blood cell index mean data into quality control programs. *Am J Clin Pathol.* 1986;86:193-199; 8) Lunetzky ES, Cembrowski GS. Performance characteristics of Bull's multirule algorithm for the quality control of multichannel hematology analyzers. *Am J Clin Pathol.* 1987;88:634-638; 9) NCCLS. *Calibration and Quality Control of Automated Hematology Analyzers; Proposed Standard.* NCCLS document H38-P [ISBN 1-56238-398-1]. NCCLS, 940 West Valley Road, Wayne, Pennsylvania 19087, U.S.A 1999.

HEM.25990**Phase II****N/A YES NO**

If a "moving averages" system is combined with another control system (e.g., commercial controls or retained patient specimens), is the process well-defined and appropriately sensitive to drift in analyzer calibration?

COMMENTARY:

N/A

REFERENCES: 1) Bull BS, *et al.* A study of various estimators for the derivation of quality control procedures from patient erythrocyte indices. *Am J Clin Pathol.* 1974;61:473-481; 2) Talamo TS, *et al.* Microcomputer assisted hematology quality control using a modified average of normals program. *Am J Clin Pathol.* 1981; 76:707-712; 3) Bull BS, Korpman RA. Autocalibration of hematology analyzers. *J Clin Lab Automation.* 1983;3:111-116; 4) Cembrowski GS, Westgard JO. Quality control of multichannel hematology analyzers: evaluation of Bull's algorithm. *Am J Clin Pathol.* 1985;83:337-345; 5) Bull BS, Hay KL. Are red blood cells indexes international? *Arch Pathol Lab Med.* 1985;109:604-606; 6) Levy WC, *et al.* Preserved blood versus patient data for quality control - Bull's algorithm revisited. *Am J Clin Pathol.* 1986;85:719-721; 7) Levy WC, *et al.* The incorporation of red blood cell index mean data into quality control programs. *Am J Clin Pathol.* 1986;86:193-199; 8) Lunetzky ES, Cembrowski GS. Performance characteristics of Bull's multirule algorithm for the quality control of multichannel hematology analyzers. *Am J Clin Pathol.* 1987;88:634-638; 9) Hackney JR, Cembrowski GS. Evaluation of intralaboratory quality control schemes, In Cavil I. *Quality Control.* Edinburgh, UK: Churchill Livingstone, 1990; 10) Lewis SM, *et al.* Current concepts in haematology 3: blood count calibration. *J Clin Pathol.* 1991;144:881-884.

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 Retained Patient Specimens

Use of retained patient specimens alone is inadequate for routine QC, and must be considered as a supplemental procedure, in combination with another QC system. Retained patient specimens, while conveniently available, present some difficulties in mathematically defining "agreement" between CBC results separated in time, as these are not stabilized samples. This is in contrast to commercial control materials that have been treated to reduce time-dependent degradation.

HEM.26660**Phase I****N/A YES NO**

When the laboratory uses retained patient samples, are statistically defined limits used to determine agreement of sequential assays of a given sample?

NOTE: Allowance should be made for time-dependent alterations in data from such labile samples.

COMMENTARY:

N/A

HEM.27330

Phase I

N/A YES NO

Is there a defined range of CBC values for which these limits are applicable?

NOTE: Because imprecision (standard deviation, coefficient of variation) is dependent upon the hematologic target value, the laboratory should restrict the use of these limits to appropriate ranges of CBC values.

COMMENTARY:

N/A

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Interinstrument Comparisons

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The laboratory may use fresh patient or donor specimens analyzed on a primary instrument for daily QC of a secondary instrument. The selection of these materials (rather than simply stabilized commercial controls) is important to directly address the issue of whether a patient sample yields the same results on all of the laboratory's instruments.

HEM.28000

Phase II

N/A YES NO

If the laboratory has more than one instrument (same or different makes/models) for performing hematology tests, are they checked against each other at least twice a year for correlation of patient results?

NOTE: The selection of fresh blood samples (rather than simply stabilized commercial controls) is important to directly address the issue of whether a patient sample yields the same results on all of the laboratory's instruments. Statistical agreement of commercial control materials across instruments does not guarantee comparability of patient specimen results.

This checklist requirement applies only to instruments/methods accredited under a single CAP number.

COMMENTARY:

N/A

COMMENTARY:

N/A

HEM.30100**Phase II****N/A YES NO****Is there a documented procedure available and in use for detecting and correcting automated WBC counts for the presence of nucleated red cells or megakaryocytes?**

NOTE: The effect of nucleated erythrocytes and blood megakaryocytes on the apparent WBC count varies with the system used for analysis. Each laboratory should evaluate its system(s) and develop appropriate detection and correction procedures. This is important to prevent reporting a falsely high WBC concentration. With some automated CBC instruments, nucleated erythrocytes or megakaryocytes may present themselves histographically or cytographically, and this can serve as an indicator for careful stained blood film inspection. The laboratory must establish if its particular instrument(s) includes some or all nucleated non-leukocytes in its apparent WBC "count".

COMMENTARY:

N/A

REFERENCES: 1) Culp NB, Wallace J. Correcting the NE-series WBC count for nucleated RBCs. *Sysmex J Intl.* 1991;1:62-65; 2) Bridgen ML, Dalal BI. Cell counter-related abnormalities. *Lab Med.* 1999;30:325-334.

HEM.30150**Phase II****N/A YES NO****Is a documented procedure in use to detect other spurious CBC instrument results that may be clinically significant (e.g., pseudomacrocytosis from rouleaux or agglutinates; pseudoleukocytosis with erroneous hemoglobin, falsely low erythrocyte count and hematocrit; hyperlipemias)?**

NOTE: Analytic sources of error with automated instruments depend on the type of instrument and reagents used by the laboratory. Common potential errors for the hemogram (without platelets) include pseudomacrocytosis (due to microclots, cold agglutinins, rouleaux, or osmotic matrix effects), pseudoleukocytosis (due to platelet agglutination, giant platelets, unlysed erythrocytes, nucleated erythrocytes, megakaryocytes, red cell inclusions, cryoproteins, circulating mucin), erroneous hemoglobin and indices (due to lipemia or leukocytosis), falsely low red cell concentration and hematocrit (due to in vitro hemolysis or extreme microcytosis), and falsely depressed results for all parameters (due to clots).

COMMENTARY:

N/A

REFERENCES: 1) Gagne CC, *et al.* Effect of hyperchylomicronemia on the measurement of hemoglobin. *Am J Clin Pathol.* 1977;68:584-586; 2) Cornbleet J. Spurious results from automated hematology cell counters. *Lab Med.* 1983;14:509-514; 3) Gloster ES, *et al.* Spurious platelet counts associated with bacteremia. *Am J Hematol.* 1985;18:329-332; 4) Savage RA. Analytic inaccuracy resulting from hematology specimen characteristics. Three cases of clinically misleading artifacts affecting white blood cell and platelet counts. *Am J Clin Pathol.* 1989;92:295-299; 5) Rohr LR, Rivers FM. Spurious automated leukopenia due to in vitro granulocyte aggregation. *Am J Clin Pathol.* 1990;93:572-574; 6) Robbins SH, *et al.* Cold-induced granulocyte aggregation. A cause of pseudoleukopenia. *Arch Pathol Lab Med.* 1991;115:155-157; 7) Gulati GG, *et al.* Interference by cryoproteins in the blood with automated CBCs. *Lab Med.* 1995;26:138-142; 8) Cantero M, *et al.* Interference from lipemia in cell count by hematology. *Clin Chem.* 1996;42:987-988; 9) Bowen KL. Clinical pathology rounds. Erroneous leukocyte counts and cold agglutinins. *Lab Med.* 1997;28:247-250; 10) Bridgen ML, Dalal BI. Cell counter-related abnormalities. *Lab Med.* 1999;30:325-334.

HEM.30200**Phase I****N/A YES NO****Are red cell indices (MCV, MCH, MCHC) monitored routinely to detect random errors?**

NOTE: Patient sample red cell indices (Wintrobe indices or MCV, MCH, MCHC) should be monitored routinely to detect random errors, instrument malfunction, or spurious results. If semiautomated methods are used, indices should be calculated. On many automated instruments, the MCHC is the most useful parameter to ensure accuracy of the red cell parameters in individual patient samples. Since MCHC varies over a narrow range, an abnormal MCHC will often flag potentially spurious red cell parameters. Truly elevated MCHCs may be seen with spherocytosis, while decreased MCHCs can accompany a low MCV in severe iron deficiency anemia. If such RBC abnormalities are not present on the blood film, one or more of the measured RBC parameters is likely erroneous. Incorrect data may be due to instrument malfunction or to problems with the blood sample itself. Some examples include: spuriously elevated MCVs and MCHCs with cold agglutinins, falsely elevated MCHCs with lipemia and plasma paraproteins, spuriously low MCHCs with leukocytosis and osmotic effects such as hyperglycemia altering MCV. MCV and MCH are fairly constant for each patient, and monitoring these indices in a delta check error detection program may provide rapid patient-based detection of instrument malfunction or specimen misidentification.

COMMENTARY:

N/A

REFERENCES: 1) Cornbleet J. How laboratories use RBC indices. *Arch Intern Med.* 1983;143:1490; 2) Houwen B. Random errors in haematology tests: a process control approach. *Clin Lab Haemat.* 1990;12:157-168; 3) Gulati GG, *et al.* Interference by cryoproteins in the blood with automated CBCs. *Lab Med.* 1995;26:138-142; 4) Cantero M, *et al.* Interference from lipemia in cell count by hematology. *Clin Chem.* 1996;42:987-988; 5) Bridgen ML, Dalal BI. Cell counter-related abnormalities. *Lab Med.* 1999;30:325-334.

HEM.30250**Phase II****N/A YES NO**

Are upper and lower limits of all reportable parameters on the CBC instrument defined, so results that fall outside these limits are verified before reporting?

NOTE: The laboratory must initially establish or verify the reportable range for each parameter of its automated or semi-automated CBC instrument. In particular, the laboratory must have data on its instrument's accuracy with thrombocytopenic and leukopenic samples. Platelet concentrations below the established lower limits must be reanalyzed by another method (e.g., manual hemocytometry, or semiquantitative blood film estimates, or fluorescence flow cytometry using specific platelet monoclonal antibodies). Particle (WBC, RBC, PLT) concentrations above the established upper limits must, as clinically needed, be reanalyzed by doing the minimum dilution necessary to bring the counts into the instrument's analytic range. When clinically appropriate, apparent analyte concentrations that are lower or higher than the reportable range may be reported as "less than" the lower limit or "greater than" the higher limit.

COMMENTARY:

N/A

REFERENCES: 1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 2003(Jan 24):7164 [42CFR493.1253]; 2) Hanseler E, *et al*. Estimation of the lower limits of manual and automated platelet counting. *Am J Clin Pathol*. 1996;105:782-787; 3) Ault KA. Implementation of the immunological platelet count on a hematology analyzer - the Abbott Cell-Dyn 4000. *Lab Hematol*. 1997;3:125-128.

HEM.30300**Phase II****N/A YES NO**

Is there an adequate system (such as microscopic correlation with the blood film) to prevent reporting of spurious thrombocytopenia when platelet clumps, giant platelets, or platelet satellitism are present?

NOTE: When PLT satellitosis (satellitism), significant numbers of giant PLT and/or PLT clumps are suspected/detected by cyto/histographic abnormalities or instrument rejection of a PLT result, the PLT concentration must be independently verified. Correlation with a well-prepared blood film must be made. If PLT are clumped after collection in an EDTA-anticoagulated tube that was well-mixed at the time of collection, this may represent in vitro EDTA-induced changes; PLT should be quantified from blood collected directly into a counting diluent, or by use of a different anticoagulant (e.g., liquid sodium citrate with subsequent adjustment for dilution) or by estimation from a non-anticoagulated blood film.

COMMENTARY:

N/A

REFERENCES: 1) Hyun BH, *et al.* Platelet satellitosis. Chicago, IL: American Society of Clinical Pathology Check Sample H-78, 1976; 2) Veenhoven WA, *et al.* Pseudothrombocytopenia due to agglutinins. *Am J Clin Pathol.* 1979;72:1005-1008; 3) Gloster ES, *et al.* Spurious platelet counts associated with bacteremia. *Am J Hematol.* 1985;18:329-332; 4) Cunningham VL, Brandt JT. Spurious thrombocytopenia due to EDTA-independent cold-reactive agglutinins. *Am J Clin Pathol.* 1992;97:359-362; 5) Hanseler E, *et al.* Estimation of the lower limits of manual and automated platelet counting. *Am J Clin Pathol.* 1996;105:782-787; 6) Bridgen ML, Dalal BU. Cell counter-related abnormalities. *Lab Med.* 1999;30:325-334; 7) Kunicka JE, *et al.* Improved platelet counting using two-dimensional laser light scatter. *Am J Clin Pathol.* 2000;114;114:283-289.

HEM.30350**Phase II****N/A YES NO**

If significant numbers of unlysed RBC, giant platelets and/or platelet clumps are suspected/detected, is the WBC concentration rechecked by another method or are blood films examined to prevent reporting spuriously high WBC concentrations?

NOTE: When unlysed RBC, PLT satellitosis, significant numbers of giant PLT and/or PLT clumps are suspected/detected by histogram abnormalities or instrument rejection of a the PLT result, the WBC count must be verified manually, by automated counting after collection into a different anticoagulant, by automated counting in a lyse-resistant mode, or by semiquantitative blood film evaluation to prevent reporting spuriously high WBC concentrations.

COMMENTARY:

N/A

REFERENCES: 1) Savage RA. Pseudoleukocytosis due to EDTA-induced platelet clumping. *Am J Clin Pathol.* 1984;81:317-322; 2) Rabinovitch A. Anticoagulants, platelets, and instrument problems. *Am J Clin Pathol.* 1984;82:132-133; 3) Cunningham VL, Brandt JT. Spurious thrombocytopenia due to EDTA-independent cold-reactive agglutinins. *Am J Clin Pathol.* 1992;97:359-362; 4) Dorner K, *et al.* Improved automated leukocyte counting and differential in newborns achieved by the haematology analyser Cell-Dyn 3500. *Clin Lab Haem.* 1995;17:23-30; 5) Bridgen ML, Dalal BU. Cell counter-related abnormalities. *Lab Med.* 1999;30:325-334; 6) Kunicka JE, *et al.* Improved platelet counting using two-dimensional laser light scatter. *Am J Clin Pathol.* 2000;114;114:283-289.

HEM.30400**Phase II****N/A YES NO**

If significant numbers of microcytic erythrocytes and/or small cell fragments are detected/suspected, is the platelet count determined or verified using an alternate method?

NOTE: When a significant number of interfering particles are identified at the upper or lower PLT counting threshold (by inspection of the PLT histogram or instrument flag), the PLT concentration

must be determined or verified by an alternate method. Such methods could include alternate instrumentation, hemocytometry, or blood film estimate, depending upon the PLT concentration and the degree of clinical accuracy required.

COMMENTARY:

N/A

REFERENCES: 1) Morton BD, *et al.* Pappenheimer bodies: an additional cause for a spurious platelet count. *Am J Clin Pathol.* 1980;74:310-311; 2) Akware AM, *et al.* Spuriously elevated platelet counts due to microspherocytosis. *Am J Clin Pathol.* 1982;77:220-221; 3) Gloster ES, *et al.* Spurious elevated platelet counts associated with bacteremia. *Am J Hematol.* 1985;18:329-332; 4) Bridgen ML, Dalal BI. Cell counter-related abnormalities. *Lab Med.* 1999;30:325-334; 5) Li S, Salhany KE. Spurious elevation of automated platelet counts in secondary acute monocytic leukemia associated with tumor lysis syndrome. *Arch Pathol Lab Med.* 1999;123:1111-1114; 6) Kunicka JE, *et al.* Improved platelet counting using two-dimensional laser light scatter. *Am J Clin Pathol.* 2000;114;114:283-289.

GENERAL INSTRUMENT ISSUES

HEM.30550	Phase II	N/A YES NO
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Is there a regular schedule for routine function checks and maintenance procedures of the cell counting system?

COMMENTARY:

N/A

HEM.30600	Phase II	N/A YES NO
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Are function checks conveniently recorded or plotted to readily detect instrument malfunction?

COMMENTARY:

N/A

N/A

REFERENCE: Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 2003(Jan 24):7168 [42CFR493.1256(d)].

HEM.33350

Phase II

N/A YES NO

For hemocytometry platelets, is the manual count correlated with a platelet estimate from a properly prepared blood film?

COMMENTARY:

N/A

REFERENCES: 1) Abbey AP, Belliveau RR. Enumeration of platelets. *Am J Clin Pathol*. 1978;69:55-56; 2) Nosanchuk JS, *et al*. The analytic basis for the use of platelet estimates from peripheral blood smears. Laboratory and clinical applications. *Am J Clin Pathol*. 1978;69:383-387; 3) Mogadam L. Application of the Miller's disc for the estimation and quality control of the platelet count. *Lab Med*. 1980;11:131-132.

AUTOMATED DIFFERENTIAL COUNTERS

HEM.34050

Phase II

N/A YES NO

Is there documentation to indicate that the automated method was carefully evaluated in the laboratory against a previously validated automated method or a manual method before it was placed into routine use?

NOTE: The laboratory should have the results of its evaluation studies, either in summary form or actual data, available to the inspector for review. The laboratory is not required to verify the manufacturer's studies on flagging of abnormal cells, although studies of the local patient population are recommended. The references that accompany this checklist question may be consulted for examples of specific evaluation protocols.

COMMENTARY:

N/A

REFERENCES: 1) Rümke CL. The statistically expected variability in differential leukocyte counts. In: Differential leukocyte counting, CAP conference/Aspen. Northfield, IL: CAP, 1977:39-45; 2) Kalish RJ, Becker K. Evaluation of the Coulter S-Plus V three-part differential in a community hospital, including criteria for its use. *Am J Clin Pathol.* 1986;86:751-755; 3) Ross DW, Bentley SA. Evaluation of an automated hematology system (Technicon H-1). *Arch Pathol Lab Med.* 1986;110:803-808; 4) Clinical and Laboratory Standards Institute (CLSI). *Reference Leukocyte (WBC) Differential Count (Proportional) and Evaluation of Instrumental Methods; Approved Standard—Second Edition.* CLSI document H20-A2 (ISBN 1-56238-628-X). Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2007; 5) Miers MK, *et al.* White blood cell differentials as performed by the Technicon H-1; evaluation and implementation in a tertiary care hospital. *Lab Med.* 1991;22:99-106; 6) Hallawell R, *et al.* An evaluation of the Sysmex NE-8000 hematology analyzer. *Am J Clin Pathol.* 1991;96:594-601; 7) Cornbleet PJ, *et al.* Evaluation of the Cell-Dyn 3000 differential. *Am J Clin Pathol.* 1992;98:603-614; 8) NCCLS. *Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline—Second Edition.* NCCLS document EP9-A2 (ISBN 1-56238-472-4). NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2002; 9) Krause JR. The automated white blood cell differential. A current perspective. *Hematol Oncol Clin North Am.* 1994;8:605-16; 10) Goyzueta FG, *et al.* Automated differential white blood cell counts in the young pediatric population. *Lab Med.* 1996;27:48-52; 11) Gulati GL, *et al.* Suspect flags and regional flags on the Coulter-STKS. An assessment. *Lab Med.* 1999;30:675-680; 12) Grimaldi E, Scopacasa F. Evaluation of the Abbott CELL-DYN 4000 hematology analyzer. *Am J Clin Pathol.* 2000;113:497-505.

HEM.34100

Phase II

N/A YES NO

Does the quality control procedure define limits of agreement with WBC subclasses from manually counted blood films or commercially available material containing at least two classes of white cells and/or surrogate particles?

NOTE: For pattern recognition microscopy systems, QC can be done by periodic processing of prepared control slides and maintenance/analysis of Levey-Jennings charts. For flow-through systems, at least two approaches are reasonable: 1) comparison of instrument differentials on fresh blood samples with a conventional manual differential count, and/or 2) use of commercially available stabilized leukocytes and/or particle surrogate control material. The automated instrument and reference determinations should be treated as replicate manual differentials and evaluated using the ± 2 or 3 S.D. agreement limits of Rümke.

For commercial controls, mixed leukocyte subclasses (e.g., "mononuclear" or "large unclassified cells") or "remainder" fractions do not need to be assessed with QC procedures. The commercial material should contain surrogate particles to measure total neutrophils, total granulocytes, total lymphoid cells, monocytes, eosinophils, and basophils, if these subtypes are enumerated by the instrument and reported by the laboratory. If discrete populations of abnormal cells are identified and enumerated by the instrument (e.g., nucleated RBC, blasts), then the QC material must contain surrogate particles to evaluate accuracy.

COMMENTARY:

N/A

REFERENCES: 1) Rümke CL. The statistically expected variability in differential leukocyte counts. In: Differential leukocyte counting, CAP conference/Aspen. Northfield, IL: CAP, 1977:39-45; 2) Kalish RJ, Becker K. Evaluation of the Coulter S-Plus V three-part differential in a community hospital, including criteria for its use. *Am J Clin Pathol.* 1986;86:751-755; 3) Ross DW, Bentley SA. Evaluation of an automated hematology system (Technicon H-1). *Arch Pathol Lab Med.* 1986;110:803-808; 4) Clinical and Laboratory Standards Institute (CLSI). *Reference Leukocyte (WBC) Differential Count (Proportional) and Evaluation of Instrumental Methods; Approved Standard—Second Edition.* CLSI document H20-A2 (ISBN 1-56238-628-X). Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2007; 5) Miers MK, *et al.* White blood cell differentials as performed by the Technicon H-1; evaluation and implementation in a tertiary care hospital. *Lab Med.* 1991;22:99-106; 6) Hallawell R, *et al.* An evaluation of the Sysmex NE-8000 hematology analyzer. *Am J Clin Pathol.* 1991;96:594-601; 7) Cornbleet PJ, *et al.* Evaluation of the Cell-Dyn 3000 differential. *Am J Clin Pathol.* 1992;98:603-614; 8) NCCLS. *Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline—Second Edition.* NCCLS document EP9-A2 (ISBN 1-56238-472-4). NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2002; 9) Krause JR. The automated white blood cell differential. A current perspective. *Hematol Oncol Clin North Am.* 1994;8:605-16; 10) Goyzueta FG, *et al.* Automated differential white blood cell counts in the young pediatric population. *Lab Med.* 1996;27:48-52; 11) Gulati GL, *et al.* Suspect flags and regional flags on the Coulter-STKS. An assessment. *Lab Med.* 1999;30:675-680; 12) Grimaldi E, Scopacasa F. Evaluation of the Abbott CELL-DYN 4000 hematology analyzer. *Am J Clin Pathol.* 2000;113:497-505.

HEM.34200**Phase II****N/A YES NO**

Has the laboratory established criteria for checking and reviewing leukocyte differential counter data, histograms, and/or blood films for clinically important results flagged by the automated differential counter?

NOTE: Clinically important results include pathologic quantities of normal cell types and abnormal cells. Flagging mechanisms include those within the particular instrument, inspection of histogram/cytographic displays, laboratory criteria based on local experience, and awareness of published evaluations.

COMMENTARY:

N/A

REFERENCES: 1) Rümke CL. The statistically expected variability in differential leukocyte counts. In: Differential leukocyte counting, CAP conference/Aspen. Northfield, IL: CAP, 1977:39-45; 2) Payne BA, Pierre RV. Using the three-part differential: part II. Implementation of the system. *Lab Med.* 1986;17:517-522; 3) Kalish RJ, Becker K. Evaluation of the Coulter S-Plus V three-part differential in a community hospital, including criteria for its use. *Am J Clin Pathol.* 1986;86:751-755;

4) Ross DW, Bentley SA. Evaluation of an automated hematology system (Technicon H-1). *Arch Pathol Lab Med.* 1986;110:803-808; 5) Clinical and Laboratory Standards Institute (CLSI). *Reference Leukocyte (WBC) Differential Count (Proportional) and Evaluation of Instrumental Methods; Approved Standard—Second Edition.* CLSI document H20-A2 (ISBN 1-56238-628-X). Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2007; 6) Miers MK, *et al.* White blood cell differentials as performed by the Technicon H-1; evaluation and implementation in a tertiary care hospital. *Lab Med.* 1991;22:99-106; 7) Hallawell R, *et al.* An evaluation of the Sysmex NE-8000 hematology analyzer. *Am J Clin Pathol.* 1991;96:594-601; 8) Cornbleet PJ, *et al.* Evaluation of the Cell-Dyn 3000 differential. *Am J Clin Pathol.* 1992;98:603-614; 9) NCCLS. *Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline—Second Edition.* NCCLS document EP9-A2 (ISBN 1-56238-472-4). NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2002; 10) Krause JR. The automated white blood cell differential. A current perspective. *Hematol Oncol Clin North Am.* 1994;8:605-16; 11) Goyzueta FG, *et al.* Automated differential white blood cell counts in the young pediatric population. *Lab Med.* 1996;27:48-52; 12) Gulati GL, *et al.* Suspect flags and regional flags on the Coulter-STKS. An assessment. *Lab Med.* 1999;30:675-680.

 MANUAL BLOOD FILM EXAMINATION (DIFFERENTIAL COUNT)

HEM.34300

Phase II

N/A YES NO

Is the quality of blood films satisfactory (properly stained, free of precipitate, good cell distribution)?

COMMENTARY:

N/A

REFERENCES: 1) Wenk RE. Comparison of five methods for preparing blood smears. *Am J Med Technol.* 1976;42:71-78; 2) College of American Pathologists. Differential leukocyte counting. CAP conference/aspen. Northfield, IL: CAP, 1977; 3) Stiene-Martihn EA. Causes for poor leukocyte distribution in manual spreader-slide blood films. *Am J Med Technol.* 1980;46:624-632; 4) Lewis SM. Blood film evaluations as a quality control activity. *Clin Lab Haematol.* 1990;12:119-127; 5) Turgeon ML. *Clinical hematology, theories and procedures*, 2nd ed. Boston, MA: Little, Brown, 1993;16-25; 6) Dacie JV, Lewis SM. *Practical hematology*, 8th ed. New York, NY: Churchill Livingstone, 1995;83-89.

HEM.34350

Phase II

N/A YES NO

Are slides uniquely identified?

NOTE: Slides or coverslips must be uniquely identified by element(s) such as specimen or accession number, or patient name and/or number.

COMMENTARY:

N/A

****REVISED**** **09/27/2007**

HEM.34400 **Phase II** **N/A YES NO**

Does the hematology laboratory have a documented system to ensure consistency of morphologic observations among all personnel performing blood cell microscopy?

NOTE: Suggested methods to accomplish this include:

1. *Circulation of blood films with defined leukocyte differential distributions and specific qualitative abnormalities of each class of cells (WBC, RBC, PLT), and/or*
2. *Multi-headed microscopy, and/or*
3. *Use of blood or marrow photomicrographs with referee and consensus identifications (e.g., former CAP surveys photomicrographs)*

The procedure manual should include definitions of semiquantitative measurements such as 1+, 2+, 3+, etc.

In the case of comparative blood film WBC differentials, the method of Rümke is recommended to define statistical agreement between observers (Rümke CL. The statistically expected variability in differential leukocyte counts. In: Differential Leukocyte Counting, CAP Conference/Aspen. Northfield, IL: CAP, 1977:39-45.

COMMENTARY:

N/A

REFERENCES: 1) Rümke CL. The statistically expected variability in differential leukocyte counts, In: Differential leukocyte counting, CAP conference/Aspen. Northfield, IL: CAP, 1977:39-45; 2) Wood B, *et al.* Teaching the clinical interpretation of peripheral blood smears to second-year medical school class using the peripheral blood-tutor computer program. *Am J Clin Pathol.* 1998;109:514-520; 3) College of American Pathologists. Surveys hematology glossary. Northfield, IL: CAP, 1999:1-26; 4) Brigden ML, Dalal BI. Morphologic abnormalities, pseudosyndromes, and spurious test results. *Lab Med.* 1999;30:397-405; 5) Haun DE, *et al.* A better way to assess WBC differential counting skills. *Lab Med.* 2000;31:329-333.

HEM.34724 **Phase I** **N/A YES NO**

Are both thick and thin films (routine blood films and/or buffy coat films) made to provide thorough examination for blood parasites?

COMMENTARY:

N/A

REFERENCES: 1) NCCLS. Laboratory diagnosis of blood-borne parasitic diseases; approved guideline M15-A. Wayne, PA: NCCLS, 2000; 2) Thomson S, *et al.* External quality assessment in the examination of blood films for malarial parasites within Ontario, Canada. *Arch Pathol Lab Med.* 2000;124:57-60.

****REVISED**** **10/31/2006**

HEM.34798 **Phase I** **N/A YES NO**

Is there documentation that malaria stains are washed with a buffer of a pH appropriate for the stain used (e.g. pH 6.8-7.2 for Giemsa, or the range specified by the manufacturer)?

COMMENTARY:

N/A

REFERENCES: 1) NCCLS. Laboratory diagnosis of blood-borne parasitic diseases; approved guideline M15-A. Wayne, PA: NCCLS, 2000; 2) Garcia LS, Bruckner DA. Diagnostic medical parasitology. Washington, DC: American Society for Microbiology, 1997:702-703.

HEM.34872 **Phase I** **N/A YES NO**

Are an adequate number of fields examined under a 100 X oil-immersion objective (e.g., 300 fields)?

COMMENTARY:

N/A

REFERENCE: NCCLS. Laboratory diagnosis of blood-borne parasitic diseases; approved guideline M15-A. Wayne, PA: NCCLS, 2000.

HEM.34946**Phase II****N/A YES NO**

Are the results of positive blood parasite films reported in accordance with laboratory policy for alert (critical) values?

COMMENTARY:

N/A

AUTOMATED RETICULOCYTES

HEM.35020**Phase I****N/A YES NO**

Is there documentation to indicate that the automated method was carefully evaluated in the laboratory against previous manual or automated reticulocyte methods before use for patient reporting?

COMMENTARY:

N/A

REFERENCES: 1) Davis BH, *et al.* Flow cytometric reticulocyte analysis: multiinstitutional laboratory correlation study. *Am J Clin Pathol.* 1994;102:468-477; 2) Buttarello M, *et al.* Laboratory evaluation of the Miles H-3 automated reticulocyte counter. A comparative study with manual reference method and Sysmex R-1000. *Arch Pathol Lab Med.* 1995;119:1141-1148; 3) Buttarello M, *et al.* Reticulocyte quantification by Coulter MAXM VCS (volume, conductivity, light scatter) technology. *Clin Chem.* 1996;42:1930-1937; 4) Cunningham MT, *et al.* Effect of normalization on the intermethod variability of reticulocyte counting. *Lab Hematol.* 1996;2:94-98; 5) Davis BH, *et al.* Immature reticulocyte fraction (IRF) and reticulocyte counts. Comparison of Cell Dyn 4000, Sysmex R-3000, thiazole orange flow cytometry, and manual counts. *Lab Hematol.* 1996;2:144-150; 6) NCCLS. *Methods for Reticulocyte Counting (Automated Blood Cell Counters, Flow Cytometry, and Supravital Dyes); Approved Guideline—Second Edition.* NCCLS document H44-A2 (ISBN 1-56238-527-5). NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2004; 7) Lacombe F, *et al.* Automated reticulocyte counting and immature reticulocyte fraction measurement. *Am J Clin Pathol.* 1999;112:677-686; 8) Buttarello M, *et al.* Flow cytometric reticulocyte counting. Parallel evaluation of five fully automated analyzers: an NCCLS-ICSH approach. *Am J Clin Pathol.* 2001;115:100-111; 9) Riley RS, *et al.* Reticulocyte enumeration: past & present. *Lab Med.* 2001;10:599-608; 10) Buttarello M, *et al.* Five fully automated methods for performing immature reticulocyte fraction. Comparison in diagnosis of bone marrow aplasia. *Am J Clin Pathol.* 2002;117:871-879.

HEM.35050**Phase I****N/A YES NO****Is there a procedure in place to determine the strength and stability of the detection dye used for flow-through instrument quantification of reticulocytes?**

NOTE: The laboratory must have a procedure to determine the strength and stability of the detection dye for reticulocytes. Automated reticulocyte enumeration depends upon fluorescent RNA (or DNA-RNA)-binding dyes such as acridine orange, pyronine Y, propidium iodine, thioflavin T, auramine O, etc., as the detection agent. Accurate determination of the RNA (or DNA-RNA) binding depends on the stoichiometric properties of each dye. The dye should be at saturating concentration, and the concentration of the dye in its buffer should be noted on the reagent container. Determination of the saturating concentration of the dye must be performed by correlative study of automated results with a manual method on a series of samples of low, normal, and high reticulocyte concentrations, with preference given to detection of low reticulocyte counts. These procedures are not required of commercial kits cleared by the Food and Drug Administration (FDA) and used according to manufacturer's instructions.

COMMENTARY:

N/A

REFERENCES: 1) Crissman HA, Steinkamp JA. Cytochemical techniques for multivariate analysis of DNA and other cellular constituents, In: Melamed MR, Lindmo T, Mendelsohn ML, eds. Flow cytometry and sorting, 2nd ed. New York, NY: Wiley-Liss, 1990:227-248; 2) Darzynkiewicz Z, Kaperscinski J. Acridine orange: a versatile probe of nucleic acids and other cell constituents, In: Melamed MR, Lindmo T, Mendelsohn ML, eds. Flow cytometry and sorting, 2nd ed. New York, NY: Wiley-Liss, 1990:291-314; 3) Riley RS, Ross W. Reticulocyte enumeration, In: Riley RS, Makin EJ, Ross W, eds. Clinical applications of flow cytometry. New York, NY: Igaku-shoin, 1993:582-611.

****REVISED**** **10/31/2006****HEM.35100****Phase I****N/A YES NO****Is there a quality control program to determine the reproducibility (precision) of reticulocyte quantification?**

NOTE: This may be accomplished by running 2 levels of control every 24 hours. Preferably, QC material should include both normal and abnormal values.

COMMENTARY:

N/A

REFERENCES: 1) Savage RA, *et al.* Analytic inaccuracy and imprecision in reticulocyte counting: a preliminary report from the College of American Pathologists reticulocyte project. *Blood Cells*.

1981;11:97-112; 2) Peebles DA, *et al.* Analysis of manual reticulocyte counting. *Am J Clin Pathol.* 1981;76:713-717; 3) Hackney JR, *et al.* Automated reticulocyte counting by image analysis and flow cytometry. *Lab Med.* 1989;20:551-555; 4) Tsuda I, Tatsumi N. Reticulocytes in human preserved blood as control material for automated reticulocyte counters. *Am J Clin Pathol.* 1990;93:109-110; 5) Hohenwallner W, *et al.* The reticulocytes; automatic counting, indication and interpretation. *Sysmex J Intl.* 1992;2:120-135; 6) Batjer JD, *et al.* Predicting bone marrow transplant engraftment by automated flow cytometric reticulocyte analysis. *Lab Med.* 1994;25:22-26; 7) Davis BH, *et al.* Flow cytometric reticulocyte analysis. Multi-institutional interlaboratory correlation study. *Am J Clin Pathol.* 1994;102:468-477; 8) Cunningham MT, *et al.* Effect of normalization on the intermethod variability of reticulocyte counting. *Lab Hematol.* 1996;2:94-98; 9) Koepke JA. Update on reticulocyte counting. *Lab Med.* 1999;30:339-343; 10) NCCLS. *Methods for Reticulocyte Counting (Automated Blood Cell Counters, Flow Cytometry, and Supravital Dyes); Approved Guideline—Second Edition.* NCCLS document H44-A2 (ISBN 1-56238-527-5). NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2004.

HEM.35150

Phase I

N/A YES NO

Are there documented criteria for identifying samples that may give spurious reticulocyte results by the automated method?

NOTE: Since all DNA- and RNA-containing cells will stain with DNA-RNA fluorescent dyes, a procedure must be in place to identify when the instrument cannot discriminate such stained particles from true reticulocytes. Potential interferences include Howell-Jolly bodies, nucleated erythrocytes, Heinz bodies, basophilic stippling of red cells, macrothrombocytes, megakaryocyte fragments, platelet clumps, and malaria or other intracellular organisms. Erythrocyte agglutination also may give spuriously high results, as may very high leukocytosis or thrombocytosis. Interfering particles may vary, depending on instrumentation, dye, and reaction conditions. Based upon initial evaluation of the instrument by the laboratory, criteria must be developed to detect samples with potentially erroneous results. This may be accomplished through flagging algorithms incorporated in the instrument and by examination of a blood film from every sample to ensure absence of relevant interferences.

COMMENTARY:

N/A

REFERENCES: 1) Jacobberger HW, *et al.* Flow cytometric analysis of blood cells stained with the cyanine dye Dioc1[3]: reticulocyte quantification. *Cytometry.* 1984;5:589-600; 2) Davis BH, *et al.* Utility of flow cytometric reticulocyte quantification as a predictor of engraftment in autologous bone marrow transplantation. *Am J Hematol.* 1989;32:81-87; 3) Davis BH, Bigelow NC. Flow cytometric quantification using thiazole orange provides clinically useful reticulocyte maturity index. *Arch Pathol Lab Med.* 1989;113:684-689; 4) Hackney JR, *et al.* Automated reticulocyte counting by image analysis and flow cytometry. *Lab Med.* 1989;20:551-555; 5) Coulet M, Bezou MJ. Utilization of the automated reticulocyte counter Sysmex R-1000. *Sysmex J.* 1990;13:393-406; 6) Wells DA, *et al.* Effect of iron status on reticulocyte mean channel fluorescence. *Am J Clin Pathol.* 1992;97:130-134; 7) Riley RS, Ross W. Reticulocyte enumeration, In: Riley RS, Makin EJ, Ross W, eds. Clinical

COMMENTARY:

N/A

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Body Fluid Cell Counting - Instrumental
.....**HEM.35414 Phase II****N/A YES NO****Are instrument background counts performed on the diluent fluid and lysing agent to check for contamination that might affect cell counts?**

NOTE: This can be done by processing these fluids on the instrument used for cell counting and checking for the presence of significant background in the diluting fluids and lysing agents.

COMMENTARY:

N/A

HEM.35433 Phase I**N/A YES NO****Has the laboratory established a sensitivity limit for each class of particle counted?**

NOTE: The sensitivity limit is readily defined by performing serial dilutions of cells and graphically plotting expected recovery against observed count.

COMMENTARY:

N/A

REFERENCES: 1) International Committee for Standardization in Haematology (ICSH). Protocol for evaluation of automated blood cell counters. *Clin Lab Haemat.* 1984;6:69-84; 2) Heaney LG, *et al.* Electronic cell counting to measure total cell numbers in bronchoalveolar lavage fluid. *Eur Respir J.* 1994;7:1527-1531; 3) Dietz LJ, *et al.* Volumetric capillary cytometry: a new method for absolute cell enumeration. *Cytometry.* 1996;23:177-186; 4) Salinas M, *et al.* Comparison of manual and automated cell counts in EDTA preserved synovial fluids. *Ann Rheum Dis.* 1997;56:622-626; 5) Subira D, *et al.* Flow cytometric analysis of cerebrospinal fluid samples and its usefulness in routine clinical practice. *Am J Clin Pathol.* 2002;117:952-958.

N/A

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Body Fluid Nucleated Cell Differentials

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HEM.35528

Phase I

N/A YES NO

Is the method for differentiating body fluid cells appropriate for the intended clinical use?

NOTE: The laboratory should use stained cytocentrifuge preparations to facilitate quantitative differentials and complete classification of nucleated cell types in body fluids, as opposed to performing differentials of unstained hemocytometer preparations. Differentials based on supravital-stained hemocytometer preparations, wedge smears and drop preparations are considered suboptimal; their use should be limited to clinical circumstances requiring differentiation of polymorphonuclear from mononuclear cells (e.g., bacterial meningitis). Further sub-classification of nucleated cells, particularly the detection of malignant cells, should be performed using slide preparation methods that provide optimal cell recovery and morphologic detail, such as cytocentrifugation. Cytocentrifuge preparations provide excellent morphologic detail, deliver a high yield of cells even when the concentration is low, and have a high rate of detection for malignant cells. In cases of leukemia or lymphoma, Romanowsky-stained cytospin slides show excellent morphologic correlation with blood and bone marrow smears. If the laboratory uses an alternate slide preparation method or stain for sub-classification of body fluid mononuclear cells and/or detection of malignant cells, it must demonstrate from literature or in-house studies that this technique is equivalent in cell yield/recovery and morphologic detail to Romanowsky-stained cytocentrifuge preparations.

COMMENTARY:

N/A

REFERENCES: 1) Mengel M. The use of the cytocentrifuge in the diagnosis of meningitis. *Am J Clin Pathol.* 1985;84:212-216; 2) Ricevuti G, et al. Meningeal leukemia diagnosed by cytocentrifuge study of cerebrospinal fluid. *Arch Neurol.* 1986;43:466-470; 3) Davey DD, et al. Millipore filter vs cytocentrifuge for detection of childhood central nervous system leukemia. *Arch Pathol Lab Med.* 1986;110:705-708; 4) Clare N, Rone R. Detection of malignancy in body fluids. *Lab Med.* 1986;17:147-150; 5) Odom LF, et al. Significance of blasts in low-cell cerebrospinal specimens from children with acute lymphoblastic leukemia. *Cancer.* 1990;66:1748-1754; 6) Craver RD, Carson TH. Hematopoietic elements in cerebrospinal fluid in children. *Am J Clin Pathol.* 1991;95:532-535; 7) Rippin KP, et al. Clinical evaluation of the slide centrifuge (cytospin) gram's stained smear for the detection of bacteriuria and comparison with the Filtracheck-UTI and UTIscreen. *Am J Clin Pathol.* 1995;103:316-319; 8) Jones CD, Cornbleet PJ. Wright-Giemsa cytology of body fluids. Techniques for optimal cytocentrifuge slide preparation. *Lab Med.* 1997;28:713-716; 9) Kleine TO, Lehmitz R. Evaluation of cytodagnosis of cerebrospinal fluid (CSF) cells. *Clin Chem.* 2000;46:A137.

COMMENTARY:

N/A

HEM.35604 Phase II

N/A YES NO

If a body fluid specimen is examined in more than one area of the laboratory, is there a mechanism to compare the data and interpretations from these different areas, particularly when a diagnosis of malignancy is rendered?

COMMENTARY:

N/A

REFERENCES: 1) Clare N, Rone R. Detection of malignancy in body fluids. *Lab Med.* 1986;17:147-150; 2) Walts AE, Strigle S. Toward optimal use of the cytology laboratory: quality improvement and cerebrospinal fluid specimens. *Diagn Cytopathol.* 1995;13:357-361.

HEM.35623 Phase I

N/A YES NO

Is there a file of unusual slides and/or an atlas of body fluid cytomorphology readily available to the technologist evaluating the slides, to assist in the identification of cell types?

COMMENTARY:

N/A

REFERENCES: 1) Kolmer HW. Atlas of cerebrospinal fluid cells, 2nd ed. New York, NY: Springer-Verlag, 1977; 2) Dieppe PA, *et al.* Synovial fluid crystals. *Quart J Med.* 1979;192:533-553; 3) Glasser L. Body fluids II. Reading the signs in synovia. *Diag Med.* 1980;3(6):35-50; 4) Glasser L. Body fluids III. Tapping the wealth of information in CSF. *Diag Med.* 1981;4:23-33; 5) Greening SE, *et al.* Differential diagnosis in effusion cytology. *J Med Tech.* 1984;1:885-895; 6) Strasinger SK. Urinalysis and body fluids. A self-instructional text. Philadelphia: FA Davis, 1985:134-186; 7) Hyun BH, Salazar GH. Cerebrospinal fluid cells in leukemias, lymphomas, and myeloma. *Lab Med.* 1985;16: 667-670; 8) Kjeldsberg CR, Knight JA. Body fluids, 3rd ed. Chicago, IL: American Society of Clinical Pathology, 1993.

HEM.35642 Phase I

N/A YES NO

Are slides retained for future reference?

2) Yeung CH, *et al.* A technique for standardization and quality control of subjective sperm motility assessments in semen analysis. *Fertil Steril.* 1997;67:1156-1158.

****NEW****

09/27/2007

HEM.35768

Phase II

N/A YES NO

Is forward progression of sperm evaluated?

NOTE: This includes training and assessing the competency of personnel to perform and document the forward progression.

COMMENTARY:

N/A

REFERENCES: 1) World Health Organization laboratory manual for the examination of human semen and sperm-cervical mucus interaction, 4th edition. New York, NY: Cambridge University Press, 1999; 2) Vulcano GJ, *et al.* A lineal equation for the classification of progressive and hyperactive spermatozoa. *Math Biosci.* 1998;149:77-93.

HEM.35775

Phase II

N/A YES NO

Is sperm motility percent and progression routinely evaluated within one hour of collection?

NOTE: Exceptions must be documented on the final report.

COMMENTARY:

N/A

REFERENCE: World Health Organization laboratory manual for the examination of human semen and sperm-cervical mucus interaction, fourth edition. New York, NY: Cambridge University Press, 1999.

HEM.35794

Phase II

N/A YES NO

Has the laboratory established a standard specimen temperature range for semen analysis assessment, and are deviations from this temperature noted on the report?

NOTE: The laboratory must establish a standard specimen temperature range for semen evaluation assessment, and deviations from this temperature must be noted on the report, since specimen motility is temperature-dependent. Specimens may be maintained at 37°C by use of an incubator and heated microscopic stage. Alternatively, a defined room temperature range is acceptable.

COMMENTARY:

N/A

REFERENCE: World Health Organization laboratory manual for the examination of human semen and sperm-cervical mucus interaction, fourth edition. New York, NY: Cambridge University Press, 1999.

HEM.35813**Phase II****N/A YES NO**

Does the laboratory have an appropriate procedure for evaluating a sufficient number of separate and randomly chosen microscopic fields and motile sperm cells?

COMMENTARY:

N/A

REFERENCE: World Health Organization laboratory manual for the examination of human semen and sperm-cervical mucus interaction, fourth edition. New York, NY: Cambridge University Press, 1999.

****NEW******09/27/2007****HEM.35822****Phase I****N/A YES NO**

Does the laboratory perform viability testing on specimens with low percent motility (e.g., less than 30%)?

NOTE: Non-motile sperm may represent forms that were originally non-viable in the ejaculate, or previously motile forms that have subsequently lost motility. Thus, viability assessment is useful in making the distinction, and is commonly performed with a dye-exclusion method such as eosin-nigrosin.

If viability testing is not performed on samples with decreased motility, the laboratory should include a comment on the patient report that the decreased motility may be due to either non-viable or non-motile sperm.

COMMENTARY:

N/A

REFERENCES: 1) World Health Organization laboratory manual for the examination of human semen and sperm-cervical mucus interaction: 4th edition. New York, NY: Cambridge University Press, 1999; 2) Gunalp S, *et al.* A study of semen parameters with emphasis on sperm morphology in a fertile population: an attempt to develop clinical thresholds. *Hum Repro.* 2001;16:110-114.

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Stained Smear - Sperm Differential
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****REVISED**** **09/27/2007**

HEM.35832 Phase II N/A YES NO

Is the sperm morphology classification method used indicated on the report?

NOTE: Different classification systems have different reference intervals for normality. To improve the consistency and usefulness of reporting, CAP recommends the use of the most current edition of the WHO Standards and the Kruger classification system, and discontinuing the use of older classification systems.

COMMENTARY:

N/A

REFERENCES: 1) Kruger, T.F., *et al.* Sperm morphology features as a prognostic factor in vitro fertilization. *Fertility and Sterility* 46:1118-1123, 1986; 2) World Health Organization laboratory manual for the examination of human semen and sperm-cervical mucus interaction, fourth edition. New York, NY: Cambridge University Press, 1999; 3) Gunalp S, *et al.* A study of semen parameters with emphasis on sperm morphology in a fertile population: an attempt to develop clinical thresholds. *Hum Repro.* 2001;16:110-114.

****REVISED**** **04/06/2006**

HEM.35851 Phase II N/A YES NO

Does the laboratory have a documented system to ensure consistency of morphologic observations among all personnel performing microscopic morphologic classification of sperm and other cells?

NOTE: Suggested elements of such a system may include:

1. *Circulation of stained semen smears with defined specific qualitative abnormalities of sperm*
2. *Multi-headed microscopy*
3. *Use of current published references*

COMMENTARY:

NOTE: If stabilized control materials are used, they should represent different analytic levels (e.g., normal and high). Similarly, retained patient specimens should be of differing counts and/or motility, as applicable.

****NEW**** **09/27/2007**

HEM.35914 **Phase II** **N/A YES NO**

Is calibration verified with materials appropriate to the reportable range of the instrument, and is verification documented?

NOTE: The quality control procedure for the automated instrument must include calibration and evaluation using defined limits of agreement with manually counted semen smears or stored digital images, as appropriate for the particular system. Automated semen analysis laboratories must periodically establish that their analysis equipment is functioning correctly and there is a protocol to determine if the analysis is in control.

COMMENTARY:

N/A

REFERENCE: Guidelines for human embryology and andrology laboratories. *Fertil Steril.* 1992;58(suppl 1):I, B, 6.

****NEW**** **09/27/2007**

HEM.35915 **Phase II** **N/A YES NO**

Does the laboratory perform and document calibration and quality control methods for the analyzer during each day of use, using an appropriate number of controls with varying ranges of values?

COMMENTARY:

N/A

REFERENCE: Guidelines for human embryology and andrology laboratories. *Fertil Steril.* 1992;58(suppl 1):I, B, 6.

3. *After major maintenance or service*
4. *When recommended by the manufacturer*
5. *At least every six months*

COMMENTARY:

N/A

REFERENCE: Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 2003(Jan 24):7165 [42 CFR 493.1255].

ABNORMAL HEMOGLOBIN DETECTION

The inspector will examine an example of the medium (media) used to identify hemoglobin variants. These may include alkaline and/or acid electrophoresis, isoelectric focusing, high performance liquid chromatography, or other methods. Hemoglobin solubility testing alone is NOT sufficient for detecting or confirming the presence of sickling hemoglobins in all situations. For purposes of diagnosing hemoglobinopathies, additional tests are required.

HEM.35925**Phase II****N/A YES NO**

Are all samples that appear to have Hb S in the primary screening (by whatever method) further examined to confirm the presence of Hb S by solubility testing or other acceptable methods?

NOTE: If the laboratory screens for sickling hemoglobins by solubility testing, a second test must be performed to confirm the presence of a sickling hemoglobin. If the laboratory does no other testing for abnormal hemoglobins, a comment must be attached to the report of positive solubility results, recommending that additional confirmatory testing be performed.

For primary screening by electrophoresis or other separation methods, all samples with hemoglobins migrating in the "S" positions or peak must be tested for solubility or by other acceptable confirmatory testing for sickling hemoglobin(s). Known sickling and non-sickling controls both must be included with each run of patient specimens tested.

COMMENTARY:

N/A

HEM.35927**Phase II****N/A YES NO**

Are controls containing at least three known major hemoglobins, including both a sickling and a non-sickling hemoglobin (e.g., A, F, and S) applied with the patient specimen(s) and are separations satisfactory?

COMMENTARY:

N/A

REFERENCES: 1) Fairbanks VF. Hemoglobinopathies and thalassemias. Laboratory methods and case studies. New York, NY: BC Decker, 1980; 2) Beuzard Y, *et al.* Isoelectric focusing of human hemoglobins, In Hanash, Brewer, eds. Advances in hemoglobin analysis. New York, NY: Alan R. Liss, 1981:177-195; 3) Cossu G, *et al.* Neonatal screening of beta-thalassemias by thin layer isoelectric focusing. *Am J Hematol.* 1982;13:149; 4) Bunn HF, Forget BG. Hemoglobin: molecular, genetic and clinical aspects. Philadelphia, PA: WB Saunders, 1986; 5) Honig GR, Adams JG III. Human hemoglobin genetics. Vienna, Austria: Springer-Verlag, 1986; 6) Jacobs S, *et al.* Newborn screening for hemoglobin abnormalities. A comparison of methods. *Am J Clin Pathol.* 1986;85:713-715; 7) Fishleder AJ, Hoffman GC. A practical approach to the detection of hemoglobinopathies: part I. The introduction and thalassemia syndromes. *Lab Med.* 1987;18:368-372; 8) Fishleder AJ, Hoffman GC. A practical approach to the detection of hemoglobinopathies: part II. The sickle cell disorders. *Lab Med.* 1987;18:441-443; 9) Fishleder AJ, Hoffman GC. A practical approach to the detection of hemoglobinopathies: part III. Nonsickling disorders and cord blood screening. *Lab Med.* 1987;18:513-518; 10) Armbruster DA. Neonatal hemoglobinopathy screening. *Lab Med.* 1990;21:815-822; 11) Adams JG III, Steinberg MH. Analysis of hemoglobins, In Hoffman R, *et al.*, eds. Hematology: basic principles and practice. New York, NY: Churchill-Livingstone, 1991:1815-1827; 12) Mallory PA, *et al.* Comparison of isoelectric focusing and cellulose acetate electrophoresis for hemoglobin separation. *Clin Lab Sci.* 1994;7:348-352; 13) Awalt E, *et al.* Tandem mass spectrometry (MS) – A screening tool for hemoglobinopathies. *Clin Chem.* 2001;47(suppl):A165; 14) Bradley CA, Kelly A. Comparison of high performance liquid chromatography with electrophoresis for measurement of hemoglobins A, A2, S, F, and C. *Clin Chem.* 2001;47(suppl):A172; 15) Bradley CA, Kelly A. Calibration verification of hemoglobins A, A2, S, and F with an automated chromatography system. *Clin Chem.* 2001;47(suppl):A17315; 16) Hoyer JD, *et al.* Flow cytometric measurement of hemoglobin F in RBCs: diagnostic usefulness in the distinction of hereditary persistence of fetal hemoglobin (HPFH) and hemoglobin S-HPFH from other conditions with elevated levels of hemoglobin F. *Am J Clin Pathol.* 2002;117:857-863.

HEM.35946**Phase II****N/A YES NO**

Are all samples with hemoglobin variants migrating in "non-A, non-S" positions on alkaline electrophoresis, isoelectric focusing, or HPLC further defined with electrophoresis at acid pH or other acceptable methods where clinically and technically appropriate?

NOTE: Electrophoresis at acid pH is useful to further characterize hemoglobin variants migrating in the Hb A2 position, if all variants are not clearly separated by the primary method. This method will

differentiate the three major hemoglobins that migrate in this position, namely Hb C, Hb E, and Hb O-Arab, as well as give information on rare variants such as Hb C-Harlem. However, for hemoglobin variants that migrate in other "non-A, non-S" positions, such as fast hemoglobin variants, electrophoresis at acid pH is generally not informative. Further workup of such variants, including referral to a reference laboratory, is dependent upon the patient's overall clinical situation, such as findings of erythrocytosis or a hemolytic anemia.

COMMENTARY:

N/A

REFERENCES: 1) Glacteros F, *et al.* Cord blood screening for hemoglobin abnormalities by thin layer isoelectric focusing. *Blood*. 1980;56:1068; 2) Beuzard Y, *et al.* Isoelectric focusing of human hemoglobins, In Hanash, Brewer, eds. *Advances in hemoglobin analysis*. New York, NY: Alan R. Liss, 1981:177-195; 3) Black J. Isoelectric focusing in agarose gel for detection and identification of hemoglobin variants. *Hemoglobin*. 1984;8:117; 4) Bunn HF, Forget BG. Hemoglobin: molecular, genetic and clinical aspects. Philadelphia, PA: WB Saunders, 1986; 5) Fishleder AJ, Hoffman GC. A practical approach to the detection of hemoglobinopathies: part I. The introduction and thalassemia syndromes. *Lab Med*. 1987;18:368-372; 6) Fishleder AJ, Hoffman GC. A practical approach to the detection of hemoglobinopathies: part II. The sickle cell disorders. *Lab Med*. 1987;18:441-443; 7) Fishleder AJ, Hoffman GC. A practical approach to the detection of hemoglobinopathies: part III. Nonsickling disorders and cord blood screening. *Lab Med*. 1987;18:513-518; 8) Adams JG III, Steinberg MH. Analysis of hemoglobins, In Hoffman R, *et al.*, eds. *Hematology: basic principles and practice*. New York, NY: Churchill-Livingstone, 1991:1815-1827; 9) Mallory PA, *et al.* Comparison of isoelectric focusing and cellulose acetate electrophoresis for hemoglobin separation. *Clin Lab Sci*. 1994;7:348-352; 10) Ou C-N, Rognerud CL. Rapid analysis of hemoglobin variants by cation exchange HPLC. *Clin Chem*. 1993;39:820-824; 11) Awalt E, *et al.* Tandem mass spectrometry (MS) – A screening tool for hemoglobinopathies. *Clin Chem*. 2001;47(suppl):A165; 12) Bradley CA, Kelly A. Comparison of high performance liquid chromatography with electrophoresis for measurement of hemoglobins A, A2, S, F, and C. *Clin Chem*. 2001;47(suppl):A172; 13) Bradley CA, Kelly A. Calibration verification of hemoglobins A, A2, S, and F with an automated chromatography system. *Clin Chem*. 2001;47(suppl):A173; 14) Hoyer JD, *et al.* Flow cytometric measurement of hemoglobin F in RBCs: diagnostic usefulness in the distinction of hereditary persistence of fetal hemoglobin (HPFH) and hemoglobin S-HPFH from other conditions with elevated levels of hemoglobin F. *Am J Clin Pathol*. 2002;117:857-863.

HEM.35984

Phase II

N/A YES NO

Are all samples that appear to have Hb S as the predominant band by the primary screening (by whatever method) and that are confirmed as sickling by appropriate methods further examined to ascertain whether the "Hb S" band or peak contains solely Hb S or both Hb S and Hb D, Hb G or other variant hemoglobins?

NOTE: When the predominant hemoglobin component appears to be Hb S, it is necessary to determine whether this represents homozygous Hb S or a heterozygote for Hb S and another variant

such as Hb D, Hb G, Hb Lepore, or other hemoglobin variant(s). Given the clinical implications of homozygous Hb S (or Hb S/β-zero thalassemia) it is imperative to exclude other hemoglobin variants, however rare. Referral of these specimens to a reference laboratory for further workup is acceptable.

COMMENTARY:

N/A

REFERENCES: 1) Black J. Isoelectric focusing in agarose gel for detection and identification of hemoglobin variants. *Hemoglobin*. 1984;8:117; 2) Bunn HF, Forget BG. Hemoglobin: molecular, genetic and clinical aspects. Philadelphia, PA: WB Saunders, 1986; 3) Fishleder AJ, Hoffman GC. A practical approach to the detection of hemoglobinopathies: part I. The introduction and thalassemia syndromes. *Lab Med*. 1987;18:368-372; 4) Fishleder AJ, Hoffman GC. A practical approach to the detection of hemoglobinopathies: part II. The sickle cell disorders. *Lab Med*. 1987;18:441-443; 5) Fishleder AJ, Hoffman GC. A practical approach to the detection of hemoglobinopathies: part III. Nonsickling disorders and cord blood screening. *Lab Med*. 1987;18:513-518; 6) Adams JG III, Steinberg MH. Analysis of hemoglobins, In Hoffman R, et al, eds. Hematology: basic principles and practice. New York, NY: Churchill-Livingstone, 1991:1815-1827; 7) Mallory PA, et al. Comparison of isoelectric focusing and cellulose acetate electrophoresis for hemoglobin separation. *Clin Lab Sci*. 1994;7:348-352.

BONE MARROW PREPARATIONS

HEM.36050

Phase II

N/A YES NO

Are bone marrow slides uniquely identified?

NOTE: Slide or coverslip identification must include a unique identifier(s), such as specimen or accession number, patient name and/or number, and date. The ability to identify the patient as well as the date the specimen was obtained applies to all parts of the bone marrow case, which may include blood films, bone marrow aspirate, marrow clot and core biopsy specimens.

COMMENTARY:

N/A

HEM.36100

Phase II

N/A YES NO

Examine a slide prepared by the laboratory. Is the preparation and staining satisfactory for interpretation?

COMMENTARY:

N/A

HEM.36150 Phase I

N/A YES NO

Are fixed sections (marrow biopsy or particle sections) used as a diagnostic aid to the smear aspirate, as appropriate for the clinical situation?

COMMENTARY:

N/A

REFERENCES: 1) Krause JR, ed. Bone marrow biopsy. New York, NY: Churchill Livingstone, 1981:1-9; 2) Bartl R, *et al.* Bone marrow biopsies revisited. Basel, Switzerland: Karger, 1982; 3) Brunning RD. Bone marrow, In Rosai J, ed. Ackerman's surgical pathology. St Louis, MO: CV Mosby, 1989:1379-1454; 4) Brunning RD. Bone marrow specimen processing, In Knowles DM, ed. Neoplastic hematopathology. Baltimore, MD: Williams & Wilkins, 1992:1081-1095; 5) Dacie JV, Lewis SM. Practical hematology, 8th ed. New York, NY: Churchill Livingstone, 1995:178-184; 6) Foucar K. Bone marrow pathology. Chicago, IL: American Society of Clinical Pathology, 1995.

HEM.36200 Phase II

N/A YES NO

Is the quality of fixed tissue sections of bone marrow conducive to a reliable diagnosis?

COMMENTARY:

N/A

HEM.36250 Phase II

N/A YES NO

If fixed tissue sections and bone marrow aspirate smears are evaluated in different sections of the laboratory, or if separate reports are released at different times, is there a mechanism to compare the data and interpretations from these different sections?

NOTE: Unified reporting of bone marrow aspirates and biopsies is strongly recommended. If aspirate smears and biopsy reports are released by different sections of the laboratory, or at different times, a mechanism must be in place to comment upon the existing report and interpretation when the subsequent report is released. Any conflicting data should be commented upon. Such data correlation is essential for diagnostic consistency and effective patient management.

COMMENTARY:

N/A

HEM.36270 Phase II

N/A YES NO

Are bone marrow reports and smears retained for 10 years?

COMMENTARY:

N/A

HEM.36300 Phase II

N/A YES NO

Are bone marrow specimens evaluated by a pathologist or qualified hematologist and formal reports prepared?

COMMENTARY:

N/A

REFERENCE: Peterson LC, *et al.* Protocol for the examination of specimens from patients with hematopoietic neoplasms of the bone marrow: a basis for checklists. *Arch Pathol Lab Med.* 2002;126:1050-1056.

HEM.36325 Phase I

N/A YES NO

Is there a mechanism to correlate the results of ancillary studies (immunohistochemistry, cytogenetics, flow cytometry, etc.) with the morphologic diagnosis?

NOTE: The pathologist or qualified hematologist should correlate all of the special studies, reconcile conflicting data, and render a final interpretation of all correlated studies where appropriate. A mechanism should exist in the laboratory that documents review of such studies not available at the time of initial request. Clinically significant discrepancies must be reconciled and documented.

COMMENTARY:

N/A

REFERENCE: Peterson LC, *et al.* Protocol for the examination of specimens from patients with hematopoietic neoplasms of the bone marrow: a basis for checklists. *Arch Pathol Lab Med.* 2002;126:1050-1056.

BLOOD COAGULATION STUDIES

HEM.37050**Phase II****N/A YES NO****Are tests for common coagulation problems available?**

NOTE: Laboratories serving acute care hospitals must be able to perform a sufficient variety of coagulation tests to evaluate common coagulation disorders. Such tests typically include platelet concentration, prothrombin time, activated partial thromboplastin time, fibrinogen assay, fibrin(ogen) degradation products or D-dimer, and platelet function tests such as bleeding time or a whole blood in vitro platelet function test.

COMMENTARY:

N/A

REFERENCES: 1) NCCLS. One-stage prothrombin time (PT) test and activated partial thromboplastin time (aPTT) test; approved guideline H47-A. Wayne, PA: NCCLS, 1996; 2) Badve S, Burns ER. D-dimer measurements unhelpful for ruling in DIC. *Lab Med.* 2000;31:383-386; 3) Staikos L, et al. Improved anticoagulation management using point of care activated partial thromboplastin time. *Clin Chem.* 2000;46:A3; 4) Lopez E, et al. Comparison of a POCT for prothrombin time measurement with conventional laboratory testing in patients with oral anticoagulant therapy. *Clin Chem.* 2000;46:A14; 5) Mammen EF, et al. PFA-100 system: a new method for assessment of platelet dysfunction. *Sem Thromb Hemost.* 1998;24:195-202; 6) Clinical and Laboratory Standards Institute (CLSI). *Performance of the Bleeding Time Test; Approved Guideline—Second Edition.* CLSI document H45-A2 (ISBN 1-56238-571-2). Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2005; 7) Taylor FB, et al. Towards definition, clinical and laboratory criteria, and a scoring system for disseminated intravascular coagulation. *Thromb Haemos* 2001;86:1327-1330.

HEM.37150**Phase II****N/A YES NO****Are tests for defining or monitoring disseminated intravascular coagulation (DIC) problems available, if applicable to the patient population served?****COMMENTARY:**

N/A

REFERENCES: 1) Bovill EG. Laboratory diagnosis of disseminated intravascular coagulation. *Sem Hematol.* 1994;31(2;suppl)35-29; 2) NCCLS. *Procedure for the Determination of Fibrinogen in*

Plasma; Approved Guideline—Second Edition. NCCLS document H30-A2 (ISBN 1-56238-439-2). NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2001; 3) Yu M, *et al.* Screening tests of disseminated intravascular coagulation: guidelines for rapid and specific laboratory diagnosis. *Crit Care Med.* 2000;28:1777-1780.

HEM.37175**Phase I****N/A YES NO**

Is there a system to periodically measure the actual platelet concentration of the usual "platelet-poor" plasma used for many coagulation tests?

NOTE: Platelet-poor plasma is particularly important in patients with the lupus anticoagulant, and in samples to be frozen for later testing. Platelet-poor plasma should have a residual platelet concentration of less than $10 \times 10^9/L$. This is important because platelet membranes form a procoagulant surface that can accelerate coagulation and spuriously shorten clotting times. It is particularly important in patients with the lupus anticoagulant; due to the high content of lipid in the platelet plasma membrane, increased platelets in samples with the lupus anticoagulant can cause the antiphospholipid antibody to bind to the platelet membrane, thus effectively removing it from plasma. In this circumstance, the presence of lupus anticoagulant may not be detected during diagnostic testing.

Samples to be frozen should be "platelet-poor" because plasma contaminated with significant numbers of platelets may yield different analytic results after thawing, due to lysis of platelets.

COMMENTARY:

N/A

REFERENCES: 1) Koepke JA, *et al.* Pre-instrumental variables in coagulation testing. *Am J Clin Pathol.* 1975;64:591-596; 2) Lupus Anticoagulant Working Party. Guidelines on testing for the lupus anticoagulant. *J Clin Pathol.* 1991;44:885-889; 3) Middleton AL, Oakley E. Activated partial thromboplastin time (aPTT): Review of Methods. Chicago, IL: American Society of Clinical Pathology Check Sample PTS 91-8, 1991; 4) Brien W, *et al.* Lupus anticoagulant testing: effect of the platelet count on the activated partial thromboplastin time. *Brit J Biomed Sci* 1993;50:114-116.

HEM.37200**Phase II****N/A YES NO**

Are coagulation tests (e.g., PT, aPTT, fibrinogen, and factor assays) performed at 37°C?

COMMENTARY:

N/A

REFERENCES: 1) NCCLS. One-stage prothrombin time (PT) test and activated partial thromboplastin time (aPTT) test; approved guideline H47-A. Wayne, PA: NCCLS, 1996; 2) NCCLS. Determination

HEM.37400 Phase I

N/A YES NO

Are guidelines established for determining when alternative procedures should be performed (e.g., lipemia, hyperbilirubinemia, turbidity, etc.)?

NOTE: Very long clotting times may not be reproducible on an automated coagulation instrument. Criteria should be established by each laboratory for performance of the PT or aPTT by an alternate technique (e.g., manual method) when the readable range of the instrument is exceeded. In addition, criteria should be provided for performance of alternate procedures in the presence of significant hyperbilirubinemia or lipemia, paradoxically short aPTTs and nonduplicating aPTTs.

COMMENTARY:

N/A

.....

Electromechanical Coagulation Systems

.....

HEM.37500 Phase II

N/A YES NO

Is the electromechanical coagulation system (for PT, aPTT, fibrinogen, and other coagulation assays) checked with 2 different levels of control material during each 8 hours of patient testing, and each time there is a change in reagents?

COMMENTARY:

N/A

HEM.37550 Phase II

N/A YES NO

Are tolerance limits defined for each instrument, component, or procedure in the system?

COMMENTARY:

N/A

HEM.37600 Phase II

N/A YES NO

If the electromechanical system has reusable probes to detect a clot, are documented guidelines for cleaning the probes available?

COMMENTARY:

N/A

.....
Manual Coagulation Systems
.....

DEFINITION: Manual coagulation systems are defined as PT, aPTT or fibrinogen testing performed using a method whereby patient plasma and reagents are pipetted into a test tube, the tube is rocked back and forth in a water bath until a clot forms. This is often referred to as a “tilt-tube” method. The following questions only apply to such methods.

HEM.37700**Phase II****N/A YES NO**

Is the manual coagulation system checked by each testing person with 2 different levels of control material in duplicate during each 8 hours of patient testing, and each time there is a change of reagents?

NOTE: The term “each testing person” applies to all individuals performing a manual tilt tube test during each 8 hour period. Thus, if two individuals both performed a tilt tube test in the same 8 hour period, the controls would have to be assayed twice (i.e., once for each person).

COMMENTARY:

N/A

REFERENCE: Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 2003(Jan 24):7168 [42CFR493.1269(c)(1)].

HEM.37750**Phase II****N/A YES NO**

Are tolerance limits defined for each manual procedure?

COMMENTARY:

N/A

HEM.37800 **Phase II** **N/A YES NO**

Are determinations performed in duplicate?

COMMENTARY:

N/A

REFERENCES: 1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 2003(Jan 24):7168 [42CFR493.1269(c)(1)]; 2) NCCLS. Collection, transport, and processing of blood specimens for coagulation testing and general performance of coagulation assays - fourth edition; approved guideline H21-A4. Wayne, PA: NCCLS, 2003.

HEM.37850 **Phase II** **N/A YES NO**

Are criteria for acceptable duplication of values available?

NOTE: Duplicates must agree within 10% of the shorter clotting time. If duplicates do not agree within these criteria, the test must be repeated. Three of the 4 times should then agree within 10% of the shortest clotting time observed.

COMMENTARY:

N/A

REFERENCE: NCCLS. Collection, transport, and processing of blood specimens for coagulation testing and general performance of coagulation assays - fourth edition; approved guideline H21-A4. Wayne, PA: NCCLS, 2003.

HEM.37900 **Phase II** **N/A YES NO**

Is the temperature of the water bath or incubator verified with a certified thermometer or equivalent technique?

NOTE: Coagulation assays must be performed at 37 °C.

COMMENTARY:

N/A

REFERENCE: NCCLS. Collection, transport, and processing of blood specimens for coagulation testing and general performance of coagulation assays - fourth edition; approved guideline H21-A4. Wayne, PA: NCCLS, 2003.

****NEW******10/31/2006****HEM.37915****Phase I****N/A YES NO**

If the laboratory reports D-dimer assay results in units other than those recommended by the assay manufacturer, are the type of unit and magnitude of the D-dimer result reported correctly?

NOTE: The units generated directly by the D-dimer method can be determined from the package insert for the method being used. D-dimer is a molecular species produced from two molecules of fibrin that were crosslinked by factor XIIIa through the adjacent D domains and then degraded by plasmin. It is a marker of ongoing in vivo fibrin formation and fibrinolysis. The reportable units of the D-dimer may vary by manufacturer, but may include both Fibrinogen Equivalent Units (FEU) and D-dimer Units (D-DU).

Some laboratories may convert the units stated in the package insert into different units for the patient report. If such is the case, the laboratory should verify that the calculations are correct. For example, a method may generate data as ug/mL D-dimer Units (D-DU), and the laboratory may choose to convert this to ng/mL Fibrinogen Equivalent Units (FEU). A critical concept for this calculation is that the mass of one unit of FEU is twice that of the mass of one unit of D-DU. (1 D-DU = 2 FEU). In this example, the correct conversion factor is 2000, which is calculated as follows: 1 ug/mL D-DU x (1000 ng/1 ug) x (2 FEU/1 D-DU) = 2000 ng/ml FEU. Please see the table below for other example conversion factors.

Manufacturer Units	Final Units	Correct Conversion Factor	Equivalency Equation
FEU ng/ml	D-DU ng/ml	0.5	1 FEU ng/ml = 0.5 D-DU ng/ml
FEU ng/ml	D-DU ug/ml	0.0005	1 FEU ng/ml = 0.0005 D-DU ug/ml
FEU ug/ml	FEU ng/ml	1000	1 FEU ug/ml = 1000 FEU ng/ml
D-DU ng/ml	FEU ng/ml	2	1 D-DU ng/ml = 2 FEU ng/ml
D-DU ug/ml	FEU ng/ml	2000	1 D-DU ug/ml = 2000 FEU ng/ml
D-DU ug/ml	D-DU ng/ml	1000	1 D-DU ug/ml = 1000 D-DU ng/ml

COMMENTARY:

N/A

REFERENCES: 1) Dempfle CE. D-dimer assays: The current status and new assay technologies. *Thromb Res.* 2005 Aug 30; [Epub ahead of print]; 2) Olson J, Cunningham M, Brandt J, *et al.* Use of the D-Dimer for Exclusion of VTE: Difficulties Uncovered through the Proficiency Testing Program of the College of American Pathologists (CAP). *J Thromb Hemostasis*, Abstract, August 2005; 3) Spannagl M, Haverkate F, Reinauer H, Meijer P. The performance of quantitative D-dimer assays in

laboratory routine. *Blood Coagul Fibrinolysis*. 2005 Sep;16(6):439-43; 4) Gardiner C, Pennaneac'h C, Walford C, *et al*. An evaluation of rapid D-dimer assays for the exclusion of deep vein thrombosis. *Br J Haematol*. 2005 Mar;128(6):842-8; 5) Perrier A. Review: several factors are associated with the performance of D-dimer assays for detecting deep venous thrombosis. *ACP J Club*. 2004 Nov-Dec;141(3):76.

NEW

10/31/2006

HEM.37923

Phase I

N/A YES NO

If calculations (including conversion of units) are used to obtain D-dimer results, does the laboratory document periodic checks to ensure that the calculations are correct?

NOTE: The D-dimer may be a calculated value. In some institutions, the D-dimer result may be calculated by the coagulation analyzer, while in others it may be calculated by the laboratory information system. The accuracy of calculations should be periodically verified. Calculations should be checked for all instruments or methodologies used to generate reportable D-dimer values. It is suggested that the calculations be checked at both a normal and elevated D-dimer value. Calculations should be checked at least once per year, whenever the instrument or manufacturer of D-dimer reagent is changed, whenever a new D-dimer reference range is established, or if a component of the calculation is changed.

COMMENTARY:

N/A

REFERENCES: 1) Dempfle CE. D-dimer assays: The current status and new assay technologies. *Thromb Res*. 2005 Aug 30; [Epub ahead of print]; 2) Olson J, Cunningham M, Brandt J, *et al*. Use of the D-Dimer for Exclusion of VTE: Difficulties Uncovered through the Proficiency Testing Program of the College of American Pathologists (CAP). *J Thromb Hemostasis*, Abstract, August 2005; 3) Spannagl M, Haverkate F, Reinauer H, Meijer P. The performance of quantitative D-dimer assays in laboratory routine. *Blood Coagul Fibrinolysis*. 2005 Sep;16(6):439-43; 4) Gardiner C, Pennaneac'h C, Walford C, *et al*. An evaluation of rapid D-dimer assays for the exclusion of deep vein thrombosis. *Br J Haematol*. 2005 Mar;128(6):842-8; 5) Perrier A. Review: several factors are associated with the performance of D-dimer assays for detecting deep venous thrombosis. *ACP J Club*. 2004 Nov-Dec;141(3):76.

NEW

10/31/2006

HEM.37925

Phase I

N/A YES NO

If a D-dimer method is used in the evaluation of venous thromboembolism, has the method been validated for this purpose?

NOTE: If a D-dimer method is used in the evaluation of deep vein thrombosis and/or pulmonary embolism, the cut-off value for exclusion of these conditions should be validated, either in the peer-reviewed published literature, by the laboratory, or, for FDA-approved methods only, by the manufacturer of the method. The validation study(ies) should establish whether the cut-off is applicable to all patients, or only those with certain pre-test probabilities of having venous thromboembolism. If the laboratory modifies the manufacturer's recommendations for an FDA-approved method, then the laboratory should perform the appropriate validation studies.

Typically, manual latex agglutination D-dimer or FDP (fibrin degradation products) assays are not adequately sensitive to be used for evaluation of deep vein thrombosis and/or pulmonary embolism.

COMMENTARY:

N/A

REFERENCES: 1) Olson J, Cunningham M, Brandt J, *et al.* Use of the D-Dimer for Exclusion of VTE: Difficulties Uncovered through the Proficiency Testing Program of the College of American Pathologists (CAP). *J Thromb Hemostasis*, Abstract, August 2005; 2) Spannagl M, Haverkate F, Reinauer H, Meijer P. The performance of quantitative D-dimer assays in laboratory routine. *Blood Coagul Fibrinolysis*. 2005 Sep;16(6):439-43; 3) Goodacre S, Sampson FC, Sutton AJ, *et al.* Variation in the diagnostic performance of D-dimer for suspected deep vein thrombosis. *QJM*. 2005 Jul;98(7):513-27. Epub 2005 Jun 13; 4) Gardiner C, Pennaneac'h C, Walford C, *et al.* An evaluation of rapid D-dimer assays for the exclusion of deep vein thrombosis. *Br J Haematol*. 2005 Mar;128(6):842-8; 5) Diamond S, Goldweber R, Katz S. Use of D-dimer to aid in excluding deep venous thrombosis in ambulatory patients. *Am J Surg*. 2005 Jan;189(1):23-6; 6) Wolf SJ, McCubbin TR, Feldhaus KM, *et al.* Prospective validation of Wells Criteria in the evaluation of patients with suspected pulmonary embolism. *Ann Emerg Med*. 2004 Nov;44(5):503-10; 7) Gould MK. Review: of the various D-dimer assays, negative ELISA results are most useful for excluding a diagnosis of deep venous thrombosis or pulmonary embolism. *ACP J Club*. 2004 Nov-Dec;141(3):77; 8) Stein PD, Hull RD, Patel KC, *et al.* D-dimer for the exclusion of acute venous thrombosis and pulmonary embolism: a systematic review. *Ann Intern Med*. 2004 Apr 20;140(8):589-602.

****NEW****

10/31/2006

HEM.37930

Phase I

N/A YES NO

If a D-dimer test is used for exclusion of deep vein thrombosis and/or pulmonary embolism, does the laboratory report the cutoff value for exclusion of venous thromboembolism, as well as the reference range?

NOTE: The cut-off can be indicated within the patient report, or by a written memorandum to clinicians. The former is preferable.

COMMENTARY:

N/A

****NEW****

10/31/2006

HEM.37935

Phase I

N/A YES NO

If a D-dimer test is not used for exclusion of deep vein thrombosis and/or pulmonary embolism, does the laboratory inform clinicians that the test should not be used to exclude deep vein thrombosis or pulmonary embolism?

NOTE: This disclaimer may be included in the laboratory report, or in a written memorandum to clinicians. The former is preferable.

COMMENTARY:

N/A

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Coagulation Factor Assays (including fibrinogen)

.....
The factor activity of a plasma sample is measured by its ability to correct the prolonged clotting time of factor-deficient plasma. The APTT or PT of mixtures of diluted test plasma and factor-deficient plasma are inversely proportional to the concentration of the factor in the test plasma mixtures. Mixtures of diluted reference plasma of known factor activity and factor-deficient plasma are used to construct a reference curve that can be used to convert APTT or PT values of the test plasma mixtures to units of activity.

HEM.37940

Phase II

N/A YES NO

For coagulation end point-based factor assays, are three or more points plotted for the standard curve?

NOTE: Plotting less than 3 points may generate an erroneous line.

COMMENTARY:

N/A

REFERENCES: 1) Arkin CF, *et al.* Factors affecting the performance of Factor VIII coagulant activity assays. Results of proficiency surveys of the College of American Pathologists. *Arch Pathol Lab Med.* 1992;116:908-915; 2) NCCLS. Determination of factor coagulant activities; approved guideline H48-

A. Wayne, PA: NCCLS, 1997; 3) NCCLS. Procedure for the determination of fibrinogen in plasma; approved guideline H30-A2 – second edition. Wayne, PA: NCCLS, 2001.

****REVISED**** **10/31/2006**

HEM.37960 **Phase I** **N/A YES NO**

Are the standard curves validated with at least two reference points for each factor assay determination each 8 hours of patient testing, or each time a factor assay is performed if factor assays are performed less frequently than one per 8 hours?

NOTE: The Y intercept of the standard curve varies according to the reagent and environmental or instrument conditions. Validating the curve (e.g., 2 or more points with assayed reference plasma) each time ensures accuracy of the result.

COMMENTARY:

N/A

REFERENCES: 1) NCCLS. Determination of factor coagulant activities; approved guideline H48-A. Wayne, PA: NCCLS, 1997; 2) NCCLS. Procedure for the determination of fibrinogen in plasma; approved guideline H30-A2 – second edition. Wayne, PA: NCCLS, 2001.

HEM.37980 **Phase II** **N/A YES NO**

Are two or more points plotted for the patient's factor assay?

NOTE: Multiple dilutions of test plasma are required to evaluate the extent of parallelism between test results and those of the reference plasma. This is necessary to be able to detect whether a factor inhibitor is present. Plotting at least 2 patient dilutions enhances accuracy by minimizing dilutor error, and allows for detection of inhibitors or anticoagulants. To be valid, all patient points must fall within the upper and lower limits of the standard curve used for the calculation of the result.

This question does not apply to fibrinogen assays.

COMMENTARY:

N/A

REFERENCES: 1) NCCLS. Determination of factor coagulant activities; approved guideline H48-A. Wayne, PA: NCCLS, 1997; 2) NCCLS. Procedure for the determination of fibrinogen in plasma; approved guideline H30-A2 – second edition. Wayne, PA: NCCLS, 2001.

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Mixing Studies

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Plasma-mixing studies (i.e., mixing patient plasma with normal plasma) may be performed to distinguish whether an abnormal screening coagulation test result (PT or aPTT) is caused by a factor deficiency or an inhibitor.

****REVISED**** **10/31/2006**

HEM.37991 **Phase II** **N/A YES NO**

When plasma-mixing studies are performed, is an appropriate pooled plasma utilized?

NOTE: It is not appropriate to use single patient plasma samples with normal PT/aPTT values as the “normal” plasma reagent, as factor levels may vary over a wide range without affecting PT/aPTT results. In general, pooled plasma prepared in the laboratory from at least 20 apparently healthy donors or commercial products are acceptable.

COMMENTARY:

N/A

REFERENCE: Kaczor DA, *et al.* Evaluation of different mixing study reagents and dilution effect in lupus anticoagulant testing. *Am J Clin Pathol.* 1991;95:408-411.

****REVISED**** **10/31/2006**

HEM.38002 **Phase I** **N/A YES NO**

For samples with positive mixing study results, is there either a procedure to detect heparin or other antithrombotic drugs that inhibit coagulation, or is the result reported with a comment that the effect of inhibitor drugs cannot be excluded?

NOTE: Anticoagulant drugs that act as coagulation inhibitors (e.g., heparin or direct thrombin inhibitors) may give falsely positive results in mixing study assays, if their presence is not detected. Laboratories should have procedures established to screen mixing study samples with elevated PT and/or aPTT results for these inhibitors. For heparin, performing a thrombin time assay, heparin Xa inhibition assay, repeating the aPTT with polybrene, or treating the sample with heparinase may be acceptable. For direct thrombin inhibitors, performing a thrombin time should detect the presence of the inhibitor. A thrombin time has the advantage of detecting not only heparin, but also the presence of direct thrombin inhibitors such as lepirudin, bivalirudin and argatroban. Alternately, the test result

HEM.50150 **Phase I** **N/A YES NO**

Is there adequate space for instruments?

COMMENTARY:

N/A

HEM.50200 **Phase I** **N/A YES NO**

Is there adequate space for shelf storage?

COMMENTARY:

N/A

HEM.50250 **Phase I** **N/A YES NO**

Is there adequate space for refrigerated/freezer storage?

COMMENTARY:

N/A

HEM.50300 **Phase I** **N/A YES NO**

Is the space available efficiently utilized?

COMMENTARY:

N/A

HEM.50350 **Phase II** **N/A YES NO**

Is sufficient space available so that there is no compromise of the quality of work, (including quality control activities) or safety of personnel?

COMMENTARY:

N/A

REFERENCES: 1) Elin RJ. Workload, space, and personnel in hematology laboratories in teaching hospitals. *Am J Clin Pathol.* 1983;80:190-196; 2) Elin RJ, Gersch SM. Considerations for the design of a new laboratory. *Am J Clin Pathol.* 1986;85:61-66.

HEM.50375 Phase I

N/A YES NO

Have ergonomic aspects of desks (or benches), chairs and microscopes been evaluated for good posture and comfort?

COMMENTARY:

N/A

REFERENCES: 1) Krueger H, *et al.* Besondere Belastungen am Mikroskoparbeitsplatz [Special stresses at microscopy work places]. *Soz Praventivmed.* 1986;31:250-251; 2) Krueger H, Conrady P. Untersuchung zur Ergonomie der Sehbedingungen bei Mikroskoparbeit [Ergonomic aspects of visual conditions in microscope work]. *Biomed Tech. (Berl)* 1988;33(9):196-202; 3) James TM. An ergonomic approach to modifying microscope design for increased comfort: a case study. *Proc Human Factors Ergonom Soc.* 1995;39th annual meeting; 4) Rorer ML. Safety first - a lesson in ergonomics. *Advance/Laboratory.* 1997(March):38-43; 5) Scott FI, Jr. The changing face of clinical microscopy: meeting new optical and ergonomic challenges. *Am Clin Lab.* 1998;17(2):8-9; 6) Vratny M. Considerations in microscope design to avoid cumulative trauma disorder in clinical laboratory applications. *Am Clin Lab.* 1999;18(3):8.

HEM.50400 Phase I

N/A YES NO

Are floors and benches clean, free of clutter and well-maintained?

COMMENTARY:

N/A

HEM.50450 Phase I

N/A YES NO

Are water taps, sinks and drains adequate?

COMMENTARY:

N/A

HEM.50500 **Phase I** **N/A YES NO**

Are electrical outlets adequate?

COMMENTARY:

N/A

HEM.50600 **Phase I** **N/A YES NO**

Is lighting adequate?

NOTE: Direct sunlight should be avoided because of its extreme variability and the need for low light levels necessary to observe various computer consoles, etc. Lighting control should be sectionalized so general levels of illumination can be controlled in areas of the room if desired.

COMMENTARY:

N/A

HEM.50650 **Phase I** **N/A YES NO**

Is ventilation adequate?

COMMENTARY:

N/A

HEM.50700 **Phase I** **N/A YES NO**

Is temperature control adequate?

COMMENTARY:

N/A

HEM.50800 **Phase I** **N/A YES NO**

Are telephones conveniently located and are calls easily transferred?

COMMENTARY:

N/A