COLLEGE of AMERICAN PATHOLOGISTS
Laboratory Quality Solutions

Proficiency Testing (PT) Manual

COLLEGE of AMERICAN PATHOLOGISTS
Laboratory Quality Solutions

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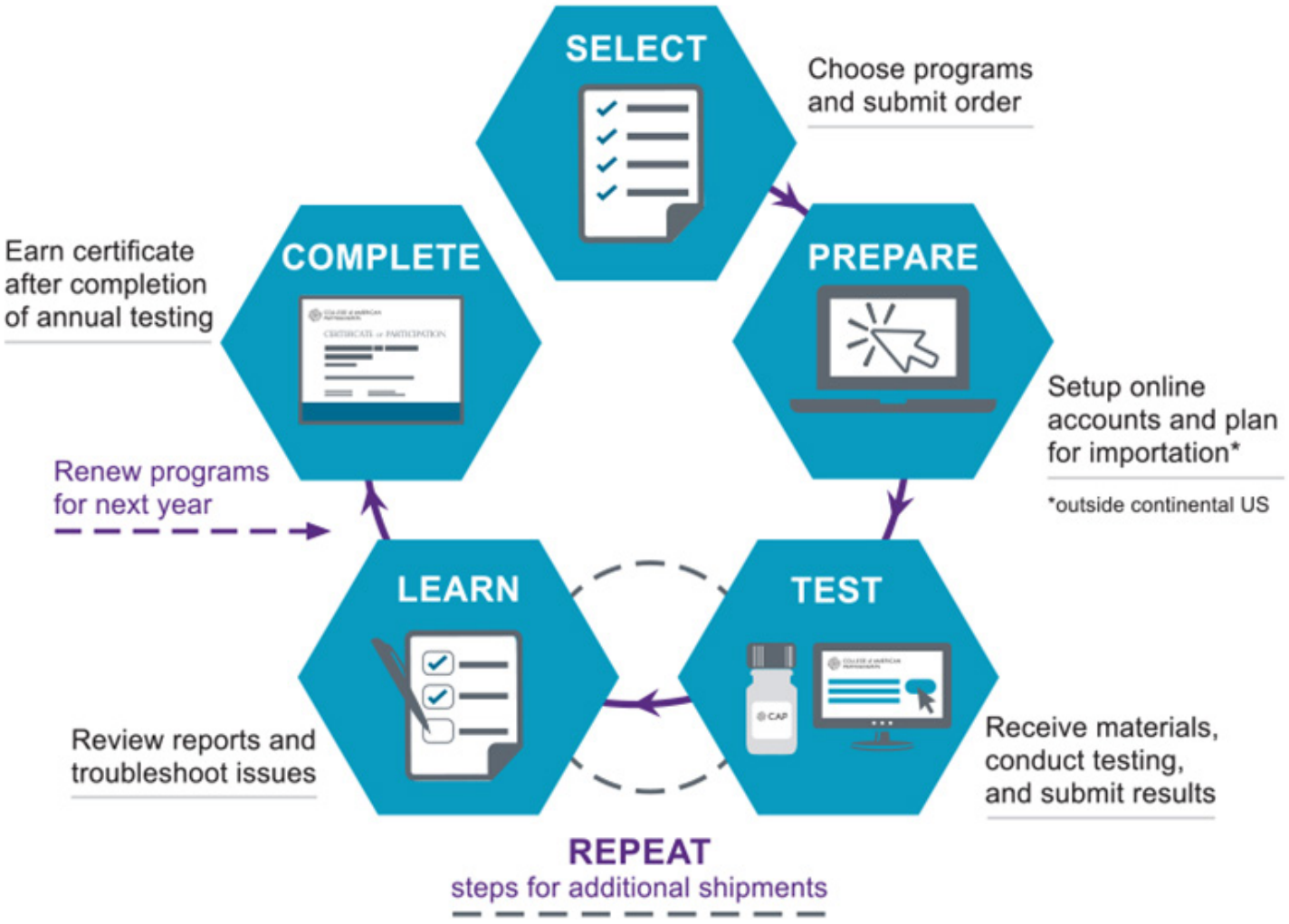
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Proficiency Testing/External Quality Assessment (PT/EQA) Cycle



1 Select: Select and Order PT/EQA Programs

The Value of PT/EQA

PT/EQA is an important tool your laboratory can use to verify the accuracy and reliability of its testing and validate the entire testing process, including competency of your testing personnel. Routine reviews of PT/EQA reports by your laboratory staff and director will alert you to areas of testing that are not performing as expected as well as indicate subtle shifts and trends that, over time, would affect patient results.[1] Designed by our scientific resource committees comprised of experts in pathology and laboratory medicine, our PT/EQA programs closely mimic patient testing across a variety of disciplines to give you confidence your laboratory is providing reliable and accurate results.

PT/EQA provides the opportunity to:

- Measure, monitor, and benchmark your performance
- Uncover early indicators of testing that is not performing as expected
- Detect trends or continuous bias that may impact patient results
- Identify analytical issues within an assay when comparing to its peer group (other laboratories running similar testing on similar instrumentation)
- Validate the testing process and assess the procedures in your laboratory
- Assess the competency of your testing personnel and identify staff needing further training
- Demonstrate compliance to regulatory/accreditation requirements during inspections

The CAP believes that all tests performed in a clinical setting, regardless of complexity, must be performed in conjunction with the safeguards provided by PT/EQA.

CAP PT/EQA programs are accredited to the ISO 17043 standard. Additional information can be found at https://www.cap.org/ISO-Accreditation. Programs included in the CAP scope of accreditation can be found in the Surveys and Anatomic Pathology Education Programs catalog.

1. https://www.cms.gov/files/document/clia-brochure-proficiency-testing-and-pt-referral-october-2024.pdf

PT/EQA Requirements

For laboratories subject to CLIA: PT/EQA is required for all tests found in the Federal Register, Title 42, Chapter IV, Subchapter G, Part 493, Subpart I, Proficiency Testing Programs for Non-Waived Testing, of the Clinical Laboratory Improvement Amendments (CLIA) regulations. If your laboratory performs any of the tests found in Subpart I, you must enroll in a Centers for Medicare and Medicaid Services (CMS)-approved PT/EQA program and perform PT/EQA on each of the tests. These are "regulated" analytes and they are **bolded** in the Surveys and Anatomic Pathology Education Programs catalog.

The CAP's PT/EQA program is approved by CMS to offer PT/EQA for regulated analytes. For "nonregulated" analytes, CLIA requires that, at least biannually, your laboratory verify the accuracy of any test or procedure that it performs that is not listed in Subpart I. This can be accomplished by methods such as splitting a patient's specimen with another laboratory or enrolling in PT/EQA with a CMS-approved PT/EQA program. Accrediting organizations (AO) may require PT/EQA for nonregulated analytes; laboratories should contact their AO if they have questions.

Limitations of PT/EQA

Due to the manufactured nature of the specimens and shipping logistics, PT/EQA does not always correlate with the way fresh and clinical specimens are handled. A letter addressing these differences is included for general use by your laboratory.

Limitations of PT Letter

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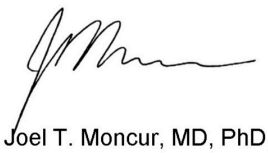
The College of American Pathologists (CAP) Proficiency Testing (PT) program is the largest external quality assessment program in the world. As such, it provides an unparalleled selection of specimen challenges and offers the largest database in existence for interlaboratory comparison. The CAP has accumulated significant experience in managing this type of program and is knowledgeable in its uses and limitations.

Performance on CAP PT programs is not to be taken as the sole indicator of a laboratory's abilities. A PT program is one of several tools that laboratories should employ to assess, manage, and improve quality. In addition to PT programs, proper method validation, quality control testing, periodic calibration and instrument maintenance, employee competency testing, and laboratory inspection and accreditation provide important tools for measuring laboratory performance and ensuring quality.

The CAP PT program, although outstanding, has well-recognized limitations that must be considered when interpreting results. Several factors can influence how closely PT performance reflects day-to-day patient testing. These include the requisite use of samples with a matrix that may affect test systems differently than patient specimens; the need to group responses according to methodology, instrumentation, or test platform; varying sizes of comparison groups with associated differences in statistical robustness; difficulties in challenging the extremes of analyte concentration; and the mandated use of CLIA-specified evaluation limits for regulated analytes.

As a result, some responses graded as unacceptable in CAP PT programs may still be acceptable for patient care in a given clinical context, and some responses graded as acceptable may nonetheless warrant closer review in a particular practice or patient care situation. Unsuccessful or unsatisfactory PT performance should therefore be viewed as an important signal that requires timely investigation and, when indicated, corrective action; by itself, it does not constitute definitive proof of inadequate performance or an inability to meet patient needs. When used thoughtfully and in conjunction with other quality practices, CAP PT provides a powerful, objective framework for monitoring performance, driving continual improvement, and supporting safe, high-quality patient care.

Sincerely,



Joel T. Moncur, MD, PhD, MS, FCAP

Chair, Council on Scientific Affairs

CAP PT/EQA Programs

The CAP offers a comprehensive PT/EQA portfolio including more than 700 programs across 16 disciplines. Our programs are continuously reviewed by our scientific resource committees and updated to address changes in practice. Each year we introduce new programs to meet evolving clinical needs. The descriptions of the PT/EQA programs can be found in the Surveys and Anatomic Pathology Education Programs catalog found on cap.org.

The catalog provides information in a chart format for each program, organized by discipline. An example is provided below:

Hematology—Basic HE		
Analyte/Procedure	**Program Code**	**Challenges per Shipment**
	HE	
Hematocrit	▮	5
Hemoglobin	▮	5
MCV, MCH, and MCHC	▮	5
MPV	▮	5
Platelet count	▮	5
RDW	▮	5
Red blood cell count	▮	5
White blood cell count	▮	5

Program Information

- Five 3.0-mL whole blood specimens
- Conventional and International System of Units (SI) reporting offered
- Three shipments per year

CE credit

The Analyte/Procedure Index is provided at the end of the catalog. It includes an alphabetical listing of all the analytes provided in the CAP PT/EQA programs. It can be used to identify which programs contain those analytes. The index also provides a column labeled **LAP ENR.** An X in this column indicates the CAP programs that can be used to fulfill the PT enrollment requirements for CAP-accredited laboratories.

Analyte/Procedure	LAP ENR	Program Code	Description	Page
Topiramate (cont.)		ZE	Therapeutic Drug Monitoring, Extended	59
Total bile acids		TBLA	Total Bile Acid	76
Total bilirubin (See Bilirubin, total)				
Total bilirubin, body fluid (See Bilirubin, total, body fluid)				
Total bilirubin, urine (See Bilirubin, urine)				
Total free fatty acids (See Fecal fat qualitative)				
Total hCG	X	**FP1T**	First Trimester Maternal Screening, Total hCG	86
Total hemolytic complement after complement 50% lysis		CH50	Total Hemolytic Complement	224
Total iron binding capacity, measured	X	**C3/C3X, CZ/CZX/CZ2X**	Chemistry and TDM	54–56
		CZQ	QCC, Chemistry and TDM	37
Total nitrogen, urine		U	Urine Chemistry—General	68
Total nucleated cells		CBT	Cord Blood Testing	242
		SCP	Stem Cell Processing	242
Total nucleated cells (WBC) automated count, (body fluid) (See WBC automated count, body fluid)				
Total nucleated cells manual differential count (body fluid) (See WBC/total nucleated cells, manual count, fluid)				
Total protein	X	**C1, C3/C3X, CZ/CZX/CZ2X**	Chemistry and TDM	54–56
		CZQ	QCC, Chemistry and TDM	37

Analyte/Procedure	LAP ENR	Program Code	Description	Page
Toxicology, serum, qualitative	X	T	Toxicology	96
	X	SDS	Serum Drug Screen	102
Toxicology, urine, qualitative	X	DMPM	Drug Monitoring for Pain Management	108
	X	T	Toxicology	96
	X	UDS, UDS6	Urine Drug Screen	98
	X	UT	Urine Toxicology	96
Toxicology, urine, qualitative/quantitative	X	DMPM	Drug Monitoring for Pain Management	108
	X	UDC	Forensic Urine Drug Testing, Confirmatory	100
Toxoplasma gondii antibodies	X	VR3	Infectious Disease Serology	215
TPMT		PGX3	Pharmacogenetics	266
Tramadol		DFC	Drug-Facilitated Crime	109
		DMPM	Drug Monitoring for Pain Management	108
		FTC	Forensic Toxicology, Criminalistics	105
		T	Toxicology	96
		UDS, UDS6	Urine Drug Screen	98
		UT	Urine Toxicology	96
Transferrin	X	C3/C3X, CZ/CZX/CZ2X	Chemistry and TDM	54–56
		CZQ	QCC, Chemistry and TDM	37
		LN7	Immunology CVL	124
	X	S2, S4	Immunology, Special	219
Transfusion medicine (See individual analytes)				
Trazodone		FTC	Forensic Toxicology, Criminalistics	105
		T	Toxicology	96
		UT	Urine Toxicology	96
Treponema pallidum (See Syphilis)				
Trichomonas vaginalis,		VS1	Vaginitis Screen	188

22 Analyte/Procedure Index

ADDITIONAL ASSISTANCE IN SELECTING A PT/EQA PROGRAM

If you require additional assistance selecting the appropriate CAP PT/EQA program(s) to meet the needs of your laboratory, contact the CAP.

Contact Information	
Customer contact center hours:	Monday–Friday, 7:00 am–5:30 pm CT Extended Support Hours: Monday–Friday, 9:00 pm–5:00 am CT (*email correspondence only*)
To contact the CAP via phone:	800-323-4040, Option 1 +1-847-832-7000, Option 1 (for customers outside the US)
To contact the CAP via email:	Email contactcenter@cap.org OR Go to cap.org and select Contact & Support at the bottom of the homepage

In countries where the CAP has a designated distributor, directly contact your CAP distributor if you have questions related to pricing. Refer to the Laboratories Outside the USA page on cap.org for additional information.

Ordering from the CAP for the First Time

US and Canadian Laboratories	Laboratories Outside the US and Canada
Obtain a copy of a US and Canadian Laboratories order form from https://www.cap.org/laboratory-improvement/catalogs-ordering-and-shipping. Pricing can be obtained by calling the CAP customer contact center.	Obtain a copy of the International Laboratories order form from https://www.cap.org/laboratory-improvement/catalogs-ordering-and-shipping.
	For inquiries related to the CAP PT/EQA programs, we have distributors in select locations and an international team to support markets outside the US. Refer to the Laboratories Outside the USA page on cap.org for additional information.
Complete all necessary fields of the order form including: • Contact information • CLIA number (if applicable) • Payment and billing information • The programs you wish to order A CAP number will be assigned to your laboratory and will appear on your order confirmation. For US and Canadian laboratories, pricing can be found at our online store or call the CAP customer contact center.	

US and Canadian Laboratories	Laboratories Outside the US and Canada
Return all pages of the order form to the CAP by email to cdm@cap.org. If needed, a quote (pro forma invoice), can be requested by emailing contactcenter@cap.org. Upon receipt of the order, an email acknowledgement will be sent to the shipping contact listed. Once processed, an order confirmation will be emailed to the shipping contact. Order changes can be made at that time.	

Additional information can be found at https://www.cap.org/laboratory-improvement/catalogs-ordering-and-shipping.

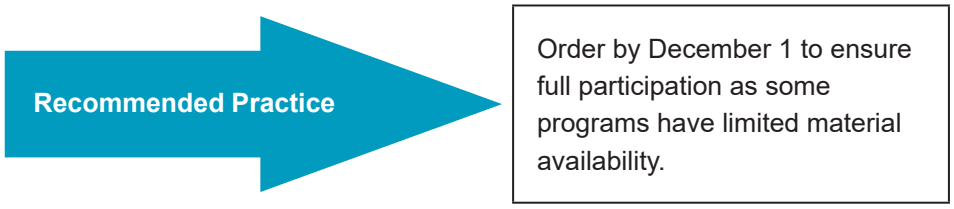
Renewal Orders

If you have ordered PT/EQA programs from the CAP during the past year, you will receive an order renewal packet from the CAP in the third quarter of the year. This packet will contain:

- a preprinted order renewal form
- a Surveys and Anatomic Pathology Education Programs catalog for the following year
- current demographic information
- a list of programs your laboratory is currently enrolled in
- a description of new programs available

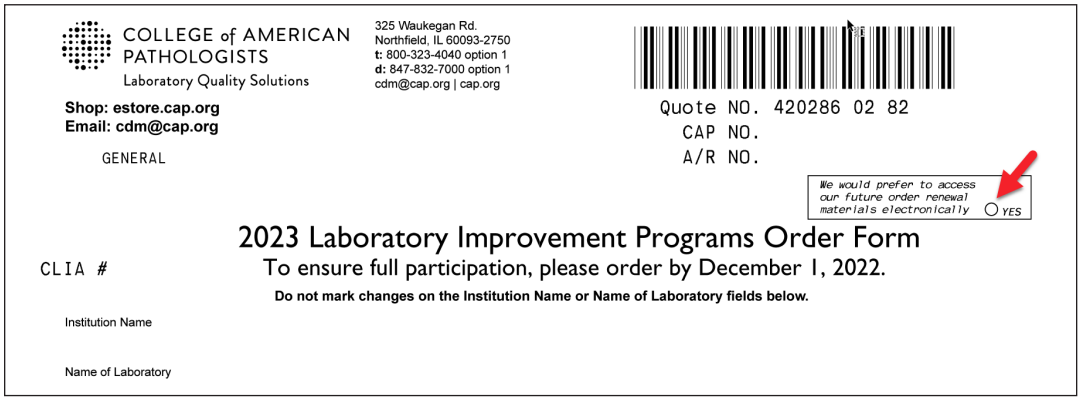
Customers should review the documents making any necessary changes to demographics (shipping, billing, contacts, etc) and the PT/EQA programs. Programs can be canceled by changing the quantity to “0.” New programs can be added to the last page by filling in the program code (eg, CZ) and the quantity needed (total number of kits received per mailing).

Once the forms are updated, customers can email the completed forms and their payment method to cdm@cap.org. When the order is processed, a confirmation will be emailed to the shipping contact(s) and ordering contact.



Opting Out of Paper

The order form provides an option to opt-out of receiving future renewal orders by paper. If your laboratory prefers to receive future renewal materials electronically, select the YES bubble. Your laboratory will not receive a mailed copy of the preprinted renewal forms or catalog for future renewal cycles.


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325 Waukegan Rd.
Northfield, IL 60093-2750
t: 800-323-4040 option 1
d: 847-832-7000 option 1
cdm@cap.org | cap.org

Shop: estore.cap.org
Email: cdm@cap.org

GENERAL

Quote NO. 420286 02 82
CAP NO.
A/R NO.

We would prefer to access our future order renewal materials electronically ○ YES

2023 Laboratory Improvement Programs Order Form
To ensure full participation, please order by December 1, 2022.
Do not mark changes on the Institution Name or Name of Laboratory fields below.

CLIA #

Institution Name

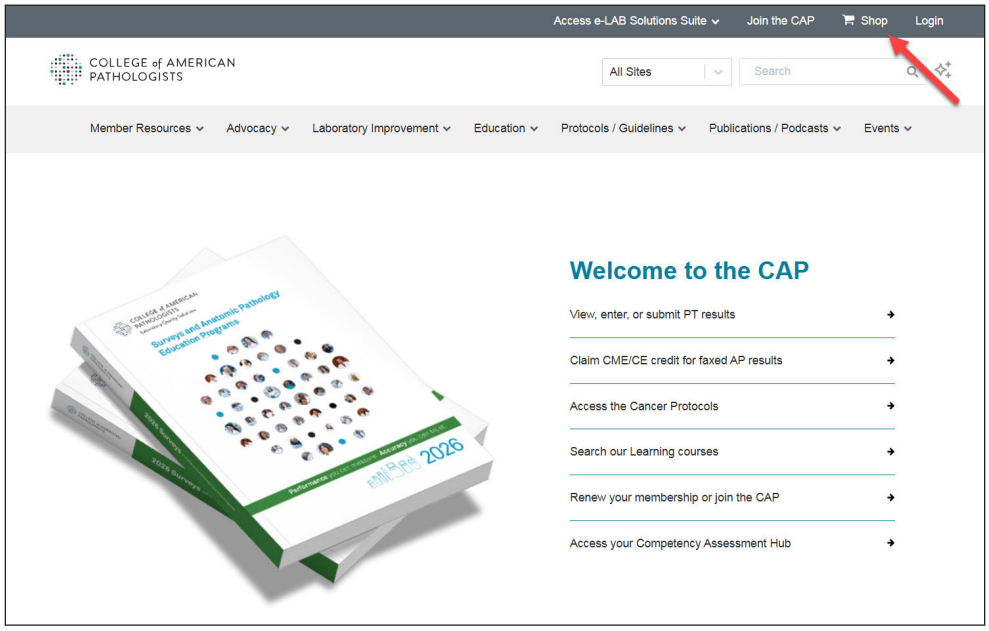
Name of Laboratory

Binders

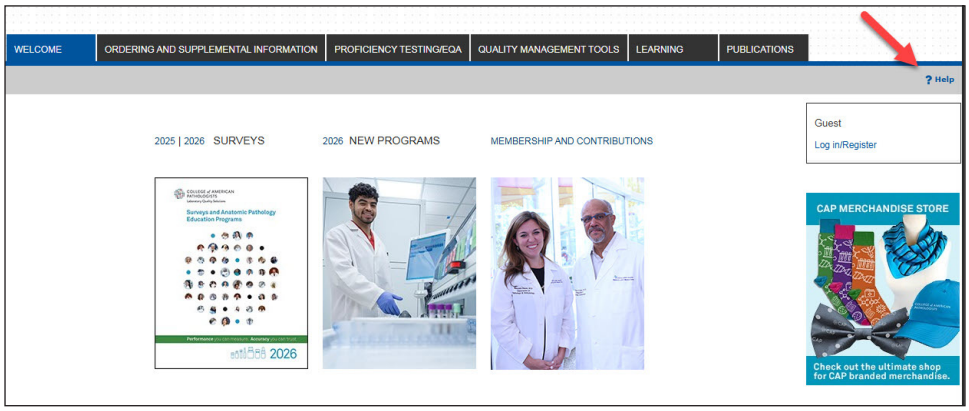
To provide you with an easy way to store your program materials, a three-ring binder with tabs and custom labels will be sent to you at no charge. The number of binders provided is based on the number of programs ordered. Binders will be shipped automatically upon placement of your order. Additional binders are available for purchase through the online store.

Ordering through the CAP Online Store

If your laboratory has an account set up in e-LAB Solutions Suite, you can order PT/EQA through the online store. To access the store, go to cap.org and click **Shop.**



For additional information on how to purchase products using the online store, click **Help.**



Shipping Information

To access the current shipping calendar, go to https://www.cap.org/ laboratory-improvement/ catalogs-ordering-and-shipping.

If a proficiency testing kit is lost in transit or received in a condition that is unacceptable for testing, replacement specimens will be available by contacting the CAP Customer Contact Center. If a shipment is delayed, your laboratory will be notified three days prior to the shipment. Also, the Expected Shipping Dates will note the shipment change as well as your laboratory's MY PT SHIPPING CALENDAR which is available in ELSS.

Payment Information

Complete the payment section of the order form, and include one of the following methods of payment to avoid delays in processing:

- Checks made payable to the College of American Pathologists.
- Credit Card: Include number, expiration, cardholder name, and authorized signature.
- Purchase order number.
- Letter of authorization with payment information.

Additional information can be found at https://www.cap.org/ laboratory-improvement/ catalogs-ordering-and-shipping.

Plan for Importation – Customers outside the US and Canada

The CAP PT/EQA programs may require additional information and steps to allow importation into your country or republic. Access the Importation Resource Guide to understand the process and resources available.

2 Prepare: Create Online Accounts With CAP

e-LAB Solutions Suite (ELSS) is the CAP's online portal to manage your laboratory improvement programs. Once your laboratory has placed an order, your site administrators (laboratory director and ship to contact) will receive an email with a link to activate your access.

Your access to the specified online information will be available within 24 hours of your web account activation.

Requesting Access

Individualized accounts for laboratory users allow flexibility in determining access levels. Because users are independent entities from the laboratory, they can be affiliated with multiple laboratories, and their security can be administered differently at each site.

To request access to a laboratory, click **Access e-LAB Solutions Suite,** and log in. Click **Request Online Access** and enter your laboratory's CAP #.

To access individual privileges, click **Update My Online Access.** The user can request access from the site administrator for the following permissions:

- Proficiency Testing - View Reports
- Proficiency Testing - Enter Data
- Proficiency Testing - Approve Enter Data
- Accreditation - View Reports and Data
- Accreditation - Enter and Edit Data
- Accreditation - Assign Tasks and Submit Data
- Organization Profile - View Data
- Organization Profile - Enter and Submit Data
- Online shopping

Additional information can be found in the ELSS Quick Start Guide link.

3 Test: Receive and Test Your PT/EQA Materials

Kit Delivery

The designated shipping contact for your laboratory will be notified of kit shipment via CAP*TRAK*er (US) or prealert email (outside the US), which will provide you with the tracking number for your PT/EQA kits.

The receiving department of your hospital or laboratory should be advised to handle CAP kits with prompt transfer to the laboratory. Kits received by the hospital but not delivered to the laboratory are not eligible for a no-charge replacement. Refer to the provided storage and stability information for proper storage of specimens.

Recommended Practice

Open your kit as soon as possible upon receipt. Visually inspect the material for any damage and verify it has arrived at the appropriate temperature (see kit instructions). Call for replacements for any unacceptable specimens.

Replacements

Contact the CAP to request replacement specimens as soon as possible if:

- your tracking information indicates your kit has been delivered and you have not received it
- If you receive material that is in an unacceptable condition for testing
- If you receive an incorrect kit

Provide your CAP #, contact information, and mailing and specimen numbers with all correspondence.

Telephone: 800-323-4040, Option 1
(Monday - Friday, 7:00 am – 5:30 pm US Central Time)
+1-847-832-7000, Option 1 (for customers outside the US)
Email: contactcenter@cap.org

Participants in countries serviced by a designated CAP distributor should contact their distributor's customer service department.

Subcontractors

The CAP may subcontract various aspects of the manufacturing of the PT material. When subcontracting occurs, it will be placed with a competent subcontractor and the CAP takes full responsibility for the subcontractor's work.

Kit Instructions

The kit instructions are shipped in your laboratory's kit and also available online. They contain important information on how to test and report your PT results.



A guide to the kit instructions and result form can be found at Proficiency Testing Kit Instructions and Result Form Resource.

MASTER LISTS

A master list appears on CAP PT/EQA kit instructions or result forms. A master list is a general term and may represent the following:

- methods
- manufacturers
- instruments
- reagents
- kits
- discipline-specific lists used for PT/EQA reporting purposes (eg, bacterial identification, amino acids, diagnosis)

Each master list item is assigned a reporting code; participants report the code on their PT/EQA result forms. These codes are used to compile PT/EQA data, calculate statistics, and at times grade by peer group. Manufacturers should request any code additions, changes, or deletions for their products. Master list changes are highlighted in the kit instructions, in the master list header, and/or on the result form.

If your instrument and/or method is not listed on a program master list, contact your manufacturer representative, and request they submit it for a master list addition.

REGULATORY INFORMATION – CLIA LABORATORIES

Laboratories subject to CLIA regulations: The CAP will report all CMS-regulated analytes to CMS unless directed otherwise by the laboratory. If your laboratory is beginning or discontinuing testing on any CMS-regulated analyte, you must check your **CMS Analyte Reporting Selections** to ensure no changes are needed (access through ELSS).

For regulatory purposes, waived methods do not contribute to the required minimum of 5 specimens per mailing. Testing done by waived methods/kits will not appear on a CMS Performance Summary Report.

Per CLIA, as Published by the United States Federal Register: PT/EQA specimens must be tested with the laboratory's regular workload, using routine methods, and testing the PT specimens the same number of times it routinely tests patient specimens.

If referral for testing is routinely performed for patient specimens, the practice cannot be followed for PT/EQA specimens. A referral is considered to be movement of the specimen from a laboratory with a CLIA identification number to another laboratory that has a different CLIA identification number. Laboratories must ensure that personnel does not share results or refer PT specimens for any reflex or testing outside their CLIA identification number.

BIOHAZARD WARNINGS

PT specimens must be handled with caution. Each shipment includes a biohazard warning statement explaining proper handling. Laboratories should not conduct additional testing or analysis of PT specimens to determine the identity of the individual(s) from whom the specimens are derived.

Incidents of personnel exposure to infectious specimens through needle sticks, contamination of the mucous membranes through splashes or aerosolization, or cuts from containers should be reported immediately to the CAP.

24-hour hotline: 800-443-3244
+1-847-470-2812 (for customers outside the US)

Have the following information available:

- CAP number
- Phone number
- Name of institution/city/state
- Name of person affected, if other than caller
- Date and time of incident
- Where and how affected
- Survey and specimen number
- Name and telephone number of laboratory director

This information will be relayed to an appropriate party, which, if etiologic, may include a pathologist member of the appropriate resource committee who will contact the participant's laboratory director or hospital employee health services physician with instructions concerning prophylaxis.

ATTESTATION PAGE

As stated in the February 28, 1992 United States Federal Register under Subpart H 493-801 (b) (1), “the individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient work load using the laboratory’s routine methods.” An attestation page is provided on the last page of the kit instructions and result form. The laboratory director or designee and the testing personnel **must sign** the attestation page included with the kit or print the online result form with attestation page for physical signature. It is also acceptable for the laboratory director to log into cap.org with their personal credentials, access the result form using ELSS, type their name on the attestation page, save, and approve using the existing online result form functionality. Retain a copy of the attestation page for your laboratory records and inspection documentation. This document does not need to be returned to the CAP.

Online Images

- Some PT/EQA programs provide online photographs or online, whole slide images. To display the online images, click **View Image(s)** on the Result Form Data Entry page via ELSS. Whole slide images are presented in the DigitalScope viewer. Some institutions may have difficulties opening up the images in this viewer due to firewall issues. Information is provided on the image access page to assist in addressing this issue. To access the image, click the image link. To change the magnification of the image(s), use your mouse scrolling wheel or the magnifying glasses in the toolbar.
- Use your mouse’s grab and drag properties to move the image, similar to moving the stage of a microscope.

Submit Results Online

The result form is available to record your methods of analysis and PT data and must be submitted by the due date listed on the form.

Results can be provided by online manual data entry or by direct transmission.

DIRECT TRANSMISSION

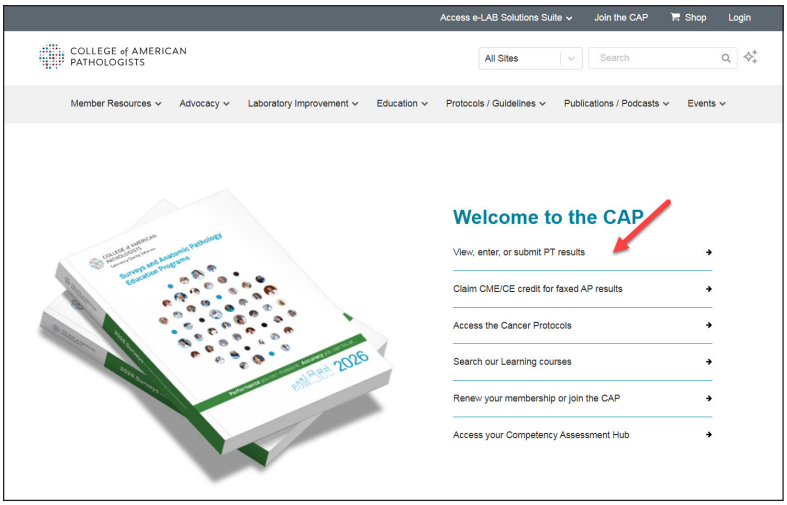
The CAP offers laboratories the option of direct transmission of PT results. This method provides faster and more accurate PT/EQA result reporting by enabling laboratories to electronically transmit quantitative results from their laboratory information system (LIS) or using Data Innovations® Instrument Manager.

Additional information about this complimentary service can be found at https://www.cap.org/laboratory-improvement/proficiency-testing/direct-transmission-pt-results or by contacting the CAP Customer Contact Center at 800-323-4040, option 1 or +1-847-832-7000, option 1 (for customers outside the US) or email to ptdirecttransmission@cap.org.

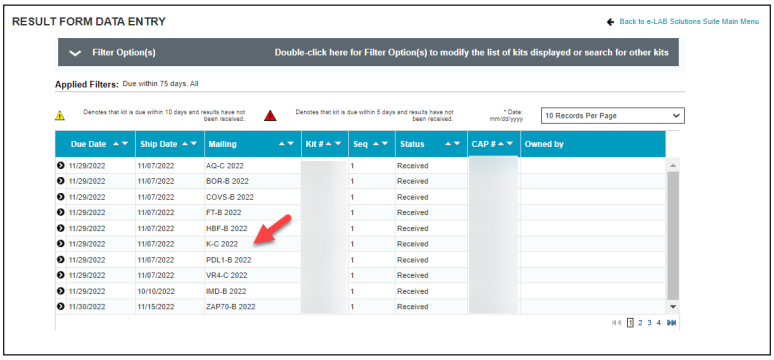
ENTERING RESULTS BY MANUAL DATA ENTRY THROUGH ELSS

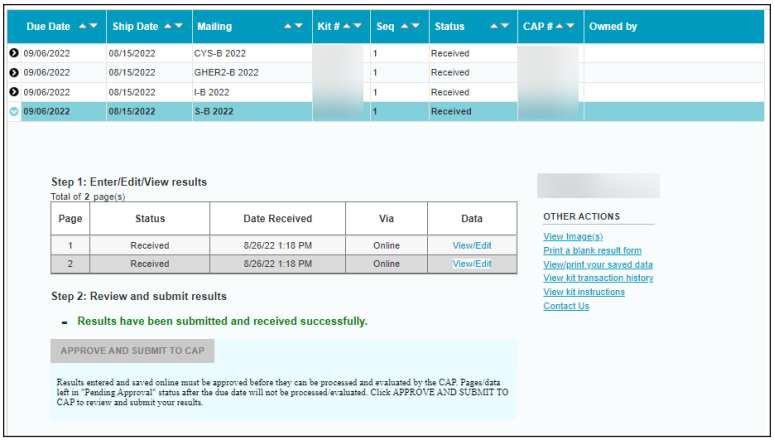
To access your result form and submit results online:

1. Go to cap.org. Click **View, enter, or submit PT results** and log in.



2. On the Result Form Data Entry page, choose your kit. Click **Enter Data** in the Data column. When your laboratory enters results online via ELSS, the date, time, and page status will appear on the result form printout.





Corrections to submitted results cannot be made after the due date on the result form.

Completing the Online Result Form

Your laboratory will receive access to the result form pages for the programs that you have ordered.

See the Kit Instructions and Result Form Resource for further information. Proficiency Testing Kit Instructions and Result Form Resource.

Most result forms have field validation capability. This technology will prevent results from being submitted without the required information and can reduce common clerical errors and increase data accuracy. Features can include:

- If a value/result is populated for any specimen for a single test, then a value/result must be populated for manufacturer, method, instrument, or reagent, which will prevent incomplete data from being submitted to the CAP. In addition, if specimen results are missing and no exception code chosen, those reporting fields will be highlighted and a pop up message will appear.
- If the laboratory fails to enter a unit of measure in the online result form, a pop-up message will appear and ask you to provide the required information.
- If a laboratory enters a value/result in an incorrect format (eg, ###.# instead of ###.) on the online result form, the reporting field(s) will be highlighted and a pop-up message will appear and ask you to revise the information.

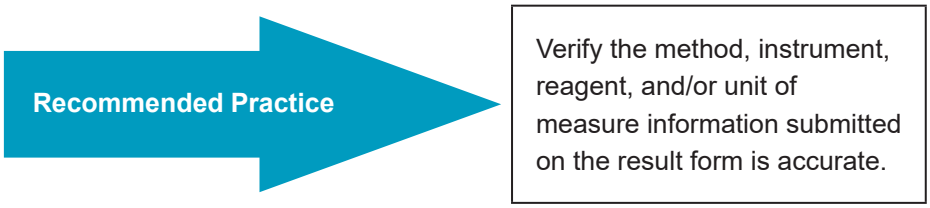
If your laboratory does not test one of the analytes included on your result form, you should leave all reporting areas blank for that analyte unless specific instructions are provided. If your laboratory would not test one of the specimens for an analyte for a reason such as a negative screen results for a confirmatory test or a specimen type not tested in your laboratory, use the test not performed reporting option provided.

Due Date

Results must be received at the CAP no later than midnight, Central Time by the due date on the result form. Result forms received beyond the date noted will not be evaluated and will result in a score of zero for the testing event for the laboratory per 42CFR Part 493 Subpart H. Participants will receive an evaluation indicating that the results were not received by the due date along with a participant summary (PS) that can be used for self-evaluation.

Reporting Code Information

The result form may contain reporting areas or bubbles to provide the method, instrument, reagent, and/or unit of measure, which applies to the testing performed. If you have participated in the program in the past year, your master list codes may be prepopulated with those previously submitted. The prepopulated reporting codes can be changed by using the drop-down menu options and selecting a different option. The reporting of an inappropriate master list code can result in an incorrect grouping of your results and a potential failure.



If there is not a specific master list code listed on the kit instructions or result form that corresponds to the testing methodology being performed, report the master list code for "Other" and provide your method on the attestation page, "Use of Other" section, at the end of the online result form. Program-specific evaluation criteria may prohibit an evaluation from being issued when other, specify is selected. In that instance, a self-evaluation should be performed using data in the PS report that is of a comparable methodology to the one in use. Further information regarding self-evaluation can be found in the Performing Self Evaluation When Proficiency Testing is Not Graded document.

UNITS OF MEASURE

Verify your analyte unit of measure matches the result form. If not, a conversion may be needed.

EXCEPTION CODES

If your laboratory needs to report an analytical problem for an entire test or individual specimens within a test, leave the result area blank and select the appropriate exception code on the result form.

It is the laboratory's responsibility to internally document the appropriate use of exception codes. Refer to the kit instructions for more information.

Corrections to Results

Corrections to results can be made any time **prior** to the due date listed on the result form; review your laboratory data carefully prior to submission. According to 42 CFR 493.903(a)(3), CAP cannot alter any laboratory data or results submitted by the laboratory for any proficiency testing event, regardless of the reason, including, but not limited to, the testing methodology, results, data, or units.

To view the status of your results, go to cap.org and click **View, enter, or submit PT results.**

Confidentiality of Results

All data and identifying information received by the CAP from its participants are considered confidential unless the participant has given express permission to pass on information. Anonymized data may be used for manuscripts with the permission of the CAP.

Participant Collusion and Falsification of Results

In PT terms, collusion is comparing data (and perhaps falsifying data) to fit in with a believed “correct” result. This is contrary to the spirit of PT programs, which are operated with the intention of providing an objective comparison of the performance of enrolled laboratories.

The CAP minimizes the risk of collusion and falsification by keeping confidential the sample content and expected results until the final report is issued.

The CAP may notify a laboratory manager in situations where it believes collusion or falsification may have occurred. However, substantiating such suspicions is both difficult and sensitive. Therefore, it is ultimately the responsibility of participating laboratories to respect the positive aims of PT programs and conduct themselves with the expected integrity. Tests should be conducted without knowledge of, nor any expectation of, the results. Answers should be reported as determined by the test outcomes.

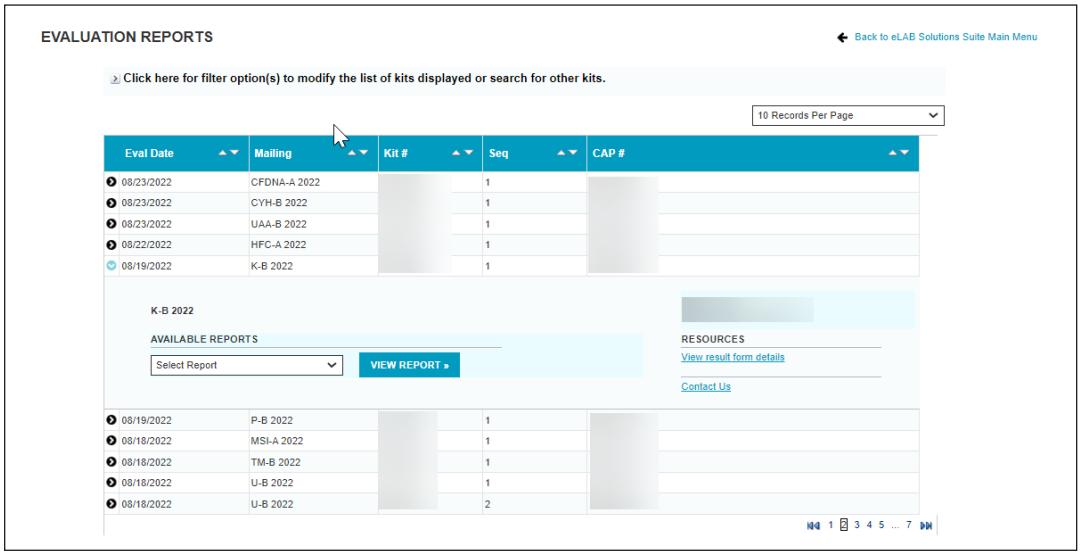
To prevent collusion and falsification our advice is:

- DO NOT confer with others about PT specimens or results.
- DO accept the fact that everyone makes errors from time to time.
- DO have confidence in your own results.
- DO NOT average the results or opinions of every person in the laboratory before selecting the answer to be submitted.

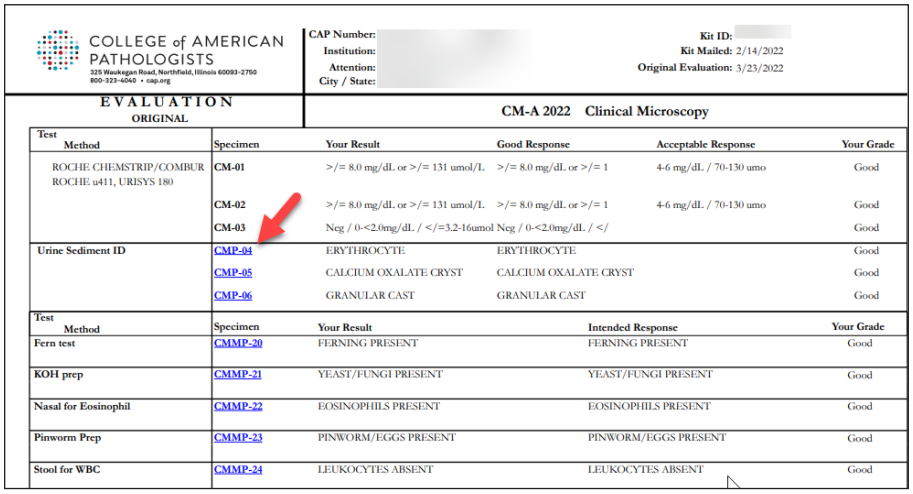
4 Learn: Review PT/EQA Reports

Online Reports

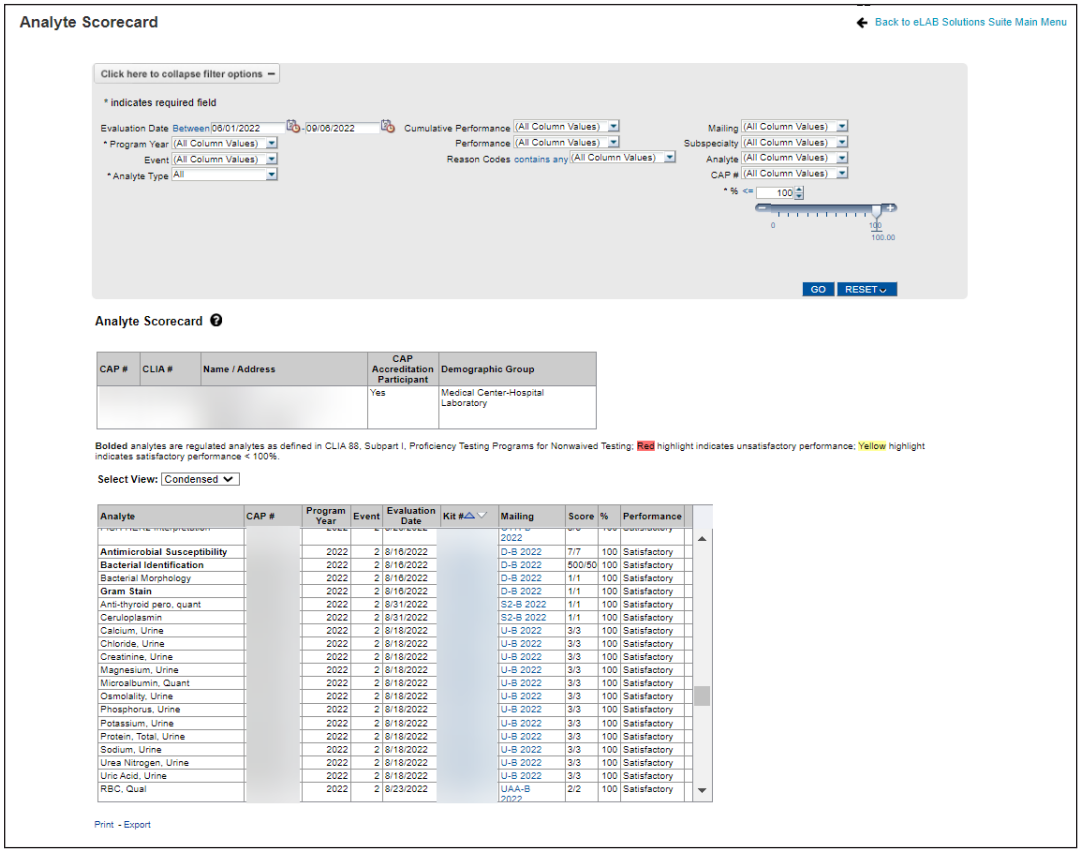
When the result form due date has passed, data are processed and graded according to US governmental and scientific committee criteria. Laboratory results and grading interpretations are displayed in an individualized report. Copies of this report and a PS can be accessed from the Performance Analytics Dashboard. To access the online versions, go to cap.org. Click **Access e-LAB Solutions Suite** and log in. Then click **Evaluation Reports** under the Proficiency Testing/Quality Improvement header. Using the filter options, select the program and report.



The online evaluation allows the user to easily navigate the data analyte by analyte. Also, users benefit by the inclusion of detailed images hyperlinked on the report for some programs.



Laboratory managers can access the scores for all graded analytes by accessing the All Analyte Scorecard, which allows them to customize the scorecard data for their laboratory as a means of identifying deficiencies or trends in performance.



Additional reports that accompany the evaluation are available online, as well, for review and to download for future reference, including the PS and final critiques (if offered), which contain useful data and education that can be reviewed and accessed by all users with appropriate security.

Calculation of Summary Statistics

PEER GROUP RESULTS

Results are grouped according to the method used for analysis and screened for outliers. Various statistics are calculated from the remaining data that summarize the peer group's responses. These summary statistics may include the following:

- the mean (the average of the reported results)
- the standard deviation (a measure of the variability of the participant results, often abbreviated as "SD")
- the coefficient of variation (CV%)
- the median (the middle value in an ordered list of the non-outlier results)
- the minimum value (the lowest value reported)
- the maximum value (the highest value reported)
- the final count of reported results that were not excluded as outliers.

OUTLIER DETECTION TECHNIQUE

Outlier exclusion is necessary because a large series of results frequently will include some aberrant values. These may arise from instrument malfunction, technical errors, specimen mix-ups, misplaced decimals, incorrect units of measure, or data entry errors. If any results are excluded, the outlier process is repeated using the remaining values. The summary statistics that appear on your reports do not reflect results that were removed as outliers during either outlier pass.

Grading Guidelines for Evaluation

On February 28, 1992, the Secretary of Health and Human Services (HHS) published the final rules implementing the Clinical Laboratory Improvement Act (CLIA) of 1988. These regulations established evaluation criteria limits for many of the analytes included in the CAP Surveys programs. For those analytes not included in the PT portion of CLIA, the target values and evaluation criteria are determined solely by the scientific committees of the CAP.

Selection of a Target Value

To minimize the effect of method differences and to allow comparison of all methods, participants' results are combined into comparable method/instrument groups called peer groups. It is important for participants to provide complete information regarding the method or instrument used to be combined in the appropriate peer group.

For most analytes, the peer group mean is designated as the target value for evaluation. The peer group must consist of a minimum of ten results after outlier exclusion, and the variability of the peer group data must not be too great.

If peer group data are not available or are too variable, method group statistics may be used. The method group must also consist of a minimum of ten results and demonstrate acceptable variability before it is used as the target group.

If peer and method group statistics are not available, a comparative method group may be designated as the target mean. The comparative method is not the method recommended by the CAP; however, it is established as a historically reliable method and is used for evaluating results from methods that have an insufficient number of participants to generate a separate peer group and/or method group statistics. If no comparative method exists for the analyte, results will not be evaluated.

QUANTITATIVE PROCEDURES/ROUNDING

All quantitative responses are evaluated based on a range of acceptability. This range is determined using a target value and a limit. The limit will be either a fixed interval (eg, ± 5 mg/dL), a percentage of the mean (eg, ± 25%), an SD (eg, ± 3 SD), or a variable range (eg, ± 6 mg/dL or 10%, whichever is greater). The PS included with your evaluations provide the criteria used to evaluate your performance. The following sections provides specific examples of how to calculate the range of acceptability depending upon the criteria used.

Mean and SD values are provided with one additional decimal place beyond what is reported on the result form so that there is not rounding bias in the reporting decimal units. In fact, rounding in the reporting decimal precision could make the evaluation limit smaller.

Once the evaluation limits are calculated with one extra decimal, the benefit of the doubt rounding is applied and it is converted back to the decimal precision at that point.

Benefit-of-the-doubt rounding is used to determine the range of acceptable results. The upper limit of acceptability is obtained by rounding up to the next reportable result, while the lower limit is determined by truncating.

FIXED RANGE EXAMPLE

Your laboratory reports a sodium result of 138 mmol/L. The peer group mean is 139.5 mmol/L. The evaluation limit for sodium is ± 4 mmol/L. The acceptable range is determined by the formula 139.5 mmol/L ± 4 mmol/L, which is 135 to 144 mmol/L when using benefit-of-the-doubt rounding; therefore, your reported result of 138 mmol/L is within the calculated acceptable range of 135 to 144 mmol/L.

PERCENTAGE OF THE MEAN EXAMPLE

Your laboratory reports an albumin result of 3.1 mg/dL. The peer group mean is 3.39 mg/dL. The evaluation limit for albumin is ± 10%. Ten percent of 3.39 mg/dL is 0.34 mg/dL. The acceptable range is determined by the formula 3.39 mg/dL ± 0.34 mg/dL, which is 3.0 to 3.8 mg/dL when using benefit-of-the-doubt rounding; therefore, your reported result of 3.1 mg/dL is within the calculated acceptable range of 3.0 to 3.8 mg/dL.

STANDARD DEVIATION EXAMPLE

Your laboratory reports a thyroid stimulating hormone (TSH) result of 16.4 µU/mL. The peer group statistics are as follows: mean = 15.70 µU/mL, SD = 1.5, and CV = 9.6. The evaluation limit for TSH is ± 3 SD. 3 x 1.5 = 4.5. The acceptable range is determined using the formula 15.70 µU/mL ± 4.5 µU/mL, which is 11.2 to 20.2 µU/mL when using benefit-of-the-doubt rounding; therefore, your result of 16.4 µU/mL is within the acceptable range of 11.2 to 20.2 µU/mL.

VARIABLE RANGE EXAMPLE

Your laboratory reports a total bilirubin result of 4.5 mg/dL. The peer group mean is 4.68 mg/dL. The evaluation limit for total bilirubin is ± 0.4 mg/dL or 20%, whichever is greater. Twenty percent of 4.68 is 0.936. Since the percentage limit of 0.936 is greater than the interval limit of 0.4, the percentage limit is applied to the target value. The acceptable range is determined using the formula: 4.68 ± 0.936, which is 3.7 to 5.7 mg/dL when using benefit-of-the-doubt rounding; therefore, your result of 4.5 mg/dL is within the acceptable range of 3.7 to 5.7 mg/dL.

Review of Your Evaluation and Participant Summary

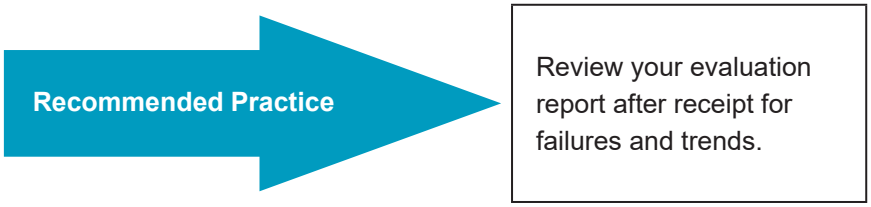
EVALUATION REPORTS

Your evaluation can be used as a quality assurance tool to assess how you performed compared to other participants. It is important that you review and understand the information presented in your evaluation:

1. Review the demographic information on the first page of the evaluation, which includes the name of your institution, your CAP identification number, and any agencies or consultants you have designated to receive copies of your evaluation. If any information is incorrect or has changed, contact the CAP Customer Contact Center at 800-323-4040, option 1 or +1-847-832-7000, option 1 (for customers outside the US).
2. Beginning on page 2 of the report, the results reported by your laboratory for the mailing are shown. For quantitative data, limits of acceptability and performance plots are provided for graded analytes. For qualitative data, an intended response is shown for graded analytes. Additional data is presented in each PS. Look for any unacceptable results. Reasons for unacceptable results may include:
   - Incorrect or incomplete method/instrument data
   - Clerical error
   - Specimen handling error
   - Analytical error

   Remember, whatever the cause, all PT deficiencies must be documented and corrective action taken to resolve the deficiency.

   For quantitative data, just knowing that you are “within limits” does not tell you if you are experiencing a slowly developing bias that may result in future failures. Additional guidance on troubleshooting errors can be found in the PT Troubleshooting guide.
3. Occasionally, incorrect entry of submitted data occurs. These clerical errors cannot be reevaluated.
4. US laboratories: Verify that all CMS-regulated analytes for which you reported results are included on the CMS Performance Summary. Laboratories outside of the US will receive a CAP Performance Summary.
5. Ensure that the laboratory director reviews and signs all PT/EQA evaluations.



CALCULATION OF THE STANDARD DEVIATION INDEX (SDI)

The evaluation lists your results, the statistics for your peer group, and your normalized results as an SDI. This value is obtained by subtracting the group mean from your result and then dividing by the SD.

The SDI is expressed in terms of the number of SDs from the mean, with an arithmetic sign indicating the direction of the difference. The calculation of the SDI normalizes your result and, therefore, allows for a comparison of results from specimens of different concentrations of an analyte.

When a comparative method has been designated for data analysis, a second set of statistics is listed comparing your results with those obtained using the comparative method. The figures shown are the mean and SD for the comparative method and your result as an SDI using these statistics. It is possible for your result to be defined as “good” performance in your method group and yet produce a comparative SDI greater than two. This will occur if your method has a large analytic bias or a large SD. It is possible to receive a comparative SDI lower than the method group SDI, although this rarely occurs. In practice, most participants receive similar method group and comparative SDIs.

PLOTS OF RELATIVE DISTANCE

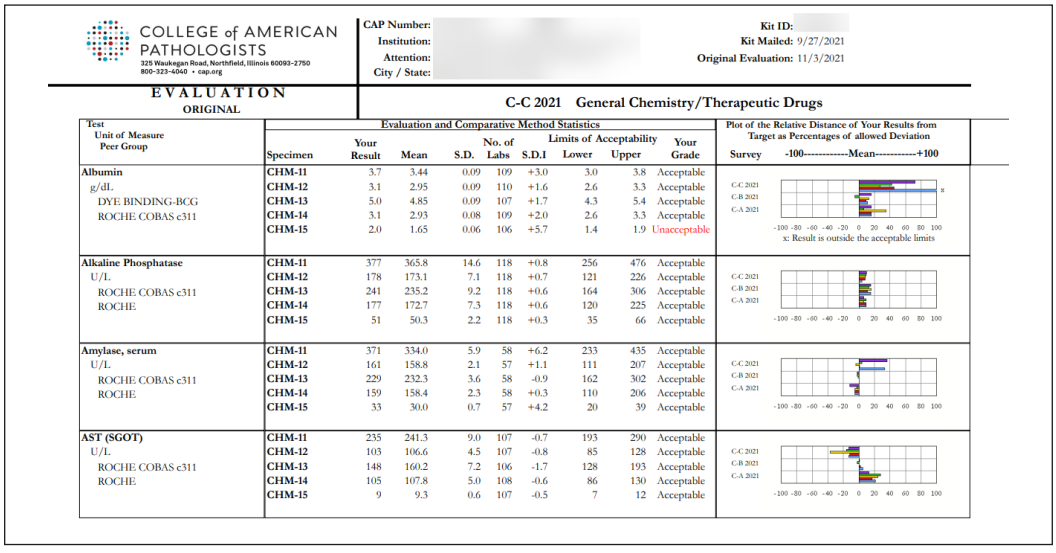
Your evaluation contains plots of the relative distance of your reported results as a percentage of allowable deviation from the target value. The numeric digit indicates the number of results at a plot location. The allowed deviation may be calculated as follows:

If your result is greater than the target mean:

$$\text{Percentage of Acceptable Deviation} = 100 \times \frac{\text{your result-target}}{\text{upper limit-target mean}}$$

If your result is less than the target mean:

$$\text{Percentage of Acceptable Deviation} = 100 \times \frac{\text{your result-target}}{\text{target mean-lower limit}}$$



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CAP Number:
Institution:
Attention:
City / State:

Kit ID:
Kit Mailed: 9/27/2021
Original Evaluation: 11/3/2021

EVALUATION
ORIGINAL

C-C 2021 General Chemistry/Therapeutic Drugs

Test / Unit of Measure / Peer Group	Specimen	Your Result	Mean	S.D.	No. of Labs	S.D.I	Limits of Acceptability Lower	Limits of Acceptability Upper	Your Grade
Albumin	**CHM-11**	3.7	3.44	0.09	109	+3.0	3.0	3.8	Acceptable
g/dL	**CHM-12**	3.1	2.95	0.09	110	+1.6	2.6	3.3	Acceptable
DYE BINDING-BCG	**CHM-13**	5.0	4.85	0.09	107	+1.7	4.3	5.4	Acceptable
ROCHE COBAS c311	**CHM-14**	3.1	2.93	0.08	109	+2.0	2.6	3.3	Acceptable
	CHM-15	2.0	1.65	0.06	106	+5.7	1.4	1.9	Unacceptable
Alkaline Phosphatase	**CHM-11**	377	365.8	14.6	118	+0.8	256	476	Acceptable
U/L	**CHM-12**	178	173.1	7.1	118	+0.7	121	226	Acceptable
ROCHE COBAS c311	**CHM-13**	241	235.2	9.2	118	+0.6	164	306	Acceptable
ROCHE	**CHM-14**	177	172.7	7.3	118	+0.6	120	225	Acceptable
	CHM-15	51	50.3	2.2	118	+0.3	35	66	Acceptable
Amylase, serum	**CHM-11**	371	334.0	5.9	58	+6.2	233	435	Acceptable
U/L	**CHM-12**	161	158.8	2.1	57	+1.1	111	207	Acceptable
ROCHE COBAS c311	**CHM-13**	229	232.3	3.6	58	-0.9	162	302	Acceptable
ROCHE	**CHM-14**	159	158.4	2.3	58	+0.3	110	206	Acceptable
	CHM-15	33	30.0	0.7	57	+4.2	20	39	Acceptable
AST (SGOT)	**CHM-11**	235	241.3	9.0	107	-0.7	193	290	Acceptable
U/L	**CHM-12**	103	106.6	4.5	107	-0.8	85	128	Acceptable
ROCHE COBAS c311	**CHM-13**	148	160.2	7.2	106	-1.7	128	193	Acceptable
ROCHE	**CHM-14**	105	107.8	5.0	108	-0.6	86	130	Acceptable
	CHM-15	9	9.3	0.6	107	-0.5	7	12	Acceptable

Plot of the Relative Distance of Your Results from Target as Percentages of allowed Deviation

Survey -100----------Mean----------+100

C-C 2021
C-B 2021
C-A 2021

-100 -80 -60 -40 -20 0 20 40 60 80 100

x: Result is outside the acceptable limits

QUALITATIVE PROCEDURES

For qualitative responses, consensus agreement of referee or participating laboratories is used for evaluation. Generally, 80% agreement is required.

Nongraded Reason Codes

At times PT/EQA results are not evaluated for a variety of reasons. A reason code explaining the specific circumstance will appear on the individual evaluation, along with a brief explanation of what that code means. Below is a ledger of possible reason codes that can be assigned. Additional information on Actions to take when you receive a nongraded reason code can be found on the last page of the PS.

Reason Code	Description or Explanation
11	Unable to analyze (documentation to be provided by laboratory).
20	Response was not formally graded due to insufficient peer group data.
21	Specimen problem.
22	Result is outside the method/instrument reportable range.
24	Incorrect response due to failure to provide a valid response code.
25	Inappropriate use of antimicrobial.
26	Educational challenge.
27, 31	Lack of participant or referee consensus.
28	Response qualified with a “greater than” or “less than” sign; unable to quantitate.
29	Inappropriate response.
30	Scientific committee decision.
33	Specimen determined to be unsatisfactory after contacting the CAP.
35	Testing not performed on this specimen type.
40	Results for this kit were not received.
41	Results for this kit were received past the evaluation cut-off date.
42	No credit assigned due to absence of response.
43	The order for this kit was canceled; results not evaluated.
44	This drug is not included in our test menu.
46	Quantitation not appropriate.
77	Improper use of exception code for this mailing.
88	Lab does not perform tests from this source or does not perform this test on patients.
91	There were an insufficient number of contributing challenges to establish a composite grade.
92	Composite grade could not be established due to the use of multiple non-graded reason codes for the individual challenges.

It is the laboratory’s responsibility to document the appropriate use of these exception codes should this be requested during a laboratory inspection.

Participant Summary

In addition to your evaluation, each laboratory receives a PS for that mailing that includes results from all participants for each analyte grouped by the methodology. This report provides valuable information to the participant in the form of comparative data and education activities. The names of the current members of the scientific committee overseeing the program are provided on the inside cover for your information.

PROGRAM UPDATE

This section can provide special instructions, updates from the last mailing, and additional information regarding the current mailing.

EVALUATION CRITERIA

This section provides the criteria used to evaluate each graded analyte result for acceptability. Analytes that are regulated in the US by CMS will appear in bold face. A list of the analytes that are not graded may also be provided.

QUANTITATIVE DATA TABLES

The PS provides the statistical data needed to review your PT/EQA results. The report lists the mean, SD, and CV% for peer groups consisting of 10 or more laboratories. For peer groups with 3 - 9 participants, a table of the median, minimum, and maximum values reported may be provided to allow participants using these methods to perform a self-evaluation.

QUALITATIVE DATA

Qualitative data evaluation is based on consensus of participant and/or referee responses. The PS lists the participant responses along with the percentage reporting that response. Where available, referee data is also included.

HOW TO PERFORM A SELF-EVALUATION

As mentioned previously, occasionally a PT/EQA challenge cannot be evaluated for a variety of reasons:

- Lack of participant consensus
- Insufficient data (<10 responses for a given method)
- Perceived compatibility issues

In order to comply with the quality assurance aspect of PT as outlined in CLIA, you must have some mechanism to evaluate your PT results. Here are a few examples of how the data presented in the PS can assist with this task.

QUANTITATIVE RESULTS

If you perform a test and there are fewer than nine other laboratories reporting results for that test, your result will not be evaluated. You can determine how well you performed compared to all participants who reported results by using the “all instrument method” data presented in the PS (if provided). For example, you perform hemoglobin analysis using the Coulter LH500. There are an insufficient number of results to form a peer group (<10); therefore, your results are not graded. Note that in the PS there is an all-instrument mean, standard deviation, and coefficient of variation, which can be used as a reference value.

By applying the published CMS evaluation limits (±7%) to this mean, you can determine how well you performed compared to this reference value. For example:

Your result:	*13.8 g/dL*
All Instrument Mean:	13.77 g/dL
Range of Acceptability:	12.8 – 14.8 g/dL

In this example, your result would be considered within range when compared to the all-instrument mean. Document this self-assessment on your evaluation. When you perform this self-assessment, any unacceptable result should be documented and investigated and corrective action should be taken as would be done for formally evaluated results. This same technique can be used when only a median, minimum, and maximum value are reported for an analyte.

QUALITATIVE RESULTS

If a qualitative result is not evaluated due to lack of referee or participant consensus, you can still evaluate how well your laboratory's result agreed with the correct response by using the data in the PS. For example, one of the Gram stain challenges could not be graded due to lack of participant consensus (77% reported gram-negative, 23% reported gram-positive). The PS indicates that the organism was *Pseudomonas aeruginosa*, a gram-negative rod/bacilli. Compare your result with the correct result. Investigate and document any corrective action taken. Review the educational critique accompanying the result for helpful suggestions on laboratory technique.

For additional information on performing a self-assessment, refer to Performing a Self-Evaluation When PT is Not Graded.

Performance Summary Report

If any of the analytes contained in your program are regulated by CMS, you will receive a performance summary on the last page of your evaluation, even if your laboratory does not have a CLIA number. This report provides a summary of performance for the regulated analytes over the past 3 mailings.

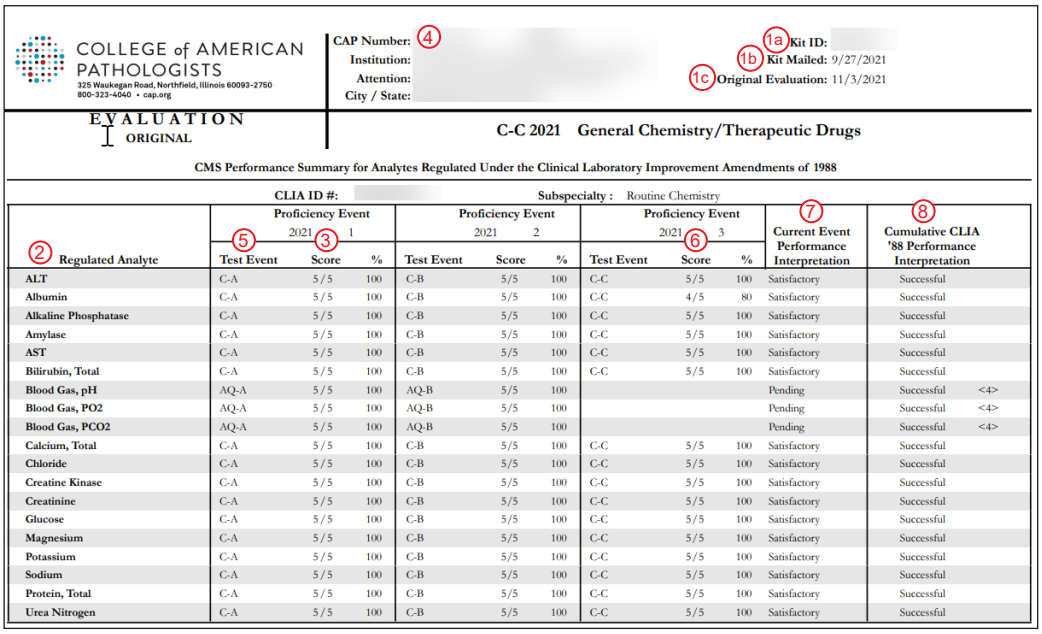
CMS Performance Summary Data

1. a. **Kit ID:** Defines the customer's unique kit number for each mailing.

   b. **Kit Mailed:** Lists the date the Surveys mailing was shipped.

   c. **Original Evaluation:** Lists the date the evaluation was originally generated.

2. **Regulated Analyte:** Lists all regulated tests included in the specialty/subspecialty as defined by the CLIA regulations for the modules in which you are enrolled.



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CAP Number: (4)
Institution:
Attention:
City / State:

(1a) Kit ID:
(1b) Kit Mailed: 9/27/2021
(1c) Original Evaluation: 11/3/2021

EVALUATION ORIGINAL

C-C 2021 General Chemistry/Therapeutic Drugs

CMS Performance Summary for Analytes Regulated Under the Clinical Laboratory Improvement Amendments of 1988

CLIA ID #: Subspecialty : Routine Chemistry

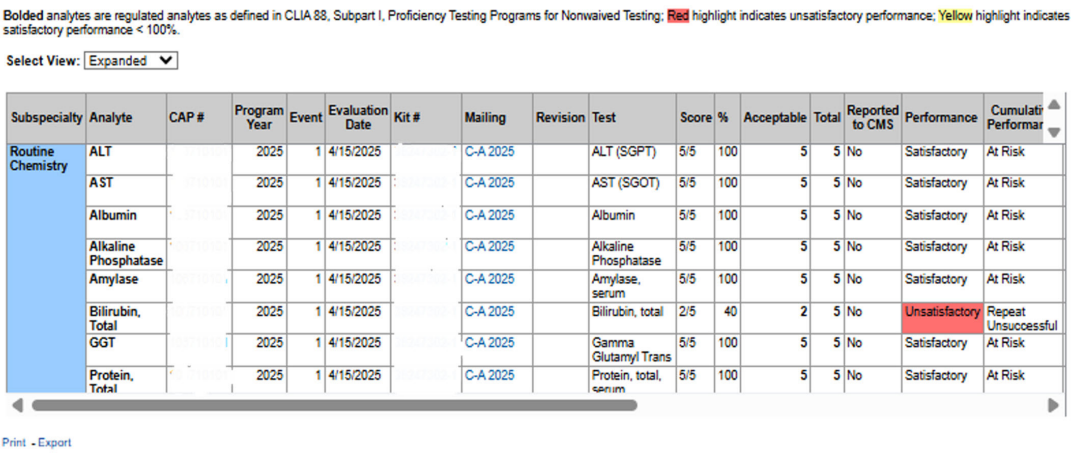
(2) Regulated Analyte	Proficiency Event 2021 1 (5) Test Event	(3) Score	%	Proficiency Event 2021 2 Test Event	Score	%	Proficiency Event 2021 3 (6) Test Event	Score	%	(7) Current Event Performance Interpretation	(8) Cumulative CLIA '88 Performance Interpretation	
ALT	C-A	5/5	100	C-B	5/5	100	C-C	5/5	100	Satisfactory	Successful	
Albumin	C-A	5/5	100	C-B	5/5	100	C-C	4/5	80	Satisfactory	Successful	
Alkaline Phosphatase	C-A	5/5	100	C-B	5/5	100	C-C	5/5	100	Satisfactory	Successful	
Amylase	C-A	5/5	100	C-B	5/5	100	C-C	5/5	100	Satisfactory	Successful	
AST	C-A	5/5	100	C-B	5/5	100	C-C	5/5	100	Satisfactory	Successful	
Bilirubin, Total	C-A	5/5	100	C-B	5/5	100	C-C	5/5	100	Satisfactory	Successful	
Blood Gas, pH	AQ-A	5/5	100	AQ-B	5/5	100				Pending	Successful	<4>
Blood Gas, PO2	AQ-A	5/5	100	AQ-B	5/5	100				Pending	Successful	<4>
Blood Gas, PCO2	AQ-A	5/5	100	AQ-B	5/5	100				Pending	Successful	<4>
Calcium, Total	C-A	5/5	100	C-B	5/5	100	C-C	5/5	100	Satisfactory	Successful	
Chloride	C-A	5/5	100	C-B	5/5	100	C-C	5/5	100	Satisfactory	Successful	
Creatine Kinase	C-A	5/5	100	C-B	5/5	100	C-C	5/5	100	Satisfactory	Successful	
Creatinine	C-A	5/5	100	C-B	5/5	100	C-C	5/5	100	Satisfactory	Successful	
Glucose	C-A	5/5	100	C-B	5/5	100	C-C	5/5	100	Satisfactory	Successful	
Magnesium	C-A	5/5	100	C-B	5/5	100	C-C	5/5	100	Satisfactory	Successful	
Potassium	C-A	5/5	100	C-B	5/5	100	C-C	5/5	100	Satisfactory	Successful	
Sodium	C-A	5/5	100	C-B	5/5	100	C-C	5/5	100	Satisfactory	Successful	
Protein, Total	C-A	5/5	100	C-B	5/5	100	C-C	5/5	100	Satisfactory	Successful	
Urea Nitrogen	C-A	5/5	100	C-B	5/5	100	C-C	5/5	100	Satisfactory	Successful	

3. **Summary of Your Previous Responses:** Lists the total number of specimens you have tested and the number of acceptable responses for previous testing events.
4. **CAP Number and Kit:** Defines the CAP number and kit sequence.
5. **Test Event:** Identifies the product fulfillment group and shipment.
6. **Summary of Your Current Responses:** Lists the total number of specimens you have reported and the number of acceptable responses for that testing event. When results are not received from your laboratory for an event, this area will be blank.
   - The score may not appear (field is blank) due to the following reasons:
     - The laboratory has indicated to the CAP that the regulated analyte should not be reported to regulatory agencies as the test/analyte is no longer on its testing menu
     - Challenges were not graded, using reason codes that are not reported on the scorecard
     - The method reported for the analyte is waived
7. **Current Event Performance Interpretation:** Indicates either satisfactory (≥ 80%) or unsatisfactory (< 80%) performance for each analyte and the overall performance for the specialty/subspecialty. For ABO group, Rh type, unexpected antibody detection, and compatibility testing, a score of 100% is required. Antibody identification remains at 80%.
   - **Satisfactory PT Performance:** In general, 80% or greater is considered satisfactory performance, except for ABO/Rh, unexpected antibody detection, and compatibility testing, which require a score of 100%.
   - **Unsatisfactory PT Performance:** In general, less than 80% is considered unsatisfactory performance, except for ABO/Rh, unexpected antibody detection, and compatibility testing, which require a score of 100%.
   - **Pending PT Performance:** Pending scorecard rows will say Pending until there is an eligible score for that analyte to be sent to CMS. For additional information on which of your scores are being reported to CMS, refer to How to Manage CMS Analyte Reporting Selections.

8. **Cumulative Performance Interpretation Provided on Evaluation:** Indicates successful or unsuccessful performance for each analyte and for the specialty/subspecialty, as measured over the past three events. Each analyte requires satisfactory scores (as previously defined) for two of the last three events to be considered successful. The symbols displayed on your evaluation are described below. These codes are applicable to both the analyte and the overall specialty/subspecialty scores.

   - <1> denotes you have satisfactory performance for the current mailing. Your cumulative performance is successful but your laboratory is at risk for the next mailing.
   - <2> denotes you have unsatisfactory performance for the current mailing. Your cumulative performance is successful but your laboratory is at risk for the next two mailings.
   - <3> denotes you currently have unsuccessful performance due to unsatisfactory scores on two of the last three mailings.
   - <4> denotes scorecard performance is pending a future evaluation or may not be applicable due to discontinued testing or the use of a waived method.
     Note: The PT Cumulative Performance Interpretation provided on your evaluation is based on three consecutive PT events. CMS and accrediting agencies monitor the performance of the most recent 12 PT events for a regulated analyte, subspecialty or specialty. Refer to the Analyte Scorecard in the Performance Analytics Dashboard for cumulative PT performance for the most recent 12 events.

9. **Cumulative Performance Interpretation Provided in ELSS:** Additional information regarding your laboratory's cumulative performance may be found by reviewing your all analyte scorecard in ELSS.



Bolded analytes are regulated analytes as defined in CLIA 88, Subpart I, Proficiency Testing Programs for Nonwaived Testing; Red highlight indicates unsatisfactory performance; Yellow highlight indicates satisfactory performance < 100%.

Select View: Expanded

Subspecialty	Analyte	CAP #	Program Year	Event	Evaluation Date	Kit #	Mailing	Revision	Test	Score	%	Acceptable	Total	Reported to CMS	Performance	Cumulati Performar
Routine Chemistry	ALT		2025	1	4/15/2025		C-A 2025		ALT (SGPT)	5/5	100	5	5	No	Satisfactory	At Risk
	AST		2025	1	4/15/2025		C-A 2025		AST (SGOT)	5/5	100	5	5	No	Satisfactory	At Risk
	Albumin		2025	1	4/15/2025		C-A 2025		Albumin	5/5	100	5	5	No	Satisfactory	At Risk
	Alkaline Phosphatase		2025	1	4/15/2025		C-A 2025		Alkaline Phosphatase	5/5	100	5	5	No	Satisfactory	At Risk
	Amylase		2025	1	4/15/2025		C-A 2025		Amylase, serum	5/5	100	5	5	No	Satisfactory	At Risk
	Bilirubin, Total		2025	1	4/15/2025		C-A 2025		Bilirubin, total	2/5	40	2	5	No	Unsatisfactory	Repeat Unsuccessful
	GGT		2025	1	4/15/2025		C-A 2025		Gamma Glutamyl Trans	5/5	100	5	5	No	Satisfactory	At Risk
	Protein, Total		2025	1	4/15/2025		C-A 2025		Protein, total, serum	5/5	100	5	5	No	Satisfactory	At Risk

Print - Export

   - **Unsuccessful cumulative performance:** PT performance has unsatisfactory scores for the same analyte or subspecialty in two consecutive or two out of three testing events. Cumulative performance is calculated based on consecutive events for the same laboratory and equivalent program offering.
   - **Repeat unsuccessful cumulative performance:** PT performance has unsuccessful event statuses for the same analyte or subspecialty in two sets of two out of three testing events over the most recent 12 testing events. Cumulative performance is calculated based on consecutive events for the same lab and equivalent program offering. Repeat unsuccessful performance will result in a cease testing notice by your accrediting agency for the analyte and require fulfillment of reinstatement activities.
   - **At Risk cumulative performance:** This status indicates that an unsatisfactory score in the next event will result in a cumulative performance status of Unsuccessful. This is the result of having an unsatisfactory event in one of the last two consecutive events within the equivalent program offering.
   - **At Risk Repeat cumulative performance:** This status indicates that an unsatisfactory score in the next event will result in a cumulative performance status of Repeat Unsuccessful. This is the result of having an unsatisfactory event in one of the last two consecutive events **and** a prior unsuccessful event within the most recent 12 events based on consecutive events for the same lab and equivalent program offering.

PT/EQA Deficiency Response

The CAP does not require that you submit documentation for all PT/EQA deficiencies. However, it is recommended that such documentation be retained in your laboratory. The CAP Laboratory Accreditation Program issues a separate report, the “Proficiency Testing Compliance Notice (PTCN),” that addresses deficiencies for CAP-accredited laboratories. Instructions for response will be included with the report.

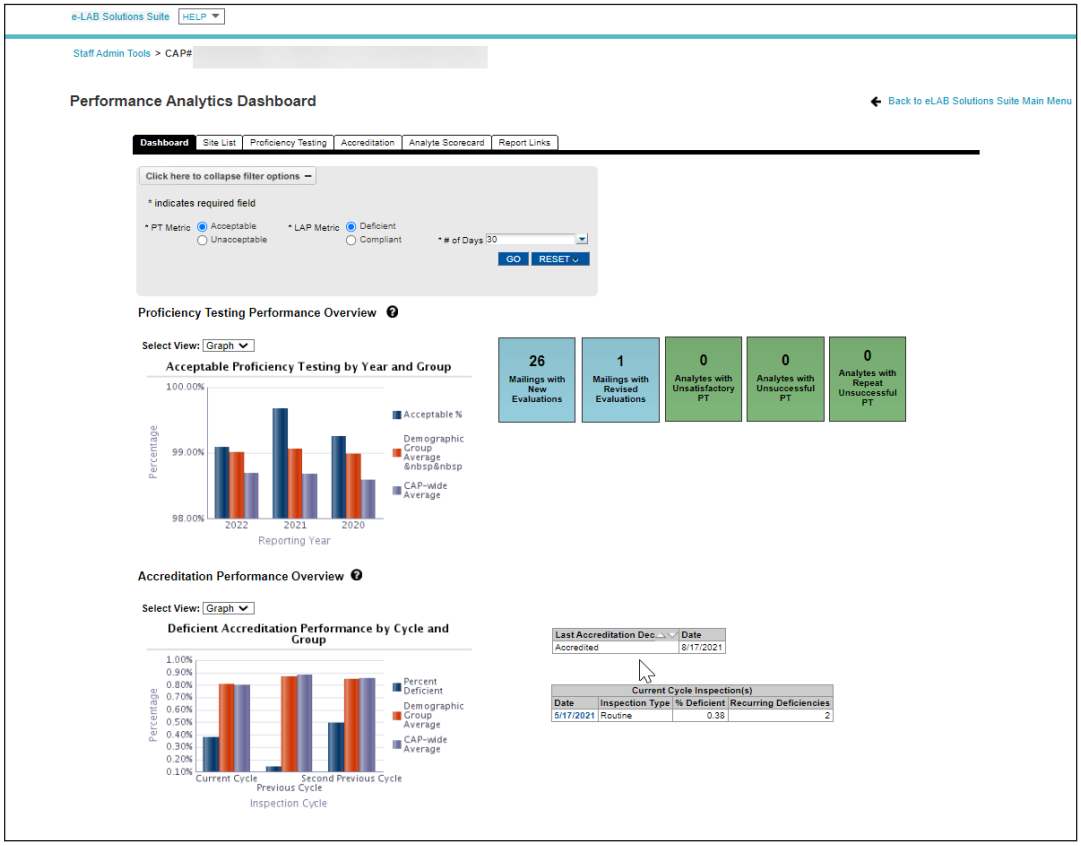
Complaints and Appeals

If participants disagree with their performance assessment on the evaluation, they may prepare and submit a written appeal to the CAP within 30 days of receiving their evaluation report. Written submissions are assessed by CAP staff and a response should be expected within 30 days which will include the CAP’s interpretation of the outcome of the re-assessment and an explanation of that outcome.

5 Complete: Complete the PT Cycle

Performance Analytics Dashboard

Our free web-based Performance Analytics Dashboard provides a comprehensive view of all of your CAP program results—both PT/EQA and accreditation to help you more effectively benchmark performance while managing risk and compliance across departments, multiple sites, or within a network/system. Updated daily, the dashboard can also provide a quick visual of problematic areas as an early indicator of potential risk or areas that need additional focus. In addition, your result forms, evaluations and participant summaries can be easily accessed from a centralized location.



Program Certificates

After the completion of the program year, participating laboratories will receive a certificate recognizing each institution's participation in the CAP PT program and its commitment to patient care. Certificates are signed by the CAP president and are suitable for framing.



COLLEGE of AMERICAN PATHOLOGISTS

CERTIFICATE OF PARTICIPATION

2024 Proficiency Testing/External Quality Assessment

Recipient Hospital

CAP Number: 123456-01

This certificate recognizes your participation in the College of American Pathologists' Proficiency Testing and/or Anatomic Pathology Education Programs for the 2024 program year.

Bobbi S. Pritt, MD, MSc, FCAP
Chair, Council on Scientific Affairs

Donald S. Karcher, MD, FCAP
President, College of American Pathologists

6 Glossary of Terms Definitions/ Usage

Accuracy-based programs: Programs that use specimens that are free from matrix effects and might have target values assigned that are traceable to a certified reference method.

Alternative performance assessment (APA): A system for determining the reliability of laboratory examinations for which no commercial PT/EQA products are available, are not appropriate for the method or patient population served by the laboratory, or participation is not required by the accrediting organization. APA is required at the analyte level and is not required for each instrument/method.

Analyte: Any substance or chemical constituent of organic material (eg, body fluids, tissues, microorganisms) that is analyzed, quantified, detected, or identified for the purpose of contributing to a clinical diagnosis or treatment of a patient. A list of analytes offered in the CAP PT/EQA programs can be found in the last section of the catalog.

Calibration Verification/Linearity: Programs that provide specimens used to verify calibration settings and assessment of the linearity for the analytical measurement range of a participant's laboratory method. This is not PT/EQA.

Challenges: The number of times one particular test or analyte must be performed in order to meet United States regulatory requirements, usually 5 challenges, 3 times per year.

CMS-regulated: Per the US Clinical Laboratory Improvement Amendments of 1988 (CLIA) regulations, there are 122 regulated analytes and the 5 subspecialties of microbiology. These analytes are bolded in the CAP catalog.

CLIA: Clinical Laboratory Improvement Amendments of 1988.

CMS: Centers for Medicare and Medicaid Services.

Continuing Education (CE) and Continuing Medical Education (CME): Consists of educational activities which serve to maintain, develop, or increase the knowledge, skills, and professional performance. These can be used to improve services for patients, the public, or the profession and for maintenance of certification and competency.

Dry challenge: A PT/EQA specimen that is provided as an opportunity for laboratories to perform an analysis when it is not possible to provide a physical specimen. These challenges may be graded or ungraded.

Educational/Ungraded: PT/EQA specimens that are distributed to laboratories for educational purposes only. They do not contribute to the assessment of a laboratory's overall PT/EQA performance. Review the participant summary for comparative results and document performance accordingly. Evaluation criteria are not established for educational challenges. Laboratories should determine their own evaluation criteria approved by the laboratory director for self-evaluation.

ELSS (e-LAB Solutions Suite): The CAP's online PT and accreditation portal. Laboratories utilize ELSS to manage all aspects of their PT/EQA including access to result forms, kit instructions, entry of PT/EQA results, evaluations, online participant summary reports, and your customized shipping calendar.

Evaluation: A report sent to participants, which includes information to be used to evaluate responses and assess performance. The report includes results reported by the laboratory, a description of any exception codes assigned, and may also include the acceptability limits or intended response for evaluation.

Exception Reason Code: Exception code options are provided on the result form and are used to indicate the laboratory is not able to perform testing and report results. Detailed instructions for the appropriate use of exception codes on the result form are found in program kit instructions. Documentation regarding your laboratory's use of these codes is the responsibility of the laboratory and should be kept internally.

Graded/ungraded PT/EQA analytes

> **Graded:** PT results receive a numeric grade based on success/failure (ie, 5/5); this grade may be reported to regulatory agencies and will appear on the Analyte Scorecard available in ELSS. For CLIA regulated analytes a scorecard will be included as the last page of an evaluation.
>
> **Ungraded:** PT for which no numeric grade is given and is not reported to regulatory agencies. Laboratories may perform a self-evaluation using the information provided in the participant summary.

Intended response: The correct response; for qualitative challenges it is based on consensus results or a reference method result.

Interactive evaluation: The online evaluation available on ELSS where participants can select customized views of their evaluation report.

Kit: A complete set of materials (either physical or online) required to perform and report results for a PT/EQA program. Items included in a kit may include specimens, either physical or online, and kit instructions.

Kit number: A unique identification number assigned to each kit. This number can be found on the shipping label, the online result form, in ELSS, and on your evaluation.

Limits of acceptability: For quantitative data, the limits of acceptability represent the range of acceptable results obtained after grading criteria is applied.

Mailing: A shipment or release of a PT/EQA program to the enrolled participants. The mailing is designated with the program code, a letter to designate which mailing in the series it is and the year. Each participant will only receive the kit materials for the programs they ordered for that mailing. The ship dates for each mailing can be found in the shipping calendar available at cap.org.

Master lists: A list of allowable reporting codes provided in the kit instructions and/or result forms. Master lists may include methods, manufacturers, instruments, reagents, kits, and/or discipline-specific lists used for PT/EQA reporting purposes (eg, bacterial identification, amino acids, diagnoses). These codes are used to compile PT data, calculate statistics, and peer group grading.

Materials: See Specimen.

Nongraded Reason Code: A nongraded reason code is a code assigned by the CAP to indicate a reason why a result was not graded. For example, a code 26 indicates a challenge was educational. A code 20 indicates there were not enough results reported for a peer group to grade the challenge. Codes used in the evaluation of results are indicated on the cover of the evaluation and recommendations for actions laboratories should take can be found at the end of the participant summary.

Online, whole slide image: A high-resolution digital image for use in PT/EQA programs that can be accessed through the result form data entry page in ELSS. Viewing the image provides the user with an experience similar to using a microscope.

Participant summary: A report summarizing PT data for all analytes tested in each program shipment including criteria used to evaluate results and may also include discussions and continuing education opportunities.

Peer group: A grouping of results that use the same instrumentation, manufacturer, reagent, and/or methodology for a specific test. A minimum of 10 results are required to generate statistics for a peer group.

Performance Analytics Dashboard: An online tool for CAP PT/EQA and accreditation customers, which allows users to review current and past PT/EQA performance. This provides participants data analysis of performance to quickly identify trends/patterns to mitigate risk, review alerts to prompt action before a cease testing notice is received, benchmark your laboratory against your peers and CAP wide performance, and prepare for accreditation inspections by identifying areas for improvement based on past deficiencies.

Performance Summary Report/Scorecard: For analytes regulated under CLIA, the evaluation will include a record of analyte(s) performance over three consecutive testing events or periods, including a cumulative performance assessment as the last page of the evaluation. Scores from all graded analytes can be viewed online via the Analyte Scorecard located within ELSS.

PT/EQA programs: PT/EQA is an external program employed to assess, manage, and improve laboratory testing quality. Laboratory (or individual) performance is evaluated based on a scientifically defensible criteria and provides the laboratory with an evaluation of their performance.

Quality Cross Check (QCC): Programs that are used to monitor performance of analyte testing across multiple instruments and to simplify biannual instrument comparability studies. Participants receive customized reports that include peer group evaluations and instrument comparability statistics. Quality Cross Check is not PT/EQA and is not subject to regulatory restrictions.

Quality Management Tools: A collection of studies that provide internal and external assessments of laboratory activities through data collection by providing benchmarks and normative ratios of key performance indicators. Studies may assist laboratory management in decision making, such as staffing level needs, education aims for staff based on competency challenges, and assist in meeting various CAP Laboratory Accreditation Program requirements.

QP Studies: Short-term quality assessments in the Quality Management Tools series that may vary annually, and may include topics such as staffing ratios, laboratory satisfaction surveys, and morphology competencies that use online, whole slide images. Reports include individual and aggregate results. A/B/C/D mailings are each approximately 8 - 12 weeks. These studies begin with the code QP.

QT Monitors: Long-term quality assessments in the Quality Management Tools series that repeat annually. Each study has 4 mailings (A/B/C/D). Performance indicators are reported using internal individual laboratory results and external aggregate comparison results, trend charts; cumulative results are provided for laboratory management lookback and improvement over the course of enrollment. These studies begin with the code QT.

Self-evaluation (assessment): The process of comparing your laboratory results against the participant summary results when an analyte is not formally graded.

Shipments: See Mailing.

Specimen: The material contained in a vial, on a slide, or other unit to be tested by PT/EQA program participants. Specimens can be in the form of liquid, lyophilized, loops, images, or slides and may be composed of chemical, biological, or organic materials.

Supplemental Questions: Questions developed by a scientific committee that are provided on the result form. These questions are used to collect additional information regarding testing practices and interest in new analytes. Completion of the supplemental questions is optional and should not delay the reporting of results.

Test: As performed in a clinical laboratory, a test is the analysis of specimens such as blood or urine that typically yields a clinical result, used either to diagnose illness or to aid in treatment.

Test result: Data obtained from a test, which can be quantitative or qualitative.

Waterfall grading: Analytes that cannot be graded by their peer group may be combined with similar groups to form a group large enough to use for grading.

Wild card challenge: A wet or dry specimen that is provided as an additional opportunity to perform testing. Wild card challenges often include specimens with atypical values, known interfering substances, unusual diagnoses, or new material. Participation in the wild card challenge is not required. These challenges are routinely only added for one mailing unless there is a need to repeat in a subsequent mailing for comparison.