CYP.07600 Statistical Records **Phase II**

For gynecologic cytopathology cases, statistical records are maintained of the number of cases of the following cytopathology results.

1. **Diagnostic category (including unsatisfactory cases), by preparation type**
2. **Significant cytologic/histologic discrepancies (as defined by laboratory policy)**
3. **Total number of negative cases rescreened before sign-out (to include but not limited to the 10% rescreen)**
4. **Cases for which the rescreen resulted in reclassification as premalignant or malignant**
5. **Cases for which histopathology results are available to compare with malignant or high-grade squamous intraepithelial lesion (HSIL) cytopathology results**

NOTE: These data should be evaluated by the laboratory and included in the annual cytopathology statistical report. Inclusion of AGC data is optional. The following benchmark data have been collected by the CAP Laboratory Accreditation Program and may be useful in evaluating the laboratory's statistical data. Separate statistics for conventional and each type of liquid-based preparations are required. These benchmarking data were collected in 2011.

In evaluating its statistics, the laboratory's patient population should be taken into consideration. Percentile-reporting rates refer to the distribution of individual laboratory responses from reporting rates in various categories. Responses are ranked from lowest to highest, and the 50th percentile-reporting rate refers to the median response. A 25th percentile-reporting rate (which corresponds to 2.0% in the table) for the ThinPrep LSIL category means that a quarter of laboratories have LSIL rates of 2.0% or less. A 90th percentile-reporting rate (which corresponds to 9.2% in the table) for ASC-US in ThinPrep preparations means that 9 of 10 laboratories have an ASC-US rate of 9.2% or less.

The reporting rates for ASC-US, ASC-H, AGC, LSIL, HSIL, and UNSATISFACTORY are given as percentages of total case volume. An ASC-US rate of 2.0% means 2/100 cases in the lab are designated ASC-US. The ASC/SIL figure is a calculated ratio: the percentage or number of a laboratory's ASC-US and ASC-H cases divided by the percentage or number of LSIL, HSIL, and malignant cases. A laboratory with 4% ASC cases and 3% SIL cases has an ASC/SIL ratio of 1.3, as compared to the median ASC/SIL ratio of 2.2 for conventional Paps, 1.7 for ThinPrep® and 1.6 for SurePath.

**Includes conventional and conventional with FocalPoint cases in laboratories with a conventional cytology volume of >180 per year.*

***Includes ThinPrep and ThinPrep with imaging cases in laboratories with a ThinPrep cytology volume of >300 per year.*

****Includes SurePath and SurePath with FocalPoint cases in laboratories with SurePath cytology volume >300 per year.*

CONVENTIONAL* ***Laboratory Percentile-Reporting Rate***							
CATEGORY	*5th*	*10th*	*25th*	*50th*	*75th*	*90th*	*95th*
ASC-US (%)	*0.5*	*0.6*	*1.5*	*2.6*	*4.5*	*6.5*	*7.5*
ASC-H (%)	*0.0*	*0.0*	*0.0*	*0.1*	*0.3*	*0.5*	*0.7*
LSIL (%)	*0.0*	*0.2*	*0.5*	*1.0*	*1.7*	*2.6*	*3.4*
HSIL (%)	*0.0*	*0.0*	*0.1*	*0.2*	*0.4*	*0.8*	*1.0*

ASC/SIL	*0.4*	*0.8*	*1.5*	*2.2*	*3.2*	*4.5*	*6.0*
AGC (%)	*0.0*	*0.0*	*0.0*	*0.1*	*0.3*	*0.6*	*0.8*
UNSATISFACTORY (%)	*0.0*	*0.2*	*0.6*	*1.2*	*2.2*	*3.7*	*5.7*

ThinPrep** ***Laboratory Percentile-Reporting Rate***							
CATEGORY	*5th*	*10th*	*25th*	*50th*	*75th*	*90th*	*95th*
ASC-US (%)	*1.9*	*2.5*	*3.7*	*5.1*	*6.8*	*9.2*	*12.0*
ASC-H (%)	*0.0*	*0.1*	*0.2*	*0.3*	*0.4*	*0.7*	*1.0*
LSIL (%)	*1.1*	*1.4*	*2.0*	*2.7*	*3.6*	*4.7*	*5.5*
HSIL (%)	*0.1*	*0.2*	*0.3*	*0.4*	*0.7*	*1.0*	*1.3*
ASC/SIL	*0.8*	*1.0*	*1.3*	*1.7*	*2.2*	*3.1*	*3.8*
AGC (%)	*0.0*	*0.0*	*0.1*	*0.1*	*0.3*	*0.5*	*0.7*
UNSATISFACTORY (%)	*0.3*	*0.4*	*0.7*	*1.1*	*1.8*	*2.9*	*3.6*

SurePath*** ***Laboratory Percentile-Reporting Rate***							
CATEGORY	*5th*	*10th*	*25th*	*50th*	*75th*	*90th*	*95th*
ASC-US (%)	*1.7*	*2.2*	*3.3*	*4.5*	*6.2*	*8.7*	*11.3*
ASC-H (%)	*0.0*	*0.1*	*0.1*	*0.2*	*0.4*	*0.6*	*0.8*
LSIL (%)	*1.2*	*1.4*	*2.0*	*2.6*	*3.5*	*4.8*	*6.1*
HSIL (%)	*0.1*	*0.1*	*0.2*	*0.3*	*0.5*	*0.8*	*1.2*
ASC/SIL	*0.7*	*0.8*	*1.3*	*1.6*	*2.0*	*2.7*	*3.2*
AGC (%)	*0.0*	*0.1*	*0.1*	*0.2*	*0.3*	*0.5*	*0.8*
UNSATISFACTORY (%)	*0.0*	*0.1*	*0.1*	*0.2*	*0.4*	*0.6*	*0.9*

Evidence of Compliance:

- ✓ Records of statistical data for defined categories **AND**
- ✓ Records of data review and evaluation against benchmark data by the laboratory director or designee

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):7169 [42CFR493.1274(c)(5)(i) through (c)(5)(vi)]
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3) Genest DR, *et al.* Qualifying the cytologic diagnosis of "atypical squamous cells of undetermined significance" affects the predictive value of a squamous intraepithelial lesion on subsequent biopsy. *Arch Pathol Lab Med.* 1998;122:338-341
4) Raab SS, *et al.* Interobserver variability of a Papanicolaou smear diagnosis of atypical glandular cells of undetermined significance. *Am J Clin Pathol.* 1998;110:653-659
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6) Schiffman M, *et al*. HPV DNA testing in cervical cancer screening results for women in a high risk province in Costa Rica. *JAMA*. 2000;283:87-93
7) Solomon D, *et al*. Comparison of three management strategies for patients with ASCUS. *J Natl Cancer Inst.* 2000;93:293-299
8) Juskevicius R, *et al*. An analysis of factors that influence the ASCUS/SIL ratio of pathologists. *Am J Clin Pathol.* 2001;116:331-335