The benchmarking data listed in the table below are based on 2021 case volumes. These benchmarking data may not be applicable for laboratories that utilize primary HPV screening for a significant portion of cervical cancer screening. Results were excluded for laboratories that included primary HPV screening results in the interpretive totals when more than 25% of their cervical/gynecologic cytology slides were from positive primary HPV screening. 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 1.7% in the table) for the ThinPrep LSIL category means that a quarter of laboratories have LSIL rates of 1.7% or less. A 90th percentile-reporting rate (which corresponds to 11.7% in the table) for ASC-US in ThinPrep preparations means that 9 of 10 laboratories have an ASC-US rate of 11.7% 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 1.5 for conventional Paps, 2.0 for ThinPrep® and 1.8 for SurePath.

CONVENTIONAL*
Laboratory Percentile-Reporting Rate

CATEGORY	5th	10th	25th	Median	75th	90th	95th
Unsatisfactory (%)	0.0	0.0	0.4	1.3	2.2	5.2	7.1
LSIL (%)	0.0	0.0	0.3	0.8	1.6	2.0	2.8
HSIL (%)	0.0	0.0	0.1	0.3	0.5	0.9	1.1
ASC-US (%)	0.1	0.3	1.0	1.8	3.6	5.3	6.7
ASC-H (%)	0.0	0.0	0.1	0.1	0.4	0.8	1.1
AGC (%)	0.0	0.0	0.0	0.1	0.2	0.6	1.2
ASC/SIL	0.4	0.5	1.0	1.5	2.7	4.2	5.6

ThinPrep**
Laboratory Percentile-Reporting Rate

CATEGORY	5th	10th	25th	Median	75th	90th	95th
Unsatisfactory (%)	0.2	0.4	0.9	1.7	2.9	4.8	5.7
LSIL (%)	0.4	0.9	1.7	2.4	3.3	4.8	6.6
HSIL (%)	0.1	0.1	0.2	0.4	0.6	1.0	1.3
ASC-US (%)	1.0	1.9	3.6	5.4	7.9	11.7	15.2
ASC-H (%)	0.0	0.1	0.2	0.4	0.6	1.1	1.5
AGC (%)	0.0	0.0	0.1	0.2	0.4	0.7	1.1
ASC/SIL	0.7	1.1	1.6	2.0	2.7	3.6	4.4

SurePath**
Laboratory Percentile-Reporting Rate

CATEGORY	5th	10th	25th	Median	75th	90th	95th
Unsatisfactory (%)	0.0	0.0	0.2	0.4	0.8	1.2	1.6
LSIL (%)	0.2	0.5	1.0	2.2	3.0	4.3	5.9
HSIL (%)	0.0	0.0	0.2	0.3	0.5	1.0	1.4
ASC-US (%)	0.3	0.7	2.1	4.2	6.6	9.2	10.6
ASC-H (%)	0.0	0.1	0.1	0.3	0.5	0.8	1.3
AGC (%)	0.0	0.0	0.1	0.2	0.5	0.7	1.6
ASC/SIL	0.5	0.9	1.2	1.8	2.9	3.6	4.2

**Includes conventional annual test volume of >60.*

***Includes SurePath and ThinPrep annual test volume of >300.*

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.* 2023(Dec 28): [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
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6) Solomon D, *et al*. Comparison of three management strategies for patients with ASCUS. *J Natl Cancer Inst.* 2000;93:293-299
7) Juskevicius R, *et al*. An analysis of factors that influence the ASCUS/SIL ratio of pathologists. *Am J Clin Pathol.* 2001;116:331-335

*****NEW** 12/26/2024***

CYP.07620 Statistical Records - Reflexed Gynecological Cytopathology **Phase I**

For gynecologic cytopathology cases reflexed from primary HPV screening, statistical records are maintained and evaluated at least annually, and include the following:

- **Number of primary HPV screening tests performed, if available**
- **Number of Paps reflexed from primary HPV screening**
- **Number of reflexed Paps reported by diagnosis for each specimen type (including the number reported as unsatisfactory for diagnostic interpretation)**
- **Number of cases with a diagnosis of HSIL, adenocarcinoma, or other malignant neoplasm for which histology results were available for comparison**
- **Number of cases where cytology and histology are discrepant**
- **Number of cases where any rescreen of a normal or negative specimen results in reclassification as low-grade squamous intraepithelial (LSIL), HSIL, adenocarcinoma, or other malignant neoplasms**
- **Number of positive and negative p16/Ki67 dual stains performed.**

NOTE: The data must be evaluated by the laboratory director or designee and included in the annual cytopathology statistical report.

If a p16/Ki67 dual stain is used as a follow-up to an HPV positive test with a negative Pap test, statistics should be maintained separate from p16/Ki67 dual stain results derived from a positive HPV screening test.

Evidence of Compliance:

- ✓ Records of statistical data for defined categories **AND**