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

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*****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**

- ✓ Records of data review and evaluation against benchmark data by the laboratory director or designee

CYP.07650 Statistical Records - Outliers **Phase I**

If the laboratory's annual ASC/SIL ratio for gynecologic cases falls outside of the 5th or 95th percentiles, the laboratory determines and records the reason(s).

NOTE: The ASC/SIL ratio is useful for interlaboratory comparisons, because the number of ASC and SIL cases varies greatly between laboratories (eg, a private practice with very few HPV infections, a sexually transmitted disease clinic, and a dysplasia clinic). This ratio is one good indicator for the under- or over-interpretation of ASC.

For example, a laboratory with 9% ASC cases might appear to be over diagnosing ASC, since this is higher than the 75% percentile-reporting rate. However, if this same laboratory also has a SIL rate of 6.0%, the ASC/SIL ratio of 1.5 is close to the national median, and it can be concluded that this laboratory serves a high-risk population. A laboratory with 3.0% ASC cases and 0.75% SIL appears to show average ASC rates, but the ASC/SIL ratio of 4.0 is higher than the average laboratory.

The benchmarking data provided in CYP.07600 may not be applicable for laboratories that utilize primary HPV screening for a significant portion of cervical cancer screening.

CYP.07653 HR-HPV Records **Phase I**

If available, records are maintained for high-risk human papillomavirus (HR-HPV) tests performed on ASC-US including:

1. **Total number of HR-HPV tests performed on ASC-US cases**
2. **Total number of positive HR-HPV ASC-US cases**

NOTE: The percentage of ASC-US cases with a positive HR-HPV result may be a helpful quality metric for both overall laboratory performance and individual performance of pathologists, especially when combined with an individual's ASC-SIL ratio. Data for other HR-HPV testing results (eg, co-testing with a Pap test in women > 30 years of age) may also be helpful quality metrics but should be kept separately.

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CYP.07655 Screening Performance **Phase II**

The laboratory evaluates and records the ongoing performance of individuals who do cervicovaginal cytology screening against the overall statistics for the laboratory as a whole.

NOTE: Mechanisms can include evaluation of rescreening and interpretive discrepancies and detection rates for abnormalities. This includes screening performance of p16/Ki67 dual stain gynecologic slides.