Revisions for Laboratory Deeming

Laboratory Accreditation Program

**Please Note: Shading and bold indicate revised requirements.**

**LD.04.05.09**

The laboratory director is responsible for developing, implementing, and maintaining policies and procedures that guide and support the provision of services.

**Elements of Performance for LD.04.05.09**

1. Laboratory procedures are current and complete. (See also DC.02.01.01, EP 1)

2. The laboratory director signs and dates new laboratory procedures or changes in laboratory procedures before they are implemented. (See also DC.02.01.01, EP 1)

3. The laboratory director requires that policies and procedures be consistently implemented and maintained.

4. Policies and procedures are readily available in writing to staff who do any kind of work for the laboratory, which includes collecting specimens and reporting test procedures.

5. Satisfactory specimen criteria are established, as are the limitations on the reliability of test results if the specimen is not satisfactory.

6. The laboratory director requires that test results be accurately reported within a defined time frame.

7. The laboratory director and/or clinical consultant require that results be reported with pertinent information as required for specific patient interpretation.

8. The laboratory director develops a process for clinical staff to request and receive test results on an emergency or stat basis.

9. The laboratory director develops criteria for notifying the responsible practitioner when critical limits or specified test results are exceeded.

10. The laboratory director or designee annually reviews and approves each laboratory procedure. This review and approval is documented. (See also DC.02.01.01, EP 1)
QSA.02.01.01
The laboratory verifies tests, methods, and instruments in order to establish quality control procedures.
Note: This standard also applies to instruments on loan when the original instrument is under repair.

Elements of Performance for QSA.02.01.01

1. When adding or replacing an unmodified U.S. Food and Drug Administration (FDA)—approved test, method, or instrument, the laboratory verifies the manufacturer's performance specifications, including the following:
   - Accuracy
   - Precision
   - Reportable range
The verification is documented.

2. When adding or replacing a modified test, method, or instrument, the laboratory establishes written performance specifications that include the following:
   - Accuracy
   - Precision
   - Reportable range
   - Analytical sensitivity
   - Analytical specificity, including interfering substances
Note: Modified tests, methods, or instruments include the following:
   - Test procedures with modifications to the U.S. Food and Drug Administration (FDA)—approved use for specimen type, reagents, instrument, procedural steps, or other components
   - Tests or methods developed in the laboratory with no FDA evaluation
   - Tests, methods, or instruments not subject to FDA clearance

3. When replacing an old test, method, or instrument, the laboratory’s verification includes a correlation between the old and new test, method, or instrument. The correlation is documented.
   Note 1: This element of performance also applies when reference tests are brought in-house.
   Note 2: The laboratory has the discretion to determine the minimum number of data points and acceptable levels of correlation required for statistical validity and clinical usage of the test result.

4. For a new test, method, or instrument, the laboratory verifies that the reference intervals (normal ranges) apply to the test, method, or instrument and population served. The verification is documented.

5. The laboratory performs verifications for each new test, method, or instrument prior to reporting patient results. These verifications are documented.

6. The laboratory's verification includes the establishment of written quality control procedures for each testing system or methodology.
7. The laboratory's quality control procedure for each testing system or methodology includes the following:
   - The range of quality control values used
   - The frequency of quality control testing
   - Adherence to the manufacturer's recommendations
   - The predicted reliability based on history
   - The specialty and subspecialty requirements included in this chapter

8. Over time, the laboratory monitors the accuracy and precision of test performance that may be influenced by changes in the following:
   - Test system performance
   - Environmental conditions
   - Variance in operator performance
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QSA.05.09.01
The laboratory has policies and procedures for serologic and computer (if performed) compatibility testing of donor blood with recipient blood.

Elements of Performance for QSA.05.09.01

1. The laboratory has written policies and procedures for compatibility testing of the donor’s blood with the recipient’s blood.

2. Policies and procedures for compatibility testing include the following:
   - A determination of recipient ABO Group and Rh type
   - A serologic and computer (if performed) crossmatch protocol
   - An antibody screening protocol
   - Actions to be taken in cases of positive antibody screens and direct antiglobulin tests
   - Actions to be taken in cases of incompatible crossmatches
   - A time frame during which a sample may be used for crossmatching before obtaining a new sample
   - A time frame not to exceed three days for recipient serum or plasma samples if the recipient has been pregnant or transfused within the previous three months or if history is unknown or unavailable. The day the sample is drawn is day zero.

3. Before administration of blood to a patient, the following occurs (unless the physician responsible for the recipient determines that the blood administration is needed for an emergency): Tests on recipient blood, including ABO group, Rh type, screening for unexpected antibodies, antibody identification, and a compatibility test major crossmatch between donor red cells and recipient serum.
   Note: When the screen and transfusion history for detection of unexpected antibodies is negative, the antiglobulin phase of testing is optional. Testing to detect ABO incompatibility (serologic or computer crossmatch) is required.

4. The laboratory evaluates the compatibility of the donor’s blood with the recipient’s blood for any blood products containing greater than 2 mL of red blood cells. The results are documented.

5. The laboratory compares current ABO group, Rh type, and antibody screen test results to historical results. Discrepancies are investigated and resolved prior to transfusion. The investigation is documented.

6. The laboratory's method to screen for unexpected red cell alloantibodies includes the use of non-pooled reagent red cells and incubation at 37°C, followed by an antiglobulin (or equivalent) test.

7. The laboratory has a process in place to identify patients who require specially selected products based on both current admission orders and transfusion history (for example, irradiated, leukoreduced, antigen-negative units).

8. The laboratory employs a direct antiglobulin technique (DAT) capable of detecting immunoglobulin G (IgG) and complement components bound to red blood cells.

9. The laboratory evaluates the compatibility of the donor’s blood with the recipient’s blood. The results of this test are documented.
QSA.08.03.01
The cytology technical supervisor uses quality improvement processes to measure, assess, and improve the cytology service.

Elements of Performance for QSA.08.03.01

1. The cytology technical supervisor establishes, in writing, the quality improvement plan to measure, assess, and improve the cytology services.
2. The quality improvement plan includes a system to detect errors in the cytological examination process and a process to report results.
3. The laboratory reviews all gynecological and nongynecological cytology reports with available patient clinical information and compares the results of the review for discrepancies.
4. The laboratory reviews all gynecological cytology reports of a diagnosis of high-grade squamous intraepithelial lesion (HSIL), adenocarcinoma, or other malignant neoplasms with available histopathology reports and compares the results of the review for discrepancies.

5. **For all gynecological slides with current high-grade squamous intraepithelial lesion (HSIL), adenocarcinoma, or other malignant neoplasm, the laboratory reviews all normal or negative gynecological specimens received within the previous five years, if available to the laboratory (on site or in storage), documents discrepancies, and issues a corrected report for any discrepancies that would affect patient care.**

6. The laboratory determines the causes of any cytology discrepancies when comparing the following:
   - Gynecological and nongynecological reports with available patient clinical information
   - Gynecological cytology reports with a diagnosis of high-grade squamous intraepithelial lesion (HSIL), adenocarcinoma, or other malignant neoplasms with the histopathology report
   - A current HSIL, adenocarcinoma, or other malignant neoplasm with the histopathology report

7. The laboratory performs reeducation and other corrective actions (for example, adjusting workload, if indicated) for significant cytology discrepancies as defined by the cytology technical supervisor. Reeducation and other corrective actions occur within a time frame that prevents recurrence. The performance is documented.

8. The laboratory annually generates an aggregated statistical report that includes the following:
   - The number of cytology cases examined
   - The number of specimens processed by specimen type
   - The number of patient cases reported by diagnosis (including the number reported as unsatisfactory for diagnostic interpretation)
   - The number of gynecological cases with a diagnosis of high-grade squamous intraepithelial lesion (HSIL), adenocarcinoma, or other malignant neoplasm for which the histology results were available for comparison
   - The number of gynecological cases in which cytology and available histology reports are discrepant
   - The number of gynecological cases in which a rescreen of a normal or negative specimen results in reclassification as low-grade squamous intraepithelial lesion (LSIL), high-grade squamous intraepithelial lesion (HSIL), adenocarcinoma, or other malignant neoplasm(s)
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9. The laboratory assesses communications with the clinical staff and makes improvements so that the following can be maintained at an acceptable level:
   - Collection and identification of specimens
   - Completion of the cytology requisition with the required information, such as date of birth, date of the last menstrual period, previous abnormal findings for Pap smears, and other abnormal findings from previous Pap smears or other specimens
   - Follow-up on abnormal findings with clinical consultation, when indicated
   - Notification of the patient’s physician and issuance of an amended report for significant cytology discrepancies

10. The laboratory measures, assesses, and improves the quality of cytology services.
QSA.08.04.01
The laboratory establishes workload limits for staff who perform primary cytology screening.

Elements of Performance for QSA.08.04.01

1. The laboratory has written policies and procedures that address cytology workload limits.
2. The cytology technical supervisor establishes in writing a maximum workload limit for each staff member who performs primary screening.
3. The cytology workload limit is based on the staff member's performance using evaluations of the following:
   - Review of 10% of the cases interpreted as negative (See also QSA.08.06.01, EP 2)
   - Comparison of the staff's interpretation of the primary cytology screening with the technical supervisor's confirmation of patient smears (See also QSA.08.07.01, EP 2)
4. Workload requirements apply to all cytotechnologists, pathologists, and fifth-year pathology residents who perform primary cytology screening.
5. For individuals who perform primary screening, the maximum total number of cytology slides staff may screen is 100 slides (or full slide equivalents) per 24-hour period for either gynecological or nongynecological specimens or both.
   For gynecological specimens screened by automated or semiautomated screening devices, workload limits must comply with those specified by the manufacturer and/or the U.S. Food and Drug Administration (FDA).
   Note 1: Liquid-based gynecologic preparations cannot be counted as a half slide. All gynecological slide preparations (liquid-based or conventional) are counted as one full slide.
   Note 2: The workload limit for staff reading slides requiring 100% manual review may not exceed 100 slides, as a result of automated or semiautomated analysis or in the routine workload.
   Note 3: Nongynecological slide preparations made using liquid-based slide preparatory techniques that result in cell dispersion over one half or less of the total available slide may be counted as one half slide.
   Note 4: The 100-slide limit includes previously unevaluated gynecological slides and nongynecological slides, 10% rescreen slides, and review slides.
   Note 5: The 100-slide limit does not include previously examined negative, reactive, atypical, premalignant, or malignant gynecological cases; previously examined nongynecological cytology preparations; slides prepared for determination of specimen adequacy; or tissue pathology slides examined by a technical supervisor.
6. The maximum number of cytology slides is examined in no less than an eight-hour workday.
   Note: For the purposes of establishing workload limits for staff examining slides by nonautomated microscopic technique on other than an eight-hour workday basis (including full-time employees with duties other than slide examination and part-time employees), a period of eight hours must be used to prorate the number of slides that may be examined. Use the following formula: (number of hours examining slides x 100) ÷ 8 = maximum slide volume to be examined.
7. Records are maintained for each staff member of the total number of cytology slides examined, regardless of the site or laboratory, and the number of hours spent examining slides for each 24-hour period.
8. The cytology technical supervisor reassesses the workload limits for each staff member every six months, or more frequently as specified in the laboratory's policy. The reassessment is documented.
9. The cytology technical supervisor reestablishes, in writing, workload limits for each staff member through a documented assessment of case reviews based on each staff member's performance against the laboratory's overall statistical values.
10. The cytology technical supervisor investigates any discrepancies with the assessment of staff performance, including reasons for deviation and any corrective actions taken. The investigation is documented.

11. The cytology technical supervisor makes adjustments in each staff member’s workload, if needed, based on the results of the workload assessment.

12. The laboratory follows its policies and procedures for cytology workload limits.
QSA.08.05.01
Cytology slide staining provides acceptable quality.

Elements of Performance for QSA.08.05.01

1. The laboratory defines, in writing, cytology stains and staining techniques that are of a quality suitable for evaluation.

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<thead>
<tr>
<th>2. All gynecological specimens are stained using a Papanicolaou or modified Papanicolaou staining method.</th>
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<tr>
<td>3. The laboratory takes measures to prevent cross-contamination between gynecological and nongynecological specimens during the cytology staining process.</td>
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<td>4. The laboratory separately stains nongynecological specimens that have a high potential for cross-contamination from other nongynecological specimens.</td>
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<td>5. The laboratory filters or changes the cytology stains following the staining of nongynecologic specimens with a high potential for cross-contamination.</td>
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<td>6. A CLIA-qualified cytotechnologist * assesses the staining quality of gynecologic and nongynecologic stains to determine the stain’s ability to facilitate a diagnosis.</td>
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QSA.08.06.01
The cytology quality assurance system includes review of a random sample of negative gynecological slides.

Elements of Performance for QSA.08.06.01

1. A qualified * individual reviews a random sample of negative gynecological slides. The review is documented.

2. The review of a random sample of negative gynecological slides includes the following:
   - A random sample of 10% of all gynecological cases read by the cytotechnologists and interpreted to be negative for epithelial cell abnormalities and malignant or premalignant conditions
   - Low-risk and high-risk patients
   - Slides from all cytotechnologists
   (See also QSA.08.04.01, EP 3)
   Note: During the initial screening process, the cytotechnologist does not know which slides will be reexamined.

3. A qualified * individual completes the review of a random sample of negative gynecological slides before reporting patient results.

4. Records of the review of a random sample of negative gynecological slides are available and include initial examinations and rescreening results. The results are documented.