

**WAC 246-338-090 Quality control.** The medical test site must use quality control procedures, providing and assuring accurate and reliable test results and reports, meeting the requirements of this chapter.

(1) The medical test site must have and follow written procedures and policies available in the work area for:

(a) Analytical methods used by the technical personnel including:

(i) Principle;

(ii) Specimen collection and processing procedures;

(iii) Equipment/reagent/supplies required;

(iv) Preparation of solutions, reagents, and stains;

(v) Test methodology;

(vi) Quality control procedures;

(vii) Procedures for reporting results (normal, abnormal, and critical values);

(viii) Reference range;

(ix) Troubleshooting guidelines - limitations of methodology;

(x) Calibration procedures; and

(xi) Pertinent literature references; and

(b) Alternative or backup methods for performing tests including the use of a reference facility if applicable.

(2) The medical test site must establish written criteria for and maintain appropriate documentation of:

(a) Temperature-controlled spaces and equipment;

(b) Preventive maintenance activities;

(c) Equipment function checks;

(d) Procedure calibrations; and

(e) Method/instrument validation procedures.

(3) The medical test site must maintain documentation of:

(a) Expiration date, lot numbers, and other pertinent information for:

(i) Reagents;

(ii) Solutions;

(iii) Culture media;

(iv) Controls;

(v) Calibrators;

(vi) Standards;

(vii) Reference materials; and

(viii) Other testing materials; and

(b) Testing of quality control samples.

(4) For **quantitative tests**, the medical test site must perform quality control as follows:

(a) Include two reference materials of different concentrations each day of testing unknown samples, if these reference materials are available; or

(b) Follow an equivalent quality testing procedure that meets federal CLIA regulations.

(5) For **qualitative tests**, the medical test site must perform quality control as follows:

(a) Use positive and negative reference material each day of testing unknown samples; or

(b) Follow an equivalent quality testing procedure that meets federal CLIA regulations.

(6) The medical test site must:

(a) Use materials within their documented expiration date;

(b) Not interchange components of kits with different lot numbers, unless specified by the manufacturer;

- (c) Determine the statistical limits for each lot number of unassayed reference materials through repeated testing;
  - (d) Use the manufacturer's reference material limits for assayed material, provided they are:
    - (i) Verified by the medical test site; and
    - (ii) Appropriate for the methods and instrument used by the medical test site;
  - (e) Make reference material limits readily available;
  - (f) Report patient results only when reference materials are within acceptable limits;
  - (g) Rotate control material testing among all persons who perform the test;
  - (h) Use calibration material from a different lot number than that used to establish a cut-off value or to calibrate the test system, if using calibration material as a control material;
  - (i) For each test system that has an extraction phase, include two control materials, including one that is capable of detecting errors in the extraction process;
  - (j) For each molecular amplification procedure, include two control materials and, if reaction inhibition is a significant source of false negative results, a control material capable of detecting the inhibition is required; and
  - (k) Comply with general quality control requirements as described in Table 090-1, unless otherwise specified in subsection (9)(a) through (l) of this section.
- (7) The medical test site must perform, when applicable:
- (a) Calibration and calibration verification for **moderate and high complexity testing** as described in Table 090-2;
  - (b) Validation for **moderate complexity testing** by verifying the following performance characteristics when the medical test site introduces a new procedure classified as moderate complexity:
    - (i) Accuracy;
    - (ii) Precision;
    - (iii) Reportable range of patient test results; and
    - (iv) If using the reference range provided by the manufacturer, that it is appropriate for the patient population;
  - (c) Validation for **high complexity testing**:
    - (i) When the medical test site introduces a new procedure classified as high complexity;
    - (ii) For each method that is developed in-house, is a modification of the manufacturer's test procedure, or is an instrument, kit or test system that has not been cleared by FDA; and
    - (iii) By verifying the following performance characteristics:
      - (A) Accuracy;
      - (B) Precision;
      - (C) Analytical sensitivity;
      - (D) Analytical specificity to include interfering substances;
      - (E) Reference ranges (normal values);
      - (F) Reportable range of patient test results; and
      - (G) Any other performance characteristic required for test performance.
- (8) When patient values are above the maximum or below the minimum calibration point or the reportable range, the medical test site must:
- (a) Report the patient results as greater than the upper limit or less than the lower limit or an equivalent designation; or

(b) Use an appropriate procedure to rerun the sample allowing results to fall within the established linear range.

**Table 090-1 General Quality Control Requirements**

	<b>Control Material</b>	<b>Frequency</b>
(a) Each batch or shipment of reagents, discs, antisera, and identification systems	<ul style="list-style-type: none"> <li>Appropriate control materials for positive and negative reactivity</li> </ul>	<ul style="list-style-type: none"> <li>When prepared or opened, unless otherwise specified</li> </ul>
(b) Each batch or shipment of stains	<ul style="list-style-type: none"> <li>Appropriate control materials for positive and negative reactivity</li> </ul>	<ul style="list-style-type: none"> <li>When prepared or opened; and</li> <li>Each day of use, unless otherwise specified</li> </ul>
(c) Fluorescent and immunohistochemical stains	<ul style="list-style-type: none"> <li>Appropriate control materials for positive and negative reactivity</li> </ul>	<ul style="list-style-type: none"> <li>Each time of use, unless otherwise specified</li> </ul>
(d) Quality control for each specialty and subspecialty	<ul style="list-style-type: none"> <li>Appropriate control materials; or</li> <li>Equivalent mechanism to assure the quality, accuracy, and precision of the test if reference materials are not available</li> </ul>	<ul style="list-style-type: none"> <li>At least as frequently as specified in this section;</li> <li>More frequently if recommended by the manufacturer of the instrument or test procedure; or</li> <li>More frequently if specified by the medical test site</li> </ul>
(e) Direct antigen detection systems without procedural controls	<ul style="list-style-type: none"> <li>Positive and negative controls that evaluate both the extraction and reaction phase</li> </ul>	<ul style="list-style-type: none"> <li>Each batch, shipment, and new lot number; and</li> <li>Each day of use</li> </ul>

**Table 090-2 Calibration and Calibration Verification—Moderate and High Complexity Testing**

	<b>Calibration Material</b>	<b>Frequency</b>
<b>CALIBRATION</b>	<ul style="list-style-type: none"> <li>Calibration materials appropriate for methodology</li> </ul>	<ul style="list-style-type: none"> <li>Initial on-site installation/implementation of instrument/method;</li> <li>At the frequency recommended by the manufacturer; and</li> <li>Whenever calibration verification fails to meet the medical test site's acceptable limits for calibration verification.</li> </ul>
<b>CALIBRATION VERIFICATION</b>	<ul style="list-style-type: none"> <li>Use assayed material, if available, at the lower, mid-point, and upper limits of procedure's reportable range; or</li> <li>Demonstrate alternate method of assuring accuracy at the lower, mid-point, and upper limits of procedure's reportable range</li> </ul>	<ul style="list-style-type: none"> <li>At least every six months;</li> <li>When there is a complete change of reagents (i.e., new lot number or different manufacturer) is introduced;</li> <li>When major preventive maintenance is performed or there is a replacement of critical parts of equipment; or</li> <li>When controls are outside of the medical test site's acceptable limits or exhibit trends.</li> </ul>

(9) The medical test site must perform quality control procedures as described for each specialty and subspecialty in (a) through (l) of this subsection.

(a) **Chemistry.**

Perform quality control procedures for chemistry as described in Table 090-3 or follow an equivalent quality testing procedure that meets federal CLIA regulations.

**Table 090-3 Quality Control Procedures—Chemistry**

Subspecialty/Test	Qualitative		Quantitative	
	Control Material	Frequency	Control Material	Frequency
Routine Chemistry	<ul style="list-style-type: none"> <li>Positive and negative reference material</li> </ul>	<ul style="list-style-type: none"> <li>Each day of use</li> </ul>	<ul style="list-style-type: none"> <li>Two levels of reference material in different concentrations</li> </ul>	<ul style="list-style-type: none"> <li>Each day of use</li> </ul>
Toxicology				
<ul style="list-style-type: none"> <li>GC/MS for drug screening</li> </ul>	<ul style="list-style-type: none"> <li>Analyte-specific control</li> </ul>	<ul style="list-style-type: none"> <li>With each run of patient specimens</li> </ul>	<ul style="list-style-type: none"> <li>Analyte-specific control</li> </ul>	<ul style="list-style-type: none"> <li>With each analytical run</li> </ul>
<ul style="list-style-type: none"> <li>Urine drug screen</li> </ul>	<ul style="list-style-type: none"> <li>Positive control containing at least one drug representative of each drug class to be reported; must go through each phase of use including extraction</li> </ul>	<ul style="list-style-type: none"> <li>With each run of patient specimens</li> </ul>		
Urinalysis				
<ul style="list-style-type: none"> <li>Nonwaived instrument</li> </ul>			<ul style="list-style-type: none"> <li>Two levels of control material</li> </ul>	<ul style="list-style-type: none"> <li>Each day of use</li> </ul>
<ul style="list-style-type: none"> <li>Refractometer for specific gravity</li> </ul>			<ul style="list-style-type: none"> <li>Calibrate to zero with distilled water</li> <li>One level of control material</li> </ul>	<ul style="list-style-type: none"> <li>Each day of use</li> </ul>
Blood Gas Analysis			<ul style="list-style-type: none"> <li>Calibration</li> </ul>	<ul style="list-style-type: none"> <li>Follow manufacturer's specifications and frequency</li> </ul>
			<ul style="list-style-type: none"> <li>One level of control material</li> </ul>	<ul style="list-style-type: none"> <li>Each eight hours of testing, using both low and high values on each day of testing</li> </ul>
			<ul style="list-style-type: none"> <li>One-point calibration or one control material</li> </ul>	<ul style="list-style-type: none"> <li>Each time patient specimen is tested, unless automated instrument internally verifies calibration every thirty minutes</li> </ul>
Electrophoresis	<ul style="list-style-type: none"> <li>One control containing fractions representative of those routinely reported in patient specimens</li> </ul>	<ul style="list-style-type: none"> <li>In each electrophoretic cell</li> </ul>	<ul style="list-style-type: none"> <li>One control containing fractions representative of those routinely reported in patient specimens</li> </ul>	<ul style="list-style-type: none"> <li>In each electrophoretic cell</li> </ul>

(b) **Hematology.**

(i) Run patient and quality control samples in duplicate for manual cell counts;

(ii) If reference material is unavailable, document the mechanism used to assure the quality, accuracy, and precision of the test; and

(iii) Perform quality control procedures for hematology as described in Table 090-4 or follow an equivalent quality testing procedure that meets federal CLIA regulations.

**Table 090-4 Quality Control Procedures—Hematology**

	Control Material	Frequency
Automated	<ul style="list-style-type: none"> <li>Two levels of reference material in different concentrations</li> </ul>	<ul style="list-style-type: none"> <li>Each day that patient samples are tested</li> </ul>

	<b>Control Material</b>	<b>Frequency</b>
Manual Blood Counts	• One level of reference material	• Every eight hours that patient samples are tested
Qualitative Tests	• Positive and negative reference material	• Each day of testing

(c) **Coagulation.**

(i) Run patient and quality control samples in duplicate for manual coagulation test (tilt tube);

(ii) If reference material is unavailable, document the mechanism used to assure the quality, accuracy, and precision of the test; and

(iii) Perform quality control procedures for coagulation as described in Table 090-5 or follow an equivalent quality testing procedure that meets federal CLIA regulations.

**Table 090-5 Quality Control Procedures—Coagulation**

	<b>Control Material</b>	<b>Frequency</b>
Automated	• Two levels of reference material in different concentrations	• Every eight hours that patient samples are tested; and • Each time reagents are changed
Manual Tilt Tube Method	• Two levels of reference material in different concentrations	• Every eight hours that patient samples are tested; and • Each time reagents are changed

(d) **General immunology.**

(i) Employ reference materials for all test components to ensure reactivity;

(ii) Report test results only when the predetermined reactivity pattern of the reference material is observed; and

(iii) Perform quality control procedures for general immunology as described in Table 090-6 or follow an equivalent quality testing procedure that meets federal CLIA regulations.

**Table 090-6 Quality Control Procedures—General Immunology**

	<b>Control Material</b>	<b>Frequency</b>
Serologic tests on unknown specimens	• Positive and negative reference material	• Each day of testing
Kits with procedural (internal) controls	• Positive and negative reference material (external controls) • Procedural (internal) controls	• When kit is opened; and • Each day of testing, or follow an equivalent quality testing procedure that meets federal CLIA regulations • Each time patient sample is tested

(e) **Syphilis serology.**

(i) Use equipment, glassware, reagents, controls, and techniques that conform to manufacturer's specifications;

(ii) Employ reference materials for all test components to ensure reactivity; and

(iii) Perform serologic tests on unknown specimens each day of testing with a positive serum reference material with known titer or graded reactivity and a negative reference material.

(f) **Microbiology.**

(i) Have available and use:

(A) Appropriate stock organisms for quality control purposes; and

(B) A collection of slides, photographs, gross specimens, or text books for reference sources to aid in identification of microorganisms;

- (ii) Document all steps (reactions) used in the identification of microorganisms on patient specimens;
- (iii) For antimicrobial susceptibility testing:
  - (A) Record zone sizes or minimum inhibitory concentration for reference organisms; and
  - (B) Zone sizes or minimum inhibitory concentration for reference organisms must be within established limits before reporting patient results; and
  - (C) Perform quality control on antimicrobial susceptibility testing media as described in Table 090-8;
- (iv) For noncommercial media, check each batch or shipment for sterility, ability to support growth and, if appropriate, selectivity, inhibition, or biochemical response;
- (v) For commercial media:
  - (A) Verify that the product insert specifies that the quality control checks meet the requirements for media quality control as outlined by the Clinical Laboratory Standards Institute (CLSI). *M22-A3 Quality Control for Commercially Prepared Microbiological Culture Media; Approved Standard-Third Edition*. June 2004. (Volume 24, Number 19);
  - (B) Keep records of the manufacturer's quality control results;
  - (C) Document visual inspection of the media for proper filling of the plate, temperature or shipment damage, and contamination before use; and
  - (D) Follow the manufacturer's specifications for using the media; and
- (vi) For microbiology subspecialties:
  - (A) **Bacteriology:** Perform quality control procedures for bacteriology as described in Tables 090-7 and 090-8.

**Table 090-7 Quality Control Procedures—Bacteriology**

	<b>Control Material</b>	<b>Frequency</b>
Reagents, disks, and identification systems Catalase, coagulase, oxidase, and Beta-lactamase Cefinase™ reagents Bacitracin, optochin, ONPG, X and V disks or strips	<ul style="list-style-type: none"> <li>• Positive and negative reference organisms, unless otherwise specified</li> </ul>	<ul style="list-style-type: none"> <li>• Each batch, shipment, and new lot number unless otherwise specified</li> </ul>
Stains, unless otherwise specified; DNA probes; and all beta-lactamase methods other than Cefinase™	<ul style="list-style-type: none"> <li>• Positive and negative reference organisms</li> </ul>	<ul style="list-style-type: none"> <li>• Each batch, shipment, and new lot number; and</li> <li>• Each day of use</li> </ul>
Fluorescent stains	<ul style="list-style-type: none"> <li>• Positive and negative reference organisms</li> </ul>	<ul style="list-style-type: none"> <li>• Each batch, shipment, and new lot number; and</li> <li>• Each time of use</li> </ul>
Gram stains	<ul style="list-style-type: none"> <li>• Positive and negative reference organisms</li> </ul>	<ul style="list-style-type: none"> <li>• Each batch, shipment, and new lot number; and</li> <li>• Each week of use</li> </ul>
Direct antigen detection systems without procedural controls	<ul style="list-style-type: none"> <li>• Positive and negative controls that evaluate both the extraction and reaction phase</li> </ul>	<ul style="list-style-type: none"> <li>• Each batch, shipment, and new lot number; and</li> <li>• Each day of use</li> </ul>

	Control Material	Frequency
Test kits with procedural (internal) controls	<ul style="list-style-type: none"> <li>Positive and negative reference material (external) controls</li> <li>Procedural (internal) controls</li> </ul>	<ul style="list-style-type: none"> <li>Each batch, shipment, and new lot number; and</li> <li>Each day of testing, or follow an equivalent quality testing procedure that meets federal CLIA regulations</li> <li>Each time patient sample is tested</li> </ul>
Antisera	<ul style="list-style-type: none"> <li>Positive and negative reference material</li> </ul>	<ul style="list-style-type: none"> <li>Each batch, shipment, and new lot number; and</li> <li>Every six months</li> </ul>

**Table 090-8 Quality Control Procedures—Bacteriology - Media for Antimicrobial Susceptibility Testing**

	Control Material	Frequency
Check each new batch of media and each new lot of antimicrobial disks or other testing systems (MIC)	<ul style="list-style-type: none"> <li>Approved reference organisms (ATCC organisms)</li> </ul>	<ul style="list-style-type: none"> <li>Before initial use and each day of testing; or</li> <li>May be done weekly if the medical test site can meet the quality control requirements for antimicrobial disk susceptibility testing as outlined by CLSI <i>M100S Performance Standards for Antimicrobial Susceptibility Testing; Twenty-Sixth Edition.</i></li> </ul>

(B) **Mycobacteriology:** Perform quality control procedures for mycobacteriology as described in Table 090-9.

**Table 090-9 Quality Control Procedures—Mycobacteriology**

	Control Material	Frequency
All reagents or test procedures used for mycobacteria identification unless otherwise specified	<ul style="list-style-type: none"> <li>Acid-fast organism that produces a positive reaction and an acid-fast organism that produces a negative reaction</li> </ul>	<ul style="list-style-type: none"> <li>Each day of use</li> </ul>
Acid-fast stains	<ul style="list-style-type: none"> <li>Acid-fast organism that produces a positive reaction and an organism that produces a negative reaction</li> </ul>	<ul style="list-style-type: none"> <li>Each day of use</li> </ul>
Fluorochrome acid-fast stains	<ul style="list-style-type: none"> <li>Acid-fast organism that produces a positive reaction and an acid-fast organism that produces a negative reaction</li> </ul>	<ul style="list-style-type: none"> <li>Each time of use</li> </ul>
Susceptibility tests performed on <i>Mycobacterium tuberculosis</i> isolates	<ul style="list-style-type: none"> <li>Appropriate control organism(s)</li> </ul>	<ul style="list-style-type: none"> <li>Each batch of media, and each lot number and shipment of antimycobacterial agent(s) before, or concurrent with, initial use</li> <li>Each week of use</li> </ul>

(C) **Mycology:** Perform quality control procedures for mycology as described in Table 090-10.

**Table 090-10 Quality Control Procedures—Mycology**

	Control Material	Frequency
Susceptibility tests: Each drug NOTE: Establish control limits and criteria for acceptable control results prior to reporting patient results	<ul style="list-style-type: none"> <li>One control strain that is susceptible to the drug</li> </ul>	<ul style="list-style-type: none"> <li>Each day of use</li> </ul>
Lactophenol cotton blue stain	<ul style="list-style-type: none"> <li>Appropriate control organism(s)</li> </ul>	<ul style="list-style-type: none"> <li>Each batch or shipment and each lot number</li> </ul>
Acid-fast stains	<ul style="list-style-type: none"> <li>Organisms that produce positive and negative reactions</li> </ul>	<ul style="list-style-type: none"> <li>Each day of use</li> </ul>
Reagents for biochemical and other identification test procedures	<ul style="list-style-type: none"> <li>Appropriate control organism(s)</li> </ul>	<ul style="list-style-type: none"> <li>Each batch or shipment and each lot number</li> </ul>

	Control Material	Frequency
<p>Commercial identification systems utilizing two or more substrates</p> <p>(D) <b>Parasitology:</b>            (I) Have available and use:            • Reference collection of slides or photographs and, if available, gross specimens for parasite identification; and            • Calibrated ocular micrometer for determining the size of ova and parasites, if size is a critical parameter.            (II) Check permanent stains each month of use with reference materials.</p> <p>(E) <b>Virology:</b>            (I) Have available:            • Host systems for isolation of viruses; and            • Test methods for identification of viruses that cover the entire range of viruses that are etiologically related to the clinical diseases for which services are offered; and            (II) Simultaneously culture uninoculated cells or cell substrate as a negative control when performing virus identification.</p> <p>(g) <b>Histopathology:</b> Fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, include a control slide of known reactivity with each slide or group of slides and document reactions.</p> <p>(h) <b>Cytology.</b>            (i) Processing specimens:            (A) Stain all gynecological smears using a Papanicolaou or a modified Papanicolaou staining method;            (B) Have methods to prevent cross-contamination between gynecologic and nongynecologic specimens during the staining process; and            (C) Stain nongynecological specimens that have a high potential for cross-contamination separately from other nongynecological specimens, and filter or change the stains following staining.            (ii) Performing specimen examinations:            (A) All cytology preparations must be evaluated on the premises of the medical test site;            (B) Technical personnel must examine, unless federal law and regulation specify otherwise, no more than one hundred cytological slides (one patient specimen per slide; gynecologic, nongynecologic, or both) in a twenty-four-hour period and in no less than an eight-hour work period;            (C) Previously examined negative, reactive, reparative, atypical, premalignant or malignant gynecological cases and previously examined nongynecologic cytology preparations and tissue pathology slides examined by a technical supervisor are not included in the one hundred slide limit;            (D) Each nongynecologic slide preparation 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; and            (E) Records of the total number of slides examined by each individual at all sites during each twenty-four-hour period must be maintained.            (iii) Establish and implement a quality assurance program that ensures:            (A) There is criteria for submission of material;</p>	<p>• Organisms that verify positive and negative reactivity of each media type</p>	<p>• Each batch or shipment and each lot number</p>



- (B) All providers submitting specimens are informed of these criteria;
- (C) All samples submitted are assessed for adequacy;
- (D) Records of initial examinations and rescreening results are available and documented;
- (E) Rescreening of benign gynecological slides is:
- (I) Performed by an individual who meets the personnel requirements for technical or general supervisor in cytology as defined under 42 C.F.R. Part 493 Subpart M;
- (II) Completed before reporting patient results on those selected cases;
- (III) Performed and documented on:
- No less than ten percent of the benign gynecological slides;
- and
- Includes cases selected at random from the total caseload and from patients or groups of patients that are identified as having a high probability of developing cervical cancer, based on available patient information;
- (F) The technical supervisor:
- (I) Confirms all gynecological smears interpreted to be showing reactive or reparative changes, atypical squamous or glandular cells of undetermined significance, or to be in the premalignant (dysplasia, cervical intraepithelial neoplasia or all squamous intraepithelial neoplasia lesions including human papillomavirus-associated changes) or malignant category;
- (II) Reviews all nongynecological cytological preparations; and
- (III) Establishes, documents, and reassesses, at least every six months, the workload limits for each cytotechnologist;
- (G) All cytology reports with a diagnosis of high-grade squamous intraepithelial lesion (HSIL), adenocarcinoma, or other malignant neoplasms are correlated with prior cytology reports and with histopathology reports if available, and the causes of any discrepancies are determined;
- (H) Review of all normal or negative gynecological specimens received within the previous five years, if available in the laboratory system, or records of previous reviews, for each patient with a current high grade intraepithelial lesion or moderate dysplasia of CIN-2 or above;
- (I) Notification of the patient's physician if significant discrepancies are found that would affect patient care and issuance of an amended report;
- (J) An annual statistical evaluation of the number of cytology cases examined, number of specimens processed by specimen type, volume of patient cases reported by diagnosis, number of cases where cytology and histology are discrepant, number of cases where histology results were unavailable for comparison, and number of cases where rescreen of negative slides resulted in reclassification as abnormal; and
- (K) Evaluation and documentation of the performance of each individual examining slides against the medical test site's overall statistical values, with documentation of any discrepancies, including reasons for the deviation and corrective action, if appropriate.
- (i) **Immunoematology/transfusion services.**
- (i) Perform ABO grouping, Rh (D) typing, antibody detection and identification, and compatibility testing as described by the Food and Drug Administration (FDA) under 21 C.F.R. Parts 606 and 640.
- (A) Perform ABO grouping:

- (I) By concurrently testing unknown red cells with FDA approved anti-A and anti-B grouping sera;
- (II) Confirm ABO grouping of unknown serum with known A1 and B red cells;
- (B) Perform Rh (D) typing by testing unknown red cells with anti-D (anti-Rh) blood grouping serum; and
- (C) Perform quality control procedures for immunohematology as described in Table 090-11.
  - (ii) Blood and blood products:
    - (A) Collecting, processing, and distributing:
      - (I) Must comply with FDA requirements listed under 21 C.F.R. Parts 606, 610.40, 610.53, and 640; and
      - (II) Must establish, document, and follow policies to ensure positive identification of a blood or blood product recipient.
    - (B) Labeling and dating must comply with FDA requirements listed under 21 C.F.R. 606 Subpart G, and 610.53.
    - (C) Storing:
      - (I) There must be an adequate temperature alarm system that is regularly inspected.
      - (II) The system must have an audible alarm system that monitors proper blood and blood product storage temperature over a twenty-four-hour period.
      - (III) High and low temperature checks of the alarm system must be documented.
    - (D) Collection of heterologous or autologous blood products on-site:
      - (I) Must register with the FDA; and
      - (II) Have a current copy of the form FDA 2830 "Blood Establishment Registration and Product Listing."
    - (iii) Must have an agreement approved by the director for procurement, transfer, and availability to receive products from outside entities.
    - (iv) Promptly investigate transfusion reactions according to established procedures, and take any necessary remedial action.

**Table 090-11 Quality Control Procedures—Immunohematology**

<b>Reagent</b>	<b>Control Material</b>	<b>Frequency</b>
ABO antisera	• Positive control	• Each day of use
Rh antisera	• Positive and negative controls • Patient control to detect false positive Rh test results	• Each day of use • When required by the manufacturer
Other antisera	• Positive and negative controls	• Each day of use
ABO reagent red cells	• Positive control	• Each day of use
Antibody screening cells	• Positive control using at least one known antibody	• Each day of use

(j) **Histocompatibility.**

- (i) Use applicable quality control standards for immunohematology, transfusion services, and diagnostic immunology as described in this chapter; and
- (ii) Meet the standards for histocompatibility as listed in 42 C.F.R. Part 493.1278, Standard: Histocompatibility, available from the department upon request.

(k) **Cytogenetics.**

- (i) Document:
  - (A) Number of metaphase chromosome spreads and cells counted and karyotyped;

- (B) Number of chromosomes counted for each metaphase spread;
  - (C) Media used;
  - (D) Reactions observed;
  - (E) Quality of banding; and
  - (F) Sufficient resolution appropriate for the type of tissue or specimen and the type of study required based on the clinical information provided;
- (ii) Assure an adequate number of karyotypes are prepared for each patient according to the indication given for performing cytogenetics study;
  - (iii) Use an adequate patient identification system for:
    - (A) Patient specimens;
    - (B) Photographs, photographic negatives, or computer stored images of metaphase spreads and karyotypes;
    - (C) Slides; and
    - (D) Records; and
  - (iv) Perform full chromosome analysis for determination of sex.
- (l) **Radiobioassay and radioimmunoassay.**
- (i) Check the counting equipment for stability each day of use with radioactive standards or reference sources; and
  - (ii) Meet Washington state radiation standards described under chapter 70.98 RCW and chapters 246-220, 246-221, 246-222, 246-232, 246-233, 246-235, 246-239, 246-247, 246-249, and 246-254 WAC.

[Statutory Authority: RCW 70.42.220, 43.70.041, and 42 C.F.R. 493.1291(l), 1832, 1241(b), 1299, 1256 (2)(iv, v), 1273(a). WSR 16-18-073, § 246-338-090, filed 9/2/16, effective 10/3/16. Statutory Authority: RCW 70.42.005 and 42 C.F.R. Part 493. WSR 05-04-040, § 246-338-090, filed 1/27/05, effective 3/19/05. Statutory Authority: RCW 70.42.005, 70.42.060. WSR 01-02-069, § 246-338-090, filed 12/29/00, effective 1/29/01. Statutory Authority: RCW 70.42.005, 70.42.060 and chapter 70.42 RCW. WSR 00-06-079, § 246-338-090, filed 3/1/00, effective 4/1/00. Statutory Authority: RCW 70.42.005. WSR 97-14-113, § 246-338-090, filed 7/2/97, effective 8/2/97. Statutory Authority: Chapter 70.42 RCW. WSR 93-18-091 (Order 390), § 246-338-090, filed 9/1/93, effective 10/2/93; WSR 91-21-062 (Order 205), § 246-338-090, filed 10/16/91, effective 10/16/91. Statutory Authority: RCW 43.70.040. WSR 91-02-049 (Order 121), recodified as § 246-338-090, filed 12/27/90, effective 1/31/91. Statutory Authority: Chapter 70.42 RCW. WSR 90-20-017 (Order 090), § 248-38-090, filed 9/21/90, effective 10/22/90.]