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Y	N		WAC 246-338-020 LICENSURE
__	__		The Medical Test Site has a current license appropriate for the services provided.

Y	N	NA	WAC 246-338-050 PROFICIENCY TESTING
			(1) All licensed medical test sites, excluding those granted a certificate of waiver, must:
__	__	__	(a) Comply with federal proficiency testing requirements listed in 42 CFR Part 493-Laboratory Requirements, Subparts H and I;

Y	N	NA	WAC 246-338-060 PERSONNEL
			(1) Medical test site owners must:
__	__	__	(a) Have a director responsible for the overall technical supervision and management of the test site personnel including oversight of the performance of test procedures and reporting of test results;
__	__	__	(b) Have technical personnel, competent to perform tests and report test results;
__	__	__	(c) Meet the standards for personnel qualifications and responsibilities in compliance with federal regulation, as listed in 42 CFR Part 493 Subpart M-Personnel for Nonwaived Testing.
			(3) Medical test site directors must:
			(a) Establish and approve policies for:
__	__	__	(i) Performing, recording, and reporting of tests;
__	__	__	(ii) Maintaining an ongoing quality assurance program;
__	__	__	(iii) Supervision of testing;
__	__	__	(iv) Compliance with chapter 70.42 RCW and this chapter;
			(b) Evaluate, verify, and document the following related to technical personnel:
__	__	__	(i) Education, experience, and training in test performance and reporting test results;
__	__	__	(ii) Sufficient numbers to cover the scope and complexity of the services provided;
__	__	__	(iii) Access to training appropriate for the type and complexity of the test site services offered;
__	__	__	(iv) Maintenance of competency to perform test procedures and report test results;
__	__	__	(c) Be present, on call, or delegate the duties of the director to an on-site technical person during testing.

Y	N	NA	WAC 246-338-070 RECORDS
			Medical test sites must maintain records as described in this section.
			(1) REQUISITIONS must include the following information, in written or electronic form:
__	__	__	(a) Patient name, identification number, or other method of patient identification;
__	__	__	(b) Name and address or other suitable identifiers of the authorized person ordering the test. The laboratory may accept oral requests for laboratory tests if it solicits a written or electronic authorization within thirty days of the oral request and maintains the authorization or documentation of its efforts to obtain the authorization;
__	__	__	(c) Date of specimen collection, and time, if appropriate;
__	__	__	(d) Source of specimen, if appropriate;
__	__	__	(e) Type of test ordered;

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Y	N	NA	WAC 246-338-070 RECORDS
__	__	__	(f) Sex, and age or date of birth, of the patient;
			(g) For cytology and histopathology specimens:
__	__	__	(i) Pertinent clinical information;
			(ii) For Pap smears:
__	__	__	(A) Date of last menstrual period;
__	__	__	(B) Indication whether the patient had a previous abnormal report, treatment, or biopsy.
			(2) TEST RECORD SYSTEMS must:
__	__	__	(a) Consist of instrument printouts, worksheets, accession logs, corrective action logs, and other records that ensure reliable identification of patient specimens as they are processed and tested to assure that accurate test results are reported;
			(b) Include:
__	__	__	(i) The patient's name or other method of specimen identification;
__	__	__	(ii) The date and time the specimen was received;
__	__	__	(iii)The reason for specimen rejection or limitation;
__	__	__	(iv) The date of specimen testing;
__	__	__	(v) The identification of the personnel who performed the test.
			(3) TEST REPORTS must:
__	__	__	(a) Be maintained in a manner permitting identification and reasonable accessibility;
__	__	__	(b) Except as provided in WAC 246-338-070 (3)(c) be released only to authorized persons or designees;
__	__	__	(c) Upon a request by a patient or patient's personal representative, the laboratory may provide patients, their personal representatives, and those persons specified under 45 C.F.R. 164.524(c)(3)(ii), with access to completed test reports that, using the laboratory's authentication process, can be identified as belonging to that patient;
			(d) Include:
__	__	__	(i) Name and address of the medical test site, or where applicable, the name and address of each medical test site performing each test;
__	__	__	(ii) Patient’s name and identification number, or a unique patient identifier and identification number;
__	__	__	(iii) Date reported;
__	__	__	(iv) Time reported, if appropriate;
__	__	__	(v) Specimen source, when appropriate, and any information regarding specimen rejection or limitations;
__	__	__	(vi) Name of the test performed, test result, and units of measurement, if applicable.
			(4) CYTOLOGY REPORTS must:
__	__	__	(a) Distinguish between unsatisfactory specimens and negative results;
__	__	__	(b) Provide narrative descriptions for any abnormal results, such as the 2001 Bethesda system of terminology as published in the Journal of the American Medical Association, 2002, Volume 287, pages 2114-2119;
__	__	__	(c) Include the signature or initials of the technical supervisor, or an electronic signature authorized by the technical supervisor, for non-gynecological preparations and gynecological preparations 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.
__	__	__	(5) HISTOPATHOLOGY REPORTS must include the signature or initials of the technical supervisor or an electronic signature authorized by the technical supervisor on all reports. Reports must be signed by the

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same qualified individual who performs the diagnostic interpretation and evaluation and must utilize appropriate terminology such as the SnoMed system.

(6) CYTOGENETICS REPORTS must:

__ __ __ (a) Use the International System for Human Cytogenetic Nomenclature on final reports;

__ __ __ (b) Include the number of cells counted and analyzed;

__ __ __ (c) Include a summary and interpretation of the observations.

(7) If a specimen is referred to another laboratory for testing, the medical test site must:

__ __ __ (a) Report the essential elements of the referred test results without alterations that could affect the clinical interpretation of the results;

__ __ __ (b) Retain or be able to produce an exact duplicate of each testing report from the referral laboratory.

__ __ __ (8) The medical test site must retain records, slides, and tissues as described in Table 070-1, under storage conditions that ensure proper preservation.

__ __ __ (9) If the medical test site ceases operation, it must make provision to ensure that all records and, as applicable, slides, blocks and tissue are retained and available for the time frames specified in Table 070-1.

Table 070-1 Record/Slide/Tissue Retention Schedule

	Two Years	Five Years	Ten Years
(a) General Requirements for all Laboratory Specialties	▪ Test requisitions or equivalent; ▪ Test records, including instrument printouts if applicable; ▪ Test reports; ▪ Quality control records; ▪ Quality assurance records; ▪ Proficiency testing records; ▪ Hard copy of report, or ability to reproduce a copy, for all specimens referred for testing; and ▪ Discontinued procedures for all specialty areas		
(b) Transfusion Services		▪ Test requisitions or equivalent; ▪ Test records; ▪ Test reports; ▪ Quality control records; ▪ Quality assurance records	▪ Individual Product Records*
(c) Cytology		▪ All cytology slides, from date of examination of the slide	▪ All cytology reports
(d) Histopathology/ Oral Pathology	▪ Specimen blocks, from date of examination		▪ All histopathology and oral pathology reports; ▪ Stained slides, from date of examination of the slide
(e) Histopathology/ Oral Pathology – Tissues	Retain remnants of tissue specimens in an appropriate preserved state until the portions submitted for microscopic examination have been examined and diagnosed		
(f) Instrument/method Validation Studies	For life of instrument/method plus two years		

*Must be retained for no less than ten years in accordance with 21 CFR 606.160(d)

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Y	N	NA	WAC 246-338-080 QUALITY ASSURANCE
__	__	__	Each medical test site performing moderate complexity (including PPMP) or high complexity testing, or any combination of these tests, must establish and follow written policies and procedures for a comprehensive quality assurance program. The quality assurance program must be designed to monitor and evaluate the ongoing and overall quality of the total testing process (pre-analytic, analytic, post-analytic). The medical test site's quality assurance program must evaluate the effectiveness of its policies and procedures; identify and correct problems; assure the accurate, reliable, and prompt reporting of test results; and assure the adequacy and competency of the staff. As necessary, the medical test site must revise policies and procedures based upon the results of those evaluations. The medical test site must meet the standards as they apply to the services offered, complexity of testing performed and test results reported, and the unique practices of each testing entity. All quality assurance activities must be documented.
			(1) The medical test site must establish and implement a written quality assurance plan, including policies and procedures, designed to:
__	__	__	(a) Monitor, evaluate, and review quality control data, proficiency testing results, and test results, including biannual verification of:
			(i) Accuracy of test results for:
__	__	__	(A) Tests that are not covered by proficiency testing;
__	__	__	(B) Tests that are covered by proficiency testing but have unsatisfactory scores, are not scored by the proficiency testing program, or where scoring does not reflect actual test performance (e.g., the proficiency testing program does not obtain the agreement required for scoring);
__	__	__	(ii) Relationship between test results when the medical test site performs the same test on different instruments or at different locations within the medical test site;
__	__	__	(b) Identify and correct problems;
__	__	__	(c) Establish and maintain accurate, reliable, and prompt reporting of test results;
__	__	__	(d) Verify all tests performed and reported by the medical test site conform to specified performance criteria in quality control under WAC 246-338-090;
__	__	__	(e) Establish and maintain the adequacy and competency of the technical personnel;
__	__	__	(f) Establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results.
			(2) The quality assurance plan must include mechanisms or systems to:
__	__	__	(a) Establish and apply criteria for specimen acceptance and rejection;
__	__	__	(b) Notify the appropriate individuals as soon as possible when test results indicate potential life-threatening conditions;
__	__	__	(c) Assess problems identified during quality assurance reviews and discuss them with the appropriate staff;
__	__	__	(d) Evaluate all test reporting systems to verify accurate and reliable reporting, transmittal, storage, and retrieval of data;
__	__	__	(e) Document all action taken to identify and correct problems or potential problems;
__	__	__	(f) Issue corrected reports when indicated;

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Y	N	NA	WAC 246-338-080 QUALITY ASSURANCE
__	__	__	(g) Provide appropriate instructions for specimen collection, handling, preservation, and transportation;
__	__	__	(h) Ensure that specimens are properly labeled, including patient name or unique patient identifier and, when appropriate, specimen source;
__	__	__	(i) Ensure confidentiality of patient information throughout all phases of the testing process;
__	__	__	(j) Provide clients updates of testing changes that would affect test results or the interpretation of test results.
__	__	__	(3) The medical test site must establish criteria for and maintain appropriate documentation of any remedial action taken in response to quality control, quality assurance, personnel, proficiency testing, and transfusion reaction investigations.
__	__	__	(4) When results of control or calibration materials fail to meet the established criteria for acceptability, the medical test site must have a system in place to determine if patient test results have been adversely affected. The system must include:
__	__	__	(a) A review of all patient test results obtained in the unacceptable test run;
__	__	__	(b) A review of all patient test results since the last acceptable test run.
			(5) The medical test site must have a system in place to assure:
__	__	__	(a) All complaints and problems reported to the medical test site are documented and investigated when appropriate;
__	__	__	(b) Corrective actions are instituted as necessary.
			(6) The owner must:
__	__	__	(a) Maintain adequate space, facilities, and essential utilities for the performance and reporting of tests;
__	__	__	(b) Ensure that molecular amplification procedures that are not contained in closed systems have a unidirectional workflow. This must include separate areas for specimen preparation, amplification and production detection, and as applicable, reagent preparation;
__	__	__	(c) Establish, make accessible, and observe safety precautions to ensure protection from physical, chemical, biochemical, and electrical hazards and biohazards;
__	__	__	(d) Establish and implement policies and procedures for infectious and hazardous medical wastes consistent with local, state, and federal authorities.
			(7) Information that must be available to authorized persons ordering or utilizing the test results includes:
__	__	__	(a) A list of test methods, including performance specifications;
__	__	__	(b) Reference ranges; and
__	__	__	(c) Test method limitations
__	__	__	(8) If the medical test site refers specimens to another site for testing, the site to which specimens are referred must have a valid medical test site license or meet equivalent requirements as determined by CMS.

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Y N NA 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;
(xi) Pertinent literature references;

__ __ __ (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;
__ __ __ (viii) Other testing materials;
__ __ __ (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;

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Y	N	NA	WAC 246-338-090 QUALITY CONTROL
__	__	__	(c) Determine the statistical limits for each lot number of un-assayed 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.

Table 090-1 General Quality Control Requirements

	Control Material	Frequency
(a) Each batch or shipment of reagents, discs, antisera, and identification systems	• Appropriate control materials for positive and negative reactivity	• When prepared or opened, unless otherwise specified
(b) Each batch or shipment of stains	• Appropriate control materials for positive and negative reactivity	• When prepared or opened; and • Each day of use, unless otherwise specified
(c) Fluorescent and immunohistochemical stains	• Appropriate control materials for positive and negative reactivity	• Each time of use, unless otherwise specified
(d) Quality control for each specialty and subspecialty	• Appropriate control materials; or • Equivalent mechanism to assure the quality, accuracy, and precision of the test if reference materials are not available	• At least as frequently as specified in this section; • More frequently if recommended by the manufacturer of the instrument or test procedure; or • More frequently if specified by the medical test site
(e) Direct antigen detection systems without procedural controls	• Positive and negative controls that evaluate both the extraction and reaction phase	• Each batch, shipment, and new lot number; • Each day of use

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Y N NA WAC 246-338-090 QUALITY CONTROL

__ __ __ (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;

Table 090-2 Calibration and Calibration Verification – Moderate and High Complexity Testing

	Calibration Material	Frequency
CALIBRATION	• Calibration materials appropriate for methodology	• Initial on-site installation/implementation of instrument/method; • At the frequency recommended by the manufacturer; • Whenever calibration verification fails to meet the medical test site's acceptable limits for calibration verification.
CALIBRATION VERIFICATION	• Use assayed material, if available, at the lower, mid-point, and upper limits of procedure's reportable range; or • Demonstrate alternate method of assuring accuracy at the lower, mid-point, and upper limits of procedure's reportable range	• At least every six months; • When there is a complete change of reagents (*i.e.*, new lot number or different manufacturer) is introduced; • When major preventive maintenance is performed or there is a replacement of critical parts of equipment; or • When controls are outside of the medical test site's acceptable limits or exhibit trends.

__ __ __ (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;
(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.

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Y N NA WAC 246-338-090 QUALITY CONTROL

(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.

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

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Y N NA WAC 246-338-090 (9) QUALITY CONTROL

__ __ __ (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	• Positive and negative reference material	• Each day of use	• Two levels of reference material in different concentrations	• Each day of use
Toxicology				
• GC/MS for drug screening	• Analyte-specific control	• With each run of patient specimens	• Analyte-specific control	• With each analytical run
• Urine drug screen	• Positive control containing at least one drug representative of each drug class to be reported; must go through each phase of use including extraction	• With each run of patient specimens		
Urinalysis				
• Non-waived instrument			• Two levels of control material	• Each day of use
• Refractometer for specific gravity			• Calibrate to zero with distilled water • One level of control material	• Each day of use
Blood Gas Analysis			• Calibration	• Follow manufacturer's specifications and frequency
			• One level of control material	• Each eight hours of testing, using both low and high values on each day of testing
			• One-point calibration or one control material	• Each time patient sample is tested, unless automated instrument internally verifies calibration every 30 minutes
Electrophoresis	• One control containing fractions representative of those routinely reported in patient specimens	• In each electrophoretic cell	• One control containing fractions representative of those routinely reported in patient specimens	• In each electrophoretic cell

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(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	• Two levels of reference material in different concentrations	• Each day that patient samples are tested
Manual Blood Counts	• One level of reference material	• Every 8 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

	Control Material	Frequency
Automated	• Two levels of reference material in different concentrations	• Every 8 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 8 hours that patient samples are tested; and • Each time reagents are changed

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(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;

__ __ __ (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

	Control Material	Frequency
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)	• When kit is opened; and • Each day of testing, or follow an equivalent quality testing procedure that meets federal CLIA regulations
	• Procedural (internal) controls	• 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;

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(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;

__ __ __ (D) Follow the manufacturer's specifications for using the media;

(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

	Control Material	Frequency
Reagents, disks, and identification systems Catalase, coagulase, oxidase, and Beta-lactamase Cefinase™ reagents Bacitracin, optochin, ONPG, X and V disks or strips	• Positive and negative reference organisms, unless otherwise specified	• Each batch, shipment and new lot number unless otherwise specified
Stains, unless otherwise specified; DNA probes; and all beta-lactamase methods other than Cefinase™	• Positive and negative reference organisms	• Each batch, shipment and new lot number; and • Each day of use
Fluorescent stains	• Positive and negative reference organisms	• Each batch, shipment and new lot number; and • Each time of use
Gram stains	• Positive and negative reference organisms	• Each batch, shipment and new lot number; and • Each week of use
Direct antigen detection systems without procedural controls	• Positive and negative controls that evaluate both the extraction and reaction phase	• Each batch, shipment and new lot number; and • Each day of use
Test kits with procedural (internal) controls	• Positive and negative reference material (external) controls	• Each batch, shipment and new lot number; and • Each day of testing, or follow an equivalent quality testing procedure that meets federal CLIA regulations
	• Procedural (internal) controls	• Each time patient sample is tested
Antisera	• Positive and negative reference material	• Each batch, shipment and new lot number; and • Every six months

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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)	• Approved reference organisms (ATCC organisms)	• Before initial use and each day of testing; or • May be done weekly if the medical test site can meet the quality control requirements for antimicrobial disk susceptibility testing as outlined by CLSI M100S Performance Standards for Antimicrobial Susceptibility Testing; Twenty-Sixth Edition.

Y N NA WAC 246-338-090 QUALITY CONTROL

__ __ __ **(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	• Acid-fast organism that produces a positive reaction and an acid-fast organism that produces a negative reaction	• Each day of use
Acid-fast stains	• Acid-fast organism that produces a positive reaction and an acid-fast organism that produces a negative reaction	• Each day of use
Fluorochrome acid-fast stains	• Acid-fast organism that produces a positive reaction and an acid-fast organism that produces a negative reaction	• Each time of use
Susceptibility tests performed on *Mycobacterium tuberculosis* isolates	• Appropriate control organisms(s)	• Each batch of media, and each lot number and shipment of antimycobacterial agent(s) before, or concurrent with, initial use • Each week of use

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Y N NA WAC 246-338-090 QUALITY CONTROL

__ __ __ **(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	• One control strain that is susceptible to the drug	• Each day of use
Lactophenol cotton blue stain	• Appropriate control organism(s)	• Each batch or shipment and each lot number
Acid-fast stains	• Organisms that produce positive and negative reactions	• Each day of use
Reagents for biochemical and other identification test procedures	• Appropriate control organism(s)	• Each batch or shipment and each lot number
Commercial identification systems utilizing 2 or more substrates	• Organisms that verify positive and negative reactivity of each media type	• Each batch or shipment and each lot number

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(D) Parasitology:

(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.

E) Virology:

(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.

__ __ __ **(g) Histopathology:** 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.

(h) Cytology:

(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;

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__ __ __ (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 technique 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;

__ __ __ (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 CFR 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

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__ __ __ (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 or 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) Immunohematology/ 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 CFR Parts 606 and 640.

(A) Perform ABO grouping:

__ __ __ (I) By concurrently testing unknown red cells with FDA approved a 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;

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__ __ __ (C) Perform quality control procedures for immunohematology as described in Table 090-11.

Table 090-11 Quality Control Procedures - Immunohematology

Reagent	Control Material	Frequency
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

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(ii) Blood and Blood Products:
(A) Collecting, processing, and distributing:
__ __ __ (I) Must comply with FDA requirements listed under 21 CFR 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 CFR 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.

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			(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 CFR 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.