PROPOSED RULE MAKING

CR-102 (June 2012)
(Implements RCW 34.05.320)
Do **NOT** use for expedited rule making

Agency: Department of Health

☒ **Preproposal Statement of Inquiry was filed as WSR** 16-03-083 **; or**
☐ **Expedited Rule Making--Proposed notice was filed as WSR _ ; or**
☐ **Proposal is exempt under RCW 34.05.310(4) or 34.05.330(1).**

☒ **Original Notice**
☐ **Supplemental Notice to WSR**
☐ **Continuance of WSR**

Title of rule and other identifying information: (Describe Subject)
Chapter 246-338 WAC--Medical Test Site Rules. Proposing amendments to rules to comply with federal regulations and statutory requirements.

Hearing location(s): Department of Health
Town Center 2 Bldg.
Conference Room 145
111 Israel Road SE
Tumwater, WA 98501

Date: August 2, 2016 Time: 1:30 p.m.

Date of intended adoption: 08/09/2016
(Note: This is **NOT** the **effective** date)

Submit written comments to:
Name: Susan Walker, Lab Quality Assurance Supervisor
Address: 20425 72nd Ave., S, Ste 310
Kent, WA 98032
e-mail: https://fortress.wa.gov/doh/policyreview
fax 253-395-6365 by (date) 08/02/2016

Assistance for persons with disabilities: Contact
Susan Walker by 07/28/2016
TTY (800) 833-6388 or () 711

Purpose of the proposal and its anticipated effects, including any changes in existing rules:
The purpose of the proposal is to add the Centers for Medicaid and Medicare (CMS) Clinical Laboratory Improvement Amendments (CLIA) new regulation regarding patients having access to laboratory results per 42 CFR 493.1291(l) and to clarify existing Medical Test Site (MTS) regulations. In addition, a directed or partial plan of correction is proposed for any laboratory with deficiencies pursuant to 42 CFR 493.1832 and RCW 43.05.100. Finally, other proposed revisions updating and clarifying existing MTS federal requirements are in response to RCW 43.70.143 that requires DOH to review rules every five years.

Reasons supporting proposal:
The proposal enables DOH to adhere to state and federal standards for all U.S. facilities that test human specimens for health assessment to diagnose, prevent, and/or treat disease. The proposal ensures: (1) standards for laboratory testing meet state and federal requirements; (2) standards for laboratory testing and provision of laboratory results are maintained per 42 CFR 493.1291(l); (3) existing regulations are clarified in response to RCW 43.70.041 and 42 CFR 493; and (4) directed corrective action requirements are added per federal regulations and state law.

Statutory authority for adoption:
RCW 70.42.220

Statute being implemented:
RCW 43.05.100, 43.70.041, 70.42.005, & 70.42.060

Is rule necessary because of a:

Federal Law?	☒ Yes	☐ No
Federal Court Decision?	☐ Yes	☒ No
State Court Decision?	☐ Yes	☒ No

If yes, CITATION:
See Attachment A

DATE 06/10/2016

NAME (type or print)
John Wiesman, DrPH, MPH

SIGNATURE

, DrPH, MPH

TITLE
Secretary of Health

CODE REVISER USE ONLY

OFFICE OF THE CODE REVISER
STATE OF WASHINGTON
FILED

DATE: June 10, 2016
TIME: 3:40 PM

WSR 16-13-057

(COMPLETE REVERSE SIDE)

Agency comments or recommendations, if any, as to statutory language, implementation, enforcement, and fiscal matters:

None.

Name of proponent: (person or organization) Department of Health

☐ Private
☐ Public
☒ Governmental

Name of agency personnel responsible for:

	Name	Office Location	Phone
Drafting.....	Maura Craig	111 Israel Rd., SE, Tumwater, WA 98504	360.236.4997
Implementation....	Susan Walker	20425 72nd Ave S., Ste 310, Kent, WA 98032	253.395.6745
Enforcement.....	Susan Walker	20425 72nd Ave S., Ste 310, Kent, WA 98032	253.395.6745

Has a small business economic impact statement been prepared under chapter 19.85 RCW or has a school district fiscal impact statement been prepared under section 1, chapter 210, Laws of 2012?

☐ Yes. Attach copy of small business economic impact statement.

A copy of the statement may be obtained by contacting:
Name:
Address:

phone
fax
e-mail

☒ No. Explain why no statement was prepared.

A small business economic impact statement (SBEIS) was not prepared. Under RCW 19.85.025 and 34.05.310(4)(c), a SBEIS is not required for proposed rules that adopt or incorporate by reference - without material change - federal statutes or regulations, Washington state law, the rules of other Washington state agencies, or national consensus codes that generally establish industry standards;

Is a cost-benefit analysis required under RCW 34.05.328?

☐ Yes A preliminary cost-benefit analysis may be obtained by contacting:
Name:
Address:

phone
fax
e-mail

☒ No: Please explain: The agency did not complete a cost benefit analysis under RCW 34.05.328. RCW 34.05.328(5)(b)(iii) exempts rules that adopt or incorporate by reference without material change federal statutes or regulations, Washington state law, the rules of other Washington state agencies, or national consensus codes that generally establish ind

CR-102

Chapter 246-338 WAC – Medical Test Site Rules

Attachment A

Is rule necessary because of a Federal Law? Yes.

If yes, CITATION:

42 CFR 493.1291(l)

42 CFR 493.1832

42 CFR 493.1241(b)

42 CFR 493.1299

42 CFR 493 1256(2)(iv,v)

42 CFR 493.1273(a)

AMENDATORY SECTION (Amending WSR 05-04-040, filed 1/27/05, effective 3/19/05)

WAC 246-338-010 Definitions. For the purposes of this chapter, the following words and phrases have these meanings unless the context clearly indicates otherwise.

(1) "Accreditation organization" means a public or private organization or agency approved by CMS as having standards which are consistent with federal law and regulation, and judged by the department to be equivalent to this chapter.

(2) "Authorized person" means any individual allowed by Washington state law or rule to order tests or receive test results.

(3) "Biannual verification" means a system for verifying the accuracy of test results, at least twice a calendar year, for those tests for which proficiency testing is not required by the department.

(4) "Calibration" means a process of testing and adjusting an instrument, kit, or test system to provide a known relationship between the measurement response and the value of the substance that is being measured by the test procedure.

(5) "Calibration verification" means the assaying of materials of known concentration in the same manner as patient samples to confirm that the calibration of the instrument, kit, or test system has remained stable throughout the laboratory's reportable range for patient test results.

(6) "Calibrator" means a material, solution, or lyophilized preparation designed to be used in calibration. The values or concentrations of the analytes of interest in the calibration material are known within limits ascertained during its preparation or before use.

(7) "Case" means any slide or group of slides, from one patient specimen source, submitted to a medical test site, at one time, for the purpose of cytological or histological examination.

(8) "CDC" means the federal Centers for Disease Control and Prevention.

(9) "CMS" means the federal Centers for Medicare and Medicaid Services.

(10) "CLIA" means Section 353 of the Public Health Service Act, Clinical Laboratory Improvement Amendments of 1988, and regulations implementing the federal amendments, 42 C.F.R. Part 493-Laboratory Requirements in effect on September 22, 2003.

(11) "Control" means a material, solution, lyophilized preparation, or pool of collected serum designed to be used in the process of quality control. The concentrations of the analytes of interest in the control material are known within limits ascertained during its preparation or before routine use.

(12) "Control slide" means a preparation of a material known to produce a specific reaction which is fixed on a glass slide and is used in the process of quality control.

(13) "Days" means calendar days.

(14) "Deemed status" means recognition that the requirements of an accreditation organization have been judged to be equal to, or more stringent than, the requirements of this chapter and the CLIA requirements, and the accreditation organization has agreed to comply with all requirements of this chapter and CLIA.

(15) "Deficiency" means a finding from an inspection or complaint investigation that is not in compliance with this chapter and requires corrective action.

(16) "Department" means the department of health.

(17) "Direct staff time" means all state employees' work time; travel time; telephone contacts and staff or management conferences; and expenses involved with a complaint investigation or an on-site follow-up visit.

(18) "Director," defined as the designated test site supervisor in RCW 70.42.010, means the individual responsible for the technical functions of the medical test site. This person must meet the qualifications for Laboratory Director, listed in 42 C.F.R. Part 493 Subpart M - Personnel for Nonwaived Testing.

(19) "Disciplinary action" means license or certificate of waiver denial, suspension, condition, revocation, civil fine, or any combination of the preceding actions, taken by the department against a medical test site.

(20) "Facility" means one or more locations within one campus or complex where tests are performed under one owner.

(21) "Forensic" means investigative testing in which the results are never used for clinical diagnosis, or referral to a health care provider for treatment of an individual.

(22) "HHS" means the federal Department of Health and Human Services.

(23) "High complexity" means a test system, assay, or examination that is categorized under CLIA as a high complexity test.

(24) "May" means permissive or discretionary.

(25) "Medical test site" or "test site" means any facility or site, public or private, which analyzes materials derived from the human body for the purposes of health care, treatment, or screening. A medical test site does not mean:

(a) A facility or site, including a residence, where a test approved for home use by the Federal Food and Drug Administration is used by an individual to test himself or herself without direct supervision or guidance by another and where this test is not part of a commercial transaction; or

(b) A facility or site performing tests solely for forensic purposes.

(26) "Moderate complexity" means a test system, assay, or examination that is categorized under CLIA as a moderate complexity test.

(27) "Must" means compliance is mandatory.

(28) "Nonwaived" means all tests categorized under CLIA as:

(a) Moderate complexity tests, including provider-performed microscopic procedures; or

(b) High complexity tests.

(29) "Owner" means the person, corporation, or entity legally responsible for the business requiring licensure or a certificate of waiver as a medical test site under chapter 70.42 RCW.

(30) "Patient's personal representative" means a person legally authorized to make health care decisions on an individual's behalf.

(31) "Performance specification" means a value or range of values for a test that describe its accuracy, precision, analytical sensitivity, analytical specificity, reportable range and reference range.

((~~(31)~~)) (32) "Person" means any individual, public organization, private organization, agent, agency, corporation, firm, association, partnership, or business.

((~~(32)~~)) (33) "Physician" means an individual with a doctor of medicine, doctor of osteopathy, doctor of podiatric medicine, or equivalent degree who is a licensed professional under chapter 18.71

RCW Physicians; chapter 18.57 RCW Osteopathy—Osteopathic medicine and surgery; or chapter 18.22 RCW Podiatric medicine and surgery.

((~~(33)~~)) (34) "Provider-performed microscopic procedures" means only those moderate complexity tests listed under WAC 246-338-020 (2)(b)(i) through (x), when the tests are performed in conjunction with a patient's visit by a licensed professional meeting qualifications specified in WAC 246-338-020 (2)(a)(i) through (vi).

((~~(34)~~)) (35) "Provisional license" means an interim approval issued by the department to the owner of a medical test site.

((~~(35)~~)) (36) "Records" means books, files, reports, or other documentation necessary to show compliance with the quality control and quality assurance requirements under this chapter.

((~~(36)~~)) (37) "Reference material" means a material or substance, calibrator, control, or standard where one or more properties are sufficiently well established for use in calibrating a process or for use in quality control.

((~~(37)~~)) (38) "Specialty" means a group of similar subspecialties or tests. The specialties for a medical test site are as follows:

(a) Chemistry;
(b) Cytogenetics;
(c) Diagnostic immunology;
(d) Immunohematology;
(e) Hematology;
(f) Histocompatibility;
(g) Microbiology;
(h) Pathology; and
(i) Radiobioassay.

((~~(38)~~)) (39) "Standard" means a reference material of fixed and known chemical composition capable of being prepared in essentially pure form, or any certified reference material generally accepted or officially recognized as the unique standard for the assay regardless of level or purity of the analyte content.

((~~(39)~~)) (40) "Subspecialty" means a group of similar tests. The subspecialties of a specialty for a medical test site are as follows, for:

(a) Chemistry, the subspecialties are routine chemistry, urinalysis, endocrinology, and toxicology;

(b) Diagnostic immunology, the subspecialties are syphilis serology and general immunology;

(c) Immunohematology, the subspecialties are ABO grouping and Rh typing, antibody detection, antibody identification, and compatibility testing;

(d) Hematology, the subspecialties are routine hematology and coagulation;

(e) Microbiology, the subspecialties are bacteriology, mycology, parasitology, virology, and mycobacteriology; and

(f) Pathology, the subspecialties are histopathology (including dermatopathology), diagnostic cytology, and oral pathology.

((~~(40)~~)) (41) "Supervision" means authoritative procedural guidance by an individual qualified under 42 C.F.R. Part 493 Subpart M - Personnel for Non-waived Testing, assuming the responsibility for the accomplishment of a function or activity by technical personnel.

((~~(41)~~)) (42) "Technical personnel" means individuals employed to perform any test or part of a test.

((~~(42)~~)) (43) "Test" means any examination or procedure conducted on a sample taken from the human body.

((~~(43)~~)) (44) "Validation inspection" means an on-site inspection by the department of an accredited medical test site to determine that the accreditation organization's regulations are equivalent to this chapter and are enforced.

((~~(44)~~)) (45) "Waived test" means a test system that is:

(a) Cleared by the Food and Drug Administration for home use; or

(b) A simple laboratory examination or procedure that has an insignificant risk of an erroneous result.

In order for a test system to be waived, it must be approved for waiver under CLIA.

((~~(45)~~)) (46) "Will" means compliance is mandatory.

AMENDATORY SECTION (Amending WSR 05-04-040, filed 1/27/05, effective 3/19/05)

WAC 246-338-028 On-site inspections. (1) The department may conduct an on-site review of a licensee or applicant at any time to determine compliance with chapter 70.42 RCW and this chapter as described in Table 020-1.

(2) The department may at any time examine records of the medical test site to determine compliance with chapter 70.42 RCW and this chapter.

(3) The department will:

(a) Provide written notice of deficiencies to the medical test site; ((~~and~~))

(b) Allow the owner a reasonable period of time, not to exceed sixty days after department approval of the written plan of correction, to correct a deficiency unless the deficiency is an immediate threat to public health, safety, or welfare; and

(c) Impose a directed plan of correction or a partial directed plan of correction as an alternative sanction for any laboratory that has serious deficiencies per 42 C.F.R. 493.1832 and RCW 43.05.100.

(4) The medical test site must:

(a) Present a written plan of correction to the department within fourteen days following the date of postmark of the notice of deficiencies;

(b) Comply with the written plan of correction within a specified time, not to exceed sixty days, after department approval of the written plan of correction which must detail how and when the medical test site will correct the deficiencies;

(c) Submit to inspections by CMS or CMS agents as a condition of licensure for the purpose of validation or in response to a complaint against the medical test site;

(d) Authorize the department to release all records and information requested by CMS to CMS or CMS agents;

(e) Cooperate with any on-site review conducted by the department; and

(f) Authorize the accreditation organization to submit, upon request of the department:

(i) On-site inspection results;

(ii) Reports of deficiencies;

(iii) Plans of corrections for deficiencies cited;

(iv) Any disciplinary or enforcement action taken by the accreditation organization against the medical test site and results of any

disciplinary or enforcement action taken by the accreditation organization against the medical test site; and

(v) Any records or other information about the medical test site required for the department to determine whether or not standards are consistent with chapter 70.42 RCW and this chapter.

AMENDATORY SECTION (Amending WSR 14-09-001, filed 4/2/14, effective 5/3/14)

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;

(f) Sex, and age or date of birth, of the patient; and

(g) For cytology and histopathology specimens:

(i) Pertinent clinical information; and

(ii) For Pap smears:

(A) Date of last menstrual period; and

(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; and

(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; and

(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 limitation; and

(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; and

(c) Include the signature or initials of the technical supervisor, or an electronic signature authorized by the technical supervisor, for nongynecological 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 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; and

(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; and

(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 provisions 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; and • 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; and 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 C.F.R. 606.160(7)(d).

AMENDATORY SECTION (Amending WSR 05-04-040, filed 1/27/05, effective 3/19/05)

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; ((~~and~~))

(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; ((~~and~~))

(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

		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

		Control Material	Frequency
(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; and • Each day of use

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; and • 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.

(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	• Positive and negative reference material	• Each day of use	• Two levels of reference material in different concentrations	• Each day of use
Toxicology				

Subspecialty/Test	Qualitative		Quantitative	
	Control Material	Frequency	Control Material	Frequency
• 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				
• Nonwaived instrument			• Two levels of control material	• Each day of use
• Refractometer for specific gravity			• Calibrate to zero with distilled water	• Each day of use
			• One level of control material	
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 specimen is tested, unless automated instrument internally verifies calibration every thirty minutes
Electrophoresis	• One control containing fractions representative of those routinely reported in patient specimens	• In each electrophore tic cell	• One control containing fractions representative of those routinely reported in patient specimens	• In each electrophoretic cell

(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 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

	Control Material	Frequency
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

	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) • 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 ((~~NCCLS~~)) Clinical Laboratory Standards Institute (CLSI), Quality Assurance for Commercially Prepared Microbiological Culture Media((~~ Second Edition; Approved Standard (1996)~~));

(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

	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 • Procedural (internal) 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 • Each time patient sample is tested
Antisera	• Positive and negative reference material	• Each batch, shipment, and new lot number; and • Every six months

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 ((~~NCCLS~~)) CLSI M100 Performance Standards for Antimicrobial Disk Susceptibility Tests((~~Eighth Edition; Approved Standard (2003)~~))

(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 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 organism(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

(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 two or more substrates	• Organisms that verify positive and negative reactivity of each media type	• Each batch or shipment and each lot number

(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 ((~~for differential or special stains~~)) 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; 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;

(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) **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 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

Reagent	Control Material	Frequency
ABO antisera	• Positive control	• Each day of use
Rh antisera	• Positive and negative controls	• Each day of use
	• Patient control to detect false positive Rh test results	• 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.