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;		

	Two Years	Five Years	Ten Years
	• 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).

[Statutory Authority: RCW 70.42.220, 43.70.041, and 42 C.F.R. 493.1291(l), 1832, 1241(b), 1299, 1256 (2)(iv, v), 1273(a). WSR 16-18-073, § 246-338-070, filed 9/2/16, effective 10/3/16. Statutory Authority: RCW 70.42.220, 42 C.F.R. 493.1273 (d) and (e), and 21 C.F.R. 606.160 (b)(3)(ii), (v), and (7)(d) a. WSR 14-09-001, § 246-338-070, filed 4/2/14, effective 5/3/14. Statutory Authority: RCW 70.42.005 and 42 C.F.R. Part 493. WSR 05-04-040, § 246-338-070, filed 1/27/05, effective 3/19/05. Statutory Authority: RCW 70.42.005, 70.42.060. WSR 01-02-069, § 246-338-070, filed 12/29/00, effective 1/29/01. Statutory Authority: RCW 70.42.005, 70.42.060 and chapter 70.42 RCW. WSR 00-06-079, § 246-338-070, filed 3/1/00, effective 4/1/00. Statutory Authority: RCW 70.42.005. WSR 97-14-113, § 246-338-070, filed 7/2/97, effective 8/2/97. Statutory Authority: Chapter 70.42 RCW. WSR 93-18-091 (Order 390), § 246-338-070, filed 9/1/93, effective 10/2/93; WSR 91-21-062 (Order 205), § 246-338-070, filed 10/16/91, effective 10/16/91. Statutory Authority: RCW 43.70.040. WSR 91-02-049 (Order 121), recodified as § 246-338-070, filed 12/27/90, effective 1/31/91. Statutory Authority: Chapter 70.42 RCW. WSR 90-20-017 (Order 090), § 248-38-070, filed 9/21/90, effective 10/22/90.]