D3000

Subpart J--Facility Administration for Nonwaived Testing

§493.1100 Condition: Facility administration.

Each laboratory that performs nonwaived testing must meet the applicable requirements under §§493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual #7.

Interpretive Guidelines §493.1100
To determine which tests are categorized as waived or nonwaived (i.e., moderate or high complexity tests), refer to the "Specific List For Categorization of Laboratory Test Systems, Assays, and Examinations by Complexity" [www.fda.gov/cdrh/clia/index.html]. Test systems, assays, and examinations not yet classified are considered high complexity.

Significant deficiencies cited under this condition may also indicate deficiencies under personnel responsibilities.

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§493.1101 Standard: Facilities.

(a) The laboratory must be constructed, arranged, and maintained to ensure the following:

D3001

§493.1101 Standard: Facilities.

(a)(1) The space, ventilation, and utilities necessary for conducting all phases of the testing process.

Interpretive Guidelines §493.1101(a)(1)
Work areas should be arranged to minimize problems in specimen handling, examination and testing of specimens, and reporting of test results.

Workbench space should be sufficient for test performance, well lit, and have water, gas, suction, and, electrical outlets as necessary. Instruments, equipment, and computer systems should be placed in locations where their operation is not affected adversely by physical or chemical factors, such as heat direct sunlight, vibrations, power fluctuations or fumes from acid or alkaline solutions. Equipment tops should not be used as workbench space.

Determination of proper lighting is subjective since the regulations do not specify the foot-candles or other measures of light intensity required. Ensure that lighting or background is appropriate for visual interpretation of test results (e.g., macroscopic evaluation of hemagglutination reactions or strep screen; dark background with reflected light for reading K-B disk diffusion AST). When citing deficiencies, document the circumstances in which lighting adversely or may adversely affect test performance or personnel safety.

Determine that the laboratory has a system to ensure its ventilation system properly removes vapors, fumes, and excessive heat, when appropriate, for the type of testing done in the laboratory.

Ensure that an adequate, stable electrical source is maintained at each location (e.g., outlets, not extension cords) and meets the power requirements for each piece of equipment.

D3003

§493.1101 Standard: Facilities.

(a)(2) Contamination of patient specimens, equipment, instruments, reagents, materials, and supplies is minimized.

D3005

§493.1101 Standard: Facilities.

(a)(3) Molecular amplification procedures that are not contained in closed systems have a uni-directional workflow. This must include separate areas for specimen preparation, amplification and product detection, and, as applicable, reagent preparation.

Interpretive Guidelines §§493.1101(a)(2)-(a)(3)
The laboratory should establish contamination prevention procedures to minimize contamination of patient specimens, equipment, instruments, reagents, materials, and supplies.

Determine if the laboratory performs wipe tests of areas where radioactive material or amplification procedures are used in order to monitor and prevent contamination.

Determine that the processing of mycobacteriology cultures is performed in a manner that prevents contamination of the environment.

Laboratories performing molecular amplification procedures should have a mechanism to detect cross-contamination of patient specimens. This may be accomplished by including a "blank" control with each run of patient specimen testing (use D5425).

Uni-directional workflow refers to the manner in which testing personnel and patient specimens move through the molecular testing process to prevent cross-contamination, and consists of separate areas for the following:

- *Reagent preparation (as applicable);*
- *Pre-amplification area for specimen preparation and amplification reaction set up; and*
- *Post-amplification area for specimen amplification and product detection.*

Reagents must be prepared in an area that is separate (as applicable) from where specimens are processed, prepared, "amplified" and detected to prevent contamination. Once a specimen enters the amplification and product detection area it should not be brought back to the reagent or specimen preparation areas. The laboratory should store amplified specimens separately from test reagents and patient specimens. All equipment (e.g., reagents, supplies, pens, pipettes and tips, laboratory coats) should remain in designated areas.

Sources of potential cross-contamination in molecular testing include:

- *Patient specimen (i.e., genomic contamination);*
- *Amplified patient specimen (i.e., amplicon contamination); and*
- *Testing personnel.*

D3007

§493.1101 Facilities

(b) The laboratory must have appropriate and sufficient equipment, instruments, reagents, materials, and supplies for the type and volume of testing it performs.

Interpretive Guidelines §493.1101(b)
Base deficiencies related to inappropriate or insufficient equipment on a determination that patient results are or may be adversely affected. Ensure that the laboratory has the appropriate equipment to prepare reagents, stains, solutions, controls, and calibration materials (e.g., pipettes, hydrometers, graduated cylinders, autoclaves, balances, centrifuges, distilled/deionized water). If the equipment or instrumentation is found to be inappropriate or insufficient, document the reasons for this finding.

Ensure that the laboratory has test systems, equipment and/or instruments capable of producing results within the laboratory's stated test performance specifications.

Ensure that the laboratory has test systems, equipment and/or instruments necessary to perform the laboratory's volume of testing (preanalytic, analytic, postanalytic) within established turnaround times.

Data capacity in the laboratory's information system should be sufficient for current data entry. If capacity is maintained by deletion of data, it should be scheduled and documented.

For Cytology, laboratories should use coverslips that cover the entire surface of the specimen.

D3009

§493.1101 Standard: Facilities.

(c) The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements.

Interpretive Guidelines §493.1101(c)
The laboratory must possess a current license issued by the State or local government, if such licensing exists. If a State or local government removes a laboratory's license and the right to operate within the State or locality, Centers for Medicare and Medicaid Services (CMS) may take an action to revoke the Clinical Laboratory Improvement Amendments (CLIA) certificate.

D3011

§493.1101 Standard: Facilities.

(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.

Interpretive Guidelines §493.1101(d)
If you observe or obtain information regarding potential safety violations not applicable under CLIA, notify the appropriate State or local authority. Consult with the Regional

Office (RO) for notification to other Federal agencies such as the Occupational Safety and Health Administration (OSHA) www.osha.gov, Environmental Protection Agency (EPA) www.epa.gov, or Nuclear Regulatory Commission (NRC). The appropriate Federal, State or local authority, if warranted, will investigate and, if necessary, conduct an on-site visit.

Probes §493.1101(d)
What safety protocols are observed and practiced in the laboratory?

How does the laboratory, including temporary testing sites or mobile units:

- *Dispose of radiological, chemical, and biological wastes (including blood drawing equipment);*
- *Clean up spills (chemical, biological, and radiological); and*
- *Determine the amount of waste that can safely be contained and the precautions necessary to ensure that liquid waste does not spill or splash while in travel status?*

What chemical, radiological, or biological precautions are taken, if any, during the preparation or handling of reagents?

D3013

§493.1101 Standard: Facilities.

(e) Records and, as applicable, slides, blocks, and tissues must be maintained and stored under conditions that ensure proper preservation.

Interpretive Guidelines §493.1101(e)
The laboratory must arrange a secure area for storage of records and, as applicable, slides, blocks, and tissues that will provide conditions that ensure proper preservation of specimens and records.

Paraffin blocks must be stored in a cool dry environment. Exposure to excessive heat may cause blocks to melt.

Probes §493.1101(e)
For Cytology and Histology, how does the laboratory ensure that the slides have completely dried prior to being stored?

D3015

§493.1103 Standard: Requirements for transfusion services.

A facility that provides transfusion services must meet all of the requirements of this section and document all transfusion-related activities.

Interpretive Guidelines §493.1103
A "facility that provides transfusion services" is any entity that may store and/or administer blood and blood products to patients.

D3017

§493.1103 Standard: Requirements for transfusion services.

(a) Arrangement for services. The facility must have a transfusion service agreement reviewed and approved by the responsible party(ies) that govern the procurement, transfer, and availability of blood and blood products.

Interpretive Guidelines §493.1103(a)
Determine which services are provided directly by the facility and which are provided through agreement and ensure that the agreement is being met.

D3019

§493.1103 Standard: Requirements for transfusion services.

(b) Provision of testing. The facility must provide prompt ABO grouping, D (Rho) typing, unexpected antibody detection, compatibility testing, and laboratory investigation of transfusion reactions on a continuous basis through a CLIA-certified laboratory or a laboratory meeting equivalent requirements as determined by CMS.

Interpretive Guidelines §493.1103(b)
Review the agreement and determine if the outside laboratory is CLIA-certified or equivalent, as determined by CMS. An equivalent laboratory is a Veterans Administration (VA) laboratory, a CLIA-exempt laboratory or a laboratory under the auspices of the Department of Defense (DoD).

D3021

§493.1103 Standard: Requirements for transfusion services.

(c) Blood and blood products storage and distribution.
(c)(1) If a facility stores or maintains blood or blood products for transfusion outside of a monitored refrigerator, the facility must ensure the storage conditions, including temperature, are appropriate to prevent deterioration of the blood or blood product.

Interpretive Guidelines §493.1103(c)(1)
Determine where blood and blood products are stored. There may be various unconventional blood storage areas such as operating rooms, nursing stations, long-term care facilities, and dialysis units. Determine that the facility ensures the appropriate temperature is maintained and documented for each storage area during the time blood and blood products are stored.

Acceptable temperature ranges must be established and actual readings of temperature-controlled storage areas must be recorded during the time that blood or blood products for transfusion are stored. Whole Blood, Red Blood Cells, and Liquid Plasma should be stored between 1 and 6ºC; room temperature Platelets and Platelet Rich Plasma between 20 and 24ºC or 1-6ºC as indicated on the product label. Fresh Frozen Plasma, Plasma, and Cryoprecipitated AHF should be stored at -18ºC or colder.

Facilities that provide transfusion services (not certified for the specialty of Immunohematology) and perform nonwaived testing are held to the requirements for the storage and distribution of blood and blood products. The laboratory providing the blood or blood products may supply these facilities with the following:

- *Policies for the proper storage and transportation of blood or blood products;*
- *Procedures to alert the laboratory of blood storage problems;*

- *Policies to ensure the positive identification of a blood or blood product recipient (use D3023);*
- *Procedures to identify a possible transfusion reaction (use D3025); and*
- *Procedures to notify the laboratory of a possible transfusion reaction (use D3025).*

Determine how the appropriate temperatures of blood storage areas are maintained during a power failure.

Probes §493.1103(c)(1)
If frozen blood products are stored, how does the facility ensure products are maintained at appropriate temperatures to prevent thawing and re-freezing of the products?

D3023

§493.1103 Standard: Requirements for transfusion services.

(c)(2) The facility must establish and follow policies to ensure positive identification of a blood or blood product recipient.

Interpretive Guidelines §493.1103(c)(2)
Review the facility's policies for ensuring positive identification of blood or blood products and the intended recipient.
When possible, observe the actual practice, including issuing the blood and blood products to the intended recipient. This includes proper verification of patient identification prior to initiation of the transfusion.

D3025

§493.1103 Standard: Requirements for transfusion services.

(d) Investigation of transfusion reactions. The facility must have procedures for preventing transfusion reactions and when necessary, promptly identify, investigate, and report blood and blood product transfusion reactions to the laboratory and, as appropriate, to Federal and State authorities.

Interpretive Guidelines §493.1103(d)
Review the procedures for preventing, identifying, and investigating transfusion reactions. Examine records of transfusion reaction investigations for completeness, promptness, and accuracy. Verify that investigations of transfusion reactions are conducted in accordance with the facility's established protocols. Also, verify that incidents such as incomplete compatibility testing or issuing the wrong unit to a specific patient are reported to the appropriate authorities. Records should include each step in the investigation and identify the reviewer.

For facilities that provide transfusion services, confirm that all transfusion reactions identified have been investigated and the Food and Drug Administration (FDA) has been notified. If FDA has not been notified, notify the FDA at:

Food and Drug Administration
Center for Biologics Evaluation and Research (CBER)
Director, Office of Compliance and Biologics Quality
Attn: Fatality Program Manager (HFM-650)
1401 Rockville Pike

Rockville, MD 20852-1448
Voicemail: 301-827-6220
E-mail: fatalities2@cber.fda.gov
Fax: 301-827-6748

***NOTE**: Send the RO reports of all the fatal transfusion reactions identified. These reports are used to ensure that the facilities have properly notified FDA of fatal transfusion reactions and that both CMS and FDA have conducted all necessary follow-ups.*

Probes §493.1103(d)
Are problems detected during the course of the transfusion reaction investigation documented, and are procedures instituted to prevent a recurrence?

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§493.1105 Standard: Retention requirements.

(a) The laboratory must retain its records and, as applicable, slides, blocks, and tissues as follows:

Interpretive Guideline §493.1105(a)
The regulation applies to manual as well as automated record system, i.e., laboratory information system (LIS). However, the regulation does not specify the mechanism or frequency for which a laboratory should evaluate its record storage and retrieval system(s). The laboratory should establish its own policies and procedures for evaluating its system(s) and maintain documentation of the evaluation.

D3027

(a)(1) Test requisitions and authorizations. Retain records of test requisitions and test authorizations, including the patient's chart or medical record if used as the test requisition or authorization, for at least 2 years.

D3029

§493.1105 Standard: Retention requirements.

(a)(2) Test procedures. Retain a copy of each test procedure for at least 2 years after a procedure has been discontinued. Each test procedure must include the dates of initial use and discontinuance.

D3031

§493.1105 Standard: Retention requirements.

(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and activities specified in §§493.1252 through 493.1289 for at least 2 years. In addition, retain the following:

Interpretive Guidelines §493.1105(a)(3)

The records must include instrument charts, graphs, printouts, transcribed data, and manufacturers' assay information sheets for control and calibration materials. If data is transcribed, ensure that the original and the transcribed copy are retained for 2 years.

Printouts from an instrument that is not directly interfaced with the laboratory information system must be retained for 2 years.

***NOTE**: Thermal paper or pressure sensitive paper may fade over time. The laboratory must copy applicable result printouts.*

The laboratory is responsible for retaining records of interpretive slide results of each gynecologic and nongynecologic cytology case that each cytotechnologist examined or reviewed for at least five years.

D3033

§493.1105 Standard: Retention requirements.

(a)(3)(i) Records of test system performance specifications that the laboratory establishes or verifies under §493.1253 for the period of time the laboratory uses the test system but no less than 2 years.

D3035

§493.1105 Standard: Retention requirements.

(a)(3)(ii) Immunohematology records, blood and blood product records, and transfusion records as specified in 21 CFR 606.160(b)(3)(ii), (b)(3)(iv), (b)(3)(v), and (d).

Interpretive Guidelines §493.1105(a)(3)(ii)
Refer to the current version of 21 CFR Parts 600-799 for the specified section.

Non-transfusion related immunohematology patient testing and quality control (QC) records, such as instrument function checks, maintenance, and temperature records, must be retained for at least 2 years.

Other immunohematology patient and QC records related to transfusion testing, including but not limited to, donor processing, compatibility testing, and transfusion reaction investigations, must be retained for the time frame stated at 21 CFR 606.160(d). This also includes the visual inspection of whole blood and red blood cells during storage and immediately before distribution [21CFR 606.160(b)(3)(ii)], record of reissue, including records of proper temperature maintenance [21CFR 606.160(b)(3)(iv)], and emergency release of blood, including signature of requesting physician obtained before or after release [21CFR 606.160(b)(3)(v)].

D3037

§493.1105 Standard: Retention requirements.

(a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years.

Interpretive Guidelines §493.1105(a)(4)
Proficiency testing (PT) records include all information regarding the PT event including testing records, signed attestation statements sent or transmitted to the PT providers, PT

results and scores from the provider, documentation of review and records of any corrective actions.

D3039

§493.1105 Standard: Retention requirements.

(a)(5) Laboratory quality system assessment records. Retain all laboratory quality system assessment records for at least 2 years.

Interpretive Guidelines §493.1105(a)(5)
Quality assessment (QA) records do not need to be maintained and stored in one location. The records may be stored in the specific area or department appropriate to the monitoring and evaluation of the laboratory activities (preanalytic, analytic, and postanalytic).

D3041

§493.1105 Standard: Retention requirements.

(a)(6) Test reports. Retain or be able to retrieve a copy of the original report (including final, preliminary, and corrected reports) at least 2 years after the date of reporting. In addition, retain the following:

Interpretive Guidelines §493.1105(a)(6)
The patient's chart or medical record may be used to report test results in lieu of a separate reporting form.

A copy of the original report includes all information sent to the individual requesting the test or using the test result(s), and includes the name and address of the laboratory performing the test. The copy need not be paper, but may be retrieved from a computer system, microfilm or microfiche record, as long as it contains the exact information in the same format as sent to the individual ordering the test or utilizing the test results. For tests requiring an authorized signature or containing personnel identifiers, the copy must include the signatures or identifiers (e.g., Pathology reports). "Pathology" includes all of its subspecialties (i.e., Histopathology, Oral pathology, Cytology).

A "preliminary report" means a test result that has been reported to the authorized person or laboratory that initially requested the test before the final test result is completed. Frequently, a preliminary report will contain significant, but not definitive information (e.g., a urine culture preliminary report of >100,000 Gram-negative bacilli after 24 hours incubation or a beta subunit preliminary report of >200 miu/ml). It should be noted on the report when the result is a preliminary result and that a final report will follow.

A "partial report" means multiple tests are ordered on the same specimen or patient. If partial reports are issued for only those tests that have been completed, then the report date will be the date when all tests have been completed. However, the laboratory should be able to identify the date that each new test is appended to the report.

The laboratory must have a system for retaining copies of all reports including original, preliminary, corrected, and final reports. This includes computer-generated reports.

Probes §493.1105(a)(6)
How has the laboratory verified that its record retrieval system functions appropriately?

(a)(6)(i) Immunohematology reports as specified in 21 CFR 606.160(d).

Interpretive Guidelines §493.1105(a)(6)(i)
Refer to the current version of 21 CFR Parts 600-799 for the specified section.

All Immunohematology test reports that are not transfusion-related must be retained for at least 2 years.

Transfusion-related Immunohematology test reports, including but not limited to, donor processing [§493.1271(b)], compatibility testing, and transfusion reaction investigations, must be retained for the time frame stated at 21 CFR 606.160(d).

(a)(6)(ii) Pathology test reports for at least 10 years after the date of reporting.

D3043

§493.1105 Standard: Retention requirements.

(a)(7) Slide, block, and tissue retention--
(a)(7)(i) Slides.
(a)(7)(i)(A) Retain cytology slide preparations for at least 5 years from the date of examination (see §493.1274(f) for proficiency testing exception).

Interpretive Guidelines §493.1105(a)(7)(i)(A)
For storage and maintenance requirements use D3013.

***NOTE**: Cytology specimens include fine needle aspirates.*

Retention of cytology slides:
A laboratory refers all cytology specimens to a reference laboratory for examination. The reference laboratory examines all slide preparations and reports results only on normal, negative, and unsatisfactory cases. At the request of the referring laboratory, the reference laboratory returns those cases that have reactive, reparative atypia (including repair), LSIL, HSIL, all invasive squamous carcinomas, adenocarcinoma, all other malignant neoplasms, and 10% of the normal or negatives cases (including reactive and reparative cases) for quality control review. The referring laboratory must maintain the slides of the cases that it examines and for which it provides diagnosis (i.e., slides exhibiting atypical including repair, LSIL, HSIL, all invasive squamous carcinomas, adenocarcinoma, all other malignant neoplasms, and slides chosen for the 10% rescreen).

The laboratory must maintain documentation to acknowledge the donation of each slide submitted to a proficiency testing program or loaned for other purposes.

Probes §493.1105(a)(7)(i)(A)
What protocol has been established to ensure prompt return of slides, when necessary?

(a)(7)(i)(B) Retain histopathology slides for at least 10 years from the date of examination.
(a)(7)(ii) Blocks. Retain pathology specimen blocks for at least 2 years from the date of examination.
(a)(7)(iii) Tissue. Preserve remnants of tissue for pathology examination until a diagnosis is made on the specimen.

D3045

§493.1105 Standard: Retention requirements.

(b) If the laboratory ceases operation, the laboratory must make provisions to ensure that all records and, as applicable, slides, blocks, and tissue are maintained and available for the time frames specified in this section.