

## Clinical Laboratory Scientist/Technician FOIA Request Overview

### Overview

The Board of Health Professions' Contractor requested the following information involving Virginia medical/clinical laboratories:

1. Complaint Investigations, Jan. 1, 2005 to Dec. 31, 2010.
2. The five most frequently cited conditional deficiencies in Virginia, Jan 1, 2005 to Dec. 31, 2010.
3. The number of times Immediate Jeopardy cased, Jan. 1, 2005 to Dec. 31 2010.

The responses for item number one appear below. In response to item number two, CMS reported that data was only available from Dec. 2006. The five most commonly cited deficiencies were:

1. §493.1403 "Laboratory Director",
2. §493.1250 "Analytic Systems",
3. §493.1421 "Testing Personnel",
4. §493.803 "PT Participation",
5. §493.803 "PT Enrollment".

CMS called immediate jeopardy on CLIA labs in Virginia a total of 23 times from 2005 to 2010. The deficiencies related to immediate jeopardy were:

1. §493.1403 "Laboratory Director",
2. §493.1250 "Analytic Systems",
3. §493.1421 "Testing Personnel",
4. §493.803 "PT Participation",
5. §493.1290 "Post Analytic Systems"

Times Cited-Top Five	Times Cited-Immediate Jeopardy	Deficiency Overview
74	8	<p><b>Laboratory Director</b>            Laboratories Performing Moderate Complexity Testing            §493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director.            The laboratory must have a director who meets the qualification requirements of §493.1405 of this subpart and provides overall management and direction in accordance with §493.1407 of this subpart.</p> <p><i>Interpretive Guidelines §493.1403:            The Condition: laboratory director is not met when the laboratory director:</i></p> <ul style="list-style-type: none"> <li>• Position is not filled;</li> <li>• Is not qualified; or</li> <li>• Does not fulfill the laboratory director's responsibilities.</li> </ul> <p><i>An individual qualified as laboratory director may not qualify as a technical</i></p>

		<i>consultant in a particular specialty or subspecialty unless he or she has the required testing experience.</i>
39	5	<p><b>Analytic Systems</b>  §493.1250 Condition: Analytic Systems.  Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in §§493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual #7, that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in §493.1289 for each specialty and subspecialty of testing performed.</p> <p><i>NOTE: Throughout the analytic systems section, the regulations require laboratories to follow test system manufacturer's instruction for performing the testing. This means the laboratory must perform and follow the manufacturer's package insert as approved or cleared by the FDA.</i></p> <p><i>Interpretive Guidelines §493.1250</i>  Significant deficiencies cited under this condition may indicate deficiencies under personnel. Use D5400 when deficiencies are identified that are significant and have the potential to, or adversely affect patient testing, are systemic and pervasive throughout the laboratory, and are not limited to any one specialty or subspecialty. Refer to §§493.1261 - 493.1278 for additional requirements for Bacteriology, Mycobacteriology, Mycology, Parasitology, Virology, Routine Chemistry, Hematology, Immunohematology, Histopathology, Cytology, Clinical Cytogenetics, and Histocompatibility.</p>
37	4	<p><b>Testing Personnel</b>  §493.1421 Condition: Laboratories performing moderate complexity testing; testing personnel.  The laboratory must have a sufficient number of individuals who meet the qualification requirements of §493.1423, to perform the functions specified in §493.1425 for the volume and complexity of tests performed.</p> <p><i>Interpretive Guidelines §493.1421</i>  The criteria used to determine the adequacy of the testing personnel involves evaluating testing personnel responsibilities, and ensuring that these responsibilities are specified in writing by the director, and that the responsibilities are appropriate to ensure compliance with the requirements concerning reporting and recordkeeping, quality control monitoring, quality assurance activities and proficiency testing participation. Cite this deficiency only when compliance problems are found in these areas that can be directly related to insufficient numbers of testing personnel. (Use D6028, which relates the finding of insufficient personnel to director responsibilities.)</p>
33	3	<p><b>PT Participation</b>  §493.803 Condition: Successful participation.</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA.</p> <p>(b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part.</p> <p>(c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists:</p>

	<p>(1) There is immediate jeopardy to patient health and safety.</p> <p>(2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance.</p> <p>(3) The laboratory has a poor compliance history.</p> <p><i>Interpretive Guidelines §493.803</i></p> <p><i>Only the PT program has the capability to correct scores. These corrections will be noted in the PT monitoring system as “non-routine” scores.</i></p> <p><i>No single PT enforcement protocol is universally applicable for all situations. Unique circumstances may require special considerations or actions that may not conform to the general approach outlined below. The laboratory’s compliance history, its willingness to take remedial actions, and the professional judgment of surveyors, RO CLIA laboratory consultants and enforcement personnel may be factors in determining an appropriate PT enforcement plan.</i></p> <p><i>Careful review of PT performance reports and other available information should always be performed to determine whether the PT results truly represent failed PT. The potential of a PT program data input error or other factors beyond the laboratory’s control should be considered. If the laboratory has made a transcription error(s), it is considered erroneous PT result(s).</i></p> <p><i>Absent any special circumstances (which must be documented in the case file), consider verified unsuccessful PT performance to represent unsuccessful PT participation and cite as a condition-level deficiency (use D2016 on the CMS-2567).</i></p> <p><i>NOTE: The CMS PT monitoring system may NOT be used alone to determine unsuccessful participation. Surveyors must verify any unsuccessful participation indicated in the PT monitoring system. This may be done by reviewing PT results supplied by the approved PT program (they will send copies to the surveyor if requested) or from results sent to the laboratory by the PT program.</i></p> <p><i>If the unsuccessful PT participation is the first occurrence for the laboratory, and there is no immediate jeopardy to patient health or safety, notify the laboratory and require that it seek training of its personnel, obtain the necessary technical assistance to correct the problem causing the unsuccessful participation, or both. SAs may initiate training and/or technical assistance after first obtaining RO concurrence. No onsite review is required to initiate this action.</i></p> <p><i>The laboratory will submit an acceptable plan of remedial action, listing projected completion dates and other pertinent information, for its training and/or technical assistance efforts. Follow-up is necessary to verify that the laboratory has carried out its plan. Satisfactory participation in the next PT event would provide verification that the laboratory’s remedial action, training and/or technical assistance were successful. The remedial action plan should demonstrate that the laboratory will correct its problems within 3 months, although special circumstances may be considered. When a laboratory refuses to take acceptable training and/or technical assistance actions (including failure to submit an acceptable plan of remedial action, or failure to complete its plan), sanction action will be initiated.</i></p> <p><i>When the unsuccessful PT participation is not the first such occurrence for the laboratory, and there is no issue of immediate jeopardy, cite as a condition-level deficiency and take appropriate enforcement action. For immediate jeopardy cases the procedures in Subpart R apply. For non-immediate jeopardy situations, enforcement procedures should be completed within 90 days from the date that the unsuccessful PT was first identified. In immediate jeopardy situations, enforcement procedures should be completed within 23 days from the date unsuccessful participation of PT is first identified.</i></p> <p><i>Example:</i></p> <p><i>A laboratory scores 60% on a testing event in mycobacteriology. On the next testing event, the laboratory fails to participate in mycobacteriology. The citations are §§493.825(b), 493.825(e), and 493.803.</i></p>
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		<p><i>Example:</i>  A laboratory scores 60% on uric acid PT samples. On the next testing event, the laboratory score 40% on the same analyte. The citations are §§493.841(a), 493.841(f), and 493.803. When recommending to the RO that a laboratory be subject to sanctions, submit copies of the laboratory's testing event or analyte score(s) that were unsatisfactory and the correct responses provided by the PT program. Also, enclose copies of any correspondence sent to or received by the laboratory concerning its PT performance.</p> <p>When recommending to the RO that a laboratory be subject to sanctions, submit copies of the laboratory's testing event or analyte score(s) that were unsatisfactory and the correct responses provided by the PT program. Also, enclose copies of any correspondence sent or received by the laboratory concerning its PT performance.</p>
33	-	<p><b>PT Enrollement</b>  §493.803—Same as Above</p>
-	3	<p><b>Post Analytic Systems</b>  Postanalytic Systems  §493.1290 Condition: Postanalytic systems.  Each laboratory that performs nonwaived testing must meet the applicable postanalytic systems requirements in §493.1291 unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7) that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the postanalytic systems and correct identified problems as specified in §493.1299 for each specialty and subspecialty of testing performed.  <i>Interpretive Guidelines §493.1290:</i>  Significant deficiencies cited under this condition may indicate deficiencies under personnel responsibilities. Use D5800 when deficiencies are identified that are: significant and have the potential to, or adversely affect, patient testing, are systemic and pervasive throughout the laboratory, and are not limited to any one specialty or subspecialty.</p>

CMS provided extensive documentation in relation to item number one, complaint investigations. BHP staff has created a summary in two sections. The first section summarizes complaints with deficiencies cited. The second section summarizes unsubstantiated claims related to personnel issues.

**Complaints with deficiencies cited:**

Intake ID: VA00016633

Performing waived tests without CLIA certification

- D1000 Certificate of Waiver Tests
  - No certificate of waiver/CLIA registration

Intake ID: VA00016196

Performing waived tests without CLIA certification

- D1000 Certificate of Waiver Tests
  - No certificate of waiver/CLIA registration

Intake No. VA00016197

Performing waived tests without CLIA certification

- D1000 Certificate of Waiver Tests
  - No certificate of waiver/CLIA registration

Intake No. VA00012755

Lab did not inform surgical center (in Texas) of lost/missing bladder tissue specimen in mailed sample packet. Patient had to repeat painful, invasive biopsy procedure. Deficiencies cited:

- D5207 Communications
  - Laboratory must have a system to identify and document communication breakdowns between lab and test orderer
- D5391 Preanalytic Systems Quality Assessment
  - Ongoing mechanism to monitor, assess and correct identified problems in preanalytic phase, including test request, specimen submission, handling and referral
- D5300 Preanalytic systems
  - Laboratories that perform non-waived tests must meet preanalytic testing requirements. Code D5300 is used when deficiencies have the potential to adversely affect patient testing, are systemic and pervasive and are not limited to any one specialty.
- D5393 Preanalytic systems quality assessment
  - Assessment must include review of corrective actions, revision of policies, and discussions with appropriate staff. Lab must document all assessment activities
- D6118 Technical Supervisor Responsibilities
  - Resolving technical problems and ensuring remedial actions are taken when test systems deviate from performance specifications

Intake No. VA00011563

Lab at large hospital system not dispersing test results in a time efficient manner. Lab results only available on computer system, which is time consuming. Problem discussed with hospital president, but no improvement, so physicians filed complaint. CMS conducted 45-day onsite survey. The following deficiency was cited:

- D5805 Test Report
  - Lists information required on test report records

Intake ID: VA00016199

Performing waived tests without CLIA certification

- D1000 Certificate of Waiver Tests
  - No certificate of waiver/CLIA registration

Intake ID: VA00018875

Complaint regarding discrepancy in lab tests was unsubstantiated due to insufficient evidence. During the investigation/survey, the following deficiencies were cited:

- D5411 Test Systems, Equipment, Instruments, Reagent
  - Test systems must be selected by laboratory. Testing must be performed following manufacturers instructions in a manner that meets the lab's stated performance specifications
- D5805 Test Report
  - Lists information required on test report records

Intake ID: VA00015006 and VA00015007

Both complaints relate to the laboratory director/physician owner of multiple labs. The physician/director had his license to practice medicine suspended by the Board of medicine. The labs did not report a new lab director, and the physician's labs continued to send out histopathology results, but without a physician's signature. It is unclear who was reviewing histopathology slides and if that person was qualified, and who was supervising an on-site Physician Assistant. One of the physician's individual offices did not have a CLIA certificate, yet was found to be conducting laboratory tests. The labs were cited for multiple deficiencies.

- D5805 Test Report
  - Lists information required on test report records
- D5891 Postanalytic Systems Quality Assurance
  - Ongoing mechanism to monitor, assess and correct identified problems in postanalytic phase, including quality of test reports, turn around times, and procedures for notification of test results
- D6076 Laboratory Director
  - Laboratory director is not qualified, failed to fulfil duties, or position is not filled
- D6078 Laboratory Director Qualifications
  - Must be a physician or hold a clinical doctorate and Board certification, or meet grandfathering requirements, and meet other qualifications
- D6079 Laboratory Director Responsibilities
  - Responsible for overall operations and administration, including employment of competent personnel and assuring regulatory compliance; if qualified, the laboratory director may act as the technical supervisor, clinical consultant, general supervisor and testing personnel, or may delegate these tasks to qualified personnel; director remains responsible for all tasks
- D5607 Histopathology
  - Tissue pathology reports must be signed by an individual qualified to examine the slides
- D5800 Postanalytic systems

- Postanalytic systems must meet statutory requirements, and must be monitored and evaluated for quality
- D5787 Test Records
  - Records must include specimen identification, date of receipt, disposition of specimen and test record including identity of personnel performing tests

Intake ID: VA00014563

Physician office did not receive results of test. Computer system labeled specimen with wrong physician ID number. Patient Service Technician retrained and computer system replaced.

- D5805 Test Report
  - Lists information required on test report records

Intake ID: VA00014564

Lab received a urine sample in an expired tube, but failed to inform physician that it did not run the lab test. Once the lab ran the test, six days after the initial test request, it revealed that the patient had a prostate infection resistant to the antibiotic.

- D5805 Test Report
  - Lists information required on test report records

Intake ID: VA00016624

CMS redacted most of this document due to privacy concerns. The original complaint was unsubstantiated but the investigation revealed the following deficiencies:

- D5413 Test Systems, Equipment, Instruments, Reagent
  - Criteria and conditions for storage of reagents
- D5431 Maintenance and Function Checks
  - Function checks must be performed as specified in manufacturer's instructions. Function checks must be within manufacturers limits before patient testing is conducted
- D5791 Analytic Systems Quality Assessment
  - Ongoing mechanism to monitor, assess and correct identified problems in analytic phase, including test procedures, test systems, specimen and reagent storage, function checks, calibration, control, test records and comparison of test results.

Intake ID VA00015720

Lab reported erroneous results for a patient, or results for the wrong patient, and refused to correct the medical record.

- D5205 Complaint Investigations

- Must have system for documenting all complaints and problems reported to the laboratory. The laboratory must conduct investigations when appropriate.

Intake ID: VA00014431

CMS redacted much of this document due to privacy concerns. A problem with a blood transfusion contributed to a patient death. The hospital lab was cited for multiple deficiencies. Of note are the technical supervisor responsibilities. The technical supervisor may be a physician, or a scientist trained at the bachelor's level or higher with experience in laboratory science.

- D5291 General laboratory systems quality assessment
  - The ongoing review process that encompasses all facets of the laboratory's technical and non-technical functions
- D5429 Maintenance and function checks
  - Maintenance performed (or service contract) on laboratory information systems.
- D5559 Innunoematology
  - Procedures for investigating, documenting transfusion reactions and remedial measures
- D6076 Laboratory Director
  - The laboratory director is not qualified, does not fulfill responsibilities or the position is not filled
- D6094 Laboratory Director Responsibilities
  - Responsibility to maintain quality assessment program and identify failures when they occur
- D6121 Technical Supervisor Responsibilities
  - Procedures for evaluation of competency of staff
- D6124 Technical Supervisor Responsibilities
  - Direct observation of performance of instrument maintenance and function checks

Intake ID: VA00015523

Much of this document was redacted for privacy reasons. Provider signed out Cytologic preparations after failing a 2<sup>nd</sup> retest (CLIA proficiency testing). These codes relate to gynecological examinations. Individuals must successfully pass an annual proficiency test. If they fail the 1<sup>st</sup> test, they must go through training, and have two more chances to pass. All tests must be reexamined by another tester in the interim. It appears that an individual at this lab failed the gynecological proficiency test three times, but continued to perform tests. It also appears that this site was not licensed or certified to provide cytology tests.

- D2148 Cytology-gynecologic exams
  - An individual is determined to have failed the third testing event if he or she scores less than 90 percent on a 20-slide test set
- D2150 Cytology-gynecologic exams

- After failing the third test, individuals may not resume examining gynecologic slides until the individual obtains at least 35 hours of documented, formal, continuing education and is retested
- D3009 Facilities
  - The laboratory must comply with Federal, state and local requirements (i.e. it must be licensed)
- D5613 Cytology
  - All cytology slide preparations must be evaluated on the premises of a laboratory certified to conduct testing in cytology
- D6076 Laboratory Director
  - Laboratory director is not qualified, failed to fulfill duties, or position is not filled
- D6079 Laboratory Director Responsibilities
  - Responsible for overall operations and administration, including employment of competent personnel and assuring regulatory compliance; if qualified, the laboratory director may act as the technical supervisor, clinical consultant, general supervisor and testing personnel, or may delegate these tasks to qualified personnel; director remains responsible for all tasks
- D6108-Laboratory Technical Supervisor
  - The laboratory technical supervisor is not qualified, failed to fulfill duties, or the position is not filled.
- D6111-Technical Supervisor Qualifications
  - Must be a physician, or must have a bachelor, master, or doctoral degree with a complementary level of experience within the specialty area.

Intake ID: VA00014799

Personnel conducting analysis not trained. Trained personnel left, and analysis performed by persons without training. The following deficiencies were cited:

- D5787 Test Records
  - Maintain records to include identification of specimen, date/time of receipt, condition and disposition of specimen, records and dates of all tests, including personnel who performed the test
- D6000 Laboratory Director
  - Must have qualified laboratory director, director must fulfill responsibilities
- D6029 Director Responsibilities
  - Ensure all personnel have the appropriate education, experience and training
- D6063 Laboratory Testing Personnel
  - The laboratory must have sufficient number of qualified individuals to handle the volume and complexity of tests performed
- D6065 Testing Personnel Qualifications-moderately complex tests
  - Must have an associate degree or higher from an accredited institution or have military training in an appropriate specialty, (personnel may also have a high school diploma and have documented training appropriate for the test performed, however violations of this training requirement involve another deficiency code).

**Complaints related to clinical laboratory technicians/scientists, no deficiencies cited:**

Intake ID: VA00017413

A complainant lodged two complaints. The first regarded physician incentives to use the lab. The second was a general statement that the lab uses unqualified staff and that “lab assistants are in charge of processing instead of people with more experience, college degrees or certified. The most important is left to unqualified technicians” and that this created poor outcomes. The complainant did not provide further information on follow up and the office did not investigate as a result.

Intake ID: VA00010486

Concerns about the manner in which “staff persons” treated a patient.

Intake ID: VA00009785

Complainant claimed there were no written procedures for employees, that the lab asks employees to perform procedures beyond their competence level, and uncredentialed staff performed moderately complex procedures. The claims were not substantiated.

Intake ID: VA00018147

Complainant claimed unqualified personnel were processing tissues from Mohs procedures and that the lab did not have personnel trained to operate the Cryostat machine, to evaluate equipment or to keep proper records. No deficiencies were cited.