

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D2286282	(X3) Date Survey Completed 11/19/2024
Name of Provider or Supplier Alamo Women's Clinic Of Illinois	Street Address, City, State 2800 W Main St, Carbondale, IL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	An initial certification survey was completed on 11/13/2024. Immediate Jeopardy existed for the following condition level deficiencies: D2000 - 42 CFR 493.801 - Condition: Enrollment and testing of proficiency samples D5026 - 42 CFR 493.1217 - Condition: Immunohematology D6076 - 42 CFR 493.1441 - Condition: Laboratories performing high complexity testing; laboratory director D6108 - 42 CFR 493.1447 - Condition: Laboratories performing high complexity testing; technical supervisor D6141 - 42 CFR 493.1459 - Condition: Laboratories performing high complexity testing; general supervisor D6168 - 42 CFR 493.1487 - Condition: Laboratories performing high complexity testing; testing personnel The laboratory ceased testing on 11/14/2024 and Immediate Jeopardy was removed.
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on review of laboratory records, American Proficiency Institute (API) proficiency testing (PT) records and interview with testing personnel (TP) #1; the laboratory failed to have PT samples tested by three of four TP who routinely perform Rhesus (Rh) factor slide method testing for four of four Rh factor events (See D2007)</p>

and failed to retain all documents related to proficiency testing for four of four Rhesus (Rh) factor testing events from the beginning of patient testing, 07/28/2023, to the date of the on-site survey, 11/13/2023 (See D2015).

D2007

TESTING OF PROFICIENCY TESTING SAMPLES

CFR(s): 493.801(b)(1)

The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods

This STANDARD is not met as evidenced by:

Based on review of laboratory records, American Proficiency Institute (API) proficiency testing (PT) records and interview with testing personnel (TP) #1; the laboratory failed to have PT samples tested by three of four TP who routinely perform Rhesus (Rh) factor slide method testing in the specialty of immunohematology for four of four events in 2023 through the on-site survey date, 11/13/2024. Findings include: 1. Review of the Laboratory Personnel Report (signed by the laboratory director on 11/10/2024) and laboratory competency documents revealed four TP authorized to perform Rh factor slide method testing. 2. Review of API PT attestation statements for four of four PT events from the beginning of patient testing, 07/28/2023, to the date of the on-site survey, 11/13/2023, revealed TP #1 performed all four Rh factor testing events. Year: Event: TP: 2023 2 1 2023 3 1 2024 1 1 2024 2 1 3. Interview with TP #1 on 11/13/2024, at 11:51 am, confirmed the laboratory failed to have PT samples tested by three of four TP who routinely perform Rhesus (Rh) factor slide method testing in the specialty of immunohematology.

D2015

TESTING OF PROFICIENCY TESTING SAMPLES

CFR(s): 493.801(b)(5)(6)

(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's American Proficiency Institute (API) proficiency testing (PT) records and interview with testing personnel (TP) #1; the laboratory failed to retain all documents related to proficiency testing for four of four Rhesus (Rh) factor testing events from the beginning of patient testing, 07/28/2023, to the date of the on-site survey, 11/13/2023. Findings include: 1. Review of four of four API PT events revealed the laboratory failed to retain the following: -Testing records, -Results/scores provided by API, -Documentation of laboratory director review of API scores, -Records of any corrective actions. 2. Interview with TP #1 on 11/13/2024, at 11:51 am, confirmed the laboratory failed to retain all documents related to PT.

<p>D5026</p>	<p>IMMUNOHEMATOLOGY CFR(s): 493.1217</p> <p>If the laboratory provides services in the specialty of Immunohematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1271, and 493.1281 through 493.1299.</p> <p>This CONDITION is not met as evidenced by: Based on review of the laboratory policy and procedure manual, laboratory records, patient test reports, lack of documentation, manufacturer's package insert, and interviews with the laboratory director (LD) and testing personnel (TP) #1; the laboratory failed to establish and follow written policies and procedures to assess TP competency (See D5209); failed to verify performance specifications for the "Blood Grouping Reagent Anti-D blend - ALBAclone" immunohematology Rhesus (Rh) factor slide method testing (See D5421); failed to ensure positive and negative control materials were tested each day of testing (D5449 and D5791); and failed to perform Rhesus (Rh) factor slide method testing as outlined in the manufacturer's package insert (See D5551).</p>
<p>D5209</p>	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory policy and procedure manual, lack of documentation, and interviews with the laboratory director (LD) and testing personnel (TP) #1; the laboratory failed to establish and follow written policies and procedures to assess TP competency for four of four TP performing Rhesus (Rh) factor testing in the specialty of immunohematology. Findings include: 1. Review of the laboratory policy and procedure manual found no policy / procedure in place used to monitor TP competency. 2. Interviews with the LD, via telephone, and TP #1 at 1:29 pm, on 11/13 /2024, confirmed that the laboratory failed to establish and follow written procedures to assess TP competency.</p>
<p>D5421</p>	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory records, lack of documentation, patient test reports, and</p>

interviews with the laboratory director (LD) and testing personnel (TP) #1; the laboratory failed to verify performance specifications for the "Blood Grouping Reagent Anti-D blend - ALBAclone" immunohematology Rhesus (Rh) factor slide method testing prior to the start of patient testing on 07/28/2023, affecting 1,015 patients. Findings include: 1. Review of laboratory records for immunohematology Rh testing found no verification study for immunohematology Rh factor slide method testing was completed using the "Blood Grouping Reagent Anti-D blend" from ALBAclone. 2. A review of patient test logs confirmed Rh factor patient testing had been conducted at the laboratory under the specialty of immunohematology beginning 07/28/2023. 3. Interviews with the LD, via telephone, and TP #1 at 12:46 pm, on 11/13/2024, confirmed that no verification of performance for Rh factor slide method testing using the ALBAclone reagents was performed prior to the start of testing on 07/28/2023. 4. Review of Rh factor patient testing logs revealed 1,015 patients tested from beginning of Rh factor testing, 07/28/2023, to the date of the on-site survey, 11/13/2024.

D5449

CONTROL PROCEDURES
CFR(s): 493.1256(d)(3)(ii)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on review of the laboratory policy and procedure manual, manufacturer's package insert for "Blood Grouping Reagent Anti-D blend - ALBAclone", patient test reports, laboratory quality control (QC) records, lack of documentation, and interview the testing personnel (TP) #1; the laboratory failed to ensure positive and negative control materials were tested each day of testing for Rhesus (Rh) factor slide method testing in the specialty of immunohematology for ten of ten patient reports reviewed, affecting 1,015 patients. Findings include: 1. Review of the laboratory's policy and procedure titled, "Rh Control Testing" revealed the following: a. Under Policy: "Alamo Women's Clinic of Illinois will conduct control tests for Rh factors." b. Under Procedure: "Verified Rh negative and positive specimens will be drawn into a sodium citrate vial on to produce the lab controls The controls will be used to compare the expected results vs. actual results to verify the accuracy of the test methods and equipment." 2. Review of the manufacturer's package insert for "Blood Grouping Reagent Anti-D blend" from ALBAclone stated, under "Quality Control": "Quality control of reagents is essential and should be performed on each day of use and in accordance with local, state and federal regulations." 3. Review of 10 of 10 patient test reports and lack of QC documentation confirmed the laboratory failed to run QC on the dates patient Rh factor testing was performed: Patient #: Report Date: 1 07/28/2023 2 09/30/2023 3 11/10/2023 4 01/17/2024 5 03/28/2024 6 05/02/2024 7 06/29/2024 8 08/09/2024 9 10/19/2024 10 11/08/2024 4. Interview with TP #1 on 11/13/2024, at 11:30 am, confirmed the laboratory failed to ensure positive and negative control material were tested each day of testing for Rhesus (Rh) factor in the specialty of immunohematology. 5. Review of Rh factor patient testing logs revealed 1,015 patients tested from beginning of Rh factor testing, 07/28/2023, to the date of the on-site survey, 11/13/2024.

D5551

IMMUNOHEMATOLOGY

CFR(s): 493.1271(a)(f)

(a) Patient testing. (a)(1) The laboratory must perform ABO grouping, D (Rho) typing, unexpected antibody detection, antibody identification, and compatibility testing by following the manufacturer's instructions, if provided, and as applicable, 21 CFR 606.151(a) through (e). (a)(2) The laboratory must determine ABO group by concurrently testing unknown red cells with, at a minimum, anti-A and anti-B grouping reagents. For confirmation of ABO group, the unknown serum must be tested with known A1 and B red cells. (a)(3) The laboratory must determine the D (Rho) type by testing unknown red cells with anti-D (anti-Rho) blood typing reagent. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:

Based on review of laboratory's policies and procedures, manufacturer's package insert for "Blood Grouping Reagent Anti-D blend - ALBAclone", and interview with testing personnel (TP) #1; the laboratory failed to perform Rhesus (Rh) factor testing as outlined in the manufacturer's package insert for the specialty of immunohematology from the start of testing, 07/28/2023, to the date of the on-site survey, 11/13/2024, affecting 1,015 patient test results. Findings include: 1. Review of the manufacturer's package insert for "Blood Grouping Reagent Anti-D blend - ALBAclone (Ref Z041U)" revealed, under "Slide Technique": "1. Add 1 drop of blood grouping reagent to an appropriately prepared area of a glass slide e.g. a wax pencil oval. "2. Add 1 drop of whole blood [WB] or 1 drop of red blood cells suspended to approximately 30-45% in group homologous plasma/serum. "3. Mix by rocking the slide for approximately 30 seconds and incubate the test at 18-24 C [64.4 - 75.2 F] for 5 minutes with occasional mixing." 2. Review of the laboratory's policy and procedure titled, "Rh Factor Procedure", revealed, under "Procedure", " ...Place two droplets of patients blood on glass slide. Place slide on the well heated lamp then place one drop of the anti-D serum on blood sample. Shift heated view box back and forth to further mix serum and patient blood samples (do not elapse 2 minutes with blood on heat lamp)." 3. Review of the laboratory's policy and procedure titled, "Rh Control Testing", revealed, under "Procedure": " ...2. Using a pipette two drops of the Rh-positive control sample will be mixed with two drops of the Anti-D reagent on a single uncontaminated slide. "3. The solution is gently swiveled on a preheated (40-50 degrees C [104 - 122 degrees F]) thermolyne view box for 2 minutes and the results are then interpreted. "4. The same process is conducted with the Rh-negative control sample." 4. Interview with TP #1 on 11/13/2024, at 12:45 pm, confirmed the laboratory failed to perform Rhesus (Rh) factor testing as outlined in the manufacturer's package insert in the following ways: Manufacturer: Laboratory Procedure: 1 drop of WB 2 drops of WB 18 - 24 degrees C 40 - 50 degrees C 5. Review of Rh factor patient testing logs revealed 1,015 patients tested from beginning of Rh factor testing, 07/28/2023, to the date of the on-site survey, 11/13/2024.

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT

CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based on review of laboratory policies and procedures, manufacturer's package insert for "Blood Grouping Reagent Anti-D blend - ALBAclone", lack of documentation, laboratory records, and interview with testing personnel (TP) #1; the laboratory quality assessment (QA) process failed to identify and correct that positive and negative control materials were not being tested each day of testing in five of five QA reports reviewed for Rhesus (Rh) factor in the specialty of immunohematology from the beginning of testing, 07/28/2023, to the date of the on-site survey, 11/13/2024, affecting 1,015 patients. Findings include: 1. Review of the laboratory's policy and procedure titled, "Rh Control Testing", manufacturer's package insert for "Blood Grouping Reagent Anti-D blend - ALBAclone", and lack of quality control (QC) documentation revealed the laboratory failed to ensure positive and negative control materials were tested each day of testing for Rhesus (Rh) factor in the specialty of immunohematology prior to reporting patient test results (See D5449). 2. Review of five of five "Quarterly Quality Assurance Committee Report" documents revealed, under "Indicators and Measurements": "2 a. Control log b. Temperature log c. Control log" 3. Review of five of five "Quarterly Quality Assurance Committee Report" documents revealed a lack of documentation of review of control logs: QA Date: Control Logs reviewed: 09/28/2024 No 06/28/2024 No 04/10/2024 No 12/07/2023 No 08/23/2023 No 4. Interview with TP #1 on 11/13/2024, at 11:51 am, confirmed the laboratory's QA process failed to identify and correct that positive and negative control materials were not being tested each day of testing for Rhesus (Rh) factor. 5. Review of Rh factor patient testing logs revealed 1,015 patients tested from beginning of Rh factor testing, 07/28/2023, to the date of the on-site survey, 11/13/2024.

D6076

LABORATORY DIRECTOR
CFR(s): 493.1441

The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.

This CONDITION is not met as evidenced by:

Based on review of the laboratory policy and procedure manual, manufacturer's package insert for "Blood Grouping Reagent Anti-D blend - ALBAclone", American Proficiency Institute (API) proficiency testing (PT) records, laboratory records, the Food and Drug Administration (FDA)'s laboratory test complexity database, CMS-209 (Laboratory Personnel Report), laboratory personnel records, lack of documentation, patient test reports, and interviews with the laboratory director (LD) and testing personnel (TP) #1; the LD failed to meet the qualifications for a high complexity laboratory testing Rhesus (Rh) factor slide method using the ALBAclone "Blood Grouping Reagent Anti-D blend" (See D6078); the LD failed to ensure verification procedures were performed to determine the performance characteristics of the Rhesus (Rh) factor slide method testing (See D6086); the LD failed to ensure the laboratory testing personnel are performing Rhesus (Rh) factor testing as outlined in the manufacturer's package insert (See D6087); the LD failed to ensure review of four of four PT reports received from API (See D6091); the LD failed to ensure positive and negative control materials were tested each day of testing (See D6093); and the LD failed to ensure three of four TP had the appropriate education for

performing Rhesus (Rh) factor slide method testing in the specialty of immunohematology (See D6102).

D6078

LABORATORY DIRECTOR QUALIFICATIONS

CFR(s): 493.1443

The laboratory director must be qualified to manage and direct the laboratory personnel and performance of high complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R. (a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory director must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2) Be a doctor of medicine, a doctor of osteopathy or doctor of podiatric medicine licensed to practice medicine, osteopathy or podiatry in the State in which the laboratory is located; and (b)(2)(i) Have at least one year of laboratory training during medical residency (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or (b)(2)(ii) Have at least 2 years of experience directing or supervising high complexity testing; or (b)(3) Hold an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution and-- (b)(3)(i) Be certified and continue to be certified by a board approved by HHS; or (b)(3)(ii) Before February 24, 2003, must have served or be serving as director of a laboratory performing high complexity testing and must have at least-- (b)(3)(ii)(A) Two years of laboratory training or experience, or both; and (b)(3)(ii)(B) Two years of laboratory experience directing or supervising high complexity testing. (b)(4) Be serving as a laboratory director and must have previously qualified or could have qualified as a laboratory director under regulations at 42 CFR 493.1415, published March 14, 1990 at 55 FR 9538, on or before February 28, 1992; or (b)(5) On or before February 28, 1992, be qualified under State law to direct a laboratory in the State in which the laboratory is located; or (b)(6) For the subspecialty of oral pathology, be certified by the American Board of Oral Pathology, American Board of Pathology, the American Osteopathic Board of Pathology, or possess qualifications that are equivalent to those required for certification.

This STANDARD is not met as evidenced by:

Based on review of laboratory policy and procedure manual, the Food and Drug Administration (FDA)'s laboratory test complexity database, laboratory personnel records, and interviews with the laboratory director (LD) and testing personnel (TP) #1; the LD failed to meet the qualifications for a high complexity laboratory testing Rhesus (Rh) factor slide method using the ALBAclone "Blood Grouping Reagent Anti-D blend" in the specialty of immunohematology. Findings include: 1. Review of the laboratory's policy and procedure manual found the laboratory used "Blood Grouping Reagent Anti-D blend - ALBAclone" for typing the patient's Rh factor in the specialty of immunohematology. 2. Review of the FDA's laboratory test complexity database found that the use of "ALBAclone - Anti-D blend Blood Grouping Reagent" is categorized as a high complexity testing methodology. 3. Review of the laboratory's personnel records found that the LD failed to qualify as a high complexity laboratory LD for the specialty of immunohematology. 4. Interviews

with the LD, via telephone, and TP #1 at 1:29 pm, on 11/13/2024, confirmed that the LD did not qualify for high complexity Rh factor testing.

D6086

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(3)(ii)

The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method.

This STANDARD is not met as evidenced by:

Based on review of laboratory records, lack of documentation, patient test reports, and interviews with the laboratory director (LD) and testing personnel (TP) #1; the LD failed to ensure verification procedures were performed to determine the performance characteristics of the Rhesus (Rh) factor slide method testing prior to patient testing, affecting 1,015 patient results (See D5421).

D6087

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(3)(iii)

The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results.

This STANDARD is not met as evidenced by:

Based on review of laboratory's policies and procedures, manufacturer's package insert for "Blood Grouping Reagent Anti-D blend - ALBAclone", and interview with testing personnel (TP) #1; the laboratory director failed to ensure four of four laboratory TP are performing Rhesus (Rh) factor testing as outlined in the manufacturer's package insert for the specialty of immunohematology (See D5551).

D6091

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(4)(iii)

The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action.

This STANDARD is not met as evidenced by:

Based on review of laboratory policies and procedures, laboratory records, American Proficiency Institute (API) proficiency testing (PT) records, and interviews with the laboratory director and testing personnel (TP) #1; the laboratory director (LD) failed to ensure review of four of four PT reports received for Rhesus (Rh) factor testing in the specialty of immunohematology from the start of testing, 07/28/2023, to the date of the on-site survey, 11/13/2024. Findings include: 1. Review of laboratory policies and procedure revealed the policy titled, "Investigation of Proficiency Failures", which stated, under "Procedure": "Upon arrival of test scores from the American Proficiency Institute the Lab Director and Lab Technician (responsible for taking scheduled proficiency test) will hold a meeting ..., the lab director and Lab technician will discuss steps taken during the initial test, probable cause for failure and how to correct the problem and prevent recurrence. A review will be performed each time

by the Lab Director when there is a failing score as well as a passing score. The Lab Director and the Lab technician will sign and date worksheet." 2. Review of the laboratory's API PT records for immunohematology Rh testing, all PT events from the beginning of patient testing, 07/28/2023, to the date of the on-site survey, 11/13/2023, revealed the LD failed to review PT scores received from API. Year: Event: Scores Received: LD review: 2023 2 09/07/2023 No 2023 3 01/02/2024 No 2024 1 04/25/2024 No 2024 2 08/29/2024 No 3. Interviews with the LD, via telephone, and TP #1 at 1:29 pm, on 11/13/2024, confirmed that the LD failed to ensure review of four of four PT reports received for Rhesus (Rh) factor testing in the specialty of immunohematology.

D6093

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:
Based on review of the laboratory policy and procedure manual, manufacturer's package insert for "Blood Grouping Reagent Anti-D blend - ALBAclone", patient test reports, laboratory quality control (QC) records, lack of documentation, and interview the testing personnel (TP) #1; the laboratory director failed to ensure positive and negative control materials were tested each day of testing for Rhesus (Rh) factor slide method testing in the specialty of immunohematology, affecting 1,015 patient results (See D5449).

D6102

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(12)

The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:
Based on review of the CMS-209 (Laboratory Personnel Report), laboratory personnel records, lack of documentation, and interviews with the laboratory director and testing personnel (TP) #1; the laboratory director failed to ensure three of four testing personnel (TP) had the appropriate education for performing Rhesus (Rh) factor slide method testing in the specialty of immunohematology prior to reporting patient results. Findings include: 1. Review of the CMS-209 (Laboratory Personnel Report) revealed four TP performing Rh factor slide method testing in the specialty of immunohematology. 2. Review of laboratory personnel records revealed three of four TP (TP #1, TP #3, and TP #4) lacked the qualifications to perform high complexity testing (See D6170). 3. Interviews with the LD, via telephone, and TP #1 at 1:29 pm, on 11/13/2024, confirmed that three of four authorized TP failed to have the appropriate education for performing Rhesus (Rh) factor slide method testing in the specialty of immunohematology.

D6108

LABORATORY TECHNICAL SUPERVISOR

CFR(s): 493.1447

The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart.

This CONDITION is not met as evidenced by:

Based on review of laboratory policies and procedures, the Food and Drug Administration (FDA)'s laboratory test complexity database, laboratory personnel and competency records, and interviews with the laboratory director (LD) and testing personnel (TP) #1; one of one technical supervisor (TS) failed to meet the qualifications for a high complexity laboratory testing Rhesus (Rh) factor in the specialty of immunohematology (See D6109) and failed to evaluate and document assessment of test performance through previously analyzed specimens (See D6125) and problem solving skills (See D6126) as part of the competency assessment for four of four TP performing Rhesus (Rh) factor slide method using the ALBAclone "Blood Grouping Reagent Anti-D blend" in the specialty of immunohematology.

D6109

TECHNICAL SUPERVISOR QUALIFICATIONS

CFR(s): 493.1449

The laboratory must employ one or more individuals who are qualified by education and either training or experience to provide technical supervision for each of the specialties and subspecialties of service in which the laboratory performs high complexity tests or procedures. The director of a laboratory performing high complexity testing may function as the technical supervisor provided he or she meets the qualifications specified in this section.

This STANDARD is not met as evidenced by:

Based on review of laboratory policies and procedures, the Food and Drug Administration (FDA)'s laboratory test complexity database, laboratory personnel records, and interviews with the laboratory director (LD) and testing personnel (TP) #1; one of one technical supervisor (TS) failed to meet the qualifications for a high complexity laboratory testing Rhesus (Rh) factor slide method using the ALBAclone "Blood Grouping Reagent Anti-D blend" in the specialty of immunohematology. Findings include: 1. Review of the laboratory's policy and procedure manual and the FDA's laboratory test complexity database, the laboratory was found to be performing high complexity Rh factor testing (See D6078). 2. Review of the laboratory's personnel records found that one of one TS (TS #1) failed to qualify as a high complexity laboratory TS for the specialty of immunohematology. 3. Interviews with the LD, via telephone, and TP #1 at 1:29 pm, on 11/13/2024, confirmed that TS #1 did not qualify for high complexity Rh factor testing.

D6125

TECHNICAL SUPERVISOR RESPONSIBILITIES

CFR(s): 493.1451(b)(8)(v)

The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples.

	<p>This STANDARD is not met as evidenced by: Based on review of laboratory personnel competency records, lack of documentation, and interview with testing personnel (TP) #1; the technical supervisor (TS) failed to evaluate and document assessment of test performance through previously analyzed specimens as part of the competency assessment for four of four TP performing Rhesus (Rh) factor in the specialty of immunohematology. Findings include: 1. Review of competency assessment records for four of four TP found the assessments failed to include assessment of test performance through previously analyzed specimens for immunohematology testing from 2022, through the date of the on-site survey, 11/13/2024. 2. Interview with TP #1 at 1:29 pm, on 11/13/2024, confirmed that competency assessments of TP failed to assessment of test performance through previously analyzed specimens for Rh factor testing.</p>
D6126	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(vi)</p> <p>The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of problem solving skills.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory personnel competency records, lack of documentation, and interview with testing personnel (TP) #1; the technical supervisor (TS) failed to evaluate and document problem solving skills as part of the competency assessment for four of four TP performing Rhesus (Rh) factor in the specialty of immunohematology. Findings include: 1. Review of competency assessment records for four of four TP found the assessments failed to include an assessment of problem solving skills for immunohematology testing from 2022, through the date of the on-site survey, 11/13/2024. 2. Interview with TP #1 at 1:29 pm, on 11/13/2024, confirmed that competency assessments of TP failed to evaluate and document problem solving skills for Rh factor testing.</p>
D6141	<p>GENERAL SUPERVISOR CFR(s): 493.1459</p> <p>The laboratory must have one or more general supervisors who are qualified under 493.1461 of this subpart to provide general supervision in accordance with 493.1463 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on review of laboratory policies and procedures, the Food and Drug Administration's laboratory test complexity database, laboratory personnel records, and interviews with the laboratory director and testing personnel (TP) #1; one of one general supervisor failed to meet the qualifications for a high complexity laboratory testing Rhesus (Rh) factor slide method using the ALBAclone "Blood Grouping Reagent Anti-D blend" in the specialty of immunohematology (See D6142).</p>
D6142	<p>GENERAL SUPERVISOR QUALIFICATIONS CFR(s): 493.1461</p> <p>The laboratory must have one or more general supervisors who, under the direction of</p>

the laboratory director and supervision of the technical supervisor, provides day-to-day supervision of testing personnel and reporting of test results. In the absence of the director and technical supervisor, the general supervisor must be responsible for the proper performance of all laboratory procedures and reporting of test results.

This STANDARD is not met as evidenced by:

Based on review of laboratory policies and procedures, the Food and Drug Administration (FDA)'s laboratory test complexity database, laboratory personnel records, and interviews with the laboratory director (LD) and testing personnel (TP) #1; one of one general supervisor (GS) failed to meet the qualifications for a high complexity laboratory testing Rhesus (Rh) factor slide method using the ALBAclone "Blood Grouping Reagent Anti-D blend" in the specialty of immunohematology. . Findings include: 1. Review of the laboratory's policy and procedure manual and the FDA's laboratory test complexity database, the laboratory was found to be performing high complexity Rh factor testing (See D6078). 2. Review of the laboratory's personnel records found that one of one GS (GS #1) failed to qualify as a high complexity laboratory GS for the specialty of immunohematology. 3. Interviews with the LD, via telephone, and TP #1 at 1:29 pm, on 11/13/2024, confirmed that GS #1 did not qualify for high complexity Rh factor testing.

D6168

TESTING PERSONNEL

CFR(s): 493.1487

The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493.1495 of this subpart for the volume and complexity of testing performed.

This CONDITION is not met as evidenced by:

Based on review of laboratory policies and procedures, the Food and Drug Administration's laboratory test complexity database, laboratory personnel records, and interviews with the laboratory director and testing personnel (TP) #1; three of four TP failed to meet the qualifications for a high complexity laboratory testing Rhesus (Rh) factor slide method using the ALBAclone "Blood Grouping Reagent Anti-D blend" in the specialty of immunohematology (See D6170).

D6170

TESTING PERSONNEL QUALIFICATIONS

CFR(s): 493.1489(a)

Each individual performing high complexity testing must possess a current license issued by the State in which the laboratory is located, if such licensing is required.

This STANDARD is not met as evidenced by:

Based on review of laboratory policies and procedures, the Food and Drug Administration (FDA)'s laboratory test complexity database, laboratory personnel records, and interviews with the laboratory director (LD) and testing personnel (TP) #1; three of four TP failed to meet the qualifications for a high complexity laboratory testing Rhesus (Rh) factor slide method using the ALBAclone "Blood Grouping Reagent Anti-D blend" in the specialty of immunohematology. Findings include: 1. Review of the laboratory's policy and procedure manual and the FDA's laboratory test complexity database, the laboratory was found to be performing high complexity Rh

factor testing (See D6078). 2. Review of the laboratory's personnel records found that three of four TP (TP #1, TP #3, and TP #4) failed to qualify as a high complexity laboratory TP for the specialty of immunohematology. 3. Interviews with the LD, via telephone, and TP #1 at 1:29 pm, on 11/13/2024, confirmed that three of four TP did not qualify for high complexity Rh factor testing.