

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D2279548	(X3) Date Survey Completed 10/11/2024
Name of Provider or Supplier Equity Clinic	Street Address, City, State 2111 W Park Court, Champaign, 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
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 procedures, American Proficiency institute (API) proficiency testing (PT) records, federal Certification and Survey Provider Enhanced Reports (CASPER) 0096D and interview with the laboratory director (LD); the laboratory failed to authorize the release of PT data to US department of Health and Human services (HHS) (See D2005); and the laboratory failed to test PT samples the same number of times as patient samples for five of five PT events between 2023 and 2024 for the specialty of Immunohematology (See D2010).</p>
D2005	<p>ENROLLMENT CFR(s): 493.801(a)(4)</p> <p>Authorize the proficiency testing program to release to HHS all data required to-- (i) Determine the laboratory's compliance with this subpart; and (ii) Make PT results available to the public as required in section 353(f)(3)(F) of the Public Health Service Act.</p>

This STANDARD is not met as evidenced by:
Based on review of laboratory American Proficiency institute (API) proficiency testing (PT) records, federal Certification And Survey Provider Enhanced Reports (CASPER) 0096D and interview with the laboratory director (LD), the laboratory failed to authorize the release of PT data to United States department of Health and Human Services (HHS) for Rhesus Factor Anti-D for five of five PT events in 2023 to 2024. Findings Include: 1. API PT results for the regulated analyte, Rhesus Factor Anti-D, were not released to HHS. The five unreleased PT events were: A. API 2024 immunology/immunohematology second event B. API 2024 immunology /immunohematology first event C. API 2023 immunology/immunohematology third event D. API 2023 immunology/immunohematology second event E. API 2023 immunology/immunohematology first event 2. PT scores were not found in the federal CASPER Report 0096D for the five PT events identified above. 3. During the survey on 10-11-2024 at 11:50 am, the LD confirmed the laboratory failed to authorize API to release PT results to HHS.

D2010

TESTING OF PROFICIENCY TESTING SAMPLES
CFR(s): 493.801(b)(2)

The laboratory must test samples the same number of times that it routinely tests patient samples.

This STANDARD is not met as evidenced by:
Based on review of laboratory procedures, American Proficiency Institute (API) proficiency testing (PT) records, and interview with laboratory director (LD), the laboratory failed to test PT samples the same number of times as patient samples for five of five PT events between 2023 and 2024 for the specialty of Immunohematology Rhesus Factor testing. Findings Include: 1. Review of the laboratory procedure, "Rh status testing", in the section titled "VII. Proficiency Testing" stated "3. Instructions provided for proficiency testing by external organization should be strictly followed." 2. Review of API PT records identified a document "RH slide test" with a section titled "testing instructions" stated "2. Test the samples as you would a patient in accordance with the manufacturer's instructions." 3. Review of API attestation statements found documentation of the PT samples being performed in duplicate by different testing personnel (TP) prior to the PT event submission deadline for five of five PT events reviewed. F.API 2024 second event attestation statement indicated that TP #2, TP #3, TP #4, TP #5, TP #6, and TP #8 tested samples: RH-06, RH-07, RH-08, RH-09, and RH-10 on 08-02-24 and/or 08-10-24. The API submission deadline for immunohematology 2024 2nd event was 08-14-24. G.API 2024 first event attestation statement indicated that TP #2, TP #4, TP #5, and seven TP no longer employed (NLE) tested samples: RH-01, RH-02, RH-03, RH-04, and RH-05 on 03-29-24 and/or 03-30-24. The API submission deadline for immunohematology 2024 1st event was 04-10-24. H.API 2023 third event attestation statement indicated that TP #1, TP #2, TP #8 and five TP NLE tested samples: RH-11, RH-12, RH-13, RH-14, and RH-15 in December of 2023. The API submission deadline for immunohematology 2023 3rd event was 12-13-24. I.API 2023 second event attestation statement indicated that TP #2, TP #7, TP #8, and three TP NLE tested samples: RH-06, RH-07, RH-08, RH-09, and RH-10 on 08-13-23 and/or 08-20-23. The API submission deadline for immunohematology 2023 2nd event was 08-23-24. J. API 2023 first event attestation statement indicated that TP #1, TP #2, TP #8, and five TP NLE tested samples: RH-06, RH-07, RH-08, RH-09, and RH-10 on 04-11-23. The API submission deadline for immunohematology 1st event was 04-12-23. 3. Interview

with LD on survey date 10-11-2024, at 11:50 am, confirmed multiple TP had analyzed the PT samples prior to the submission deadline for the five PT events identified in 2023 through 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 policies and procedures, manufacturer's package inserts, direct observation, and interview with testing personnel (TP) #1 and TP # 3, the laboratory failed to perform Rhesus (Rh) factor testing as outlined in the manufacturer's package insert for the specialty of immunohematology from 05-05-2023 to 10-06-2024 affecting 433 patient test results. Findings include: 1. Review of the manufacturer's package insert for "Blood Grouping Reagent Anti-D blend ALBAclone (human/Murine monoclonal IgM/IgG Blend) For Slide and Tube Techniques" (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 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 for 5 minutes with occasional mixing." 2. Direct observation on 10-11-24 at 10:23 of TP #3 performing Rh factor testing revealed TP #3 lancing the patient's fingertip, then pressing the patient's finger on the glass slide to collect blood sample. Next TP #3 added one drop of two different reagents to the blood sample before mixing with a clean mixing device and placing the slide with sample on the Rh view box with the incubation temperature at 37 Celsius and setting a timer for three minutes. A. TP# 3 failed to adhere to the following steps of the Rh Slide technique, as specified by the manufacturer's instructions: i.Add blood grouping reagent to slide first. ii.Incubate at the temperature of 18-24 Celsius. iii.Incubate for a period of five minutes. 3. Interview with TP #3 on 10-11-2024, at 10:53 AM, confirmed that the sample was added to the slide first then one drop of each reagent was directly mixed on the blood sample on the slide. Reagent one: ALBAcheck-BGS Monoclonal control Ref: Z271U Reagent two: Blood Grouping Reagent Anti-D blend Albaclone (Human/Murine Monoclonal IgM/IgG Blend) for slide and tube techniques Ref: Z041U 4. Interview with TP #1 on 10-11-24, at 11:03 AM, during a demonstration of Rh factor testing technique, confirmed the testing technique was to add two drops of blood to the slide one for the sample and one for control. 5. Review of patient test records fund 433 patient tests for Rh factor were performed from 05-05-2023 to 10-06-2024.

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 policy and procedures, manufacturer's instructions, and interview with laboratory director (LD), the laboratory quality assessment process failed to identify and correct that manufacturer's guidance for addition of reagents, incubation temperature, and incubation time was not followed during analytical performance of Rhesus (Rh) factor testing in 2023 through the date of survey 10-11-2024. Findings include: 1. Review of the Laboratory procedure titled "C.

Manufacturer's Guidance", stated "All test must be performed in accordance with the manufacturer's guidelines/instructions unless stated otherwise in this manual." 2. Review of manufacturer's instructions for "Blood Grouping Reagent Anti-D blend ALBAclone (human/Murine monoclonal IgM/IgG Blend) For Slide and Tube Techniques" (Ref Z041U) revealed, under section titled "Slide technique", which stated "3. mix by rocking the slide for approximately 30 seconds and incubate the test at 18-24 C for 5 minutes with occasional mixing. 3. Review of the Laboratory procedure titled "5. Rh Status Testing", which states "2. During specimen testing gently rock the view box back and forth for 3 minutes before interpreting the results. 3. Temperature for the view box must be 37-39 degrees Celsius before slides are placed on the view box." 4. Interview with LD at 11:50, on 10-11-24 the LD confirmed that laboratory testing personnel were not performing Rh factor testing in accordance with the manufacturer's guidance.

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 laboratory policies and procedures, manufacturer's package insert, laboratory records, American Proficiency Institute (API) proficiency testing (PT) records, the Food and Drug Administration (FDA)'s laboratory test complexity database, the CMS-209 (Laboratory Personnel Report), laboratory personnel records, lack of documentation, and interviews with the laboratory director (LD) and testing personnel (TP); the LD failed to meet the qualification requirements as a high complexity LD (See D6078); the LD failed to ensure that TP was performing Rhesus (Rh) factor testing as outlined in the laboratory's procedure or as outlined in the manufacturer's package insert (See D6087); and the LD failed to ensure TP had the appropriate education for performing high complexity Rhesus (Rh) factor testing (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 policies and procedures, the Food and Drug Administration (FDA)'s laboratory test complexity database, laboratory personnel records, and interviews with the laboratory director (LD), the LD failed to meet the qualifications for a high complexity Rhesus (Rh) factor testing in the specialty of immunohematology. Findings include: 1. Review of the laboratory's policy and procedure manual found the laboratory used "ALBAclone Anti-D Blood Grouping Reagent" for Rh factor testing in the specialty of immunohematology. 2. Review of the FDA's laboratory test complexity database found that the use of "ALBAclone Anti-D Blood Grouping Reagent" was 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 director. 4. Interview with the LD, at 11:50 am, on 10/11/2024, confirmed the LD failed to qualify as a high complexity laboratory director.

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 policies and procedures, manufacturer's package inserts, and interview with testing personnel (TP) #1 and TP #3; the laboratory director failed to ensure that laboratory TP are performing Rhesus (Rh) factor testing as outlined in the manufacturer's package insert for the specialty of immunohematology (See D5551) and the laboratory quality assessment process failed to identify and correct that manufacturers guidance for addition of reagents, incubation temperature, and incubation time was not being followed during analytical performance of Rhesus (Rh) factor testing in 2023 through the date of survey 10-11-2024 (See D5791).

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 laboratory policies and procedures, the CMS-209 (Laboratory Personnel Report), laboratory personnel records, lack of documentation, and interview with the laboratory director (LD), the LD failed to ensure eight of eight testing personnel (TP) had the appropriate education to perform high complexity Rhesus (Rh) factor testing in the specialty of immunohematology prior to reporting patient results. Findings include: 1. Review of the laboratory's policy and procedure manual revealed the procedure titled, "b. Laboratory roles:", which stated, under "i. Laboratory director", " ...4. Sufficient numbers of appropriately educated, experienced, and/or trained personnel who provide appropriate consultation, properly supervise, and accurately perform tests ..." 2. Review of the CMS-209 (Laboratory Personnel Report) revealed eight TP performing Rh factor testing in the specialty of immunohematology. 3. Review of laboratory personnel records revealed TP #1, TP #2, TP #3, TP #4, TP #5, TP #6, TP #7 and TP #8 lacked the qualifications to perform high complexity testing. See D6170. 4. Interview with the laboratory director at 11:50 am, on 10/11/2024, confirmed eight of eight TP failed to meet the educational requirements to perform high complexity immunohematology Rh factor testing.

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

records, and interview with the laboratory director (LD), one of one technical supervisor's (TS) failed to meet the qualifications for high complexity Rhesus (Rh) factor testing in the specialty of immunohematology (See D6109).

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), one of one technical supervisor's (TS) failed to meet the qualifications for high complexity Rhesus (Rh) factor testing 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. Interview with the LD, at 11:50 am, on 10/11 /2024, confirmed TS #1 failed to qualify as a TS for immunohematology.

D6141

GENERAL SUPERVISOR
CFR(s): 493.1459

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.

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 records, and interviews with the laboratory director (LD), one of one general supervisor's (GS) failed to meet the qualifications for high complexity Rhesus (Rh) factor testing in the specialty of immunohematology (See D6142).

D6142

GENERAL SUPERVISOR QUALIFICATIONS
CFR(s): 493.1461

The laboratory must have one or more general supervisors who, under the direction of 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.

	<p>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), one of one general supervisor's (GS) failed to meet the qualifications for high complexity Rhesus (Rh) factor testing 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. Interview with the LD, at 11:50 am, on 10/11/2024, confirmed GS #1 failed to qualify as a high complexity GS for immunohematology.</p>
<p>D6168</p>	<p>TESTING PERSONNEL CFR(s): 493.1487</p> <p>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.</p> <p>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 records, and interviews with the laboratory director (LD); eight of eight testing personnel (TP) failed to meet the qualifications for high complexity Rhesus (Rh) factor testing in the specialty of immunohematology (See D6170).</p>
<p>D6170</p>	<p>TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(a)</p> <p>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.</p> <p>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), eight of eight testing personnel (TP) failed to meet the qualifications for high complexity Rhesus (Rh) factor testing 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 eight of eight TP (TP#1,2,3,4,5,6,7, and 8) failed to qualify as a high complexity TP for the specialty of immunohematology. 3. Interview with the LD at 11:50 am, on 10/11/2024, confirmed eight of eight laboratory TP did not qualify for high complexity testing.</p>