

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 14D0412257	<b>(X3) Date Survey Completed</b> 09/09/2024
<b>Name of Provider or Supplier</b> Access Healthcare Center	<b>Street Address, City, State</b> 110 S River Rd, Des Plaines, IL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5551</b>	<p>IMMUNOHEMATOLOGY CFR(s): 493.1271(a)(f)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, manufacturer's package insert, and interview with testing personnel (TP) #1; the laboratory failed to perform Rhesus (Rh) factor testing as outlined in the laboratory's procedure or as outlined in the manufacturer's package insert for the specialty of immunohematology. Findings include: 1. Review of the laboratory's policy and procedure manual revealed the procedure, "Point-of-Care Rh Factor Testing", which stated, under "Tube Technique - Immediate Spin", " ....4. Mix the contents of the test tube and centrifuge at [approximately] 3400 [rotations per minute] rpm for 10-15 seconds." 2. Review of the manufacturer's package insert revealed, under "Tube Technique - Immediate Spin", " ....4. Mix the contents of the test tube and centrifuge. NOTE: Suggested centrifugation: [approximately 3400 rpm] for 10 seconds ...." 3. Interview with TP #1 on 09/05/2024, at 1:48 PM, during a demonstration of Rh factor testing technique stated that the contents of the test tube were spun for 30 seconds.</p>
<b>D6076</b>	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), laboratory representative, and testing personnel (TP) #1; the laboratory director (LD) failed to provide overall management and direction to the laboratory performing high complexity Rhesus (Rh) factor testing in the specialty of immunohematology. Findings include: 1. The LD failed to meet the qualification requirements as a high complexity LD. See D6078. 2. The LD failed to ensure one of one TP was competent to perform high complexity Rhesus (Rh) factor testing. See D6079. 3. The LD failed to ensure that one of one 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. 4. The LD failed to ensure no inter-laboratory communications pertaining to the results of PT samples took place for five of six PT events reviewed. See D6089. 5. The LD failed to ensure TP had the appropriate education and received the appropriate training 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) and laboratory representative; the LD failed to meet the qualifications for a high complexity laboratory testing Rhesus (Rh) factor 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 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 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 director. 4. Interviews with the LD, via telephone, and the laboratory representative at 10:15 am, on 09/05/2024, confirmed that the LD did not qualify as a high complexity laboratory director.

**D6079**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(a)(b)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reappoints performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

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 representative; the laboratory director failed to ensure one of one testing personnel (TP) performing Rhesus (Rh) factor testing in the specialty of immunohematology was competent to perform the testing prior to reporting patient results. Findings include: 1. Review of the laboratory's policy and procedure manual revealed the procedure entitled, "Personnel", which stated, under "Position: Laboratory Director", "Personnel Duties ....Ensure that prior to testing patient specimens, all personnel have the appropriate education and experience, and receive the appropriate training for the type and complexity of services offered, and have demonstrated that they can perform all testing operations reliably to provide and

report accurate results". 2. Review of the CMS-209 (Laboratory Personnel Report) revealed one TP performing Rh factor testing in the specialty of immunohematology. 3. Review of laboratory personnel records revealed a lack of documentation of training and competency records, as required above, for one of one TP (TP #1) performing Rh factor testing. 4. Interview with the laboratory representative at 12:35 pm, on 09/05/2024, confirmed no training or competency documentation was available for one of one TP performing immunohematology testing.

**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 insert, and interview with testing personnel (TP) #1; the laboratory director failed to ensure that laboratory TP are performing Rhesus (Rh) factor testing as outlined in the laboratory's procedure or as outlined in the manufacturer's package insert for the specialty of immunohematology. See D5551.

**D6089**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(e)(4)(i)

The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part.

This STANDARD is not met as evidenced by:

Based on review of the laboratory policies and procedures, laboratory records, American Proficiency Institute (API) proficiency testing (PT) records, and interviews with the laboratory representative and testing personnel (TP) #1; the laboratory director failed to ensure no inter-laboratory communications pertaining to the results of PT samples took place for five of six PT events reviewed for the years of 2022 through 2024. See D2011.

**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 representative; the laboratory director failed to ensure one of one testing personnel (TP) had the appropriate education and received the appropriate training for performing 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 entitled, "Personnel", which stated, under "Position: Laboratory Director", "Personnel Duties ... Ensure that prior to testing patient specimens, all personnel have the appropriate education and experience, and receive the appropriate training for the type and complexity of services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results". 2. Review of the CMS-209 (Laboratory Personnel Report) revealed one TP performing Rh factor testing in the specialty of immunohematology. 3. Review of laboratory personnel records revealed TP #1 lacked the qualifications to perform high complexity testing. See D6170. 4. Review of laboratory personnel records revealed a lack of documentation of training records for one of one TP performing Rh factor testing. See D6079. 5. Interview with the laboratory representative at 12:35 pm, on 09/05/2024, confirmed no training documentation was available for one of one TP (TP #1) performing immunohematology 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 interviews with the laboratory director (LD) and laboratory representative; 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.

**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 laboratory representative; 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. 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

	<p>qualify as a high complexity laboratory TS for the specialty of immunohematology. 3. Interviews with the LD, via telephone, and the laboratory representative at 10:15 am, on 09/05/2024, confirmed that TS #1 did not qualify for a high complexity laboratory.</p>
<p><b>D6141</b></p>	<p><b>GENERAL SUPERVISOR</b> 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 (FDA)'s laboratory test complexity database, laboratory personnel records, and interviews with the laboratory director (LD) and laboratory representative; one of one general supervisor (GS) failed to meet the qualifications for a high complexity laboratory testing Rhesus (Rh) factor in the specialty of immunohematology. See D6142.</p>
<p><b>D6142</b></p>	<p><b>GENERAL SUPERVISOR QUALIFICATIONS</b> CFR(s): 493.1461</p> <p>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> <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) and laboratory representative; one of one general supervisor (GS) failed to meet the qualifications for a high complexity laboratory testing Rhesus (Rh) factor 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 the laboratory representative at 10:15 am, on 09/05/2024, confirmed that GS #1 did not qualify for a high complexity laboratory.</p>
<p><b>D6168</b></p>	<p><b>TESTING PERSONNEL</b> 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:</p>

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 laboratory representative; one of one testing personnel (TP) failed to meet the qualifications for a high complexity laboratory testing Rhesus (Rh) factor 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 laboratory representative; one of one testing personnel (TP) failed to meet the qualifications for a high complexity laboratory testing Rhesus (Rh) factor 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 TP (TP #1) failed to qualify as a high complexity laboratory TP for the specialty of immunohematology. 3. Interviews with the LD, via telephone, and the laboratory representative at 10:15 am, on 09/05/2024, confirmed that TP #1 did not qualify for high complexity testing.