

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  52D0691475	<b>(X3) Date Survey Completed</b>  09/28/2021
<b>Name of Provider or Supplier</b>  Interstate Blood Bank Inc	<b>Street Address, City, State</b>  2126 W Fond Du Lac Ave, Milwaukee, WI	
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>D2004</b>	<p>ENROLLMENT CFR(s): 493.801(a)(3)</p> <p>For each specialty, subspecialty and analyte or test, participate in one approved proficiency testing program or programs, for one year before designating a different program and must notify CMS before any change in designation;</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of proficiency testing (PT) records, federal Certification and Survey Provider Enhanced Reports (CASPER), and interview with the center manager, the laboratory changed proficiency testing (PT) providers for refractometer protein testing after one event in 2021 and did not participate in a single approved proficiency testing program for all of 2021. Findings include: 1. Review of PT records and reports for refractometer protein testing in 2021 showed the laboratory participated in the Accutest PT program for event one. Records for event two and three in 2021 showed the laboratory tested samples and received reports from the AAB (American Association of Bioanalysts) PT program. 2. Review of the CASPER 155D Individual Laboratory Profile report showed the laboratory received acceptable results from Accutest Inc. for the first event in 2021 and received a 0% score for event two in 2021. 3. Interview with the center manager (staff C) on September 28, 2021 at 11:45 AM confirmed the laboratory submitted refractometer protein results to Accutest Inc. for the first event in 2021 then submitted results to AAB for the second and third events and did not submit results to Accutest for the second and third events to complete the 2021 year.</p>
<b>D3037</b>	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4)</p> <p>Proficiency testing records. Retain all proficiency testing records for at least 2 years.</p>

This STANDARD is not met as evidenced by:  
Based on surveyor review of proficiency testing (PT) records and interview with the center manager, the laboratory did not retain testing records for one of six PT events in 2020 and 2021 for refractometer protein testing. Findings include: 1. Review of PT records for six events from 2020 and 2021 for refractometer protein testing showed only a result sheet from the AAB (American Association of Bioanalysts) for event two in 2021. No testing records for this event were available. 2. Interview with the center manager (staff C) on September 28, 2021 at 1:18 PM confirmed the testing records for the second event in 2021 were not retained.

**D5407**

**PROCEDURE MANUAL**  
CFR(s): 493.1251(d)

Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

This STANDARD is not met as evidenced by:  
Based on surveyor review of procedures and interview with the center manager, the current laboratory director did not approve, sign and date the procedures for protein measurement using the digital refractometer. Findings include: 1. Review of procedures for use of the digital refractometer for measuring protein showed no evidence the procedure was approved by the current laboratory director. 2. Interview with the center manager (staff C) on September 28, 2021 at 1:11 PM confirmed staff D became the laboratory director in February 2021. Further interview confirmed the laboratory had no documentation to show the current director approved, signed and dated the procedures for use of the digital refractometer for protein testing.

**D6053**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:  
Based on surveyor review of quality control records, Centers for Medicare and Medicaid Services (CMS) Form CMS-209 "Laboratory Personnel Report (CLIA)" and personnel records, and interview with the center manager, the laboratory did not have documentation showing the technical consultant completed a semi-annual evaluation for one of five new testing personnel. Findings include: 1. Review of quality control records showed Staff B performed protein quality control testing on September 15, 2021. 2. Review of Form CMS-209 submitted for this survey and signed by the laboratory director on September 22, 2021 showed staff B was not listed on the form. Comparison of the submitted Form CMS-209 with the Form CMS-209 from the last survey showed there were an additional four new testing personnel in this lab since the last survey. 3. Review of personnel records showed staff B started at the facility February 19, 2020 and completed donor processing training in May 2020. The record showed the only other evaluation was completed in July 2021. 4. Interview

with the center manager (staff C) on September 28, 2021 at 1:15 PM confirmed staff B should have been included on the Form CMS-209 as testing personnel and that documentation of the semi-annual evaluation for staff B was not completed.

**D6063**

**LABORATORY TESTING PERSONNEL**  
CFR(s): 493.1421

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.

This CONDITION is not met as evidenced by:  
Based on surveyor review of the Centers for Medicare and Medicaid Services (CMS) Form CMS-209 "Laboratory Personnel Report (CLIA)", quality control and personnel records, and interview with the center manager, one of five new testing personnel did not have credentials available showing they met the qualification requirements for moderate complexity testing personnel. Findings include: 1. One of five new testing personnel did not have credentials available showing they met the qualification requirements for moderate complexity testing. See D 6065.

**D6065**

**TESTING PERSONNEL QUALIFICATIONS**  
CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:  
Based on surveyor review of laboratory records, Centers for Medicare and Medicaid Services (CMS) Form CMS-209 "Laboratory Personnel Report (CLIA)" and personnel records, and interview with the center manager, one of five new testing personnel did not have documented evidence showing they met the qualification requirements to perform moderate complexity testing. Findings include: 1. Review of laboratory records and the Form CMS-209 submitted for this survey and signed by the laboratory director on September 22, 2021 showed the laboratory had five new testing personnel since the last survey. 2. Review of personnel records showed staff A held a Bachelor of Arts (BA) degree from the University of Minnesota. Records for staff A did not show that the BA degree was in a chemical, physical, biological or clinical laboratory science, or medical technology. No other academic credentials were available for staff A. 3. Interview with the center manager (staff C) on September 28, 2021 at 1:15 PM confirmed documented credentials were not available showing staff A met the requirements for moderate complexity testing personnel.