

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  52D0691476	<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>  1530 W National 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 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 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 A) on September 28, 2021 at 9:30 AM confirmed the laboratory submitted results to Accutest Inc. for the first event in 2021 and submitted results to AAB for the second and third event and did not submit results to Accutest to complete the 2021 year with the Accutest PT provider for refractometer protein testing.</p>
<b>D5407</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p>

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 A) on September 28, 2021 at 10:25 AM confirmed staff B 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.