

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  24D0405325	<b>(X3) Date Survey Completed</b>  06/18/2021
<b>Name of Provider or Supplier</b>  Avera Tyler	<b>Street Address, City, State</b>  240 Willow Street, Tyler, MN	
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>D5421</b>	<p><b>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE</b> 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 observation, document review, and interview with laboratory personnel, the laboratory failed to ensure 1 of 6 reportable ranges obtained during performance verification activities completed between May 2019 and June 2021 and reviewed on date of survey was adopted by the laboratory. Findings are as follows: 1. The laboratory performed Chemistry testing as confirmed by the General Supervisor (GS) during a tour of the laboratory at 8:10 a.m. on 06/18/21. 2. An Abbott Afinion 2 chemistry analyzer was observed as present and available for use during the tour of the laboratory. 3. Performance verification (PV) activities for Hemoglobin A1c (HbA1c) tested on the Afinion 2 were completed and the laboratory began testing patient specimens using this analyzer on 11/22/19 as indicated by the GS and confirmed by laboratory records. 4. The adopted lower limit of the reportable range for HbA1c did not reflect the actual reportable range value obtained by the laboratory during the PV. See below. Analyte PV Adopted HbA1c 4.68-14.7 4.0-13.9 5. In an interview at 12:15 p.m. on 06/18/21, the GS confirmed the above finding. 6. HbA1c testing was performed on 2038 patient specimens since date of implementation through date of survey, 11/22/19-06/18/21, as indicated on laboratory reports provided by the GS via email at 8:16 a.m. on 06/19/21. See below. Year Number Tested 2019 109 2020 1278 2021 651 .</p>