

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  35D0669946	<b>(X3) Date Survey Completed</b>  04/27/2022
<b>Name of Provider or Supplier</b>  Ashley Medical Center	<b>Street Address, City, State</b>  612 Center Ave N, Ashley, ND	
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>D5447</b>	<p><b>CONTROL PROCEDURES</b> CFR(s): 493.1256(d)(3)(i)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on record review, staff interview, and policy review, the laboratory failed to perform two levels of quality control (QC) 3 of 5 patient testing days (01/03, 01/11, and 01/20) for free thyroxine (FT4) and 3 of 11 patient testing days (01/06, 01/07, 01/11) for hemoglobin A1C (HgbA1C) in January 2022. The laboratory performed four FT4 and seven HgbA1C patient tests on the days in January when the laboratory performed only one level of QC. Findings include: 1. Review of the January 2022 QC results for analytes on the Ortho Vitros 5600 chemistry analyzer occurred on 04/27/22. The laboratory performed one level of QC for FT4 on 01/03, 01/11, and 01/20. The laboratory performed one level of QC for HgbA1C on 01/06, 01/07, and 01/11. 2. During interview at 12:10 p.m. on 04/27/22, the laboratory supervisor (#1) stated the laboratory should perform two levels of QC on days when the laboratory tests patient specimens and confirmed the laboratory performed one level of QC for FT4 on 01/03, 01/11, and 01/20 and for HgbA1C on 01/06, 01/07, and 01/11 in January 2022. 3. The undated policy "Quality Control Processing, Reviewing, Corrective Actions," stated, ". . . 6. Procedure: . . . c) Patient results of analytical procedures must not be revealed or released unless the controls are verified for acceptability. . . . A. Internal Quality Control (IQC) for Quantitative Tests: . . . Routine Chemistry 1) Internal QC (2 levels) is run once a day at the beginning of the shift for all routine chemistry tests that are</p>

available in house, cardiac markers, and immunoassays. Internal quality controls of Hgba1c . . . are only performed when there are patient samples available for processing. . . ."