

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  35D0693180	<b>(X3) Date Survey Completed</b>  11/24/2020
<b>Name of Provider or Supplier</b>  South Central Health	<b>Street Address, City, State</b>  1007 4 Ave S, Wishek, 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>D5481</b>	<p><b>CONTROL PROCEDURES</b> CFR(s): 493.1256(f)(g)</p> <p>(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (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 ensure quality control (QC) results met the criteria for acceptability for 2 of 30 patient testing days (09/06/20 and 09/08/20) in September 2020 for four analytes on the Dimension EXL200 chemistry analyzer. The laboratory performed seventeen patient tests on 09/06/20 and 09/08/20. Findings include: 1. Review of the September 2020 QC results for analytes on the Dimension EXL200 chemistry analyzer occurred on 11/24/20. On 09/06/20 and 09/08/20 levels 1 and 3 QC were out of the laboratory's acceptable range for the following: alkaline phosphatase, blood urea nitrogen, calcium, and glucose. The laboratory reported results for alkaline phosphatase, blood urea nitrogen, calcium, and glucose when the QC was out of the acceptable range for two patient tests on 09/06/20 and fifteen patient tests on 09/08/20. 2. During interview at 2:30 p.m. on 11/24/20, a technical consultant (#1) confirmed the laboratory reported patient test results for alkaline phosphatase, blood urea nitrogen, calcium, and glucose on 09/06/20 and 09/08/20 when the QC was not in acceptable range. 3. Reviewed at 2:35 p.m. on 11/24/20, the policy "Chemistry Quality Control," revised 06/2004, stated, ". . . Internal Control . . . A. Control Material Two levels of control material are used daily to monitor normal and abnormal ranges. . . . E. Guidelines for Acceptance of Patient Results 1. Random Errors Rule . . . 3. Two controls exceed mean +/- 2 SD [standard deviation] Action . . . Rejection . . ."</p>