

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 27D0652518	(X3) Date Survey Completed 07/22/2025
Name of Provider or Supplier Big Sandy Medical Center	Street Address, City, State 166 Montana Avenue E, Big Sandy, MT	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5425	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(3)</p> <p>(b)(3) The laboratory must determine the test system's calibration procedures and control procedures based upon the performance specifications verified or established under paragraph (b)(1) or (b)(2) of this section.</p> <p>This STANDARD is not met as evidenced by: Based on a review of microbiology records and an interview with Laboratory Director (LD) #1, it was found that the laboratory failed to include a verification study in their Individualized Quality Control Plans (IQCP) to support its quality control (QC) practices for new lots of agar media used for patient urine cultures from July 22, 2023, to July 22, 2025. Findings: 1. A review of microbiology's IQCP lacked records of a QC verification study for new lots of trypticase soy agar (TSA)-5% Sheep Blood agar and MacConkey agar biplates to support the manufacturer's QC frequency. 2. A review of the test volume sheet revealed 124 urine cultures using TSA-5% Sheep Blood agar and MacConkey agar biplates were performed in the last 12 months (July 1, 2024, to July 1, 2025). 3. An interview with the LD #1 on July 22, 2025, at 3:00 PM, confirmed the laboratory failed to perform a verification study to support its quality control (QC) practices for new lots of agar media used for patient urine cultures from July 22, 2023, to July 22, 2025.</p>