

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 27D0409839	<b>(X3) Date Survey Completed</b> 11/15/2018
<b>Name of Provider or Supplier</b> Sidney Health Center	<b>Street Address, City, State</b> 216 14th Avenue Sw, Sidney, MT	
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>D0000</b>	Based on an on-site recertification survey conducted on 11/14/18-11/15/18, deficiencies were cited for Sidney Health Center in Sidney, MT.
<b>D5449</b>	<p><b>CONTROL PROCEDURES</b> CFR(s): 493.1256(d)(3)(ii)(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 qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to perform positive and negative quality controls every day of patient testing on the rapid test for fetal membrane rupture (ROM Plus kit) for 17 of 17 patients between 4/1/18 and 11/14/18. The findings include: 1. A review on 11/14/18 at 11:00 a.m. of the ROM Plus logs lacked controls run every day of patient testing for 17 days. a. 4/18/18, 5/1/18, 5/2/18, 5/13/18, 5/23/18, 7/17/18, 7/18/18, 7/28/18, 8/16/18, 8/20/18, 9/13/18, 9/22/18, 10/2/18, 10/5/18, 10/9/18, 10/13/18, and 10/30/18. 2. On 11/14/18 at 11:00 a.m., staff member A stated the laboratory did not have an Individualized Quality Control Plan (IQCP) for the ROM kit.</p>
<b>D6120</b>	<p><b>TECHNICAL SUPERVISOR RESPONSIBILITIES</b> CFR(s): 493.1451(b)(7)(8)</p> <p>(7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain</p>

their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory technical supervisor failed to evaluate the competency of 8 of 8 testing personnel in 2017 and 2018. The findings include: 1. A review on 11/14/18 at 11:20 a.m. of the competency assessments lacked four of the six required elements of competency for testing personnel B, C, D, E, F, G, H, and I. a. Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. b. Monitoring the recording and reporting of test results. c. Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records. d. Direct observation of performance of instrument maintenance and function checks. 2. On 11/14/18 at 11:20 a.m., staff member A stated the competency assessments consisted of proficiency sample testing records and continuing education webinars.