

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 27D0410643	(X3) Date Survey Completed 05/16/2019
Name of Provider or Supplier Bozeman Clinic	Street Address, City, State 1245 North 15th Avenue, Bozeman, 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
D0000	Based on an on-site recertification survey conducted on 5/16/19, deficiencies were cited for Bozeman Clinic in Bozeman, MT.
D5411	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.</p> <p>This STANDARD is not met as evidenced by: Based on observation, record review, and interview, the laboratory failed to include the identity of the assay used on the prostate specific antigen (PSA) test report as required by the manufacturer directions from January 31, 2019 through May 16, 2019. The findings include: 1. On 5/16/19 at 8:45 a.m., a Tosoh AIA-360 analyzer was observed in the laboratory. 2. On 5/16/19 at 8:45 a.m., staff member A stated PSA was performed on the Tosoh AIA-360 analyzer. 3. A review on 5/16/19 at 10:30 a.m. of a patient (#32366) PSA test report lacked the identity of the assay used for PSA. 4. A review on 5/16/19 at 10:30 a.m. of the Tosoh AIA manufacturer instructions for PSA included it "is mandatory that results reported by the laboratory to the physician include the identity of the assay used." 5. On 5/16/19 at 10:30 a.m., staff member A stated the electronic medical record system was implemented in January of 2019 and the methodology was not programmed for the PSA test report.</p>
D5435	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2)</p> <p>For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check</p>

protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.

This STANDARD is not met as evidenced by:

Based on observation and interview, the laboratory failed to check rotor speed for two of two centrifuges in the laboratory from 3/24/17 through 5/16/19. The findings include: 1. Two centrifuges were observed in the laboratory on 5/16/19 at 8:45 a.m. a. Horizon mini-E centrifuge. b. Hamilton Bell centrifuge. 2. An observation on 5/16/19 at 2:00 p.m. of the stickers on the centrifuges showed the last rotor speed check occurred on both centrifuges in 8/16. 3. On 5/16/19 at 2:00 p.m., staff member A stated the centrifuge speed had not been verified since 2016.