

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 43D0407574	(X3) Date Survey Completed 10/24/2018
Name of Provider or Supplier Woonsocket Community Health Center	Street Address, City, State 302 S Dumont, Woonsocket, SD	
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	A recertification survey for compliance with 42 CFR Part 493, Requirements for Laboratories, was conducted on 10/24/18. The Woonsocket Community Health Center laboratory was found not in compliance with the following requirement: D2015.
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) events and interview with laboratory personnel A, the laboratory failed to ensure the laboratory director had signed five of five attestation statements (American Proficiency Institute [API] hematology /coagulation 2017 first, second, and third PT events, and 2018 hematology /coagulation first and second PT events) that attested PT samples had been tested in the same manner as patient specimens. The laboratory also failed to have testing personnel sign three of five attestation statements (API hematology/coagulation 2017 second and third events and 2018 second event). Findings include: 1. Review of PT events for 2017 and 2018 revealed: %Two PT events (API hematology/coagulation 2017 first event and 2018 first event) had attestation statements signed by testing</p>

personnel A as the laboratory director or designee. % Three PT events (API hematology/coagulation 2017 second and third events and 2018 second event) had no attestation statements signed by the testing personnel or the laboratory director or designee. Interview on 10/24/18 at 8:55 a.m. with laboratory personnel A revealed she was not aware she was not qualified to sign the attestation statements for PT testing. She stated the laboratory had recently changed reporting methods for PT surveys and she must have forgotten to print the attestation statements.