

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 43D0658941	(X3) Date Survey Completed 01/16/2019
Name of Provider or Supplier South Dakota Public Health Laboratory	Street Address, City, State 615 East Fourth Street, Pierre, 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
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on review of proficient testing documentation and interview with the technical supervisor, the laboratory director and testing personnel failed to sign the attestation statement on proficiency testing modules. Findings include: 1. Review of WSLH Measles and Mumps proficiency testing modules revealed the attestation statement was not signed by the laboratory director and the testing personnel for 2 of 4 PT events in 2017 (2017-1) and 2018 (2018-2). 2. Review of WSLH Frozen Media proficiency testing modules revealed the attestation statement was not signed by the laboratory director and the testing personnel for 1 of 2 PT events in 2018 (2018-1). 3. Review of WSLH CRE proficiency testing modules revealed the attestation statement was not signed by the laboratory director and the testing personnel for 1 of 2 PT events in 2018 (2018-2). 4. During an interview conducted on 01/15/2019 at approximately 1:00 PM, the technical supervisor confirmed the laboratory director and testing personnel failed to sign the attestation statement on proficiency testing modules mentioned above.</p>
D5221	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d)</p> <p>All proficiency testing evaluation and verification activities must be documented.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on review of proficiency testing documentation (PT) and staff interview, the laboratory failed to document corrective actions for CDC LRN-C Quality Assurance Program results that were unsatisfactory in 2 of 2 years (2017 and 2018). Findings include: 1. Review of CDC LRN-C VOC proficiency testing modules revealed the laboratory received scores of 97% for events 2017-1, 2017-2, and 2017-3; and 96% for events 2018-1 and 2018-2. No corrective actions were found to explain why the specific analytes had failed in those particular modules. 2. Review of CDC LRN-C S OPNA proficiency testing modules revealed the laboratory received a score of 98% on event 2017-3. No corrective actions were found to explain why the specific analytes had failed in the module. 3. Review of the CDC LRN-C ABRC proficiency testing modules revealed event 2018-01 received a score of 0% with a note stating the sample were not received by the due date. No corrective actions were found to explain why the module was not turned in by the due date specified by CDC. 4. During an interview conducted on 01/16/2019 at approximately 9:00 AM, the technical supervisor confirmed the no corrective actions were written for the modules mentioned above.

D5435

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(b)(2)

For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check 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 review of maintenance documentation and staff interview, the laboratory failed to document maintenance activities on the Gene Expert (serial number 80881) for 9 of 15 months in 2017 and 2018. Findings include. 1. Review of Gene Expert (serial number 80881) maintenance logs revealed quarterly maintenance was not performed from October 2017 through June 2018. 2. During an interview conducted on 01/16/2019 at approximately 10:00 AM, the technical supervisor confirmed quarterly maintenance was not performed on the Gene Expert in the time frame mentioned above.