

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 43D0407349	(X3) Date Survey Completed 09/25/2019
Name of Provider or Supplier Sanford Deuel County Medical Center	Street Address, City, State 701 3rd Avenue South, Clear Lake, 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 9/25/19. The Sanford Deuel County Medical Center laboratory was found not in compliance with the following requirements: D2015, D3031, D5221, and D5775.
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 American Proficiency Institute (API) proficiency testing (PT) records and interview with the laboratory supervisor, the laboratory failed to ensure each step in the PT process had been documented for 19 of 19 API PT events reviewed (2018 first, second, and third chemistry core, hematology/coagulation, and microbiology events; 2019 first, second, and third chemistry core events; 2019 first and second hematology/coagulation, microbiology and immunohematology events; and 2019 first chemistry miscellaneous event). Findings include: 1. Review of 2018 and to date 2019 API PT records revealed laboratory staff had failed to complete the proficiency testing worksheet for the reviewed PT testing events. That worksheet documented the receipt, acceptability, and handling of PT samples. Interview on 9/25</p>

/19 at 9:45 a.m. with the laboratory supervisor revealed she had been aware the PT worksheets had been used in the past. She had quit using them as she thought they were no longer required. She agreed the worksheets should have been completed.

D3031

RETENTION REQUIREMENTS

CFR(s): 493.1105(a)(3)

Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.

This STANDARD is not met as evidenced by:

Based on record review, observation, and interview with laboratory supervisor, the laboratory failed to retain the results of the daily background checks from the Abbott Emerald hematology analyzer for approximately 8 of 15 months (July 2018 to February 2019) to ensure critical operating characteristics that affected the stability and calibration of the analyzer met specific criteria defined by the manufacturer. Findings include: 1. Observation and demonstration on 9/25/19 at 12:05 p.m. of the Abbott Emerald hematology analyzer's electronic files revealed the oldest background count retained was dated 3/1/19. Interview with the laboratory supervisor on 9/25/19 at 12:05 p.m. revealed: *The analyzer had been placed into service July 2018. *She had thought all background check results had been stored electronically. *Background checks had been performed as part of daily start-up procedures with acceptable results. *No other log such as paper or a spreadsheet had been kept of the results.

D5221

EVALUATION OF PROFICIENCY TESTING PERFORMANCE

CFR(s): 493.1236(d)

All proficiency testing evaluation and verification activities must be documented.

This STANDARD is not met as evidenced by:

Based on review of American Proficiency Institute (API) proficiency testing (PT) events, review of performance improvement reports and interview with the laboratory supervisor, the laboratory failed to ensure PT results had been reviewed, evaluated, and those activities documented for 6 of 18 PT events reviewed (2018 first chemistry core, 2018 first and second hematology/coagulation, 2018 second microbiology, 2019 first hematology/coagulation, and 2019 first chemistry miscellaneous events). Findings include: 1. Review of the 2018 API PT events revealed the following unacceptable or ungraded results: *Chemistry core first event: -Total cholesterol, sample CH-02, ungraded. -LDL (low density lipoprotein) calculated, sample CH-02, ungraded. *Hematology/coagulation first event: blood cell identification, sample BCI-01, ungraded. *Hematology/coagulation second event: urine sediment, sample US-03, unacceptable. *Microbiology second event: potassium hydroxide (KOH) preparation, sample KOH-03, unacceptable. Review of the 2019 API PT events revealed the following ungraded results: *Hematology first event: -Blood cell identification (educational), samples E01-E05, ungraded. -Platelet count, sample HEM-02, ungraded. -Urine sediment, sample US-02, ungraded. -Vaginal wet preparation/KOH, VKP-01, ungraded. *Chemistry miscellaneous first event: UDS (urine drug screen) opiates, sample UDS-02, ungraded. Review of the laboratory's PT reports revealed there had been no investigation on unacceptable or ungraded results for the above listed samples. Review of the laboratory's 2018 Performance Improvement Summary

Form signed by the laboratory supervisor on 1/22/19 revealed: *Reviewed 2018 Proficiency Testing: -Heme 1st event: 80% RBC, 80% Granulocytes, 80% Lymphocytes- reviewed -Heme 2nd event: 80% Blood Cell ID, 80% Hematocrit, 0% RBC- reviewed, new analyzer implemented -Action Taken: N/A Print out all reports needed -Re-evaluation procedure (when and how this activity will be reassessed): review annually" Interview on 9/25/19 at 9:45 a.m. with the lab supervisor revealed: *She thought all unacceptable and ungraded samples had been reviewed. *She confirmed there was no documentation the above samples had been reviewed.

D5775

COMPARISON OF TEST RESULTS
CFR(s): 493.1281(a)(c)

(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.

This STANDARD is not met as evidenced by:
Based on review of the quality assessment (QA) activities, annual test volume form, and interview with the laboratory supervisor, the laboratory failed to establish criteria for acceptable differences between one of one test performed by multiple methodologies (manual white blood cell differential versus automated). The two methods had not been compared twice a year in 2018 to determine if their differences had been acceptable. Findings include: 1. Review of the laboratory's 2018 QA activities revealed there had been no comparison testing for white blood cell differential manual versus automated. Review of the annual test volume form revealed thirty-three manual differential patient tests had been performed in 2018 without the difference of the two test methods being evaluated for acceptability. Interview on 9/25 /19 at 11:05 a.m. with the laboratory supervisor revealed the laboratory had not documented the twice a year comparisons between manual and automated differentials. She stated, "It was supposed to be done in December." She was not aware it needed to be done twice a year.