

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D1018843	(X3) Date Survey Completed 08/26/2021
Name of Provider or Supplier Sanford Luverne Medical Center	Street Address, City, State 1600 N Kniss Ave, Luverne, MN	
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
D5211	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory failed to review and evaluate proficiency testing (PT) results from 2 PT events in 2019. Findings are as follows: 1. The laboratory performed Chemistry and Hematology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory at 8:05 a.m. on 08/26/21. 2. The laboratory performed PT using the American Proficiency Institute (API) program. 3. The laboratory failed to review and evaluate PT results for the events listed below. API 2019 Chemistry 2nd miscellaneous event API 2019 Hematology 3rd event 4. Review and evaluation of PT results was required as established in the Proficiency Testing Protocol, located in the procedure software PolicyTech. 5. The laboratory was unable to provide documented review and evaluation of the PT results from the above 2019 events upon request. 6. In an interview at 3:30 p.m. on 08/26/21, the GS confirmed the above finding.</p>
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p>

This STANDARD is not met as evidenced by:

. Based on observation, document review, and interview with laboratory personnel, the laboratory failed to ensure 1 of 3 reportable ranges obtained during performance verification activities completed in 2020 on a Hematology analyzer were adopted by the laboratory. Findings are as follows: 1. The laboratory performed Hematology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory at 8:05 a.m. on 08/26/21. 2. A Stago STA Compact Max coagulation analyzer was observed as present and available for use during the tour of the laboratory. 3. Performance verification (PV) activities on the analyzer for D-Dimer were completed in February 2020. The Laboratory Director approved the PV activities on 03/02/20 and testing was implemented on 03/03/20. 4. The upper limit of the reportable range for D-Dimer listed in the D-Dimer - STA Compact Max procedure, located in the procedure software PolicyTech, did not reflect the actual reportable range value obtained by the laboratory during the PV. See below. Analyte PV Procedure D-Dimer 0.21-16.90 0.27-20.0 5. The total number of D-Dimer test results obtained from 03/03/20 to 08/26/21 was 890. 6. In an interview at 3:55 p.m. on 08/26/21, the GS confirmed the above finding. .

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES
 CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

. Based on document review and interview with laboratory personnel, the technical consultant (TC) failed to ensure 5 of 5 testing personnel were evaluated for test procedure competency in all testing areas in 2020. Findings are as follows: 1. The laboratory performed Chemistry testing as confirmed by General Supervisor during a tour of the laboratory at 8:05 a.m. on 08/26/21. 2. An Opti CCA-TS chemistry analyzer and an Olympus CX31 microscope were observed as present and available for use during the tour. Blood Gas testing was performed on the Opti CCA-TS analyzer and Urine Sediment examinations were performed on the Olympus CX31 microscope as indicated by the GS during the tour. 3. The laboratory's Competency Assessment Procedure, found in the procedure software PolicyTech, indicated TP were evaluated for competency in all testing areas annually. 4. Competency assessments for Blood Gas testing and Urine Sediment examinations were not included in the Annual Competency - Direct Observation of "Objective" Testing forms completed in 2020 for 5 of 5 testing personnel. 5. The laboratory was unable to provide the missing evaluations upon request. 6. In an interview at 10:00 a.m. on 08/26/21, the GS confirmed the above finding.

D6102

LABORATORY DIRECTOR RESPONSIBILITIES
 CFR(s): 493.1445(e)(12)

The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate

results.

This STANDARD is not met as evidenced by:
missing or incomplete training tp3 . Based on document review and interview with laboratory personnel, the laboratory failed to ensure documented training and initial competency assessments were performed for 1 of 1 new testing personnel (TP) hired in 2020. Findings are as follows: 1. The laboratory performed Microbiology, Immunology, Chemistry, Hematology, and Immunochemistry as confirmed by the General Supervisor (GS) during a tour of the laboratory at 8:05 a.m. on 08/26/21. 2. TP3 began employment with the laboratory on 04/12/21 as indicated in laboratory records. The GS confirmed TP3 performed testing independently in the laboratory. 3. The laboratory's Competency Assessment Procedure, found in the procedure software PolicyTech, indicated TP were trained at hire and evaluated for competency in all testing areas. 4. Documentation of TP3's initial training and competency assessment in each of the testing areas was either incomplete or not found during review of laboratory records- see below. The laboratory was unable to provide additional documentation upon request. Incomplete training records Chemistry -Tox/See urine drug screen -Serum hCG Immunology -Amnisure Missing training records Microbiology -GeneXpert analyzer -Vaginal Wet Preparation -Scabies examination Hematology -STA Compact Max analyzer -Manual Differentials -Hematology cell identification -Post vasectomy examination Chemistry -Urine Sediment examination Immunochemistry -All analytes 5. In an interview on at 10:00 a.m., the GS confirmed the above finding.

D6127

TECHNICAL SUPERVISOR RESPONSIBILITIES

CFR(s): 493.1451(b)(9)

The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:
. Based on document review and interview with laboratory personnel, the Technical Supervisor failed to ensure 1 of 1 new testing personnel (TP) hired in 2020 was evaluated for competency in all testing platforms in use by the laboratory at least semiannually during the first year of patient specimen testing. Findings are as follows: 1. The laboratory performed Microbiology, Immunology, Chemistry, Hematology, and Immunochemistry as confirmed by the General Supervisor (GS) during a tour of the laboratory at 8:05 a.m. on 08/26/21. 2. TP3 was hired 04/12/20 as indicated in laboratory records. 3. The laboratory's Competency Assessment Procedure, found in the procedure software PolicyTech, indicated TP were evaluated for competency in all testing areas semi-annually during the first year of patient testing. 4. A semi-annual competency assessment was not found for TP3 during review of laboratory records. The laboratory was unable to provide the semi-annual assessment upon request. 5. In an interview at 10:00 a.m. on 08/26/21, the GS confirmed the above finding. .