

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0406702	(X3) Date Survey Completed 03/13/2019
Name of Provider or Supplier Kittson Memorial Hospital Association	Street Address, City, State 1010 S Birch Ave, Hallock, 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
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 document review and interview with laboratory personnel, the Laboratory Director or designee and Testing Personnel failed to attest to the integration of proficiency testing samples into the routine patient workload on two occasions in 2018. Findings are as follows: 1. The laboratory Chemistry and Immunohematology testing as confirmed by the General Supervisor during a tour of the laboratory on 03/13/19 at 8:10 a.m. 2. The laboratory performed proficiency testing (PT) using the American Proficiency Institute (API) PT provider. 3. The Laboratory Director and Testing Personnel were required to sign the attestation statements as established in the Quality Plan Proficiency Testing procedure located in the Quality Assurance manual. 4. The Laboratory Director or designee and Testing Personnel failed to attest to the integration of PT samples into the routine patient workload for 2 of 23 API PT events reviewed in the June 2017 through March 2019 timeframe. See below. Event Specialty missing attestation 2018-2 Chemistry Miscellaneous (document absent) 2018-3 Immunohematology (document blank) 5. In an interview on 03/13/19 at 11:05 a.m., Technical Consultant 1 confirmed the above finding.</p>
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>

This STANDARD is not met as evidenced by:
 . Based on document review and interview with laboratory personnel, the laboratory failed to investigate unacceptable Hematology (Coagulation) proficiency testing (PT) results for 2 analytes in 2018. Findings are as follows: 1. The laboratory performed proficiency testing (PT) through the American Proficiency Institute (API) program. 2. The laboratory received unacceptable PT result in the API 2018 Hematology /Coagulation 3rd event for the analytes listed below. Sample Test Lab result API range COA-11 APTT* 59 42-58 COA-12 PT* 14.3 10.4-14.1 3. Investigation of unacceptable results was required within 30 days of receipt as established in the Quality Plan Proficiency Testing procedure located in the Quality Assurance manual. 4. An investigation of the unacceptable PT results was not found during review of laboratory records. The laboratory was unable to provide investigation documentation completed within 30 days of receiving the unacceptable results upon request. 5. In an interview on 03/13/19 at 10:55 a.m., Technical Consultant 2 confirmed a documented investigation of the unacceptable results was not performed. * Note APTT - Activated Partial Thromboplastin Time PT - Prothrombin Time

D5217

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
 CFR(s): 493.1236(c)(1)

At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.

This STANDARD is not met as evidenced by:
 . Based on document review and interview with laboratory personnel, the laboratory failed to verify the accuracy of non-regulated Hematology analyte at least twice annually in 2017 and 2018. Findings are as follows: 1. The laboratory performed Hematology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory on 02/07/19 at 8:20 a.m. 2. The Semen Analysis microscopic examination was included on the Kittson Healthcare Annual Average Assay Count 2018 document provided by the laboratory. 3. Twice annual verification of accuracy documents for Semen Analysis were not found during review of laboratory records from 2017 and 2018. The laboratory was unable to provide the documents upon request. 4. In an interview on 03/13/19 at 9:45 a.m., Technical Consultant 2 confirmed the accuracy of the Semen Analysis microscopic examination had not been verified twice annually in 2017 and 2018.

D5403

PROCEDURE MANUAL
 CFR(s): 493.1251(b)

The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in

the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:

. Based on observation, document review and interview with laboratory personnel, the laboratory failed to include accurate Chemistry and Hematology reference intervals (normal values) in the procedure manual (10). Findings are as follows: The laboratory performed Chemistry and Hematology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory on 03/13/19 at 8:10 a.m. A. Chemistry 1. An Alere Triage Meter and a Siemens Dimension EXL 200 chemistry analyzer were observed as present and available for use during the tour. The GS indicated BNP* testing was performed on the Triage Meter and routine chemistry testing was performed on the Dimension EXL 200. 2. The BNP normal value found in the Kittson Memorial Hospital Normal Ranges chart was discrepant with that indicated on patient test report reviewed on date of survey. See below. Test Chart Report BNP 5-100 0-100 3. The normal values found in the Kittson Memorial Hospital Normal Ranges chart for the analytes below, tested using the Dimension EXL 200, were discrepant with those indicated on patient test reports reviewed on date of survey. See below. Test* Chart Report Glu 74-106 70.0-100.0 BUN 7-20 7-18 Crea 0.7-1.3 0.52-1.25 Na 137-145 136-145 K 3.5-5.0 3.5-5.1 CO2 22-30 21-32 Ca 8.4-10.2 8.5-10.1 4. In an interview on 03/13/19 at 2:45 p.m., Technical Consultant 1 confirmed the BNP normal value discrepancy between the test report and the chart. At 4:25 p.m., the GS confirmed the normal value discrepancies between the routine chemistry test report and the chart. B. Hematology 1. An Instrument Labs ACL Elite analyzer and a Sedimat 15 analyzer were observed as present and available for use during the tour. The GS indicated Prothrombin Time (PT) testing was performed on the ACL Elite and Erythrocyte Sedimentation Rate (ESR) testing was performed on the Sedimat 15 . 2. The PT normal value found in the Kittson Memorial Hospital Normal Ranges chart was discrepant with that indicated on patient test report reviewed on date of survey. See below. Test Chart Report PT 12-15 9.6-12.3 3. The male patient ESR normal value found in the Erythrocyte Sedimentation Rate (Sediplast System) procedure was discrepant with that indicated on patient test report reviewed on date of survey. See below. Test Procedure Report ESR 0-15 0-20 4. In an interview on 03/13/19 at 2:35 p.m. and 2:10 p.m. respectively, Technical Consultant 1 confirmed the PT and ESR normal value discrepancy between the test reports and the chart or procedure. *Note Glu - Glucose BUN - blood Urea Nitrogen Crea - Creatinine Na - Sodium K - Potassium CO2 - Bicarbonate Ca - Calcium

D5421

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE
CFR(s): 493.1253(b)(1)

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.

This STANDARD is not met as evidenced by:
 . Based on observation, document review and interview with laboratory personnel, the laboratory failed to ensure the reportable range obtained during performance verification of a new Chemistry analyzer was accurate in the procedure manual (6). Findings are as follows: 1. The laboratory performed Chemistry testing as confirmed by the General Supervisor (GS) during a tour of the laboratory on 03/13/19 at 8:10 a. m. 2. A Siemens Dimension EXL 200 chemistry analyzer was observed as present and available for use during the tour of the laboratory. The laboratory completed performance verification (PV) activities and began testing patient specimens using this analyzer in July 2017 as indicated by the GS during the tour and confirmed via laboratory records. 3. The Sodium (Na), Potassium (K), Chloride (Cl), and Calcium (Ca) reportable ranges found in procedures located in the Dimension EXL Correspondence manual did not reflect the actual reportable range values obtained by the laboratory during the PV. See below. Analyte PV Procedure Na 66.2-189.2 50-200 K 1.42-9.66 1.0-10.0 Cl 54.0-191.4 50-300 Ca 3.81-13.46 5.0-30.0 4. In an interview on 03/13/19 at 4:25 p.m., the GS confirmed the above finding and indicated the laboratory had included the manufacturer's analytical measurement range as the reportable range in the procedures.

D5793

ANALYTIC SYSTEMS QUALITY ASSESSMENT
 CFR(s): 493.1289(b)(c)

(b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:
 . Based on document review and interview with laboratory personnel, the laboratory failed to perform an annual quality assessment for 4 of 5 Individualized Quality Control Plans (IQCP) in 2018 Findings are as follows: 1. IQCP's for the following tests were found in laboratory records on date of survey, 03/13/19. Clostridium difficile - kit test Microalbumin - Siemens Advantage DCA Serum hCG* - kit test BNP* - Alere Triage Influenza and RSV* - Cepheid GeneXpert 2. Annual review of the Clostridium difficile, Microalbumin, Serum hCG, and BNP IQCP's was not performed in 2018. The laboratory was unable to provide documentation of these reviews upon request. 3. In an interview on 03/13/19 at 1:00 p.m., Technical Consultant 1 confirmed the above findings. *Note hCG - Human Chorionic Gonadotropin BNP - Brain Natriuretic Peptide RSV - Respiratory Syncytial Virus