| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 53D0519784 | 06/25/2021 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Niobrara Community Hospital | 921 S Ballencee Ave, Lusk, WY | |

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** | EVALUATION OF PROFICIENCY TESTING PERFORMANCE<br>CFR(s): 493.1236(a)<br><br>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of proficiency testing records, lack of documentation, and staff interview, the laboratory failed to review and evaluate proficiency testing results for 4 of 37 testing events from January 2019 through January 2021. The findings were: 1. Review of the American Proficiency Institute (API) proficiency testing (PT) report failed to include documentation the laboratory had evaluated test scores of less than 100%. The following concerns were identified: a. Review of the 2019 API hematology Event 1 PT results showed the laboratory scored an 80% on blood cell identification. There was no documentation the laboratory had evaluated the proficiency results. b. Review of the 2019 API hematology Event 3 PT results showed the laboratory scored an 80% on blood cell identification. There was no documentation the laboratory had evaluated the proficiency results. c. Review of the 2020 API routine chemistry Event 1 PT results showed the laboratory scored an 80% on the carbon dioxide analyte. There was no documentation the laboratory had evaluated the proficiency results. d. Review of the 2020 API hematology Event 3 PT results showed the laboratory scored an 80% on hematocrit. There was no documentation the laboratory had evaluated the proficiency results. 2. Interview with the laboratory manager on 6/25/21 at 10:30 AM confirmed the laboratory had failed to evaluate the reason for the 80% proficiency scores. |
| **D5403** | PROCEDURE MANUAL<br>CFR(s): 493.1251(b)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on procedure manual review, review of instrumentation printouts, lack of documentation, and staff interview, the laboratory failed to revise the laboratory procedure manual to include the current step-by-step procedure for performing hematology slide reviews. The laboratory performed approximately 8826 complete blood counts (CBCs) per year. The findings were: 1. Review of the Sysmex XS-1000i instrument printout for patient #194999 dated 11/5/19 and patient #194981 dated 11/5 /19 showed the test results were marked as "Positive" with white blood cells (WBCs), neutrophils, lymphocytes, monocytes, and eosinophils all flagged with an asterisk. In addition, an IP (interpretive program) message informed the testing personnel nucleated red blood cells (NRBCs) may be present. There was no documentation the laboratory had verified the accuracy of the instrument printout. 2. Review of the Sysmex XS-1000i instrument printout for patient #204816 dated 7/19/20 showed it was marked as "Positive" with neutrophils, eosinophils, and basophils all flagged with an asterisk. In addition, an IP message warned the testing personnel monocytosis, immature granulocytes, or a left shift might be present. There was no documentation the laboratory had verified the accuracy of the instrument printout. 3. Interview with the laboratory manager on 6/24/21 at 2 PM revealed the laboratory had installed the Sysmex XS 1000i on 5/18/16 and testing personnel used the guidelines established in the procedure manual titled "Hematology Slide Review" to determine when to perform a slide review or a manual differential. Review of the Hematology Slide Review procedure last revised 4/4/11 showed the laboratory was using a Medonic Hematology Analyzer and listed the conditions for when a stained slide would be manually reviewed. There was no documentation the laboratory had a procedure for what to do to verify a "Positive" patient test result. The laboratory manager confirmed the Hematology Slide Review procedure had not been updated when the Sysmex XS-1000i analyzer had been installed. 4. Review of the Sysmex XS-1000i manufacturer's instructions for use stated an asterisk indicated "data of low reliability" and if an "abnormality exists, determine a corrective action and verify results according to your laboratory's protocol." Further, "The XS-1000i is a screening device which judges and marks each sample as either Positive or Negative. This judgment is based on the presence or absence of IP messages (flags). The system evaluates numerical data, scattergrams, and particle size distributions for 21 reportable parameters and generates flags when abnormalities are or may be present." |
| | |

| | |
|---|---|
| **D5413** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(b)<br><br>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory's environmental records, review of manufacturer's instructions, and staff interview, the laboratory failed to monitor humidity in the testing and reagent storage areas. The laboratory conducted approximately 28,254 patient tests annually. The findings were: 1. Review of the daily environmental log showed the humidity level in the lab was not monitored. 2. Review of the instrument manual for the Siemens Dimension EXL chemistry analyzer showed "...Room Temperature Requirements... relative humidity must be maintained at greater than 20% and less than 80%." 3. Review of the iSTAT chemistry analyzer instrument manual dated 9/15/10 showed "...trouble shooting...relative humidity above 90% and less than 10% will give results higher or lower than expected." 4. Interview with testing personnel #1 on 6/25/21 at 9:10 AM revealed the laboratory did not measure, monitor, or record relative humidity. 5. Interview with the lab manager on 6/25/21 at 10 AM confirmed the relative humidity level in the lab was not monitored. 41190 |