| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 37D0471956 | 04/11/2018 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Mercy Hospital Healdton, Inc | 3462 Hospital Rd, Healdton, OK | |

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** | The findings were reviewed with regional director of laboraory services, laboratory director, technical consultant, hospital administrator, testing person #4 and testing person #7 |
| **D1001** | CERTIFICATE OF WAIVER TESTS<br>CFR(s): 493.15(e)<br><br>Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of records, manufacturer's instructions, and interview with the regional director of laboratory services, the laboratory failed to follow the manufacturer's storage insructions for a waived analyzer. Findings include: (1) On the first day of the survey, the director of laboratory services stated to the surveyor Urinalysis testing was performed on the Clinitek Status+ analyzer; (2) Later during the survey, the surveyor reviewed the manufacturer's environmental requirement for the analyzer. The manufacturer required the operating temperature be maintained within the range of 18 - 30 degrees Celsius; (3) The surveyor reviewed laboratory temperature records from December 2017 through the first day of the survey, which verified the temperature readings were less than 18 degrees Celsius (minimum to accommodate all analyzers) for 3 of 5 months as follows: (a) December 2017- 3 of 31 temperature readings were documented as less than 18 degrees Celsius (days 26,27,31); (b) January 2018 - 2 of 31 temperature readings were documented as less than 18 degrees Celsius (days 2,3); (c) February 2018 - 1 of 28 temperature readings were documented as less than 18 degrees Celsius (day 4); (4) The surveyor reviewed the records with the regional director of laboratory services who stated the temperature of the laboratory had been maintained below 18 degrees Celsius as indicated above. |

| | |
|---|---|
| **D2015** | TESTING OF PROFICIENCY TESTING SAMPLES<br>CFR(s): 493.801(b)(5)(6)<br><br>(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.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of records and interview with the regional director of laboratory services, the laboratory failed to ensure a proficiency testing attestation statement had been signed by the laboratory director or designee. Findings include: (1) On the first day of the survey, the surveyor reviewed 2016, 2017 and 2018 proficiency testing records. The following was identified for 2 of 26 testing events: (a) Third 2016 Chemistry Group 2 Event (i) The attestation was not signed by the laboratory director or designee. (b) Second 2016 Chemistry Group 2 Event (i) The attestation was not signed by the laboratory director or designee. (2) The findings were reviewed with the regional director of laboratory services who stated the attestations were not signed as indicated above. |
| **D5209** | PERSONNEL COMPETENCY ASSESSMENT POLICIES<br>CFR(s): 493.1235<br><br>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of policies and procedures, and interview with the regional director of laboratory services, the laboratory failed to have written policies and procedures for assessing employee competency. Findings include: (1) On the first day of the survey, the surveyor reviewed the laboratory's policies and procedures. A policy that explained how employees were assessed for competency could not be located; (2) The surveyor asked the regional director of laboratory services if a competency policy was available for review. The regional director of laboratory services stated a policy had not been written. NOTE: For non-waived testing, the regulations require initial training, a semiannual evaluation during the first year, and an annual evaluation thereafter for each testing person for ensuring competency. The policy/procedure for evaluating competency must include, but is not limited to: *Direct observation of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing *Monitoring the recording and reporting of test results *Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records *Direct observation of |

| | |
|---|---|
| | performance of instrument maintenance and function checks *Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples *Assessment of problem solving skills |
| **D5215** | EVALUATION OF PROFICIENCY TESTING PERFORMANCE<br>CFR(s): 493.1236(b)(2)<br><br>The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of records and interview with the regional director of laboratory services, the laboratory failed to verify the accuracy of testing when the proficiency testing program did not evaluate submitted results. Findings include: (1) On the first day of the survey, the surveyor reviewed 2016, 2017 and 2018 proficiency testing records and identified the following had not been evaluated by the proficiency testing program: (a) Hematology/Coagulation (i) 2017 second event (aa) 2 of 2 Blood Cell ID - BCI-13 and BCI-14 (2) The surveyor further reviewed the records and could not locate documentation verifying the laboratory had performed a self-evaluation of the non-graded results; (3) The surveyor asked the regional director of laboratory services if the results had been documented as evaluated. The regional director of laboratory services reviewed the records and stated the non-graded results had not been documented as reviewed. |
| **D5421** | ESTABLISHMENT AND VERIFICATION OF PERFORMANCE<br>CFR(s): 493.1253(b)(1)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of records and interview with regional director of laboratory services, the laboratory failed to ensure the verified reportable ranges for a new coagulation analyzer were used by the laboratory. Findings include: (1) On the first day of the survey, the regional director of laboratory services stated to the surveyor the laboratory began using the Stago Satellite analyzer to perform PT (Prothrombin Time), PTT (Partial Thromboplastin Time) and D-Dimer testing on 09/07/17; (2) On the second day of the survey, the surveyor reviewed validation records for the analyzer and identified the reportable ranges had been verified by the laboratory as follows: (a) PT - 12.8 - 97.3 (b) PTT - 28.1 - 118.3 (c) D-Dimer - 0.03 - 12.22 (3) The surveyor then requested a printout from the analyzer to verify the reportable ranges that had been programmed into the analyzer and were currently in use. The printout verified the laboratory was using reportable ranges that were wider than the verified |

| | |
|---|---|
| | ranges: (a) PT - 0 - 120 (b) PTT - 10 - 240 (c) D-Dimer - 0.27 - 20 (4) The surveyor reviewed the findings with regional director of laboratory services. The regional director of laboratory services stated the laboratory was using the manufacturer's default reportable ranges for PT, PTT, and D-Dimer instead of the reportable ranges that had been verified by the laboratory. |
| **D5429** | MAINTENANCE AND FUNCTION CHECKS<br>CFR(s): 493.1254(a)(1)<br><br>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of records, manufacturer's instructions, and interview with the regional director of laboratory services, the laboratory failed to ensure equipment maintenance was performed as required by the manufacturer. Findings include: (1) On the first day of the survey, the regional director of laboratory services stated to the surveyor *CMP, Direct Bilirubin, Amylase, CK (Creatine Kinase), Triglycerides, HDL (High Density Lipoprotein), LDL (Low Density Lipoprotein), Lipase, Magnesium, Uric Acid, Acetaminophen, Digoxin, Ethanol and Phenytoin were performed using the Roche Cobas c 311 analyzer; (2) On the second day of the survey, the surveyor reviewed 2016, 2017 and 2018 maintenance records, and identified the following: (a) 2 month maintenance - Replace ISE Measuring Cartridge (i) The 2 month maintenance procedure had not been documented as performed: (aa) between 05/30/16 and 09/12/16 (due 07/2016) (b) Quarterly - Clean Sonic Mixer, Replace the Sipper Tubing, Replace ISE Valve (i) The quarterly maintenance procedure had not been documented as performed as follows: (aa) Replace the ISE valve (i) between 03/21/17 and 09/21/17 (bb) Clean Sonic Mixer (i) between 09/28/17 and 01/02/18 (3) The surveyor reviewed the records with the regional director of laboratory services who stated there was no evidence the above maintenance had been documented as performed. *Comprehensive Metabolic Panel (CMP) - Albumin, Alkaline Phosphatase, ALT (Alanine Amino Transferase), AST (Aspartate Amino Transferase), BUN (Blood Urea Nitrogen), Calcium, Chloride, CO2, Creatinine, Glucose, Potassium, Sodium, Total Bilirubin and Total Protein |
| **D5439** | CALIBRATION AND CALIBRATION VERIFICATION<br>CFR(s): 493.1255(b)<br><br>Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or |

| | |
|---|---|
| | replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of records and interview with the regional director of laboratory services, the laboratory failed to perform calibration verification procedures at least once every 6 months. Findings include: (1) On the first day of the survey, the regional director of laboratory services stated to the surveyor Troponin I testing was performed using the Abbott iSTAT 1 analyzer; (2) On the third day of the survey, the surveyor requested 2016 and 2017 calibration verification records for the analyzer (since calibration procedures were not routinely performed, calibration verification procedures, using three or more levels of calibration materials, were required every 6 months). The regional director of laboratory services provided documentation that verified calibration verification procedures had not been performed as follows: (a) Between 06/29/16 and 4/14/17 (due in December 2016). (3) The surveyor reviewed the records with the regional director of laboratory services who stated calibration verification procedures had not been performed every six months as indicated above. |
| **D5479** | CONTROL PROCEDURES<br>CFR(s): 493.1256(e)(5)(g)<br><br>(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (5) Follow the manufacturer's specifications for using reagents, media, and supplies and be responsible for results. (g) The laboratory must document all control procedures performed.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of records, manufacturer's instructions, and interview with the regional director of laboratory services, the laboratory failed to follow the manufacturer's specifications for a new coagulation analyzer. Findings include: (1) On the first day of the survey, the regional director of laboratory services stated to the surveyor the Stago STA Satellite was put into use to perform PT/INR (Protime /International Normalized Ratio) testing on 09/07/17; (2) On the second day of the survey, the surveyor reviewed the manufacturer instructions for the establishment of the geometric mean for PT reference intervals (used to calculate the INR value). After providing detailed instructions for establishing the normal reference intervals, the instructions stated: (a) "The data will be compiled to develop reference ranges to be used by the site." (i) "Determination of the Geometric Mean for INR calculation" (aa) "Using Excel software, the Geometric Mean of the individual reference ranges values of PT is computed. (See legend for complete definition of the Geometric Mean)." (bb) "This new geometric mean must be entered when a new lot number of Neoplastine reagent is put into use to allow for the correct calculation of the INR." (3) The surveyor reviewed the laboratory implementation records and identified the laboratory had calculated a Geometric Mean of 13.0; (4) The regional director of laboratory services then showed the surveyor the laboratory programmed Geometric Mean of 13.5 in the analyzer, which did not match the laboratory established Geometric Mean (13.0); (4) The findings were reviewed with the regional director of laboratory |

| | |
|---|---|
| | services who stated the Geometric Mean had not been programmed into the analyzer correctly. |
| **D5791** | ANALYTIC SYSTEMS QUALITY ASSESSMENT<br>CFR(s): 493.1289(a)(c)<br><br>(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of records and interview with the regional director of laboratory services, the laboratory failed to have a policy for monitoring the effectiveness of their IQCP. Findings include: (1) On the first day of the survey, the director of laboratory services stated the following to the surveyor: (a) The laboratory performed Urine Drug Screen testing on the MedTox Scan analyzer; (b) An IQCP (Individualized Quality Control Plan) had been developed for the test system. (2) The surveyor reviewed the IQCP (dated as effective 04/27/16). The QA (Quality Assessment) portion of the IQCP did not include a schedule for evaluating the QCP to ensure it continued to provide accurate and reliable test results. There was no evidence of QA reviews for the IQCP since the effective date; (3) The surveyor reviewed the records with the regional director of laboratory services and asked if there was a policy to address how the laboratory will monitor the IQCP, including the frequency of the reviews and if a QA review had been performed since 04/27/16. The regional director of laboratory services stated a policy had not been written and QA reviews had not been performed. |