| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 37D0475908 | 01/13/2023 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Creek Nation Community Hospital | 1800 E Coplin Rd, Okemah, 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 |
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| **D0000** | The recertification survey was performed on 01/10,11,12/2023. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the administrative director of hospital services, director of quality, quality specialist #1, quality specialist #2, laboratory director, director of laboratory services, assistant director of laboratory services, laboratory supervisor, and testing person #5 during an exit conference performed at the conclusion of the survey. |
| **D5401** | PROCEDURE MANUAL<br>CFR(s): 493.1251(a)<br><br>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of records, policies and procedures, and interview with the director of laboratory services, assistant director of laboratory services, and the laboratory supervisor, the laboratory failed to follow their written procedure for coagulation lot rollover studies for two of four reagent lot numbers. Findings include: (1) On 01/10 /2023 at 10:30 am, the assistant director of laboratory services stated the laboratory performed PT/INR (Prothrombin Time/International Normalized Ratio) and PTT (Partial Thromboplastin Time) testing using the ACL TOP 300 analyzer; (2) On 01/11 /2023 at 02:45 pm, the assistant director of laboratory services stated the following reagents were put into use on 08/31/2022: (a) PT Reagent - HemosIL RecombiPlasTin, lot #N0129629 (b) PTT Reagent - HemosIL APTT-SP, lot #N0129380 (3) A review of the procedure titled, "ACL TOP New Reagent Lot Studies Work Instructions" identified the following: (a) The section titled, "Verification of Reference Interval" stated "Minimum of 20 screened normal samples (10 male and 10 female)"; (b) The section titled, "Comparison Study" stated |

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| | "Minimum of 20 normal samples (can be the same used in VRI study); Minimum of 20 abnormal samples that span the AMR, Run all samples concurrently with the old and new lots of reagents". (4) A review of the implementation records for the new reagent lot numbers identified the written procedure had not been followed: (a) For the verification of reference interval, eight male and 13 female donor samples had been used; (b) For the comparison study, the 20 abnormal samples did not span the AMR (Analytical Measurement Range) of the analyzer: (i) PT - The AMR was 8.0-320.0 and the samples that had been used spanned a range of 17.3-34.7; (ii) PTT - The AMR was 16.0-400.0 and the samples that had been used spanned a range of 33.2-47.1. (5) The records were reviewed with the director of laboratory services, assistant director of laboratory services, and the laboratory supervisor. All stated on 01/12/2023 at 12:04 pm, the laboratory had not followed their procedure for the coagulation lot rollover studies. |
| **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 assistant director of laboratory services, the laboratory failed to ensure the manufacturer's instructions were followed for performing maintenance procedures for one of five analyzers reviewed from 08/01/2021 through 12/31/2022. Findings include: (1) On 01/10/2023 at 10:45 am, the assistant director of laboratory services stated the following: (a) The Abbott Architect ci4100 analyzer consisted of the c4000 and i1000SR modules; (b) HCG (human Chorionic Gonadotropin), TSH (thyroid stimulating hormone), Free T4 (Thyroxine), Folate, Vitamin D, Vitamin B12, Acetaminophen, Digoxin, Dilantin, Valproic Acid, and Vancomycin testing were performed on the i1000SR module. (2) On 01/12/2023, a review of the "Architect Systems Operations Manual" identified the following maintenance requirements for the i1000SR module: (a) Section 6440 "Daily Maintenance" required the following: (i) Clean the outside of the probes in the wash zone (ii) Mix the microparticle bottles on the reagent carousel (iii) Dry the vacuum pump filter (iv) Flush and prime the wash zone, pre-trigger, and trigger manifolds (v) Verify that a backup has been peformed in the last thirty (30) days. If it has not the operator is instructed to perform one (vi) Check the database integrity (b) Sections 6407, 6445, and 6450 "Weekly" required the following: (i) Probe Cleaning - Manual (ii) Pipettor/WZ Probe Cleaning (iii) Wash Cup Cleaning (c) Section 6405 "Monthly" required the following: (i) Air Filter Cleaning (3) A review of maintenance records from 08/01/2021 through 12/31/2022 identified no documentation to prove the maintenance procedures had been performed as follows: (a) Daily - Between 12/31/2021 and 02/01/2022 (b) Weekly - Between 12 /31/21 and 02/04/2022 (c) Monthly - Between 12/10/2021 and 02/11/2022 (4) The records were reviewed with the assistant director of laboratory services who stated on 01/12/2023 at 02:30 pm, there were no records to prove the above maintenance procedures had been performed. |
| **D5791** | ANALYTIC SYSTEMS QUALITY ASSESSMENT<br>CFR(s): 493.1289(a)(c) |

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| | (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 director of laboratory services, assistant director of laboratory services, and laboratory supervisor, the laboratory failed to follow their policy for monitoring the effectiveness of their QCP (Quality Control Plan) for one of one test system. Findings include: (1) On 01/10/2023 at 10:15 am, the assistant director of laboratory services stated the following: (a) Urine Drug Screen testing was performed using the Bio-Rad TOX/SEE test kit; (b) An IQCP (Individualized Quality Control Plan) had been developed for the test system. (2) On 01/11/2023, a review of the IQCP identified that QA (Quality Assessment) reviews of the QCP (Quality Control Plans) were to be performed on an annual basis; (3) A review of records for the test systems during 2021 and 2022 identified no documentation an annual QA review had been performed during 2022; (4) The records were reviewed with the director of laboratory services, assistant director of laboratory services, and laboratory supervisor. All stated on 01/11/2023 at 12:55 pm, an annual QA review had not been documented as performed in 2022. |
| **D5807** | TEST REPORT<br>CFR(s): 493.1291(d)<br><br>Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of patient reports and interview with the director laboratory services and assistant director of laboratory services, the laboratory failed to make appropriate reference ranges available for two of two coagulation reagent lot number changes. Findings include: (1) On 01/10/2023 at 10:30 am, the assistant director of laboratory services stated the laboratory performed PT/INR (Prothrombin Time /International Normalized Ratio) and PTT (Partial Thromboplastin Time) testing using the ACL TOP 300 analyzer; (2) On 01/11/2023 at 02:45 pm, the assistant director of laboratory services stated the following reagents were put into use on 08/31 /2022: (a) PT Reagent - HemosIL RecombiPlasTin, lot #N0129629 (b) PTT Reagent - HemosIL APTT-SP, lot #N0129380 (3) A review of PT and PTT reagent implementation records identified the following normal reference intervals had been verified: (a) PT - 9.5-11.9 (b) PTT - 27.0-37.9 (4) A review of two random patient reports identified the following: (a) PT Patient Report - Testing performed on 01/04 /2023 at 11:06 am had a normal reference range of 9.4-12.6; (b) PTT Patient Report - Testing performed on 10/23/2022 at 01:09 pm had a normal reference range of 25.1-36.5. (5) The reports and implementation records were reviewed with the director of laboratory services who stated on 01/12/2022 at 01:42 pm, the laboratory had not updated the normal reference ranges into the laboratory's computer information system. |
| **D6016** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(4)(i) |

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| | The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of records and interview with the director of laboratory services, the laboratory director failed to attest that, at the time of testing, proficiency testing samples were tested in the same manner as patient specimens as required under Subpart H for four of eight events reviewed in 2022. Findings include: (1) On 01/10 /2023, a review of 2022 proficiency testing events identified the attestation statements had been signed approximately two to four months after the samples had been tested for four of eight events reviewed: (a) First 2022 Hematology/Coagulation Event - The sample testing had been completed on 03/23/2022 and the attestation statement had not been signed by the laboratory director until 06/03/2022; (b) Second 2022 Hematology/Coagulation Event - The sample testing had been completed on 07/29 /2022 and the attestation statement had not been signed by the laboratory director until 09/30/2022; (c) Third 2022 Hematology/Coagulation Event - The sample testing had been completed on 11/30/2022 and the attestation statement had not been signed by the laboratory director until 01/06/2023; (d) First 2022 Chemistry Core Event - The sample testing had been completed on 02/01/2022 and the attestation statement had not been signed by the laboratory director until 06/03/2022. (2) The records were reviewed with the director of laboratory services who stated on 01/10/2022 at 03:40 pm, the attestation had not been signed until approximately two to four months after the proficiency samples had been tested. |
| **D6029** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(11)<br><br>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) 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.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of records and interview with the assistant director of laboratory services, the laboratory director failed to ensure that personnel performing moderate complexity testing had the appropriate training for one of two persons. Findings include: (1) On 01/10/2023, a review of personnel records identified the following for one of two testing persons hired after the previous recertification: (a) Testing Person #8 - This person was hired to perform patient testing on 12/06/2021. There was no documentation this person had been initially trained. A competency evaluation had not been documented as performed until 12/14/2022. (2) The records were reviewed with the assistant director of laboratory services who stated on 01/10/2023 at 01:40 |

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| | pm, there was no documentation to prove the testing person had been initially trained to perform moderate complexity testing. |
| **D6054** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413(b)(9)<br><br>The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of records and interview with the assistant director of laboratory services, the technical consultant failed to evaluate personnel performing moderate complexity testing at least annually for two of six persons. Findings include: (1) On 01/10/2023, a review of personnel records for six persons who performed moderate complexity testing during 2021, 2022, and to date in 2023 identified no evidence of annual evaluations as follows: (a) Testing Person #2 - Annual competencies had not been documented as performed between 06/08/2020 and 12/14/2022; (b) Testing Person #4 - Annual competencies had not been documented as performed between 09/17/2020 and 12/15/2022. (2) The records were reviewed with the assistant director of laboratory services who stated on 01/10/2023 at 01:30 pm, the annual competency evaluations had not been performed as shown above. |