Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0472787	03/17/2023
Name of Provider or Supplier	**Street Address, City, State**	
Newman Memorial Hospital	905 S Main St, Shattuck, 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 recertification survey was performed on 03/14,15/16/17/2023. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with technical consultant #2 at the conclusion of the survey.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (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. This STANDARD is not met as evidenced by: Based on a review of records and interview with technical consultant #2, the laboratory director or designee failed to sign proficiency testing attestation statements for three of 18 events. Findings include: (1) On 03/14/2023 a review of the 2021 and 2022 proficiency testing records identified the following for three of 18 events: (a) Third 2021 Hematology/Coagulation Event - The attestation statement had not been signed by the laboratory director or designee; (b) Third 2021 Chemistry Core Event - The attestation statement had not been signed by the laboratory director or designee; (c) Second 2022 Chem Core Event - The attestation statement had not been signed by the laboratory director or designee. (2) The findings were reviewed with technical consultant #2 who stated on 03/15/2023 at 11:39 am the attestation statements had not been signed by the laboratory director or designee.

D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with technical consultant #2, the laboratory failed to follow the manufacturer's instructions for implementing coagulation reagents for two of two lot numbers. Findings include: (1) On 03/14/2023 at 02:56 pm, technical consultant #2 stated: (a) The Sysmex CA-660 analyzer was used to perform PT/INR (Prothrombin Time/International Normalized Ratio) and PTT (Partial Thromboplastin Time) testing; (b) The following reagent lot numbers were put into use on 11/22/2022: (i) PT - Innovin reagent, lot #564604 (ii) PTT - Actin FSL reagent, lot #562699 (2) On 03/15/2023 a review of the manufacturer's instructions contained in the "Sysmex CA-600 Series Lot Rollover Information" for implementing new reagents stated under "Lot-to-Lot Method Correlation": (a) "Minimum of 40 samples : 20 normal, 20 abnormal"; (b) "Abnormal samples should span the reportable range of the assay"; (c) "Test samples on current and new reagent lot numbers simultaneously or within one (1) hour of each other". (3) A review of the implementation records for the lot changes identified the following: (a) Innovin Reagent - Although the laboratory had tested 41 samples, seven of the samples (instead of 20) were abnormal and did not span the reportable range of the assay; (b) Actin FSL Reagent - Although the laboratory had tested 41 samples, seven of the samples (instead of 20) were abnormal and did not span the reportable range of the assay. (4) The records were reviewed with technical consultant #2 who stated on 03/15/2023 at 03:20 pm, the laboratory had not followed the manufacturer's instructions for the lot changes as shown above.
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 a review of records and interview with technical consultant #2, the laboratory failed to utilize the demonstrated reportable ranges for two of four new test methods; and failed to ensure the performance specification data had been evaluated prior to implementing the new testing for two of four new test methods introduced into the laboratory. Findings include: MINII SED ANALYZER (1) On 03/16/2023 at 10:30 am, the laboratory manager stated the laboratory began performing automated ESR testing using the miniiSED analyzer on 07/08/2022; (2) A review of the performance specification records for the new test system identified the laboratory

	had demonstrated a reportable range of 1-94 mm/hr; (3) Interview with technical consultant #2 on 03/16/2023 at 11:10 am confirmed the laboratory was using the manufacturer's reportable range of 1-120 mm/hr instead of the reportable range that had been demonstrated by the laboratory. AMMONIA TESTING (1) On 03/16/2023 at 01:00 pm, technical consultant #2 stated the laboratory added Ammonia testing to the Dimension EXL 200 test menu on 11/26/2022; (2) A review of the performance specification records for the new test identified the following: (a) The laboratory had demonstrated a reportable range of 0-876 umol/L; (b) There was no evidence the performance specification data had been signed and dated as approved by the laboratory prior to putting into use for patient testing. (3) Interview with technical consultant #2 on 03/16/2023 at 02:20 pm confirmed the following: (a) The laboratory was using the manufacturer's reportable range of 0-1000 umol/L instead of the reportable range that had been demonstrated by the laboratory; (b) There was no documentation to prove the performance specification data had been reviewed and approved by the laboratory prior to putting into use. C-REACTIVE PROTEIN TESTING (1) On 03/16/2023 at 01:00 pm, technical consultant #2 stated the laboratory added CRP (C-Reactive Protein) testing to the Dimension EXL 200 test menu on 11/26/2022; (2) A review of the performance specification records for the new test identified no evidence the data had been signed and dated as approved by the laboratory prior to putting into use for patient testing; (3) Interview with technical consultant #2 on 03/16/2023 at 02:20 pm confirmed there was no documentation to prove the performance specification data had been reviewed and approved by the laboratory prior to putting into use. VITAMIN D TESTING (1) On 03/16/2023 at 01: 00 pm, technical consultant #2 stated the laboratory added Vitamin D testing to the Dimension EXL 200 test menu on 11/26/2022; (2) A review of the performance specification records for the new test identified no evidence the data had been signed and dated as approved by the laboratory prior to putting into use for patient testing; (3) Interview with technical consultant #2 on 03/16/2023 at 02:20 pm confirmed there was no documentation to prove the performance specification data had been reviewed and approved by the laboratory prior to putting into use.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) 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. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with technical consultant #2, the laboratory failed to ensure the manufacturer's instructions were followed for performing weekly maintenance procedures for the Dimension EXL analyzer during the review period of January 2022 through December 2022. Findings include: (1) On 03/14/2023 at 02:45 pm, technical consultant #2 stated the laboratory performed Albumin, Ammonia, Alkaline Phosphatase, ALT (Alanine Aminotransferase), AST (Aspartate Aminotransferase), Amylase, Total Bilirubin, BUN, Calcium, Chloride, CK (Creatine Kinase), CKMB (Creatine Kinase Isoenzyme), CO2, Creatinine, CRP (C-Reactive Protein), Glucose, Magnesium, Potassium, Total Protein, Sodium, Troponin I, Uric Acid, Acetaminophen, Direct Bilirubin, Alcohol, Vitamin D, Lactic Acid, HCG (Human Chorionic Gonadotropin), Phosphorus, TSH (Thyroid Stimulating Hormone), Free T4 (Thyroxine) and Vancomycin testing using the Siemens Dimension EXL 200 analyzer; (2) On 03/17

	/2023 a review of the manufacturer's maintenance log showed the following required weekly maintenance procedures: (a) Clean outside of R2 Probe (b) Clean outside of HM Wash Probe (3) A review of maintenance logs from 01/01/2022 through 12/31 /2022 identified weekly maintenance had not been documented as performed between: (a) 02/18/2022 and 03/04/2022 (b) 04/22/2022 and 05/06/2022 (c) 05/20/2022 and 06 /03/2022 (d) 06/24/2022 and 07/07/2022 (e) 07/21/2022 and 08/05/2022 (4) The records were reviewed with technical consultant #2 who stated on 03/17/2023 at 10:00 am, the weekly maintenance had not been documented as performed as shown above.
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with technical consultant #2, the laboratory failed to perform function checks every six months as defined by the manufacturer for the iSTAT 1 analyzer during the review period of 06/01/2021 through the current date. Findings include: (1) On 03/14/2023 at 02:30 pm, technical consultant #2 stated the laboratory performed Blood Gas pH, pCO2, and pO2 testing using the EG6+ cartridge and the iSTAT 1 analyzer; (2) On 03 /16/2023 a review of the i-STAT1 System Manual in the section titled, "Checking the Thermal Probes in the i-STAT analyzer" stated "Use the procedure below to check the thermal probes on each analyzer every six months"; (3) A review of records from 06 /01/2021 through the current date identified no evidence the thermal probe checks had been performed during the review period; (4) The findings were reviewed with the technical consultant #2 who stated on 03/16/2023 at 09:45 am, the thermal probe checks had not been performed every six months.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of records and interview with technical consultant #2, the laboratory failed to have control procedures that monitored the accuracy and precision of the testing process; and that would detect immediate errors that would occur due to test system failure, adverse environmental conditions, and operator performance for

	automated ESR (Erythrocyte Sedimentation Rate) testing for four of four months. Findings include: (1) On 03/16/2023 at 10:30 am, the laboratory manager stated the laboratory began performing automated ESR testing using the miniiSED analyzer on 07/08/2022; (2) On 03/16/2023 at 11:30 am, technical consultant #2 stated the following: (a) Two levels of Alcor SediTrol QC (quality control) materials were performed each day of patient testing; (b) Laboratory established ranges were used to determine acceptability of QC results; (c) Level one lot #140 and level two lot #240 had been used during the review period of 07/11/2022-11/23/2022; (4) A review of QC records for patient testing performed from 07/11/2022 through 11/23/2022 identified the following for one of two levels of QC (level one lot #140): (a) A two SD (Standard Deviation) range of 3.4-13 had been established by the laboratory when the lot numbers had been put into use. A range of 2-16 had been used to evaluate QC results during the review period. (5) The records were reviewed with technical consultant #2 who stated on 03/16/2023 at 01:15 pm the laboratory had evaluated QC results using the package insert guideline ranges instead of laboratory established ranges.
D5537	ROUTINE CHEMISTRY CFR(s): 493.1267(b)(d) For blood gas analyses, the laboratory must perform the following: (b) Test one sample of control material each 8 hours of testing using a combination of control materials that include both low and high values on each day of testing. (d) Document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on a review of records and interview with technical consultant #2, the laboratory failed to perform one sample of control material each 8 hours of patient blood gas testing using a combination of control materials that include both low and high values on each day of testing for three of 34 patients reviewed. Findings include: (1) On 03/14/2023 at 12:33 pm, technical consultant #2 stated the following: (a) Blood gas testing (pH, pCO2, pO2) was performed using the iSTAT 1 analyzer and the Eg6+ cartridge; (b) Two levels of quality control (QC) material (level one and level three) were tested each eight hours of patient testing. (2) On 03/16/2023, a review of QC and patient records for testing performed from 06/01/2021 through 02 /28/2023 identified that QC had not been performed each eight hours of patient testing for three of 34 patients reviewed. The records showed that QC testing was performed after patient testing had been performed as follows: (a) Patient was tested on 09/12 /2022 at 01:40 pm. Level one QC had not been performed until 09/12/2022 at 02:48 pm, and level three QC had not been performed until 09/12/2022 at 02:53 pm; (b) Patient was tested on 09/19/2022 at 10:38 pm. Level one QC had not been performed until 09/19/2022 at 10:57 pm, and level three QC had not been performed until 09/19 /2022 at 11:08 pm; (c) Patient was tested on 11/19/2022 at 01:50 am. Level one QC had not been performed until 11/19/2022 at 02:05 am, and level three QC had not been performed until 11/19/2022 at 01:58 am. (3) The records were reviewed with technical consultant #2 who stated on 03/16/2023 at 03:02 pm, QC testing had not been performed each eight hours of patient testing as shown above.
D5555	IMMUNOHEMATOLOGY CFR(s): 493.1271(c)(f) (c) Blood and blood products storage. Blood and Blood products must be stored under

	appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on a review of records, policies and procedures, and interview with technical consultant #2, the laboratory failed to ensure units of blood were stored under appropriate conditions during the review period of June 2021 through December 2022. Findings include: (1) On 03/14/2023 at 02:20 pm, technical consultant #2 stated the laboratory stored units of packed red blood cells in the Helmer blood bank refrigerator. The units were to be used for patient transfusions; (2) A review of the policy titled "Blood Bank Alarm System" stated, "Alarms are checked quarterly for operation"; (3) A review of alarm check records from June 2021 through December 2022 identified no evidence the alarm checks had been performed between 05/18 /2022 and 12/13/2022; (4) The findings were reviewed with technical consultant #2 who stated on 03/15/2023 at 12:19 pm there was no documentation to prove the alarm checks had been performed between 05/18/2022 and 12/13/2022.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) 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; This STANDARD is not met as evidenced by: Based on a review of records and interview with technical consultant #2, 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 one of four Immunohematology proficiency testing events reviewed in 2021 and 2022. Findings include: (1) On 03/14/2023 a review of 2021 and 2022 proficiency testing events identified an attestation statement had been signed approximately two months after the samples had been tested for one of four Immunohematology events reviewed: (a) Second 2022 Immunohematology Event - The sample testing had been completed on 08/15/2022 and the attestation statement had not been signed by the laboratory director until 10/26/2022. (2) The records were reviewed with technical consultant #2 who stated on 03/15/2023 at 11:39 am, the attestation statement had not been signed until approximately two months after the proficiency samples had been tested.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

	This STANDARD is not met as evidenced by: Based on a review of records and interview with technical consultant #2, the technical consultant failed to ensure competency evaluations for moderate complexity testing had been performed semiannually during the first year of testing for one of one testing person. Findings include: (1) On 03/14/2023 a review of personnel records for one person hired to perform moderate complexity testing after the previous recertification survey identified the following for one of one person: (a) Testing Person #3 - The initial training was complete on 05/03/2022. There was no evidence a competency evaluation had been performed to date. (2) The records were reviewed with technical consultant #2 who stated on 03/14/2023 at 12:05 pm, a semiannual competency evaluation had not been performed as stated above.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) 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. This STANDARD is not met as evidenced by: Based on a review of records and interview with technical consultant #2, the technical consultant failed to evaluate personnel performing moderate complexity testing at least annually and failed ensure evaluations included all moderate complexity testing for one of one testing person. Findings include: (1) On 03/14/2023 at 02:40 pm technical consultant #2 stated Wet Prep analysis, Urine Microscopic, and Post Vasectomy Qualitative Semen Analysis (presence or absence) were performed in the laboratory; (2) A review of personnel records for one person performing moderate complexity testing during 2020, 2021, 2022, and to date in 2023 identified the following for one of one person: (a) Testing Person #1 - An annual competency assessment had not been documented as performed between 08/13/2020 and 02/24 /2023. In addition, the 2023 competency did not include an assessment of Wet Prep analysis, Urine Microscopic, and Post Vasectomy Qualitative Semen Analysis. (3) The records were reviewed with technical consultant #2 who stated on 03/14/2023 at 12:35 pm, annual competency assessments had not been performed as stated above and the competency performed in 2023 did not include included an assessment of Wet Prep analysis, Urine Microscopic, and Post Vasectomy Qualitative Semen Analysis.