Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 37D0472787	**(X3) Date Survey Completed** 05/07/2021
Name of Provider or Supplier Newman Memorial Hospital	**Street Address, City, State** 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 05/06,07/2021. Immediate Jeopardy was determined during the survey due to issues identified with Coagulation testing. The laboratory voluntarily ceased patient testing, which abated the Immediate Jeopardy. The laboratory was found out of compliance with the following CLIA regulations: 493.1215; D5024: Hematology 493.1403; D6000: Laboratory Director, Moderate Complexity The findings were reviewed with the laboratory manager/technical consultant #1 and technical consultant #2 at the conclusion of the survey.
D5024	HEMATOLOGY CFR(s): 493.1215 If the laboratory provides services in the specialty of Hematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1269, and 493. 1281 through 493.1299. This CONDITION is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the laboratory manager/technical consultant #1, the laboratory failed to ensure the requirements were met for the specialty of Hematology for Coagulation testing. Findings include: (1) The laboratory failed to follow the manufacturer's instructions for implementing coagulation reagents. Refer to D5411; (2) The laboratory failed to have an ongoing mechanism for performing effective analytic quality assessment. Refer to D5791.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) 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. This STANDARD is not met as evidenced by: Based on a review of records, policy and procedure manual, and interview with the laboratory manager/technical consultant #1, the laboratory failed to follow written procedures for Hemoglobin A1c testing for 2 of 2 quality control lot number. Findings include: (1) On 05/06/2021 at 10:00 am, the laboratory manager/technical consultant #1 stated the following to surveyor #2: (a) Hemoglobin A1c (glycated hemoglobin) testing was performed on the Dimension EXL 200 analyzer; (b) Two levels of Bio-Rad Liquichek Diabetes Control materials were used each day of patient testing. (2) On 5/07/2021, surveyor #2 reviewed the written procedures titled, "Establishing and Evaluating Quality Control", which stated: (a) "When a new lot of Quality Control is being implemented it is required to run both the new and the old lot number in tandem. A 20-day comparison will need to be completed prior to implementing the new lot number. This will allow time to verify that the new lot of controls is acceptable and allow the new mean to be set. This laboratory uses historical Standard Deviations." (3) Surveyor #2 reviewed records for two control lot numbers (Level 1 lot#55711 and Level 2 lot#55712) that were currently in use. For 2 of 2 lot numbers the old lot numbers and new lot numbers were tested in tandem as follows: (a) Lot# 55711 - Ran 10 times and not the laboratory policy of 20 runs; (b) Lot# 55712 - Ran 9 times and not the laboratory policy of 20 runs. (3) Surveyor #2 reviewed the findings with the laboratory manager/technical consultant #1 who stated on 05/07/2021 at 01: 50 pm the laboratory procedure had not been followed as indicated above.
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 the laboratory manager/technical consultant #1, the laboratory failed to follow the manufacturer's instructions for implementing coagulation reagents. Findings include: (1) On 05/06/2021 at 10:15 am, the laboratory manager/technical consultant #1 stated the following to surveyor #1: (a) The Sysmex CA-600 analyzer was used to perform PT/INR (Prothrombin Time/International Normalized Ratio) and PTT (Partial Thromboplastin Time) testing (the INR was calculated using the PT reference interval mean; (b) The following reagent lot numbers were put into use as follows: (i) PT - Dade Innovin reagent, lot #549736 in use on 10/09/2020 (ii) PTT - Dade Actin reagent, lot #562624 in use on 05/01/2020 (2) Surveyor #1 reviewed the manufacturer's instructions titled, "Sysmex CA-600 Series Lot Rollover Information" for implementing new reagents. The manufacturer required the following: (a) Section titled "Verification of Reference Range" (i) "Use 20 Normal Individuals * 10 males; 10 females * Medication History: no aspirin, no hormones, no herbal supplements; (ii) "Samples should be run on current and new reagent lots"; (iii) "Calculate mean and 2 SD range"; (iv) "MNPT for INR calculation should be the geometric mean". (b) Section titled, "Lot-to-Lot Method Correlation" (i) "40 samples: 20 normal, 20 abnormal"; (ii) "Normal samples (Section I) may be used for the Method Correlation

and Verification of Reference Range"; (iii) "Abnormal samples should span the Reportable Range of assay"; (iv) "Assay samples on current and new lot number reagents simultaneously or within 1 our of each other"; (v) "Calculate Linear Regression statistics". (c) Section titled, "Quality Control" (i) "Assay new lot number of QC material with the new lot of reagent in PTN and APTTN protocols"; (ii) Collect a minimum of 30 data points over multiple days and stability limits of control"; (iii) Calculate the mean, 2 SD and 3 SD range". (3) The surveyor reviewed the Normal Patient Mean that had been programmed into the analyzer, with the assistance of the laboratory manager/technical consultant #1, and reviewed the records for the lot changes. The following was identified: (a) PT - Innovin reagent, lot #549736 (i) Although the normal patient mean had been calculated using 10 males and 10 females, there was no documentation of the age, medication history, and health status of the donors; (ii) The geometric mean that had been calculated using the values was 10.3, which did not match the normal patient mean (10.1) that had been programmed into the analyzer to calculate the INR; (iii) For the method correlation, the laboratory had used 10 normal samples and 5 abnormal samples which did not span the reportable range. In addition, there was no documentation to prove a linear regression had been calculated. (b) PTT - Dade Actin reagent, lot #562624 (i) Although the normal reference interval had been performed using 20 donors (10 males and 10 females), there was no evidence of the age, medication history, and health status of the donors; (ii) For the method correlation, the laboratory had used 10 normal samples and no abnormal samples to span the reportable range. In addition, there was no documentation to prove a linear regression had been calculated. (4) The surveyor reviewed the records and the findings with the laboratory manager/technical consultant #1, who stated the following on 05/07/2021 at 01:30 pm: (a) The laboratory did not have documentation to prove the samples used for the normal reference interval studies were normal donors for PT and PTT; (b) It was identified the PT geometric mean that had been programmed into the analyzer to calculate the INR was from the previous lot change that had been performed on 01/12/2020 and the laboratory failed to update the value in the analyzer; (c) The laboratory did not perform the method correlation for PT and PTT using 20 normal samples and 20 abnormal samples, and calculate a linear regression; (d) The laboratory had not followed the manufacturer's instructions for implementing the coagulation reagents. (5) The following were examples of patient PT/INR testing performed: (a) Patient #10227306164 - Testing performed on 12/01/2020 (b) Patient #10904310230 - Testing performed on 12/15/2020 (c) Patient #E12042622 - Testing performed on 01/10/2021 (d) Patient #E5032315 - Testing performed on 01/28/2021 (e) Patient #E6204612 - Testing performed on 02/23/2021 (f) Patient #10227306164 - Testing performed on 03/04/2021 (g) Patient #E6206473 - Testing performed on 03/28/2021 (h) Patient #10344307112 - Testing performed on 03/31/2021 (i) Patient #E5032315 - Testing performed on 04/04/2021 (j) Patient #10595608255 - Testing performed on 04/13/2021 (k) Patient #E6197552 - Testing performed on 04/20/2021 (l) Patient #576553 - Testing performed on 04/26/2021 (m) Patient #E5032259 - Testing performed on 04/30/2021 (n) Patient #E5218330 - Testing performed on 05/03/2021 (o) Patient #E6196530 - Testing performed on 05/05/2021 (6) The following were examples of patient PTT testing performed: (a) Patient #E10962940 - Testing performed on 03/31/2021 (b) Patient #1151703266 - Testing performed on 04/02/2021 (c) Patient #E10362847 - Testing performed on 04/07/2021 (d) Patient #E4914492 - Testing performed on 04/17/2021 (e) Patient #E12166547 - Testing performed on 04/26/2021 (f) Patient #E4741149 - Testing performed on 05/05/2021 39088 Based on a review of records, manufacturer's instructions, and interview with the laboratory manager/technical consultant #1, the laboratory failed to follow the manufacturer's instructions for verifying morphology flags for 3 of 10 patient reports.

	Findings include: (1) On 05/06/2021 at 10:05 am, the laboratory manager/technical consultant #1 stated to the surveyors CBC (Complete Blood Count) testing was performed on the Sysmex XN-450 analyzer; (2) On 05/07/2021, surveyor #2 reviewed the manufacturer's instructions for verifying morphology flags obtained on the analyzer. The following were examples of flags, with the corresponding instructions: (a) WBC abn scat - "Perform manual differential" (b) Neutrophilia - "Perform Smear Review" (c) Monocytosis - "Perform Smear Review" (d) IG Suspect - ""Perform Smear Review" (3) Surveyor #2 randomly reviewed 10 patient records which contained morphology flags from CBC testing performed between 09/08/2020 and 01 /05/2021. For 3 of the records, there was no evidence the laboratory followed the manufacturer's instructions for verifying the flags. The findings for the 3 records were: (a) Patient Record #1 - Testing performed on 09/18/2020 with WBC abn scat, Lymphocytosis, and Monocytosis flags obtained; (b) Patient Record #2 - Testing performed on 11/18/2020 with a Neutrophilia and IG Suspect flag obtained; (c) Patient Record #3 - Testing performed on 01/05/2021 with an Monocytosis flag obtained. (4) Surveyor #2 reviewed the records with the laboratory manager/technical consultant #1 who stated on 05/07/2021 at 01:35 pm, that the flags obtained for the above 3 patients had not been verified as indicated above.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager/technical consultant #1, the laboratory failed to ensure reagents had not exceeded their expiration date for 3 of 5 days of testing. Findings include: (1) On 05/06/2021 at 10: 20 am, the laboratory manager/technical consultant #1 stated to surveyor #1 Crossmatch testing was performed in the laboratory which included ABO Typing using the tube method; (2) On 05/06/2021, surveyor #2 reviewed quality control and patient testing records for testing performed from 10/23/2020 through 11/30/2020 and identified expired Anti-D Cells had been used 3 of 5 days of testing reviewed. The quality control and patient testing had been performed on 11/23/2020, 11/24/2020, and 11/30/2020 using the expired following reagents: (a) Alba Biosciencee Anti-D lot #V201406, expiration date 11/21/2020. (3) Surveyor #2 reviewed the records with the laboratory manager/technical consultant #1 who stated on 05/06/2021 at 04:10 pm expired reagents had been used as indicated 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 the laboratory manager/technical consultant #1, the laboratory failed to ensure the verified reportable ranges were used by the laboratory for a new test method. Findings include: (1) On 05/06/2021 at 10:15 am, the laboratory manager/technical consultant #1 stated to surveyor #1 the laboratory began performing pH, pCO2, and pO2 testing using the EG6+ cartridge and the iSTAT 1 analyzer on 06/29/2020; (2) Surveyor #1 reviewed the performance specification records and identified the laboratory had demonstrated the following reportable ranges: (a) pH - 6.512-7.868 (b) PCO2 - 20.8-101.4 (c) PO2 - 50-423 (3) Surveyor #1 requested the reportable ranges that were being utilized by the laboratory. The laboratory manager/technical consultant #1 provided surveyor #1 with the manufacturer's reportable ranges as follows: (a) pH - 6.5-8.2 (b) pCO2 - 5.0-130.0 (c) pO2 - 5.0-800 (4) Surveyor #1 reviewed the findings with the laboratory manager /technical consultant #1, who stated on 05/06/2021 at 11:30 am the laboratory was not using the reportable ranges that had been demonstrated by the laboratory.
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 the laboratory manager/technical consultant #1, the laboratory failed to follow the manufacturer's instructions for performing maintenance procedures. Findings include: (1) On 05/06/2021 at 10:15 am, the laboratory manager/technical consultant #1 stated the following to surveyor #1: (a) The Sysmex CA-600 analyzer was used to perform PT/INR (Prothrombin Time/International Normalized Ratio) and PTT (Partial Thromboplastin Time) testing (the INR was calculated using the PT reference interval mean; (2) On 05/07/2021, surveyor #2 reviewed the manufacturer's maintenance requirements, which required the following: (a) Quarterly Maintenance (i) Perform LED Calibration; (ii) Clean DI H2O Rinse Bottle w/alcohol; (iii) Clean Filters. (b) Yearly Maintenance (i) Replace Rinse Filter. (3) Surveyor #2 reviewed maintenance records from 2019 and 2020 and identified the following: (a) Quarterly Maintenance had not documented as performed between 02/03/2020 and 08/10/2020; (b) Yearly Maintenance had not documented as performed in 2019 and 2020. (4) The records were reviewed with the laboratory manager/technical consultant #1 who stated on 05 /07/2021 at 11:35 am the quarterly and yearly maintenance had not been documented as performed as indicated 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 the laboratory manager/technical consultant #1 and technical consultant #2, the laboratory failed to perform function checks on the blood bank centrifuge as required by the manufacturer. Findings include: (1) On 05/06/2021 at 10:25 am, the laboratory manager/technical consultant #1 stated the following to surveyor #1: (a) The laboratory performed ABO/Rh Type, Antibody Screen, and Compatiblity testing using the tube method; (b) Specimens were processed using the UltraCW Automatic Cell Washing System. (2) On 05/07/2021, surveyor #2 reviewed the manufacturer's instructions titled, "UltraCW Automatic Cell Washing System Operations Manual" for the UltraCW Automatic Cell Washing System. Under the section titled, "6 Maintaining the cell washer" the instructions stated the following: (a) Annually (i) "Replace the supply and drain tubing." (ii) "Replace the pump tubing." (iii) "Replace the tue holder inserts for 10 mm x 75 mm tubes." (3) Surveyor #2 reviewed the 2019 and 2020 cell washer records. There was no documentation to prove the preventative maintenance had been performed during the review period; (4) Surveyor #2 reviewed the records with the laboratory manager/technical consultant #1 who stated on 05/07 /2021 at 11:40 am there was no documentation to prove the the annaual preventative maintenance was performed on the UltraCW Automatic Cell Washing System as indicated above.
D5559	IMMUNOHEMATOLOGY CFR(s): 493.1271(e)(f) (e) Investigation of transfusion reactions. (e)(1) According to its established procedures, the laboratory that performs compatibility testing, or issues blood or blood products, must promptly investigate all transfusion reactions occurring in facilities for which it has investigational responsibility and make recommendations to the medical staff regarding improvements in transfusion procedures. (e)(2) The laboratory must document, as applicable, that all necessary remedial actions are taken to prevent recurrences of transfusion reactions and that all policies and procedures are reviewed to assure they are adequate to ensure the safety of individuals being transfused. (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 written policies and interview with the laboratory manager /technical consultant #1 and the director of nursing, the laboratory failed to ensure that written policies provided safety for individuals being transfused for 5 of 11 units of packed red blood cells. Findings include: (1) On 05/06/2021 at 10:20 am, the laboratory manager/technical consultant #1 stated to surveyor #2 the laboratory stored units of packed red blood cells in the blood bank refrigerator. The units were to be used for patient transfusions; (2) Surveyor #2 reviewed the hospital policy regarding transfusion reactions. The policy titled, "GUIDELINES FOR THE ADMINISTRATION OF BLOOD AND BLOOD PRODUCTS" under the section titled, "Transfusion Administration", stated: (a) "Blood/blood components must be hung within 15 minutes." (b) "Vital signs are obtained the following times:" (i) "Immediately prior to the start of blood administration" (ii) "After the blood starts, Q5 minutes for 15 minutes (q5x3)" (iii) "Q15 minutes for 30 minutes (q15x2)" (iv) "Q30 minutes for the duration of the transfusion" (v) "Immediately after the blood is finished" (vi) "Final set obtained 30 minutes after the transfusion has ended" (3) Surveyor #2 then reviewed records for 11 units of PRBCs (Packed Red Blood Cells)

	that had been transfused between 04/20/2019 through 06/15/2020 for 2 patients, and identified the following: (a) Blood components must be hung within 15 minutes (i) Patient #1605003266 - Transfused with 1 unit PRBCs (unit #W091019157838) on 04 /20/2019. The unit was checked out from the laboratory at 06:30 pm and hung at 07: 00 pm, 30 minutes later; (ii) Patient #1605003266 - Transfused with 1 unit PRBCs (unit #W091019404108) on 12/21/2019. The unit was checked out from the laboratory at 10:18 am and hung at 10: 50 am, 32 minutes later; (iii) Patient #1605003266 - Transfused with 1 unit PRBCs (unit #W091020198371) on 06/15 /2020. The unit was checked out from the laboratory at 12:34 pm and hung at 02:02 pm, 1 hour and 28 minutes later. (b) Vital immediately prior to the start of blood administration (i) Patient #1605003266 - Transfused with 1 unit PRBCs (unit #W091020216876) on 06/14/2020. Vital signs were not documented prior to the start of the blood transfusion. (c) Final set of vitals obtained 30 minutes after the transfusion (i) Patient #4291 - Transfused with 1 unit of PRBCs (unit #W091020316090) on 09/20/2020. The 30 minute post transfusion vitals had not been taken. (4) Surveyor #2 reviewed the findings with the director of nursing. The director of nursing stated on 05/06/2021 at 10:30 am the written policy and procedure for blood administration had not been followed as indicated above.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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. This STANDARD is not met as evidenced by: Based on a review of records, policy and procedure manual, manufacturer's instructions, and interview with the laboratory manager/technical consultant #1, technical consultant #2, and the director of nursing, the laboratory failed to have an ongoing mechanism for performing effective analytic quality assessment. Findings include: (1) It was determined the laboratory did not have an effective mechanism for performing analytic quality assessment because of the following issues identified during the survey: (a) The laboratory failed to follow written procedures for Hemoglobin A1c testing. Refer to D5401; (b) The laboratory failed to follow the manufacturer's instructions for implementing coagulation reagents; and failed to follow the manufacturer's instructions for verifying morphology flags Refer to D5411; (c) The laboratory failed to ensure reagents had not exceeded their expiration date. Refer to D5413; (d) The laboratory failed to ensure the verified reportable ranges were used by the laboratory for a new test method. Refer to D5421; (e) The laboratory failed to follow the manufacturer's instructions for performing maintenance procedures. Refer to D5429; (f) The laboratory failed to perform function checks on the blood bank centrifuge as required by the manufacturer. Refer to D5431; (g) The laboratory failed to ensure that written policies provided safety for individuals being transfused. Refer to D5559.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance

	with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the laboratory manager/technical consultant #1, the laboratory director failed to provide overall management and direction for moderate complexity testing. Findings include: (1) The laboratory director failed to ensure test methods were performed as required by the manufacturer to ensure accurate and reliable results were reported. Refer to D6014. (2) The laboratory director failed to ensure a quality assessment program had been established and maintained. Refer to D6021.
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii) 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)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the laboratory manager/technical consultant #1, the laboratory director failed to ensure test methods were performed as required by the manufacturer to ensure accurate and reliable results were reported. Findings include: (1) The laboratory failed to ensure the laboratory followed the manufacturer's instructions for implementing coagulation reagents. Refer to D5411.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the laboratory manager/technical consultant #1, the laboratory director failed to ensure a quality assessment program had been established and maintained. Findings include: (1) The laboratory director failed to ensure the laboratory had an ongoing mechanism for performing effective analytic quality assessment. Refer to D5791.
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 the laboratory manager/technical consultant #1, the technical consultant failed to ensure that a person performing moderate complexity testing had been evaluated semiannually during the first year of testing for 1 of 4 testing persons. Findings include: (1) On 05/06/2021, surveyor #2 reviewed 2019 and 2020 personnel records. The following was identified: (a) Testing Person #4 - The initial training for this person was completed on 06/11/2019. There was no evidence that a semiannual evaluation had been performed (due 12/19); (2) Surveyor #2 reviewed the records with the laboratory manager/technical consultant #1 who stated on 05/06/2021 at 11:08 am there were no records to prove the above person had been evaluated semiannually.
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 the laboratory manager/technical consultant #1, the technical consultant failed to ensure evaluations included all moderate complexity testing performed for 1 of 4 testing persons. Findings include: (1) On 05/06/2021 at 10:00 am, the laboratory manager/technical consultant #1 stated to surveyor #1 qualitative serum pregnancy testing was performed using the ICON 25 hCG test kit; (2) Surveyor #2 reviewed 2019 and 2020 personnel records for 4 persons performing serum pregnancy testing in the laboratory. The records showed that an evaluation had been performed for testing person #3 on 08/14/2019; (3) There was no evidence the evaluation for testing person #3 included an assessment of qualitative serum pregnancy testing; (4) Surveyor #2 reviewed the findings with laboratory manager/technical consultant #1, who stated on 05/06/2021 at 11:05 am the above evaluation did not include serum pregnancy testing.