Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0050739	03/28/2025
Name of Provider or Supplier	**Street Address, City, State**	
Beaver County Hospital Authority	212 East 8th Street, Beaver, 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 03/25,26,27,28/2025. The laboratory was found out of compliance with the following CLIA Conditions: 493.1213; D5022: Toxicology, High Complexity 493.1441; D6076: Laboratory Director, High Complexity The findings were reviewed with the chief executive officer, laboratory director, technical consultant, and testing person #2 at the conclusion of the survey.
D5022	TOXICOLOGY CFR(s): 493.1213 If the laboratory provides services in the subspecialty of Toxicology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on a review of records, urine drug screen package insert, FDA database, email correspondence with FDA representative, and interview with the technical consultant, the laboratory failed to ensure the requirements were met for the subspecialty of toxicology for ten of ten months of patient testing. Findings include: (1) The laboratory failed to verify the accuracy for the iCassette Urine Test - Drug Screen Cassette at least twice annually. Refer to D5217; (2) The laboratory failed to establish the performance specifications for the iCassette Urine Test - Drug Screen Cassette not cleared or approved by the FDA. Refer to D5423; (3) The laboratory failed to perform a negative and positive control material each day of patient urine drug screen testing. Refer to D5449.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 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. This STANDARD is not met as evidenced by: Based on a review of records, written policies, and interview with the technical consultant, the laboratory failed to establish a written clinical consultant competency assessment policy, based on the position responsibilities as listed in the Subpart M. Findings include: (1) A review of written policies and interview with the technical consultant on 03/25/2025 at 02:40 pm identified no evidence of a policy for assessing the competency of the clinical consultant; (2) A review of Form CMS-209 (Laboratory Personnel Report) and personnel records for competency assessments performed during the review period of March 2023 through the current date identified no documentation competency assessments had been performed based on position responsibilities for one of one clinical consultant; (3) The findings were reviewed with the technical consultant on 03/25/2025 at 02:49 pm, who confirmed the laboratory failed to define and perform assessments based on the specific position responsibilities.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on a review of records and interview with the technical consultant, the laboratory failed to review and evaluate proficiency testing results for one of three Hematology Proficiency testing events reviewed in 2024. Findings include: (1) A review of Hematology Proficiency testing records for three events (First 2024, Second 2024, and Third 2024) identified the following failure with no evidence that corrective action had been documented as performed: (a) Second 2024 Event - The laboratory attained a score of 80% for Blood Cell Identification (Sample BCI-10). (2) Interview with the technical consultant on 03/26/2025 at 10:22 am confirmed corrective action had not been taken and documented for the failure.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on a review of records and interview with the technical consultant, the laboratory failed to verify the accuracy for one of one test method at least twice annually during the review period of May 3023 through the current date. Findings include: (1) On 03/26/2025 at 09:20 am, the technical consultant stated the laboratory performed urine drug screen testing using iCassette Urine Test - Drug Screen Cassette which included the following analytes; (a) Amphetamine (AMP) (b) Barbiturates (BAR) (c) Benzodiazepines (BZO) (d) Cocaine (COC) (e) Marijuana (THC) (f) Methylenedioxymethamphetamine (MDMA) (g) Opiates (OPI) (h) Oxycodone (OXY) (i) Phencyclidine (PCP) (j) Propoxyphene (PPX) (k) Tricyclic Antidepressants

	(TCA) (2) A review of 2024 proficiency testing records identified the laboratory had not enrolled and participated in proficiency testing for the above analytes, therefore, it was determined the laboratory must verify the accuracy of the testing at least twice annually; (3) Interview with the technical consultant 03/27/2025 at 01:30 pm confirmed the laboratory did not have a method in place to verify the accuracy of the testing at least twice annually and it had not been verified during the review period of May 2023 through the current date because it was believed the test kit was categorized as waived; (4) The following were examples of patient testing performed on the iCassette Urine Test - Drug Screen Cassette: (a) Patient # 2303 - testing performed on 05/03/2023 (b) Patient # 7630 - testing performed on 05/07/2023 (c) Patient # 538 - testing performed on 05/20/2023 (d) Patient # 7652 - testing performed on 5/25/2023 (e) Patient # 1779 - testing performed on 05/25/2023 (f) Patient # 3075 - testing performed on 09/30/2023 (g) Patient # 6874 - testing performed on 08/10/2023 (h) Patient # 3113 - testing performed on 08/11/2023 (i) Patient # 2052 - testing performed on 08/19/2023 (j) Patient # 856 - testing performed on 09/02/2023 (k) Patient # 3755 - testing performed on 09/04/2023 (l) Patient # 599 - testing performed on 12/04/2023 (m) Patient # 1923 - testing performed on 12/10/2023 (n) Patient # 7923 - testing performed on 12/28/2023 (o) Patient # 6409 - testing performed on 03 /05/2024 (p) Patient # 8037 - testing performed on 03/25/2024 (q) Patient # 7255 - testing performed on 05/17/2024 (r) Patient # 1237 - testing performed on 05/31/2024 (s) Patient # 891 - testing performed on 08/11/2024 (t) Patient # 1779 - testing performed on 08/17/2024 (u) Patient # 260 - testing performed on 08/20/2024 (v) Patient # 6411 - testing performed on 08/22/2024 (w) Patient # 46 - testing performed on 12/03/2024 (x) Patient # 56 - testing performed on 12/10/2024 (y) Patient # 1779 - testing performed on 12/12/2024 (z) Patient # 355 - testing performed on 12/13/2024 (aa) Patient # 775 - testing performed on 12/17/2024 (bb) Patient # 6199 - testing performed on 12/27/2024 (cc) Patient # 2914 - testing performed on 01/03/2025 (dd) Patient # 7224 - testing performed on 01/17/2025 (ee) Patient # 3526 - testing performed on 01/19/2025 (ff) Patient # 1574 - testing performed on 01/27/2025 (gg) Patient # 4582 - testing performed on 02/10/2025 (hh) Patient # 47171 - testing performed on 02/12/2025 (ii) Patient # 839 - testing performed on 02/21/2025 (jj) Patient # 839 - testing performed on 02/23/2025 (kk) Patient # 8588 - testing performed on 02/24/2025
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (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, written policy, and interview with the technical consultant and the nursing director, the laboratory failed to follow the written policy to ensure that emergency release of blood forms had been signed by the physician for one of two emergency releases reviewed; failed to follow their written procedure for quality control lot changes for one of one lot number. Findings include: EMERGENCY RELEASE FORMS (1) On 03/26/2025 at 11:00 am, the technical consultant stated the laboratory maintained one unit of O positive and one unit of O negative PRBC's (packed red blood cells). The units were to be used for emergency transfusions; (2) A review of the policy titled, "Emergency Release of

	Uncrossmatched Blood for Transfusion" required an Emergency Release form be completed and signed by a physician upon release of blood products"; (3) A review of an emergency release documentation identified the following for one of two patient records: (a) Unit #W2009230143800E - O negative PRBC had been released to a patient on 05/20/2023; (b) The "Emergency Release of Uncrossmatched Blood for Transfusion" form appeared to be signed by a physician assistant and not a physician. (4) The documentation was reviewed with the technical consultant and the nursing director who stated on 03/27/2025 at 11:00 am, the emergency release had not been signed by a physician. COAGULATION QC LOT CHANGES (1) 03/26/2025 at 10: 20 am, the technical consultant stated the following: (a) The laboratory performed PT /INR (Prothrombin Time/International Normalized Ratio) and PTT (Partial Thromboplastin Time) testing were performed using the Sysmex CA-600 analyzer. (2) On 03/27/2025 at 10:20 am, the technical consultant stated the following (QC) quality control materials were put into use approximately on 02/17/2025: (a) Dade Ci-Trol level 1 control, lot #564877 (b) Dade Ci-Trol level 3 control, lot #556577 (2) A review of the procedure titled, "Coagulation Reagent Lot Roll-Over Studies" identified the following: (a) Under section III. "Quality Control" stated: (i) "Assay new lot number of QC material with the new lot of reagent in the 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". (iv) "QC data for PTN and APTTN will be entered under QC settings for PT and APTT when the new reagent lot goes live for QC files to reflect the lot number in use." (3) A review of QC lot change records identified the following for the PT and PTT testings; (a) Dade Ci-Trol level 1 quality control, lot #564877 - The QC means and ranges had been established using 20 data points instead of 30 data points. (b) Dade Ci-Trol level 3 quality control, lot #556577 - The QC means and ranges had been established using 20 data points instead of 30 data points. (4) Interview with the technical consultant on 03/28/2025 at 09:50 am, confirmed the laboratory had not followed their policy for establishing new means and ranges for the new lot numbers of QC materials.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (b) 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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on observation and interview with the technical consultant, the laboratory failed to ensure five of five types of blood collection tubes were stored as required by the manufacturer in the supply area located outside the laboratory. Findings include: (1) Observation of the supply area located outside the laboratory and interview with the technical consultant 03/26/2025 at 09:40 am, identified the following: (a) Two packages of BD Vacutainer Sodium Fluoride 10 mg Potassium Oxalate 8 mg tubes, lot # 4318891, storage temperature requirement of 4-25 degrees (C) centigrade; (b) Two packages of BD Vacutainer SST tubes, lot # 4292267, storage temperature requirement of 4-25 degrees C; (c) Five packages of BD Vacutainer K2 EDTA 7.2 mg

	tubes, lot # 4318859, storage temperature requirement of 4-25 degrees C; (d) Five packages of BD Vacutainer Lithium Heparin (LH) 95 USP units tubes, lot # 4288204, storage temperature requirement of 4-25 degrees (C); (e) Four packages of BD Vacutainer Rapid Serum Tubes (RST), lot # 241026, storage temperature requirement of 4-25 degrees (C). (2) Interview with the technical consultant 03/26/2025 at 09:45 am confirmed the laboratory was not monitoring the temperature of the supply area located outside of the laboratory.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) (c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observation and interview with the technical consultant, the laboratory failed to label three of three containers with the identity, expiration date, and lot number of the contents. Findings include: (1) On 03/26/2025 at 09:15 am, the technical consultant stated the laboratory stained peripheral blood smears to perform manual differential testing; (2) Observation of the area, denoted by the laboratory as "Micro Room" on 03/26/2025 at 09:15 am identified three unlabeled Coplin jars, appearing to contain materials used to stain peripheral blood smears; (3) The findings were reviewed with the technical consultant who on 03/26/2025 at 09:18 am stated the Coplin jars contained staining material had not been labeled with the identity, expiration date, and lot numbers.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) (b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (b)(2)(i) Accuracy. (b)(2)(ii) Precision. (b)(2)(iii) Analytical sensitivity. (b)(2)(iv) Analytical specificity to include interfering substances. (b)(2)(v) Reportable range of test results for the test system. (b)(2)(vi) Reference intervals (normal values). (b)(2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on a review of records, urine drug screen package insert, FDA database, email correspondence with FDA representative, and interview with the technical consultant, the laboratory failed to establish the performance specifications for the iCassette Urine Test - Drug Screen Cassette not categorized by the FDA. Findings include: (1) On 03/26/2025 at 09:55 am, the technical consultant stated the laboratory performed urine drug screen using the iCassette Urine Test - Drug Screen Cassette for patient testing; (2) A review of the FDA (Food and Drug Administration) test classification

	database did not include a classification for the test kit (if a test is not included on the FDA site, then it did not go through the FDA approval process, which defaults the categorization of the test as high complexity). This was also confirmed following the survey during email correspondence with an FDA representative on 04/18/2025; (3) Interview with technical consultant on 03/27/2025 at 11:00 am confirmed the test kit had been put into use for patient testing on or around 05/03/2023; (4) A review of records for the test system revealed no evidence the performance specifications of accuracy, precision, analytical sensitivity, analytical specificity, reportable range, and reference intervals as applicable, had been established prior to putting the test into use for patient testing; (5) The findings were reviewed with the technical consultant, who stated on 03/27/2025 at 01:00 pm the laboratory did not establish the performance specifications prior to putting the test kit into use because it was believed the test kit was categorized as waived; (6) Refer to D5217 for examples of patient urine drug screen testing performed.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) (a)(1) 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 technical consultant, the laboratory failed to ensure the manufacturer's instructions were followed for performing maintenance procedures for two of two analyzers reviewed from February 2024 through November 2024, and one of one analyzer reviewed from April 2024 through February 2025. Findings include: SIEMENS DIMENSION EXL 200 ANALYZER (1) On 03/26/2025 at 09:00 am, the technical consultant stated the following: (a) The laboratory performed routine chemistry testing using the Siemens Dimension EXL 200 analyzers (2) On 03/26/2025, a review of the manufacturer's maintenance checklist showed the following required maintenance procedures: (a) Weekly: (i) Clean outside of R2 probe (ii) Clean outside of HM wash probes (b) Monthly: (i) Clean clot/check drain on IMT Port (ii) Replace IMT pump tubing (iii) Clean IMT system (If more than 100 IMT samples were run daily, clean IMT System everyday) (iv) Replace/clean air filters (v) Stylette HM wash probes (vi) Replace HM pump Heads (perform system check after replacing HM pump heads) (vii) Clean R1/R2 drain (viii) Clean R3 drain (Instrument with RMS only) (3) A review of maintenance records from February 2024 through November 2024 identified weekly and monthly maintenance had not been documented as performed as follows: (a) Weekly (i) between 03/22/2024 and 04/05/2024 (ii) between 04/19/2024 and 05/03/2024 (iii) between 07/19/2024 and 08/02/2024 (iv) between 08 /23/2024 and 09/13/2024 (b) Monthly (i) March 2024 - Replace IMT pump tubing, replace/clean air filters, and replace HM Pump heads procedures were not performed. (ii) April 2024 - Clean clot/check drain on IMT port, replace IMT pump tubing, replace/clean air filters, stylette HM wash probes, and replace HM pump heads procedures were not performed. (iii) May 2024 - Replace IMT pump tubing and replace HM pump heads procedures were not performed. (iv) June 2024 - Clean clot /check drain on IMT port, replace IMT pump tubing, clean IMT system, replace/clean air filters, and replace HM pump heads procedures were not performed. (v) July 2024 - Clean clot/check drain on IMT port, replace IMT pump tubing, replace/clean air filters, and replace HM pump heads procedures were not performed. (vi) August 2024 - Clean clot/check drain on IMT port, replace IMT pump tubing, replace/clean air

	filters, stylette HM wash probes, and replace HM pump heads procedures were not performed. (vii) September 2024 - Clean clot/check drain on IMT port, replace IMT pump tubing, replace/clean air filters, stylette HM wash probes, and replace HM pump heads procedures were not performed. (viii) October 2024 - Clean clot/check drain on IMT port, replace IMT pump tubing, replace/clean air filters, stylette HM wash probes, replace HM pump heads, and clean R1/R2 drain procedures were not performed. (ix) November 2024 - Clean clot/check drain on IMT port, replace IMT pump tubing, replace/clean air filters, stylette HM wash probes, and replace HM pump heads procedures were not performed. (4) The records were reviewed with the technical consultant who stated on 03/27/2025 at 11:00 am, the monthly maintenance procedure had not been documented as performed as stated above. SYSMEX XN 450 (1) On 03/26/2025 at 09:15 am, the technical consultant stated the following: (a) CBC (Complete Blood Count) testing was performed using the Sysmex XN450 analyzer; (2) A review of the manufacturer's maintenance log showed the following required maintenance procedure: (a)Weekly: (i) Routine cleaning: (3) A review of maintenance logs from February 2024 through November 2024 identified maintenance had not been documented as performed as follows: (a) Weekly: (i) between 03/22/2024 and 04 /05/2024 (ii) between 08/16/2024 and 09/06/2024 (4) The records were reviewed with the technical consultant who stated on 03/27/2025 at 11:05 am, the monthly maintenance procedure had not been documented as performed as stated above. SYSMEX CA 660 (1) On 03/26/2025 at 09:10 am, the technical consultant stated the laboratory performed Protime and Activated Partial Prothrombin Time testing using the Sysmex CA-600 series analyzer; (2) A review of the manufacturer's CA-600 maintenance Checklist required the following maintenance procedure: (a) Weekly: (i) Clean instrument interior and exterior (3) A review of maintenance logs from April 2024 through February 2025 identified maintenance had not been documented as performed as follows: (a) Weekly: (i) between 04/26/2024 and 05/04/2024 (ii) between 05/24/2025 and 06/07/2024 (iii) between 08/16/2024 and 09/06/2024 (iv) between 01/24/2025 and 02/07/2025 (v) between 02/14/2025 and 02/28/2025 (4) The findings were reviewed with the technical consultant who stated on 03/27/2025 at 04: 00 pm the laboratory was unable to provide documentation of maintenance performed as stated above.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) (b)(2)(i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (b)(2)(ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on a review of records and interview with the technical consultant, the laboratory failed to have a written function check protocol to ensure the urine centrifuge was functioning properly during the review period of March 2023 through the current date. Findings include: (1) On 03/27/2025 at 09:00 am, the technical consultant stated the laboratory performed urine microscopic testing and urine specimens were processed at a speed of 1500-2000 rpm (revolutions per minute) for 5 minutes using the EasySpin Sorvall Instrument centrifuge; (2) Although the speed and time function checks had been performed annually for the urine centrifuge, a function

	check protocol that defined the frequency of the speed and timer checks and limits of acceptability could not be located; (3) The findings were reviewed with the technical consultant who confirmed on 03/28/2025 at 09:49 am, there was no written protocol that defined the centrifuge speed and timer function check.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) (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. This STANDARD is not met as evidenced by: Based on a review of records and interview with the technical consultant, the laboratory failed to perform calibration verification procedures at least once every six months for two of two test systems during the review period of March 2023 through the current date. Findings include: ISTAT1 - BLOOD GASES (1) On 03/26/2026 at 9:00 am, the technical consultant stated the laboratory performed Blood Gas (pH, pO2, and pCO2) testing using the iSTAT 1 analyzers serial number 328729 and the EG7+ cartridge; (2) A review of calibration records from March 2023 through the current date identified no evidence calibration verification had been performed at least once every six months between 03/22/2024 and 10/16/2024; (3) The records were reviewed with the technical consultant who stated on 02/28/2025 at 09:49 am, calibration verification procedures had not been performed every six months as stated above. BIOSITE TRIAGE METER PRO (1) On 03/26/2026 at 9:10 am, the technical consultant stated the laboratory performed D-Dimer testing using Biosite Triage Meter Pro analyzer; (2) a review of calibration records from March 2023 through the current date identified no evidence calibration verification had been performed at least once every six months between 02/01/2024 and 09/04/2024; (3) The records were reviewed with the technical consultant who stated on 02/28/2025 at 09:50 am, calibration verification procedures had not been performed every six months as stated above.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) (d)(3)(ii) Each qualitative procedure, include a negative and positive control material;

	This STANDARD is not met as evidenced by: Based on a review of records and interview with the technical consultant, the laboratory failed to perform a negative and positive control materials for 36 of 36 days of patient urine drug screen testing. Findings include: (1) On 03/25/2025 at 09:20 am, the technical consultant stated the laboratory performed urine drug screen testing using iCassette Urine Test - Drug Screen Cassette; (2) A review of QC (Quality Control) and patient testing records from May 2023 through the current date identified negative and positive QC materials had not been performed each day of patient testing for 36 of 36 days of patient testing and there was no evidence an IQCP (Individualized Quality Control Program) had been developed; (3) On 03/28/2025 at 09:45 am, the technical consultant stated the laboratory performed negative and positive QC materials with each new lot of test kit and had not performed negative and positive QC materials on each day of patient testing because it was believed the test kit was categorized as waived; (4) Refer to D5217 for examples of patient urine drug screen testing performed.
D5479	CONTROL PROCEDURES CFR(s): 493.1256(e)(5)(g) (e)(5) Follow the manufacturer's specifications for using reagents, media, and supplies and be responsible for results. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, observation, and interview with the technical consultant, the laboratory failed to follow the manufacturer's specifications for storing two of two lot numbers of quality control materials. Findings include: (1) On 03/26/2025 at 09:00 am, the technical consultant stated the following: (a) The laboratory performed routine chemistry testing using the Dimension EXL 200 analyzer; (b) Two levels of Bio-Rad Liquid Assayed Multiqual (QC) quality control materials were tested each day of patient testing. (2) A review of the manufacturer's storage and stability instructions for the control materials contained in the Bio-Rad control package insert stated the following: (a) "Thawed Unopened" - When thawed and stored unopened at 2 to 8 degrees (C) centigrade, this product will be stable as follows: (i) All analytes: 30 days, except: (ii) Bilirubin (Direct): 11 days; (iii) Cholesterol (HDL), Phosphorus and Triglycerides: 7 days. (b) "Thawed Opened": Once thawed, opened, and stored tightly capped at 2 to 8C, this product will be stable as follows: (i) All analytes: 14 days, except: (ii) Alkaline Phosphatase, AST/SGOT, Bilirubin (Total): 9 days; (iii) Bilirubin (Direct), Cholesterol (HDL), Creatine Kinase (CK), Phosphorus and Triglycerides: 7 days." (3) On 03/26/2025 at 09:05 am, observation of the refrigerator contents identified the following: (a) Liquid Assayed Multiqual QC material Level 1, lot #45951 - Thawed date or open date was not posted on the bottle, and modified expiration date could not be determined; (b) Liquid Assayed Multiqual QC material Level 3, lot #45953 - Thawed date or open date was not posted on the bottle, and modified expiration date could not be determined. (4) The findings were reviewed with the technical consultant, who stated on 03/26/2025 at 09:10 am, the controls had not been dated with the appropriate modified expiration date.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) (b)(9) Thereafter, evaluations must be performed at least annually

	This STANDARD is not met as evidenced by: Based on a review of records and interview with the technical consultant, the technical consultant failed to ensure personnel performing moderate complexity testing had been evaluated at least annually for two of two testing persons during the review period of March 2023 through the current date. Findings include: (1) On 03/25/2025, a review of personnel records for two persons performing moderate complexity testing from March 2023 through the current date identified no evidence an annual competency evaluation had been performed for two of two testing persons as follows: (a) Testing Person #2 - Prior to 01/10/2024 (note: the last documented annual evaluation had been performed on 06/29/2022) (b) Testing Person #3 - After 08/31 /2023 (2) The records were reviewed with the technical consultant who stated on 03/26 /2025 at 10:25 am, the annual evaluations had not been documented as performed.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on a review of records, urine drug screen package inserts, FDA database, email correspondence with an FDA representative, and interview with the laboratory director and testing person #1, the laboratory director failed to provide overall management and direction for a urine drug screen test for five of five months of testing. Findings include: (1) The laboratory director failed to ensure the Clearrapids Drug Test Card - 12 Panel Drug Test Card provided quality results for patient care for five of five months of testing. Refer to D6085.
D6085	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3) (e)(3) Ensure that-- (e)(3)(i) The test methodologies selected have the capability of providing the quality of results required for patient care; This STANDARD is not met as evidenced by: Based on a review of records, urine drug screen package insert, FDA database, email correspondence with FDA representative, and interview with the technical consultant, the laboratory director failed to ensure a urine drug screen test provided quality results for patient care for ten of ten months of patient testing. Findings include: (1) The laboratory director failed to ensure the FDA categorization of the iCassette Urine Test - Drug Screen Cassette prior to using for patient testing. Refer to D5217, D5423, and D5449.