Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	22D1042991	05/21/2024
Name of Provider or Supplier	**Street Address, City, State**	
Lab Usa, Inc	108r Merrimack Street, Haverhill, MA	

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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on record review and interview the laboratory did not enroll in an approved proficiency testing (PT) program for the subspecialty of Bacteriology. This deficiency was also cited at the last CLIA inspection performed on 3/31/2022. Findings include: 1. Record review on 5/15/2024 of the laboratory's CASPER Report 0096D 'CLIA Application and Survey Summary Report' revealed the laboratory did not have PT scores for the regulated analyte 005 Bacteriology for 2024 Event 1. 2. Record review on 5/15/2024 of the laboratory's CASPER Report 0157D Excused Nonparticipation Report revealed the laboratory was excused for 2023 event 3, Bacteriology. 3. Record review on 5/21/2024 of the laboratory's current and discontinued test list dated 5/21 /2024 (received by email on 5/21/2024 at 11:01 AM) revealed throat cultures were discontinued on 5/2024. The laboratory was unable to give an exact date that throat culture testing was stopped. 4. During staff interview with testing personnel #2 (TP2) on 5/15/2024 at 4:45 PM, TP2 stated, "We are no longer performing throat culture testing. We are only performing QC to use up supplies."
D2003	ENROLLMENT CFR(s): 493.801(a)(2)(ii)

	For those tests performed by the laboratory that are not included in subpart I of this part, a laboratory must establish and maintain the accuracy of its testing procedures, in accordance with 493.1236(c)(1) This STANDARD is not met as evidenced by: Based on record review and staff interview with technical supervisor #4 (TS4) and the Laboratory Director (LD) the laboratory failed to verify at least twice annually the accuracy of Influenza A and Influenza B Findings include: 1. Record review on 5/15 /2024 of the laboratory's 2022, 2023 and 2024 to date American Proficiency Institute (API) proficiency testing (PT) records revealed, the laboratory was not enrolled in PT for the non-regulated analytes Influenza A and Influenza B. 2. Staff interview with TS4 and the LD on 5/15/2024 at 4:30 PM confirmed the laboratory was not enrolled in PT in 2022, 2023 and 2024 for the non-regulated analytes Influenza A and Influenza B and the laboratory failed to verified their accuracy at least twice annually in another way. 3. The laboratory performs 2,079 test annually in the specialty of Microbiology.
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on record review and staff interview the laboratory failed to ensure proficiency testing (PT) was rotated amongst 2 testing personnel (TP) in the subspecialty of Toxicology. Finding include: 1. Record review on 5/15/2024 of the laboratory's 2022, 2023, and 2024 to date American Proficiency Institute (API) Toxicology PT records revealed, one of two liquid chromatography mass spectrophotometry (LCMS) Toxicology TP (ToxTP2) did not run PT samples in 2022, 2023 and 2024 to date. 2. Record review on 5/15/2024 of the laboratory's competency records for ToxTP2, revealed, ToxTP2 did not have documented LCMS competency records and did not run a PT sample in 2022, 2023 and 2024 to date. 3. Staff interview on 5/15/2024 at 11: 00 AM with ToxTP2 confirmed ToxTp2 did not participate in PT in 2022, 2023 and 2024 to date. 4. The laboratory performs 162,011 tests annually in the specialty of Chemistry.
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 American Proficiency Institute (API) proficiency testing (PT) record review and interview with Technical Supervisor #4 (TS4), the laboratory failed to maintain a copy of all proficiency testing records in the specialty of Microbiology. Findings include: 1. Record Review on 5/15/2024 of the laboratory's CASPER Report 0096D 'CLIA Application and Survey Summary Report' revealed the laboratory had PT scores for the regulated analyte 005 Bacteriology for 2022 Events 2 and 3 and 2023 Events 1, 2, and 3. 2. Record review on 5/15/2024 of the laboratory's CASPER Report 0157D Excused Nonparticipation Report revealed the laboratory was excused for 2023 event 3. 3. Record review on 5/15/2024 of the laboratory's 2022, 2023 and 2024 to date API PT records revealed, the laboratory did not have PT records for the subspecialty Bacteriology. 4. Staff interview with TS4 on 5/15/2024 at 10:30 AM confirmed the above findings. 5. The laboratory performs 2,079 tests annually in the specialty of Microbiology.
D2093	ROUTINE CHEMISTRY CFR(s): 493.841(d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event. This STANDARD is not met as evidenced by: Based on record review of the laboratory's 2023 American Proficiency Institute (API) proficiency testing (PT) records and interview with Technical Supervisor #2 (TS2), the laboratory failed to submit the Routine Chemistry results for 2023 Event 2. Findings include: 1. Record review on 5/15/2024 of the laboratory's CASPER Report 0096D 'CLIA Application and Survey Summary Report' revealed the laboratory received an overall testing score of 0 percent for Routine Chemistry for 2023 Event 2. 2. Record review on 5/15/2024 of the laboratory's Core Chemistry 2023 Event 2 survey packet with the results that were run by the laboratory revealed: a. The laboratory did not submit results for Core Chemistry 2023 Event 2. b. The laboratory did not employ corrective action for the above failure to return PT results on time. 3. Staff interview with TS2 on 5/15/2024 at 10:30 AM confirmed the laboratory did not submit API PT results for Core Chemistry for 2023 Event 2. TS2 stated, "We ran the survey, but we did not send it in." 4. The laboratory performs 162,011 tests annually in the specialty of Chemistry.
D2104	ENDOCRINOLOGY CFR(s): 493.843(d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event. This STANDARD is not met as evidenced by: Based on record review of the laboratory's 2023 American Proficiency Institute (API) proficiency testing (PT) records and interview with Technical Supervisor #2 (TS2),

	the laboratory failed to submit the Endocrinology results for 2023 Event 2. Findings include: 1. Record review on 5/15/2024 of the laboratory's CASPER Report 0096D 'CLIA Application and Survey Summary Report' revealed the laboratory received an overall testing score of 0 percent for Endocrinology for 2023 Event 2. 2. Record review on 5/15/2024 of the laboratory's Endocrinology 2023 Event 2 survey packet with the results that were run by the laboratory revealed: a. The laboratory did not submit results for Endocrinology 2023 Event 2. b. The laboratory did not employ corrective action for the above failure to return PT results on time. 3. Staff interview with TS2 on 5/15/2024 at 10:30 AM confirmed the laboratory did not submit API PT results for Endocrinology for 2023 Event 2. TS2 stated, "We ran the survey, but we did not send it in." 4. The laboratory performs 162,011 tests annually in the specialty of Chemistry.
D2128	HEMATOLOGY CFR(s): 493.851(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on record review of the laboratory's American Proficiency Institute (API) proficiency testing (PT) scores and staff interview, the laboratory failed to investigate and perform corrective action when a (PT) score of less than 100% was received. Findings include: 1. Record review on 5/15/2024 of the CASPER 0096D, 'CLIA Application and Survey Summary' report revealed the laboratory received a score of 50% for the regulated analyte platelets for 2023 Event 3. 2. Record review on 5/15 /2024 of the laboratory's API PT Hematology/Coagulation 2023 Event 3 records revealed: a. The laboratory received a score of 50% for the regulated analyte platelets. b. The PT Performance Evaluation report was signed as reviewed by the laboratory director (LD). c. The laboratory did not investigate or document corrective action for the above 50% score. 3. Staff interview with Technical Supervisor #4 (TS4) on 5/15 /2024 at 9:30 AM confirmed the laboratory received a score of 50% for the regulated analyte platelets for 2023 Event 3 and the laboratory did not investigate or document corrective action. TS4 stated, "The laboratory is not doing Hematology anymore, hope to start it back up in the future."
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 record review and confirmed through an interview with the Laboratory Director (LD) and Technical Supervisor #4 (TS4), the laboratory did not have an

	ongoing mechanism to evaluate the TS, General Supervisor (GS) or Clinical Consultant (CC) based on their CLIA responsibilities. Findings Include: 1. Record review on 5/15/2024 of the laboratory's CMS-209 form signed by the LD on 5/7/2024 revealed, four TS, three GS and one CC. 2. Record review on 5/15/2024 of the laboratory's 2022, 2023 and 2024 to date personnel competency records revealed the laboratory did not have documented competency evaluation for the four TS, three GS and one CC based on their CLIA responsibilities. 3. Staff Interview on 5/15/2024 at 11:00 AM with the LD and TS4 confirmed the above findings.
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: Refer to D2003. This deficiency was also cited at the last CLIA inspection performed on 3/31/2022.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on surveyor observation, record review and staff interview, the laboratory failed to monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1251 through 493.1283 for each specialty and subspecialty performed. The cumulative effect of this lack of oversight resulted in the laboratory's inability to ensure accuracy and reliability of patient test results in the specialties of Microbiology, Hematology, Diagnostic Immunology and Chemistry. Refer to D5401, D5403, D5409, D5421, D5429, D5435, D5439, D5441, D5455, D5471, D5481, D5783, and 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: A. Based on surveyor observation, record review, interview with Technical Supervisor #4 (TS4) and the laboratory director (LD), the laboratory failed to have

procedures available for Microbiology Polymerase Chain Reaction (PCR) testing. Findings include: 1. During surveyor observation on 5/15/24 at 4:30 PM of the Liquid Chromatography/Mass Spectrophotometry laboratory: a. Surveyor noticed a Plexiglas door leading to an adjacent room with laboratory containing laboratory equipment. TS4 stated, "That was for COVID 19 testing and we are no longer using that room." b. Surveyor noticed a notebook with patient names and laboratory results for Influenza A and Influenza B in the LCMS area dating back to 12/18/2023. 2. During interview with the LD and TS4 on 5/15/2024 at 4:30 PM: a. Surveyor asked the LD if the laboratory was performing Influenza A and Influenza B testing. b. The LD answered, "No." c. Surveyor pointed to the patients noted in #1 above and asked, "Are these patient results for Influenza A and Influenza B?" d. LD answered, "These are just a kit." e. Surveyor asked to see the kit indicated in 2d above. f. LD went into the adjacent room noted in 1a above and returned with a package insert for Respiratory Syncytial Virus (RSV). g. Surveyor asked, "Can I see this kit? Is this a waived test? h. TS4 responded, "It's high complexity. It involves pipetting and reagents." i. Surveyor asked to see how Influenza A and Influenza B testing is performed. 3. Surveyor observation on 5/15/2024 4:35 PM of the laboratory testing area noted in 1a above (where Influenza A and Influenza B testing is performed)revealed a BioRad CFX 96 thermoclycler for PCR testing. 4. During interview with the LD and TS4 on 5/15/2024 at 4:35 PM: a. Surveyor asked, " Is there a written procedure for Influenza A and Influenza B testing using the BioRad CFX 96 thermoclycler. b. LD asked TS4, "Where is the procedure manual." c. TS4 responded. "You didn't tell me to write that one." d. LD responded, "Yes, I did." e. TS4 stated, "We do not have a procedure." 5. The laboratory performs 2,079 tests annually in the specialty of Microboiology. B. Based on surveyor observation, record review and staff interview with Technical Supervisor #2 (TS2) and the laboratory director (LD) the laboratory failed to follow the procedure manual as written. Findings include: 1. Surveyor observation of the laboratory 'Refrigerator Room' on 5/15/2024 at 4:50 PM revealed: a. 4 50 gallon drums full of liquid: b. 3 of 4 were labeled: Hazardous Waste, Contents Composition, Flame liquids, (non-corrosive) Ethanol 10-30%, Hexane 1 - 20%, Methanol 1-20%, Urine 0-2%, and water 1-30%. c. One of the 3 drums indicated in 1 above had a box stored on top of it. d. 1 of 4 was labeled UN3291, Regulated Medical Waste. e. The unlabeled drum had a heavy box filled with binders on top. The box was under a sign that read. "No boxes here! Do not block or obstruct the power cord." f. Survey observed the LD trying to lift the box off of the drum indicated in 2 above. The LD was unable to lift the box. 2. During staff interview with the LD and TS2 on 5/15 /2024 at 5:00 PM: a. The LD and TS2 confirmed the above findings. The LD stated, "The box is too heavy for me to lift. I will hurt my back." b. TS2 stated, the box was placed on one of the drums indicated in 1 above because the laboratory had a leak and the repairman placed the box on top of the drum. TS2 also stated, "The chemical waste has not been picked up for years. One company closed and Stericycle and Bioserv won't pick up." 3. Record review on 5/17/2024 of the laboratory's 'Hazardous Material and Waste Management Plan' received from TS4 via email on 5/16/2024 at 6: 56 PM revealed: a. Page 3 of 15, "Each department is responsible for identifying and labeling all hazardous materials within their department/area." b. Page 10 of 15, "The department manager is responsible for the ensuring the waste is placed in properly constructed and labeled containers." "Biohazardous waste will be stored in a designated locked and secure holding area located in the environmental holding area on the facility property." 4. Record review on 5/15/2024 of the laboratory's monthly Levy Jennings Quality Control (QC) review charts revealed: a. The monthly Levy Jennings charts from July 2023 to April 2024 were printed on April 30, 2024. 5. Record review on 5/15/2024 of the laboratory's, 'Quality Control Monthly Reports' procedure revealed: "After QC has been updated a report will be printed monthly,

	reviewed and signed by a supervisor. The standard approved Levy Jennings chart and a detailed report with statistics are printed for each level of each control product in use. The statistics will be reported to the interlaboratory commercial QC program for those control results which are included in the program." 6. Staff interview with Technical Supervisor #4 (TS4) on 5/15/2024 at 11:00 AM, TS4 stated: a. "Nobody has been paid for a year. I was not here from July 2023 to April 2024. When I returned, I printed the AU680 Levy Jennings Charts from July 2023 to April 2024 on April 30, 2024. I signed all the review sheets after printing them on April 30, 2024, but did not add a date. b. TS4 stated he prints the Levy Jennings charts every month, then he changed his mind and said, he does not print them due to too much paper. TS4 stated he only reviews them on the analyzer. c. "Right now, there is no commercial interlaboratory quality control program. It was stopped several years ago." The laboratory failed to have written procedures for Influenza A, Influenza B and RSV testing. The laboratory failed to follow the 'Hazardous Material and Waste Management Plan' procedure as wriiten.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: A. Based on record review and interview with the Technical Supervisor #4 (TS4) the laboratory's procedure manual failed to include quality control (QC) acceptance criteria or steps to take if a QC failure occurs in the specialty of Chemistry. Findings include: 1. Record review on 5/15/2024 of the laboratory's AU680 Chemistry analyzer's Levy Jennings charts from July 2023 to April 2024 revealed QC results out of range greater than 2SD without corrective action. 2. Surveyor requested the laboratory's AU680 Chemistry analyzer's QC procedure for QC acceptance criteria and corrective action to take if QC results are out of range. 3. Staff interview with TS4 on 5/15/2024 at 11:00 AM: a. Confirmed the findings in #1 above. b. TS4 stated, "We do not have it." 4. The laboratory performs 162,011 Chemistry tests annually. B. Based on record review and interview with the Technical Supervisor #4 (TS4) the Chemistry procedure manual failed to include patient normal values. Findings include: 1. Record Review on 5/15/2024 of the laboratory Chemistry Procedure Manual revealed the manual did not contain patient normal values for the following

	tests, Glucose, Blood Urea Nitrogen, Creatinine, Sodium, Potassium, Chloride, Carbon Dioxide, Alkaline Phosphatase, Alanine Aminotransferase, Aspartate Aminotransferase, Total Bilirubin, Direct Bilirubin, Total Protein, Albumin, Phosphorous, Calcium, Cholesterol, Triglyceride, Direct High Density Lipoprotein, Creatine Kinase, Magnesium, Gamma-Glutamyl Transferase, Uric Acid, Iron, Total Iron Binding Capacity, Vitamin B12, Vitamin D, Thyroid Stimulating Hormone, Total Thyroxine, Ferritin, and Prostate Specific Antigen. 2. Staff interview on 5/15/2024 at 10:30 AM with the TS4 confirmed the Chemistry procedure manual did not contain patient normal values for the analytes listed in B1 above. TS4 stated, "The procedure manual has reportable ranges, but not normal values." 3. The laboratory performs 162,011 Chemistry tests annually.
D5409	PROCEDURE MANUAL CFR(s): 493.1251(e) The laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance as described in 493.1105(a)(2). This STANDARD is not met as evidenced by: Based on record review and interview with Technical Supervisor #4 (TS4) the laboratory failed to document discontinuation of procedures and remove them from the procedure manual. 1. Record review on 5/21/2024 of the updated laboratory test list dated 5/21/2024 and received from TS2 on 5/21/2024 at 11:01 AM revealed: a. The laboratory stopped Complete Blood Count and Manual White Blood Cell Differential (2/28/2023), Urine Pregnancy (11/23/2023), Throat Culture (5/2024), Rheumatoid Factor (2/2024), Gonorrhea Polymerase Chain Reaction (PCR) and Chlamydia trachomatis PCR (9/13/2023), COVID 19, and Respiratory Syncytial Virus (4/12/2024), Glucose (1/30/2024), Creatinine non-adulterated (10/10/2023), Carbon Dioxide (12/26/2023), Alkaline Phosphatase (11/13/2023), Alanine Aminotransferase (12/8/2023), Aspartate Aminotransferase (1/26/2024), Blood Urea Nitrogen (10/10/2023), Total Bilirubin (11/22/2023), Direct Bilirubin (9/12/2023), Phosphorous (3/13/2024), Triglyceride (2/6/2024), Vitamin B12 (8/7/2023), Vitamin D (9/12/2023), Thyroid Stimulating Hormone (12/13/2023), Folate (9/12/2023), Ferritin (12/8/2023), Total Thyroxine (9/12/2023), Prostate Specific Antigen (9?12 /2023), Erythrocyte Sedimentation Rate (4/2023), Free Thyroxine, Free Triiodothyronine Total Triiodothyronine (9/12/2023), Magnesium (9/22/2023), Creatine Kinase (1/26/2024), and High Density Lipoprotein (1/31/2024). 2. Record review on 5/15/2024 of the current laboratory procedure manuals for Hematology and Chemistry revealed: a. The procedures for the analytes listed in 1a were still included in the manuals. b. The procedures for the analytes listed in 1a did not have a date of discontinuance. 3. Interview with Chemistry testing personnel (TP) on 05/15/24 at 12: 00 PM confirmed that testing has been stopped and the procedures were not removed from the Hematology and Chemistry procedure manuals. 4. Interview with Microbiology TP on 5/15/24 at 4:45 PM confirmed that Throat Culture testing has been stopped and the procedure was not removed from the procedure manual The laboratory was unable to give an exact date when throat culture testing was stopped.
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 record review and staff interview the laboratory did not verify the performance specifications for Influenza A, Influenza B and Respiratory Syncytial Virus (RSV) before testing patient samples on the BioRad CFX 96. This deficiency was also cited at the last CLIA inspection performed on 3/31/2022. Findings include: 1. During surveyor observation on 5/15/24 at 4:30 PM of the Liquid Chromatography /Mass Spectrophotometry laboratory: a. Surveyor noticed a Plexiglas door leading to an adjacent room containing laboratory equipment. TS4 stated, "That was for COVID testing and we are no longer using that room." b. Surveyor noticed an open notebook with patient names and laboratory test results for Influenza A and Influenza B with dates from 3/29/2024 to 4/12/2024 in the LCMS area. c. Further examination of the notebook referred to in 1b revealed the notebook contained patient names and laboratory test results for Influenza A and Influenza B dating back to 12/18/2023. 2. Record review on 5/21/2024 of the laboratory's current test list dated 5/21/2024 compared to the laboratory's test list received at the previous inspection (exit date 3/31 /2022) revealed Influenza A, Influenza B and RSV were not on the test list from the 3 /31/2022 laboratory inspection, 3. During interview with the LD and TS4 on 5/15 /2024 at 4:30 PM: a. Surveyor asked the LD if the laboratory was performing Influenza A and Influenza B testing. b. The LD answered, "No." c. Surveyor pointed to the patients noted in #1b above and asked, "Are these patient results for Influenza A and Influenza B?" d. LD answered, "These are just a kit." e. Surveyor asked to see the kit indicated in 3d above. f. LD went into the adjacent room noted in 1a above and returned with a package insert for Respiratory Tract 4T-q PCR Kit. 4. The LD was unable to produce readable validation records, including validation acceptance criteria, raw data and the date the validation was approved by the LD for Influenza A, Influenza B and RSV.
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 record review of the laboratory's preventive maintenance logs and confirmed by staff interview with Technical Supervisor #4 (TS4), Technical Supervisor #3 (TS3) and the Laboratory Director (LD) the laboratory failed to perform and document maintenance and function checks in the specialties of Hematology and Chemistry. Findings include: 1. Record review on 5/15/2024 of the laboratory's 2022, 2023 and 2024 to date maintenance records revealed: a. The laboratory did not have documented routine maintenance or yearly preventative maintenance (PM) on the AB Sciex 4500 MD instrument used to perform liquid chromatography/mass spectrophotometry in 2022 and 2023. b. The laboratory did not have preventative maintenance records for the BioRad CFX 96 thermocycler in 2022,

	2023 and 2024 to date. c. The laboratory did not have yearly PM records for the Siemens Advia 120 for 2022, 2023 and 2024 to date. d. The LD produced a laboratory notebook with numbers written in it as record of the AB Sciex routine maintenance and yearly PM. There were no notations as to what the numbers meant or what they were measuring. 2. During interview with TS4 and the LD on 5/15/2024 at 3:00 PM: a. TS4 stated, "The LD is a certified tech with Sciex, so he usually does the maintenance, but did not document it." b. TS4 confirmed the laboratory did not have any maintenance records for the BioRad CFX 96 thermocycler in 2022, 2023 and 2024 to date. c. The LD stated, "I do the routine maintenance and the yearly PM on the AB Sciex. I do not use the laboratory AB Sciex routine maintenance log sheet. I write it in the laboratory notebook." 3. During interview with TS3 on 5/15/2021 at 1: 00 PM, TS3 stated, "We are no longer doing Hematology testing. The company service rep. does the PM for the Advia and they have the records. You will have to check with TS2." 4. The laboratory performs 162,011 tests annually in the specialty of Chemistry.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (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. (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 record review and interview with Technical Supervisor #4 (TS4) and with Technical Supervisor #3 (TS3) , the laboratory failed to perform function checks on laboratory pipettes to ensure accurate and reliable test results. Findings include: 1. Surveyor observation on 5/15/2024 at 1:00 PM of 2 pipettes brought to surveyors by TS3 from the Routine Chemistry laboratory revealed both pipettes were last calibrated on 12/8/2022. 2. During observation on 5/15/2024 at 4:30 PM of the Liquid Chromatography Mass Spectrophotometry (LCMS) laboratory testing area, surveyor observed a 0.5 - 10ul pipette and a 10-100ul pipette in an adjacent room separated from the LCMS laboratory by a Plexiglass door. The laboratory did not have calibration records for these pipettes. 3. During staff interview with TS4 on 5/15/2024 at 4:30 PM: a. TS4 stated, "We usually send the pipettes out to Lab Solutions for calibration or the Laboratory Director (LD) does it." b. TS4 confirmed the pipettes in 1 above have not been calibrated since 12/8/22. c. TS4 confirmed the laboratory did not have calibration records for the 2 pipettes observed in the room adjacent to the LCMS laboratory. d. TS4 stated, "The LCMS pipettes are used to pipette standards and controls and sample prep."
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions;

	(b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on record review and confirmed through an interview with Technical Supervisor #4 (TS4) and Technical Supervisor #3 (TS3), the laboratory failed to perform calibration verification at least twice annually for analytes run on the AU680 Chemistry analyzer in the specialty of Chemistry. This deficiency was cited at the last two CLIA inspections performed on 11/13/2019 and 3/31/2022. Findings include: 1. Record review on 5/15/2024 of the laboratory's 2022 and 2023 Chemistry quality control (QC) records revealed,: a. Calibration verifications were not performed once every six months for 43 of 43 analytes performed. b. A review of calibration verification documentation revealed that the laboratory performed calibration /verification on 3/2022, 6/2022 and 1/2023. There were no calibration verifications performed during the second half of 2023 or 2024 to date. 2. Staff interview with TS3 on 5/15/2024 at 11:00 AM confirmed that calibration verifications of at least 3 points had not been performed at least once every six months for analytes run on the AU680. TS3 stated "We did not do the second calibration last year because we stopped testing." 3. Record review on 5/21/2024 of the laboratory's current test menu and discontinued test menu received from the laboratory via email on 5/21/2024 at 11:01 AM revealed: a. The laboratory currently performs 18 Chemistry tests on the AU680 Chemistry analyzer. b. The first discontinued Chemistry test performed on the AU680 was 8/7/2023. This date is greater than 6 months from the previous calibration. All other discontinued Chemistry AU680 tests had discontinue dates after 9/12/2023. 4. The laboratory performs 162,011 tests annually in the specialty of Chemistry. .
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 surveyor review of quality control (QC) and quality assessment records and interview with Technical Supervisor #4 (TS4), the laboratory failed to have a written policy for QC acceptance for Chemistry tests run on the AU680 and failed to monitor Chemistry (QC) records to identify system failures, shifts and trends. Refer to D5481 and D5403.
D5455	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(v)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each molecular amplification procedure, include two control materials and, if reaction inhibition is a significant source of false negative results, a control material capable of detecting the inhibition. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to document quality control results for Influenza A, Influenza B, Respiratory Syncytial Virus and COVID 19 testing by Polymerase Chain reaction (PCR). Findings include: 1. Record review on 5/15/2024 of the laboratory's PCR notebook revealed: a. The notebook contained hand written information as well as typed patient names and numbers cut out and taped to the pages. The hand written information in the notebook was not labeled as to what it identified. b. Surveyor was unable to confirm PCR quality control was performed for the above tests by looking at the notebook noted in 1 above. c. Surveyor then asked to see a PCR plate record with laboratory results. 2. Record review on 5/15/2024 of a sheet of paper given to surveyor by the LD revealed: a. A photocopy of a grid with 12 columns and 8 rows containing letters and numbers. Column 1 row 1 was labeled A Negative. Column 1 row 2 was labeled B Positive. b. Below the grid was a series of hand written numbers and letters with no identifiers as to what the numbers and letters mean. 3. Staff interview with the laboratory director (LD) on 5/15/2024 at 4:30 PM: a. LD pointed to an area of the PCR notebook with hand written information and said, "This is the QC." b. Surveyor responded, "How can you tell? It is not labeled." c. LD responded, "It is."
D5471	CONTROL PROCEDURES CFR(s): 493.1256(e)(1)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: Based on record review and interview with Technical Supervisor #2 (TS2) the laboratory failed to test the negative reactivity of Bacitracin discs using the organisms required by the manufacturer's package insert. Findings Include: 1. Record review on 5 /15/2024 of the 'QC Bacitracin Disc Weekly' Log revealed: a. Bacitracin disc QC was still being performed in May of 2024. b. Positive and negative control results were recorded on the log sheet. 2. Record review on 5/21/2024 of the updated test list received from the laboratory on 5/15/2021 at 11:01 AM revealed Throat Culture testing was stopped on 5/2024. The laboratory was unable to give an exact date that Throat Culture testing was discontinued. 3. Record review on 5/16/2024 of the Taxo A Disc package insert User Quality Control Section revealed, "at the time of use, check performance with pure cultures of stable control organisms producing known desired reactions. One or more beta-hemolytic streptococcal species belonging to groups B, C, D and/or G may be employed to demonstrate lack of zone formation." 4. Staff interview with TS2 on 5/15/2024 at 4:50 PM revealed: a. When asked by the surveyor which organisms were used to run the weekly Bacitracin QC, TS2 responded, "Group A strep for the positive control and water for the negative control." b. TP2 also stated, "We are not doing Throat Cultures anymore. I am still running QC to use up the media."
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on surveyor review of the laboratory's quality control (QC) records and Levy Jennings charts and interview with Technical Supervisor #4 (TS4) the laboratory failed to ensure the results of control materials were within the acceptable ranges prior to reporting patient test results in the specialty of Chemistry. Findings include: 1. Record review on 5/15/2024 of the laboratory's AU680 Chemistry analyzer's Levy Jennings QC records revealed: a. Two levels of control material are run daily for Buprenorphine (BUP), Ethylglucuronide (ETG), Total Bilirubin (Tbili), Oxycodone (Oxy), Creatinine (Creat), Amphetamine (Amp), Methadone (Met), Opiates (Opi), Fentanyl (Fen), Chloride (CL) and Phosphorous (Phos). b. The monthly Levy Jennings charts from July 2023 to April 2024 were printed out on April 30, 2024. c. Each Month had a cover page, 'Quality Assurance/Assessment Checklist' that contained the following: i. The Quality Control Section, Drugs of Abuse section was checked of as 'met'. ii. The Laboratory Director (LD) and TS4 signed as reviewed, but did not include a date of review for 9 of 10 months., iii. The October 2023 sheet had a date of 11/10/2023 beside the LD and TS4 signatures. d. August 2023 - Bup SQ Negative Control, lot 10872272-R1, Exp. 2/10/2024, 6 of 13 results were out of range greater than 2 Standard Deviations (SD). e. September 2023 i. ETG High control, ETG 625, lot WO14786, Exp. 7/31/2024, 9 of 20 results were out of range greater than 2 SD. ii. ETG Low control, ETG 375, lot WO147865, Exp. 7/31/2024, 8 of 20 results were out of range greater than 2 SD. f. October 2023 i. ETG High control, ETG 625, lot WO14786, Exp. 7/31/2024. 6 of 10 results were out of range greater than 2 SD. ii. ETG Low control ETG 375, lot WO147865, Exp. 7/31/2024, 8 of 10 results were out of range greater than 2 SD. g. November 2023 i. Bup SQ Negative Control, lot 10872272-R1, Exp. 2/10/2024, 6 of 20 results were out of range greater

than 2 SD. ii. Bup SQ Positive Control, lot 10872273-R1 Exp. 2/10/2024, 3 of 20 results were out of range greater than 2 SD. iii. BIORAD 3 T Bili Control, lot 45933 Exp. 7/31/2024, 1 of 15 results were out of range greater than 2 SD. iv. ETG High control, ETG 625 lot, WO14786, Exp. 7/31/2024, 11 of 20 results were out of range greater than 2 SD. v. ETG Low control ETG 375 lot, WO147865, Exp. 7/31/2024, 17 of 20 results were out of range greater than 2 SD. vi. OXY Negative Control lot, 11275167 -R3 Exp. 7/31/2024, 18 of 20 results were out of range greater than 2 SD. vii. Creat UTAK Control Low 3, lot C8930 Exp. 11/30/2023, 1 of 18 results were out of range greater than 2 SD. h. December 2023 i. ARK Fentanyl High Control, lot WO17596, Exp. 9/30/2024, Levy Jennings chart blank. N=20. ii. ARK Fentanyl Low Control, lot WO17595, Exp. 9/30/2024, Levy Jennings chart blank. N=20. CV 37.2% iii. Bup SQ Negative Control, lot 10872272-R1, Exp. 2/10/2024, 6 of 21 results were out of range greater than 2 SD. iv. Methadone EMIT 4 High Control, Lot 9A589UL-R3, Levy Jennings chart blank. N=22. v. Amphetamine EMIT 5 High Control, lot 9A608UL, Levy Jennings chart blank. N=21. vi. Opiates EMIT 5 Control, lot 9A608UL, Levy Jennings chart blank. N= 17. vii. ETG High Control, ETG 625, lot WO14786, Exp. 7/31/2024, 11 of 20 results were out of range greater than 2 SD. viii. ETG Low Control, ETG 375, lot WO147865, Exp. 7/31/2024, 15 of 20 results were out of range greater than 2 SD. CV 114%. ix. Oxy Positive Control, lot 11275169-R3, Exp. 7/31/2024, 1 of 21 results were out of range greater than 2 SD. x. Creat UTAK Control Low 3, lot C8930 Exp. 11/30/2023, 1 of 20 results were out of range greater than 2 SD. xi. Creat UTAK Control High 4 Lot C9731, 1 of 21 results were out of range greater than 2 SD. i. January 2024 i. Fen ARK Fen High lot WO17596 Exp. 9/30 /2024, Levy Jennings chart blank. N= 23 ii. Fen ARK Fen Low lot WO17595 Exp. 9 /30/2024, Levy Jennings chart blank. N= 23 iii. Bup SQ Negative Control, lot 10872272-R1, Exp. 2/10/2024, 7 of 12 results were out of range greater than 2 SD. iv. Bup SQ Positive Control, lot 10872273-R1 Exp. 2/10/2024, 10 of 11 results were out of range greater than 2 SD. v. Amp EMIT 5 High Control, lot 9A608UL Exp. 6/30 /2024, 4 of 5 results were out of range greater than 2 SD. vi. Opi EMIT 5 lot 9A610UL Exp. 6/30/2024, Levy Jennings chart blank. N= 17. vii. ETG High Control, ETG 625, lot WO14786, Exp. 7/31/2024, 20 of 29 results were out of range greater than 2 SD. viii. ETG Low Control, ETG 375, lot WO147865, Exp. 7/31/2024, 20 of 22 results were out of range greater than 2 SD. ix. Oxy Positive Control, lot 11275169-R3, Exp. 7/31/2024, 7 of 19 results were out of range greater than 2 SD. x. Oxy Negative Control, lot 11275167-R3, Exp. 7/31/2024, 7 of 18 results were out of range greater than 2 SD. j. February 2024 i. Fen ARK Fen High lot WO17596 Exp. 9/30 /2024, Levy Jennings chart blank. N=20. ii. Fen ARK Fen Low lot WO17595 Exp. 9 /30/2024, Levy Jennings chart blank. N= 20. iii. Bup SQ Negative Control, lot 10872272-R1, Exp. 2/10/2024, 6 of 7 results were out of range greater than 2 SD. iv. Bup SQ Negative Control, lot 10872273-R1, Exp. 2/28/2025, 6 of 13 results were out of range greater than 2 SD. v. Bup SQ Positive Control, lot 10872273-R1 Exp. 2/10 /2024, 4 of 7 results were out of range greater than 2 SD. vi. Bup SQ Positive Control, lot 10872274-R1 Exp. 2/28/2025, 11 of 12 results were out of range greater than 2 SD. vii. Phos BioRad 1 lot # 45931 Exp. 7/31/2024, 1 of 20 results were out of range greater than 2 SD. viii. Phos BioRad 3 lot #45933 Exp. 7/31/2024, 1 of 20 results were out of range greater than 2 SD. ix. CL BioRad 3 lot # 45933 Exp. 7/31/2024, 1 of 20 results were out of range greater than 2 SD. x. Opi EMIT 2 Low, lot 9A565UL-S1 Exp. 6/30/2024, Levy Jennings chart blank. N= 13. xi. Met EMIT 4 High lot 9A588UL-S1 Exp. 6/30/2024, Levy Jennings chart blank. N= 18. xii. Amp EMIT 5 lot 9A610UL Exp. 6/30/2024, 17 of 18 results were out of range greater than 2 SD. xiii. Opi EMIT 5 lot 9A610UL Exp. 6/30/2024, Levy Jennings chart blank. N=18. xiv. ETG High lot WO14786 Exp. 7/31/2024, 6 of 20 results were out of range greater than 2 SD. xv. ETG Low lot WO14785 Exp. 7/31/2024, 16 of 21 results were out of

	range greater than 2 SD. xvi. Oxy 100 Neg lot 11275167-R3 Exp. 7/31/2024, 1 of 20 results were out of range greater than 2 SD. k. March 2024 i. Bup SQ Negative Control, lot 10872273-R1, Exp. 2/28/2025, 3 of 3 results were out of range greater than 2 SD. ii. Bup SQ Positive Control lot 10872274-R1 Exp. 2/28/2025, 3 of 3 results were out of range greater than 2 SD. iii. ETG High Control, ETG 625, lot WO14786, Exp. 7/31/2024, 12 of 15 results were out of range greater than 2 SD. iv. ETG Low Control, ETG 375, lot WO147865, Exp. 7/31/2024, 2 of 15 results were out of range greater than 2 SD. v. Oxy Pos Control lot 11275169-R3 Exp. 7/31/2024, 11 of 12 results were out of range greater than 2 SD. 2. The laboratory did not have a written procedure for Chemistry AU680 QC acceptance criteria or corrective action to take if QC is out of range. 3. During Staff Interview with TS4 on 5/15/2024 at 11:00 AM TS4 stated: a. "The above out of range QC does not have documented corrective action." b. In reference to the procedure noted in #2 above, TS4 stated, "We do not have it." c. "Nobody has been paid for a year. I was not here from July 2023 to April 2024. When I returned, I printed the AU680 Levy Jennings Charts from July 2023 to April 2024 on April 30, 2024. I signed all the review sheets after printing them on April 30, 2024, but did not add a date. It is too late now to go back and perform corrective action on QC from a year ago." d. "The laboratory does not participate in a peer group program for Chemistry." e. "The testing personnel who performed the above QC is afraid to speak with inspectors to explain what happened." f. "When the Levy Jennings charts are blank, that means that the expected control values were never entered into the computer, therefore testing personnel have no way of knowing if the control results are in range or out of range." 4. The laboratory performs 162,011 tests annually in the specialty of Chemistry.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on surveyor review of the laboratory's quality control (QC) records and Levy Jennings charts and interview with Technical Supervisor #4 (TS4) the laboratory failed to investigate or employ corrective action when QC results were outside of the acceptable ranges to ensure accurate and reliable patient test results in the specialty of Chemistry. Findings include: 1. Record review on 5/15/2024 of the laboratory's Au680 Chemistry analyzer QC records revealed: a. Two levels of control material are run daily for Buprenorphine (BUP), Ethylglucuronide (ETG), Total Bilirubin (Tbili), Oxycodone (Oxy), Creatinine (Creat), Amphetamine (Amp), Methadone (Met), Opiates (Opi), Fentanyl (Fen), Chloride (CL) and Phosphorous (Phos). b. The monthly Levy Jennings charts from July 2023 to April 2024 were printed out on April 30, 2024. c. Each Month had a cover page, 'Quality Assurance/Assessment Checklist' that contained the following: i. The Quality Control Section, Drugs of Abuse section was checked of as 'met'. ii. The Laboratory Director (LD) and TS4 signed as reviewed, but did not include a date of review for 9 of 10 months., iii. The October 2023 sheet had a date of 11/10/2023 beside the LD and TS4 signatures. d. August

2023 - Bup SQ Negative Control, lot 10872272-R1, Exp. 2/10/2024, 6 of 13 results were out of range greater than 2 Standard Deviations (SD). e. September 2023 i. ETG High control, ETG 625, lot WO14786, Exp. 7/31/2024, 9 of 20 results were out of range greater than 2 SD. ii. ETG Low control, ETG 375, lot WO147865, Exp. 7/31 /2024, 8 of 20 results were out of range greater than 2 SD. f. October 2023 i. ETG High control, ETG 625, lot WO14786, Exp. 7/31/2024. 6 of 10 results were out of range greater than 2 SD. ii. ETG Low control ETG 375, lot WO147865, Exp. 7/31 /2024, 8 of 10 results were out of range greater than 2 SD. g. November 2023 i. Bup SQ Negative Control, lot 10872272-R1, Exp. 2/10/2024, 6 of 20 results were out of range greater than 2 SD. ii. Bup SQ Positive Control, lot 10872273-R1 Exp. 2/10 /2024, 3 of 20 results were out of range greater than 2 SD. iii. BIORAD 3 T Bili Control, lot 45933 Exp. 7/31/2024, 1 of 15 results were out of range greater than 2 SD. iv. ETG High control, ETG 625 lot, WO14786, Exp. 7/31/2024, 11 of 20 results were out of range greater than 2 SD. v. ETG Low control ETG 375 lot, WO147865, Exp. 7/31/2024, 17 of 20 results were out of range greater than 2 SD. vi. OXY Negative Control lot, 11275167 -R3 Exp. 7/31/2024, 18 of 20 results were out of range greater than 2 SD. vii. Creat UTAK Control Low 3, lot C8930 Exp. 11/30/2023, 1 of 18 results were out of range greater than 2 SD. h. December 2023 i. ARK Fentanyl High Control, lot WO17596, Exp. 9/30/2024, Levy Jennings chart blank. N=20. ii. ARK Fentanyl Low Control, lot WO17595, Exp. 9/30/2024, Levy Jennings chart blank. N=20. CV 37.2% iii. Bup SQ Negative Control, lot 10872272-R1, Exp. 2 /10/2024, 6 of 21 results were out of range greater than 2 SD. iv. Methadone EMIT 4 High Control, Lot 9A589UL-R3, Levy Jennings chart blank. N=22. v. Amphetamine EMIT 5 High Control, lot 9A608UL, Levy Jennings chart blank. N=21. vi. Opiates EMIT 5 Control, lot 9A608UL, Levy Jennings chart blank. N= 17. vii. ETG High Control, ETG 625, lot WO14786, Exp. 7/31/2024, 11 of 20 results were out of range greater than 2 SD. viii. ETG Low Control, ETG 375, lot WO147865, Exp. 7/31/2024, 15 of 20 results were out of range greater than 2 SD. CV 114%. ix. Oxy Positive Control, lot 11275169-R3, Exp. 7/31/2024, 1 of 21 results were out of range greater than 2 SD. x. Creat UTAK Control Low 3, lot C8930 Exp. 11/30/2023, 1 of 20 results were out of range greater than 2 SD. xi. Creat UTAK Control High 4 Lot C9731, 1 of 21 results were out of range greater than 2 SD. i. January 2024 i. Fen ARK Fen High lot WO17596 Exp. 9/30/2024, Levy Jennings chart blank. N= 23 ii. Fen ARK Fen Low lot WO17595 Exp. 9/30/2024, Levy Jennings chart blank. N= 23 iii. Bup SQ Negative Control, lot 10872272-R1, Exp. 2/10/2024, 7 of 12 results were out of range greater than 2 SD. iv. Bup SQ Positive Control, lot 10872273-R1 Exp. 2/10/2024, 10 of 11 results were out of range greater than 2 SD. v. Amp EMIT 5 High Control, lot 9A608UL Exp. 6/30/2024, 4 of 5 results were out of range greater than 2 SD. vi. Opi EMIT 5 lot 9A610UL Exp. 6/30/2024, Levy Jennings chart blank. N= 17. vii. ETG High Control, ETG 625, lot WO14786, Exp. 7/31/2024, 20 of 29 results were out of range greater than 2 SD. viii. ETG Low Control, ETG 375, lot WO147865, Exp. 7/31 /2024, 20 of 22 results were out of range greater than 2 SD. ix. Oxy Positive Control, lot 11275169-R3, Exp. 7/31/2024, 7 of 19 results were out of range greater than 2 SD. x. Oxy Negative Control, lot 11275167-R3, Exp. 7/31/2024, 7 of 18 results were out of range greater than 2 SD. j. February 2024 i. Fen ARK Fen High lot WO17596 Exp. 9/30/2024, Levy Jennings chart blank. N=20. ii. Fen ARK Fen Low lot WO17595 Exp. 9/30/2024, Levy Jennings chart blank. N= 20. iii. Bup SQ Negative Control, lot 10872272-R1, Exp. 2/10/2024, 6 of 7 results were out of range greater than 2 SD. iv. Bup SQ Negative Control, lot 10872273-R1, Exp. 2/28/2025, 6 of 13 results were out of range greater than 2 SD. v. Bup SQ Positive Control, lot 10872273-R1 Exp. 2/10 /2024, 4 of 7 results were out of range greater than 2 SD. vi. Bup SQ Positive Control, lot 10872274-R1 Exp. 2/28/2025, 11 of 12 results were out of range greater than 2 SD. vii. Phos BioRad 1 lot # 45931 Exp. 7/31/2024, 1 of 20 results were out of range

	greater than 2 SD. viii. Phos BioRad 3 lot #45933 Exp. 7/31/2024, 1 of 20 results were out of range greater than 2 SD. ix. CL BioRad 3 lot # 45933 Exp. 7/31/2024, 1 of 20 results were out of range greater than 2 SD. x. Opi EMIT 2 Low, lot 9A565UL-S1 Exp. 6/30/2024, Levy Jennings chart blank. N= 13. xi. Met EMIT 4 High lot 9A588UL-S1 Exp. 6/30/2024, Levy Jennings chart blank. N= 18. xii. Amp EMIT 5 lot 9A610UL Exp. 6/30/2024, 17 of 18 results were out of range greater than 2 SD. xiii. Opi EMIT 5 lot 9A610UL Exp. 6/30/2024, Levy Jennings chart blank. N=18. xiv. ETG High lot WO14786 Exp. 7/31/2024, 6 of 20 results were out of range greater than 2 SD. xv. ETG Low lot WO14785 Exp. 7/31/2024, 16 of 21 results were out of range greater than 2 SD. xvi. Oxy 100 Neg lot 11275167-R3 Exp. 7/31/2024, 1 of 20 results were out of range greater than 2 SD. k. March 2024 i. Bup SQ Negative Control, lot 10872273-R1, Exp. 2/28/2025, 3 of 3 results were out of range greater than 2 SD. ii. Bup SQ Positive Control lot 10872274-R1 Exp. 2/28/2025, 3 of 3 results were out of range greater than 2 SD. iii. ETG High Control, ETG 625, lot WO14786, Exp. 7/31/2024, 12 of 15 results were out of range greater than 2 SD. iv. ETG Low Control, ETG 375, lot WO147865, Exp. 7/31/2024, 2 of 15 results were out of range greater than 2 SD. v. Oxy Pos Control lot 11275169-R3 Exp. 7/31/2024, 11 of 12 results were out of range greater than 2 SD. 2. During Staff Interview with TS4 on 5/15/2024 at 11:00 AM TS4 stated: a. "The above out of range QC does not have documented corrective action." b. "Nobody has been paid for a year. I was not here from July 2023 to April 2024. When I returned, I printed the AU680 Levy Jennings Charts from July 2023 to April 2024 on April 30, 2024. I signed all the review sheets after printing- them on April 30, 2024, but did not add a date. It is too late now to go back and perform corrective action on QC from a year ago." c. "The testing personnel who performed the above QC is afraid to speak with inspectors to explain what happened." d. "When the Levy Jennings charts are blank, that means that the expected control values were never entered into the computer, therefore testing personnel have no way of knowing if the control results are in range or out of range." 3. The laboratory performs 162,011 tests annually in the specialty of Chemistry.
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: Refer to D5401, D5481 and D5783.
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 surveyor observation, record review, staff interview, and the fact that 4 of the deficiencies cited during this CLIA recertification had been cited at the previous

	CLIA survey (refer to D2000, D5217, D5421, and D6079) and 1 of the deficiencies cited during this CLIA recertification had been cited at the last two CLIA surveys (refer to D5439), the laboratory director failed to provide overall management and direction in accordance with 493.1445 of this subpart and did not ensure that deficiencies cited were corrected and remained corrected through the implementation of appropriate monitoring mechanisms. The cumulative effect of this lack of oversight resulted in the laboratory's inability to ensure accuracy and reliability of patient test results in the specialties of Microbiology, Hematology, Diagnostic Immunology and Chemistry. Refer to D6079, D6084, D6086, D6087, D6088, D6089, D6090, D6092, D6093, D6094, D6097, D6103 and D6107.
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) 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, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on record review and staff interview with the laboratory Director (LD) and Technical Supervisor #4 (TS4) the laboratory director failed to document delegation of the TS and General Supervisor (GS) duties to TS and GS personnel. Findings include: 1. Record review on 5/15/2024 of the laboratory's CMS-209 form 'Laboratory Personnel Report' signed by the LD on 5/7/2024 revealed: a. Four TS and three GS. b. The LD is one of the 4 TS. c. The LD did not have document delegation of duties for the 3 other TS. 2. Staff interview with the LD and TS4 on 5/15/2024 at 11:00 AM confirmed the above findings. TS4 stated, "The other TS's are listed on the 209 form because they qualify to be a TS."
D6084	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(2) The laboratory director must ensure that the physical plant and environmental conditions provide a safe environment in which employees are protected from physical, chemical, and biological hazards. This STANDARD is not met as evidenced by: Refer to D5401.
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of

	the method. This STANDARD is not met as evidenced by: Refer to D5421.
D6087	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(iii) The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on record review and staff interview with Technical Supervisor #4 the LD failed to ensure the competency of all testing personnel to ensure accurate and reliable test results. Findings include: 1. Record review on 5/15/2024 of the laboratory's 2022, 203 and 2024 to date competency records revealed the 2024 'Laboratory Personnel Evaluation' forms for 3 of 4 testing personnel TP2 were signed by TS4 with a date of 2 /12/2024. 2. Interview with TS4 and the LD on 5/15/2024 at 11:00 AM: a. TS4 stated, "Nobody has been paid for a year. I was not here from July 2023 to April 2024." When I came back TS2 gave me a stack of papers and told me to sign them." b. TS4 confirmed he did not perform the competency assessments dated 2/12/2024.
D6088	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4) The laboratory director must ensure that the laboratory is enrolled in an HHS-approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Refer to D2000.
D6089	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(i) The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part. This STANDARD is not met as evidenced by: Refer to D2003, D2007, D2015, D2093, D2104 and D2128.
D6090	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(ii) The laboratory director must ensure the results are returned within the timeframes established by the proficiency testing program. This STANDARD is not met as evidenced by: Refer to D2093 and D2104.

D6092	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iv) The laboratory director must ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on record review and staff interview with technical supervisor #4 (TS4) and the Laboratory Director (LD) the laboratory failed to verify at least twice annually the accuracy of Influenza A, Influenza B, Phosphorous, Gamma Glutamyl Transferase (GGT), and Low Density Lipoprotein (LDL). Findings include: 1. Record review on 5 /15/2024 of the laboratory's 2022, 2023 and 2024 to date American Proficiency Institute (API) proficiency testing (PT) records revealed: a. The laboratory received a score of 0 for the non-regulated analyte Phosphorous for 2024 Event 1. b. The laboratory received unacceptable scores for 2 of 5 results for the non-regulated analyte GGT for 2024 Event 1. c. The laboratory received unacceptable scores for 2 of 5 results for the non-regulated analyte LDL for 2024 Event 1. d. The PT scores noted in 1a, 1b and 1c above were signed as reviewed by the LD. e. The laboratory did not investigate or document corrective action for the unacceptable PT scores noted above in 1a, 1b and 1c. 2. Staff interview with TS4 and the LD on 5/15/2024 at 4:30 PM, confirmed the laboratory received the unacceptable scores noted in 1a, 1b and 1c above, the scores were signed as reviewed by the LD and the laboratory did not investigate or document corrective action. 3. Record review on 5/15/2024 of the laboratory's API PT Hematology/Coagulation 2023 Event 3 records revealed: a. The laboratory received a score of 50% for the regulated analyte platelets. b. The PT Performance Evaluation report was signed as reviewed by the laboratory director (LD). c. The laboratory did not investigate or document corrective action for the above 50% score. 4. Staff interview with Technical Supervisor #4 (TS4) on 5/15/2024 at 9:30 AM confirmed the laboratory received a score of 50% for the regulated analyte platelets for 2023 Event 3 and the laboratory did not investigate or document corrective action. TS4 stated, "The laboratory is not doing Hematology anymore, hope to start it back up in the future." 5. The laboratory performs 162,011 tests annually in the specialty of Chemistry.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Refer to D5403, D5439, D5441, D5455, D5471, D5481 and D5783
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

	This STANDARD is not met as evidenced by: Refer to D5409, D5421, D5429, D5435, D5791, D6092 and D6087.
D6097	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(7) The laboratory director must ensure that patient test results are reported only when the system is functioning properly. This STANDARD is not met as evidenced by: Refer to D5481.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Refer to D5209.
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Refer to D6079.