Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0483784	01/12/2024
Name of Provider or Supplier	**Street Address, City, State**	
Trinity Valley Diagnostic Clinic	2217 S Sycamore, Palestine, TX	

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	An onsite validation survey conducted on 1/11/2024 and 1/12/2024 found the laboratory out of compliance with 42 CFR Part 493, Requirements for Laboratories, for the following conditions: D5400 - 42 C.F.R. 493.1250 Condition: Analytic systems; D6000 - 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director; D6033 - 42 C.F.R. 493.1409 Condition: Laboratories performing moderate complexity testing; technical consultant;
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 review of CMS (Centers for Medicare and Medicaid Services)-209 form, laboratory policies, competency assessments, and confirmed in interview, the laboratory failed to have documentation of a policy to address competency assessments for 1 of 1 technical consultant (TC-1) and 3 of 3 testing personnel (TP) in 2022 and 2023. Findings Included: 1. Review of CMS-209 form submitted at time of survey, revealed one technical consultant (TC-1) and three testing personnel (TP-1, TP-2 and TP-3) providing services to the laboratory. 2. Review of laboratory policies revealed no documentation of a policy to address competency assessment performance of individuals in the TC and TP laboratory roles in 2022 and 2023. 3. Review of laboratory competency assessments revealed no annual competency documentation for TC-1 in 2022 and 2023. Further review revealed TC-1 did not perform TP-1, TP-2 and TP-3 competencies in 2022 and 2023. Refer to D6046. 4. In an interview on 01/11/2024 at 01:43 p.m., TP-1 confirmed the laboratory failed to have documentation of a policy to address competency assessments for 1 of 1 technical consultant (TC-1) and 3 of 3 testing personnel (TP) in 2022 and 2023.

D5213	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1) The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: Based on review of laboratory PT (proficiency testing) documentation in 2022 and 2023, and confirmed in interview, the laboratory failed to evaluate and document proficiency testing performances in Hematology and Coagulation that were not evaluated or scored by a CMS-approved PT program for 3 of 5 events in 2022 and 2023. Findings Included: 1. Review of the laboratory American Proficiency Institute (API) PT event documentation for 2022 and 2023 revealed the following analytes /methods that were not evaluated or scored by API: a. 2022 Hematology / Coagulation 2nd Event Analyte / Method: Basophil (DIF) (%)^ Sample - Performance DIF-02 - Not Graded Analyte / Method: Eosinophil (DIF) (%)^ Sample - Performance DIF-02 - Not Graded Analyte / Method: Lymphocyte (DIF) (%)^ Sample - Performance DIF-02 - Not Graded Analyte / Method: Monocyte (DIF) (%)^ Sample - Performance DIF-02 - Not Graded Analyte / Method: Neutrophil, seg or band (DIF) (%)^ Sample - Performance DIF-02 - Not Graded Analyte / Method: NRBC/100 WBC (DIF) (%)^ Sample - Performance DIF-02 - Not Graded Analyte / Method: Platelet estimate (DIF) ^ Sample - Performance DIF-01 - Not Graded Analyte / Method: Blood Cell ID (Educational) Sample - Performance ECI-06 - Not Graded ECI-07 - Not Graded ECI-08 - Not Graded ECI-09 - Not Graded ECI-10 - Not Graded b. 2022 Hematology / Coagulation 3rd Event Analyte / Method: Basophil (DIF) (%)^ Sample - Performance DIF-03 - Not Graded Analyte / Method: Eosinophil (DIF) (%)^ Sample - Performance DIF-03 - Not Graded Analyte / Method: Lymphocyte (DIF) (%)^ Sample - Performance DIF-03 - Not Graded Analyte / Method: Monocyte (DIF) (%)^ Sample - Performance DIF-03 - Not Graded Analyte / Method: Neutrophil, seg or band (DIF) (%)^ Sample - Performance DIF-03 - Not Graded Analyte / Method: NRBC/100 WBC (DIF) (%)^ Sample - Performance DIF-03 - Not Graded Analyte / Method: Blood Cell ID (Educational) Sample - Performance ECI-11 - Not Graded ECI-12 - Not Graded ECI-13 - Not Graded ECI-14 - Not Graded ECI-15 - Not Graded c. 2023 Hematology / Coagulation 2nd Event Analyte / Method: Basophil (DIF) (%)^ Sample - Performance DIF-02 - Not Graded Analyte / Method: Eosinophil (DIF) (%)^ Sample - Performance DIF-02 - Not Graded Analyte / Method: Lymphocyte (DIF) (%)^ Sample - Performance DIF-02 - Not Graded Analyte / Method: Monocyte (DIF) (%)^ Sample - Performance DIF-02 - Not Graded Analyte / Method: Neutrophil, seg or band (DIF) (%)^ Sample - Performance DIF-02 - Not Graded Analyte / Method: NRBC/100 WBC (DIF) (%)^ Sample - Performance DIF-02 - Not Graded Analyte / Method: Platelet estimate (DIF)^ Sample - Performance DIF-01 - Not Graded Analyte / Method: Blood Cell ID (Educational) Sample - Performance ECI-06 - Not Graded ECI-07 - Not Graded ECI-08 - Not Graded ECI-09 - Not Graded ECI-10 - Not Graded The surveyor requested laboratory documentation of performance review for the above analytes/methods not evaluated or scored by the PT program, and none were provided. 2. In an interview on 01/11/2024 at 01:45 p.m., in the laboratory, TP-1 confirmed the laboratory failed to evaluate and document proficiency testing performances in Hematology and Coagulation that were not evaluated or scored by a CMS-approved PT program for 3 of 5 events in 2022 and 2023.
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 review of laboratory control documents, laboratory policy, and laboratory patient test results laboratory failed to meet the condition of Analytic systems for records reviewed in 2022 and January to October 2023 to include the following: 1. The laboratory failed to follow its individualized quality control plan (IQCP) to perform a positive and negative QC every 30 days for 2 of 2 panels ran on the BioFire Film Array 2 for records reviewed from January 2022 to October 2023. (Refer to D5445) 2. The laboratory failed to have a step-by-step procedure for the establishment and implementation of statistical parameters (mean and standard deviation (S.D.)) for two of two lot roll overs of unassayed control materials put into use on the Architect ci8200 in December 2022 and September 2023. (Refer to D5403) 3. The laboratory failed to ensure expired chemistry reagents were removed from the Abbott Architect ci8200 analyzer before being used in patient testing for 15 patients reviewed for nine of nine instances identified in records reviewed in May 2022 and June 2023. (Refer to D5417 I) 4. The laboratory failed to document acceptable QC prior to reporting patient results for 19 of 19 patients reviewed in June 2023. (Refer to D5481)
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on surveyor observation, review of laboratory policy, the Centers for Medicare and Medicaide Services (CMS) form 116, patient results and confirmed in interview, the laboratory failed to follow its policy for the centrifugation of urine for urine sediment analysis for 22 of 22 months reviewed from January 2022 to October of 2023. The findings included: 1. In a tour of the laboratory on 1/11/2024 at 0925 hours, surveyor noted a "LabCorp horizon mini E" centrifuge next to the Cobas u411 urine analyzer. Surveyor queried for the centrifuge used for urine sediment analysis and testing person (TP) 1 indicated the LabCorp horizon mini E centrifuge was utilized. 2. Review of laboratory policy titled "Microscopic Examination of Urine" , section "Procedure" had the following instructions: "All urine specimens will receive a microscopic inspection. After running the macroscopic chemistry, centrifuge the disposable centrifuge tube for 2 minutes @ 2000 RPM ..." 3. Review of the laboratory form titled "Centrifuge Maintenance Log" for had the following centrifuge verification performed: Centrifuge - Measured RPM - ... - ... - Date Centrifuge Checked "Horizon - 3373RPM - 4/20/2023" 4. Review of the CMS116, section VIII "Non-Waived testing" listed an annual test volume of 6,661 for urinalysis to include

	the following random 20 patients with urine microscopic testing performed: Patient MRN - Date Tested CUEJUA0001 - 11/22/2022 HELSAR0001 - 11/22/2022 STETHO0004 - 11/22/2022 PATROY0001 - 11/22/2022 DECCRA0001 - 11/22/2022 ROGMAR0002 - 11/22/2022 CALDON0001 - 11/22/2022 THOMAR0006 - 11/22 /2022 HOWDEB0001 - 11/22/2022 GARDON0001 - 11/22/2022 DAVALE0002 - 3 /06/2023 KOKPAU0001 - 3/06/2023 HARULY0001 - 3/06/2023 BILCAR0001 - 3/09 /2023 SINJAM0004 - 3/13/2023 SHEDOR0001 - 3/20/2023 BACFLO0001 - 3/27 /2023 SHUSLO0001 - 3/27/2023 DICCHA0001 - 3/27/2023 ZZZZZZ0019 - 4/28 /2023 5. In an interview on 1/11/2024 at 15:46 hours, in the laboratory, testing person (TP) 1 confirmed that all patients with a urinalysis received a urine microscopic, and that the RPM on the horizon mini E centrifuge used to spin down urine for urine sediment analysis was too fast.
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: Based on a review of laboratory policy, laboratory quality control (QC) documents, and interview, the laboratory failed to have a step-by-step procedure for the establishment and implementation of statistical parameters (mean and standard deviation (S.D.)) for two of two lot roll overs of unassayed control materials put into use on the Architect ci8200 in December 2022 and September 2023. The findings included: 1. Review of laboratory QC records included the following two lot roll overs in December 2022 and September 2023: In use 12/8/2022: BioRad Liquichek Unassayed Chemistry Control Lot 92940, Expires 5/31/2024; previous lot BioRad Liquichek 92920, Expiration 6/30/2023. In use 9/7/2023: BioRad Liquichek Unassayed Chemistry Control Lot 92960, Expires 12/31/2024; previous lot BioRad Liquichek Unassayed Chemistry Control Lot 92940. Surveyor asked for the statistical establishment documentation for the above used in determination of acceptable chemistry QC and none was provided. 2. Review of laboratory policy titled "Quality Control" did not include step by step instructions for the establishment of statistical parameters, mean and S.D., for new lot of unassayed control materials. 3. In an interview on 1/12/2024 at 09:37 hours, in the laboratory, testing personnel (TP) 1 confirmed that the laboratory did not have a step-by-step policy for the establishment

	and implementation of the BioRad Liquichek unassayed control materials used in the determination of acceptability for chemistry assays on the Architect ci8200.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on surveyor observation, review of manufacturer's instructions, patient reports and confirmed in interview, the laboratory failed to follow manufacturer's instructions for CBC analysis for 3,277 of 3,277 CBC's (Complete Blood Count) performed in 2023 (June-October). Findings Included: 1. During a tour of the facility on 01/11/2024 at 09:44 a.m., the surveyor observed 1 Sysmex XN-350 Hematology Analyzer (Serial Number: 26352; Implemented in 06/2023) in the patient testing area. The surveyor also observed in the testing a specimen rocker, currently mixing 4 CBC specimens. The surveyor requested the final patient reports of the CBC specimens on the rocker, but none were provided. 2. Review of manufacturer's instructions, "Sysmex XN-350 Automated Hematology Analyzer CLSI Procedure" (Document Number: CF-CLSI-07203 April 2023; Approved by the Laboratory Director on: 06/13/23) revealed the following: " ...II. Specimen Requirements ...4. Do not place CBC and Diff samples on a mechanical rocker. Constant rocking may alter white cell membranes, resulting in false interpretive messages." 3. Review of patient CBC reports in 2023 (06/01/2023-10/31/2023) revealed 3,277 CBC specimens were reported. 4. In an interview on 01/11/2024 at 01:24 p.m., in the laboratory, TP-1 stated all CBC specimens, prior to analysis, were placed on the rocker. TP-1 stated they were aware of the manufacturer's instructions but felt rocking the specimens produced quality results. This confirmed the laboratory failed to follow manufacturer's instructions for 3,277 of 3,277 CBCs performed in 2023 (June-October).
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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: (1) Water quality. (2) Temperature. (3) Humidity. (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 surveyor observation, control instructions for use (IFU), laboratory temperature records, and confirmed in interview, the laboratory failed to ensure chemistry controls were stored under the correct conditions for 42 of 42 days reviewed in September and October of 2023. The findings included: 1. In a tour of the laboratory on 1/12/2024 at 09:05 hours the surveyor noted a small, single door, "summit" freezer on top of a "hotpoint" refrigerator freezer. The contents of the

	summit freezer had the following control reagents: Bio-Rad Liquichek Unassayed Chemistry Control Level 1 Lot 92961, expiration 12/31/2024 Bio-Rad Liquichek Unassayed Chemistry Control Level 2 Lot 92962, expiration 12/31/2024 Bio-Rad Liquichek Diabetes Control Level 1; lot 89221, expiration 9/90/2024 Bio-Rad Liquichek Diabetes Control Level 2; lot 89222, expiration 9/90/2024 Bio-Rad Liquichek Immunology Control Level 1; lot 85701, expiration 8/31/2024 Bio-Rad Liquicheck Immunology Control Level 2; lot 85702, expiration 8/31/2024 Technopath Multichem IA Plus Lot 37109220, expiration 12/31/2024 2.Review of the Bio-Rad Liquichek Unassayed Chemistry Control Instructions for use, section "Storage and Stability" stated the following: "This product will be stable until the expiration date when stored unopened at -20 to -70(degrees) C." Review of the Bio-Rad Liquichek Diabetes Control IFU, section "Storage and Stability" stated the following: "This product will be stable until the expiration date when stored unopened at -20 to -70 (degrees) C." Review of the Bio-Rad Liquichek Immunology Control, section "S Storage and Stability" stated the following: "This product will be stable until the expiration date when stored unopened at -20 to -70(degrees) C." Review of the Technopath Multichem IA Plus IFU, section "Storage and Stability" stated the following: "This product will be stable until the expiration date when stored unopened at -20 to -80(degrees) C." 3. Review of the laboratory document titled "Temperature and Barometric Pressure Log" for September and October 2023 had the following 42 days where the temperature in the Summit freezer did not meet the manufactures storage specifications: September 2023: 20 days 09/01/2023 -14 (degrees)C 09/05 /2023 -16 (degrees)C 09/06/2023 -12 (degrees)C 09/07/2023 -12 (degrees)C 09/08 /2023 -14 (degrees)C 09/11/2023 -10 (degrees)C 09/12/2023 -12 (degrees)C 09/13 /2023 -14 (degrees)C 09/14/2023 -12 (degrees)C 09/15/2023 -12 (degrees)C 09/18 /2023 -16 (degrees)C 09/19/2023 -14 (degrees)C 09/20/2023 -12 (degrees)C 09/21 /2023 -12 (degrees)C 09/22/2023 -10 (degrees)C 09/25/2023 -12 (degrees)C 09/26 /2023 -10 (degrees)C 09/27/2023 -12 (degrees)C 09/28/2023 -10 (degrees)C 09/29 /2023 -12 (degrees)C October 2023: 22 days 10/02/2023 -16 (degrees)C 10/03/2023 -14 (degrees)C 10/04/2023 -14 (degrees)C 10/05/2023 -14 (degrees)C 10/06/2023 -14 (degrees)C 10/09/2023 -10 (degrees)C 10/10/2023 -14 (degrees)C 10/11/2023 -12 (degrees)C 10/12/2023 -12 (degrees)C 10/13/2023 -10 (degrees)C 10/16/2023 -16 (degrees)C 10/17/2023 -14 (degrees)C 10/18/2023 -10 (degrees)C 10/19/2023 -14 (degrees)C 10/20/2023 -16 (degrees)C 10/23/2023 -14 (degrees)C 10/24/2023 -12 (degrees)C 10/25/2023 -14 (degrees)C 10/26/2023 -16 (degrees)C 10/27/2023 -12 (degrees)C 10/30/2023 -16 (degrees)C 10/31/2023 -14 (degrees)C 4. In an interview on 1/12/2024 at 12:30 hours, in the laboratory, testing personnel (TP) 1 confirmed that the above chemistry controls had not been stored at the correct conditions as specified by the manufacturer.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on surveyor observation, review of laboratory documentation and confirmed in interview, the laboratory failed to document hematology stain secondary containers

	with identifying information for 2 of 2 containers observed in 2024. Findings Included: 1. During a tour of the facility on 01/11/2024 at 09:44 a.m., the surveyor observed 1 Sysmex XN-550 Hematology Analyzer (Serial Number: 26352; Implemented in 06/2023) in the patient testing area. The surveyor also observed two urine collection containers in the sink beside the hematology analyzer. Both containers were labeled with the date of 12/19/2023, and 1 stated "Stain" and 1 stated "Buffer" on the container lids. The surveyor inquired as to the contents of the containers. TP-1 stated the containers were "hematology stain". The surveyor asked the significance of the date listed on the containers, and TP-1 stated this was the transfer date of the stain to the secondary containers. No other identifying information was listed on the containers to include storage requirement, expiration dates, lot numbers or other pertinent information required for proper use. The surveyor also observed the following information on the hematology stain currently in use: QuickLink I Wright's Stain Lot Number: 3068 Expiration Date: 06/09/2024 2. Review of laboratory documentation submitted at time of survey revealed the laboratory performed 7,272 CBCs annually. 3. In an interview on 01/11/2024 at 01:40 p.m., in the laboratory, TP-1 confirmed the laboratory failed to document hematology stain secondary containers with identifying information for 2 of 2 containers observed in 2024.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: I. Based on a review of quality control (QC) records, instrument operator's manual, and confirmed in interview, the laboratory failed to ensure expired chemistry reagents were removed from the Abbott Architect ci8200 analyzer before being used in patient testing for 15 patients reviewed for nine of nine instances identified in records reviewed in May 2022 and June 2023. The findings included: 1. Review of the Architect Ci8200 System Training Workbook, Lesson 9: "Quality Control", subsection "Control Result Flags" had the following statement: "Control Result Flags: The following are descriptions of control result flags displayed on the QC Result review screen and Stored QC results screen. Flag - Description EXP - The control result was measured using expired reagent, ARCHITECT Pre-Trigger, or Trigger Solutions." 2. A review of laboratory QC and patient testing records in May 2022 and June 2023 had the following nine days where QC had been performed on expired reagents with no documentation of retesting on non-expired reagents: May 2022: Date: Analyte - Reagent Lot Number - QC Flag 5/06/2022: AlkP - 14980UN21 - EXP The following patient had AlkP testing performed on 5/6/2022: Order number: 181531 June 2023: Date: Analyte - Reagent Lot Number - QC Flag 6/01/2023 - AlkP - 53994UN22 - EXP The following patient had AlkP testing performed on 6/01/2023: Order number: 193836 Date: Analyte - Reagent Lot Number - QC Flag 6/02/2023 - AlkP - 53994UN22 - EXP The following patient had AlkP testing performed on 6/02 /2023: Order number: 193878 Date: Analyte - Reagent Lot Number - QC Flag 6/12 /2023 - Estradiol - 44509UD00 - EXP The following two patients had Estradiol testing performed on 6/12/2023: Account #: KAMTER0001 MCCDON0003 Date: Analyte - Reagent Lot Number - QC Flag 6/13/2023 - AlkP - 53994UN22 - EXP 6/13 /2023 - Estradiol - 44509UD00 - EXP The following patient had AlkP testing

	performed on 6/13/2023: Order number: 194222 The following patient had Estradiol testing performed on 6/13/2023: Account#: FONCRY0001 Date: Analyte - Reagent Lot Number - QC Flag 6/14/2023 - AlkP - 53994UN22 - EXP 6/14/2023 - AMM - 20988Y600 - EXP The following two patients had AlkP testing performed on 6/14 /2023: Order number: 194259 Order number: 194299 The following patient had AMM testing performed on 6/14/2023: Order number: 194299 Date: Analyte - Reagent Lot Number - QC Flag 6/19/2023: GGT - 94008UN22 - EXP The following two patients had GGT testing performed on 6/19/2023: Account #: GAUTIF0001 MCKJOH0001 Date: Analyte - Reagent Lot Number - QC Flag 6/20/2023 - AMM - 20988Y600 - EXP 6/20/2023: GGT - 94008UN22 - EXP The following patient had AMM testing performed on 6/20/2023: Order number: 194477 The following two patients had GGT testing performed on 6/20/2023: Order number: 194477 Order number: 194439 Date: Analyte - Reagent Lot Number - QC Flag 6/22/2023: AlkP - 88221UN23 - EXP 6/22/2023: GGT - 94008UN22 - EXP The following two patients had GGT testing performed on 6/22/2023: Order number: 194542 Order number: 194546 The following three patients had AlkP testing performed on 6/22/2023: Order number: 194562 Order number: 194542 Order number: 194546 3. In an interview on 01/12/2024 at 10:00 hours, in the office, testing personnel (TP) 1 confirmed that the laboratory failed to remove expired chemistry reagents from the Architect ci8200 chemistry analyzer before quality control and patients had been performed. Key: Alkaline Phosphatase: AlkP Ammonia: AMM EXP: Expired Gamma-Glutamyl Transferase: GGT II. Based on surveyor observation and confirmed in interview, the laboratory failed to ensure that expired control materials were not available for use for eight of eight bottles of urine chemistry control for the Abbott Architect C8000 chemistry analyzer, observed on 1/12/2024. The findings included: 1. On 1/12/2024 at 08:47 hours, in the laboratory, the surveyor noted the following control bottles available for use in the Frigidaire refrigerator: Bio-Rad Liquichek Urine Chemistry Control Level 1: Lot 88171, Expiration 12/31/2023 1 bottle with an open date of 1/5 /2024 3 control bottles unopened Bio-Rad Liquichek Urine Chemistry Control Level 2: Lot 88172, Expiration 12/31/2023 1 vial with an open date of 1/5/2024 3 control bottles unopened 2. In an interview on 1/12/2024 at 09:00 hours, in the laboratory, testing personnel (TP)1 confirmed that the expired controls had been used to determine analyzer acceptability for patient testing on the Abbot Architect C8000 chemistry analyzer on 1/12/2024.
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 surveyor observation, review of manufacturer's instructions, laboratory Sysmex XN-350 maintenance documentation, patient reports, and confirmed in interview, the laboratory failed to document maintenance every 1,000 analyses (or weekly) for 20 of 20 weeks in 2023 (June-October). Findings Included: 1. During a tour of the facility on 01/11/2024 at 09:44 a.m., the surveyor observed 1 Sysmex XN-550 Hematology Analyzer (Serial Number: 26352; Implemented in 06/2023) in the patient testing area. 2. Review of manufacturer's instructions, "Sysmex XN-350 Automated Hematology Analyzer CLSI Procedure" (Document Number: CF-CLSI-07203 April 2023; Approved by the Laboratory Director on: 06/13/23) revealed the

	following: "Maintenance ...2.6 Executing routine cleaning (XN-350) The routine cleaning must be executed once every 1,000 analyses, or once a week." 3. Review of laboratory Sysmex XN-350 maintenance documentation, revealed the laboratory failed to document maintenance every 1,000 analyses or weekly for 20 of 20 weeks in 2023 (June-October). 4. Review of patient CBC reports in 2023 (06/01/2023-10/31 /2023) revealed 3,277 CBC specimens were reported. 5. In an interview on 01/11 /2024 at 01:45 p.m., in the laboratory, TP-1 confirmed the laboratory failed to document maintenance every 1,000 analyses (or weekly) for 20 of 20 weeks in 2023 (June-October).
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on laboratory policy, laboratory quality control (QC) records, patient results, and confirmed in interview, the laboratory failed to follow its individualized quality control plan (IQCP) to perform a positive and negative QC every 30 days for two of two panels ran on the BioFire Film Array 2 for records reviewed from January 2022 to October 2023. The findings included: 1. Review of the laboratory test menu included the following two panels ran on the BioFire 2 Array PCR system: A) Respiratory 2.1 Panel B) Gastrointestinal (GI) Panel A. 1.A review of the laboratory document titled "IQCP Summary of BioFire Respiratory Panel 2", subsection "External Quality Controls" had the following statement: "External Quality Controls (Positive and Negative) will be assayed with: Each new lot Each new shipment Every 30 days after the lot/shipment is in use" A. 2. A Review of the BioFire Respiratory Panel 2.1 included the following 15 viral targets and 4 bacterial target organisms: VIRUSES: Adenovirus Coronavirus 229E Coronavirus HKU1 Coronavirus NL63 Coronavirus OC43 Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Human Metapneumovirus Human Rhinovirus/Enterovirus Influenza A virus Influenza A virus A/H1 Influenza A virus A/H3 Influenza A virus A/H1-2009 Influenza B virus Parainfluenza virus 1 Parainfluenza virus 2 Parainfluenza virus 3 Parainfluenza virus 4 Respiratory syncytial virus BACTERIA: Bordetella parapertussis Bordetella pertussis Chlamydia pneumoniae Mycoplasma pneumoniae A.3. A review of the laboratory quality control documents had the following QC documentation for 2022: January 2022: No positive or negative QC was documented for the 19 BioFire Respiratory Panel 2.1 targets. February 2022: 8 days past the 30-day QC requirement 2/8/2022: Sample ID: EC 325944, expiration 3/4/2022: Detected (positive): Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) No negative QC for SARS-CoV-2 was documented. No positive QC was documented for the remaining 18 targets on the Respiratory Panel 2.1 March 2022: No positive or negative QC was documented for the 19 BioFire Respiratory Panel 2.1 targets. April 2022: No positive or negative QC was documented for the 19 BioFire Respiratory Panel 2.1 targets. May 2022: 5/18/2022: 69 days past the 30-day QC requirement

Sample ID: ZeptoMetrix Lot 327602, exp 5/18/2022: Detected: Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) No negative QC was documented for SARS-CoV-2 No positive QC was documented for the remaining 18 targets on the Respiratory Panel 2.1 June 2022: 6/7/2022: Sample ID: EC 327602, Exp: 10/26/2022: Detected: Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) No negative QC was documented for SARS-CoV-2 No positive QC was documented for the remaining 18 targets on the Respiratory Panel 2.1 July 2022: No positive or negative QC was documented for the 19 BioFire Respiratory Panel 2.1 targets. August 2022: No positive or negative QC was documented for the 19 BioFire Respiratory Panel 2.1 targets. September 2022: No positive or negative QC was documented for the 19 BioFire Respiratory Panel 2.1 targets. October 2022: No positive or negative QC was documented for the 19 BioFire Respiratory Panel 2.1 targets. November 2022: 11/15/2022: 131 days past the 30-day QC requirement. Sample ID: QC ERC 328452, EXP 3/16/2023: Detected: Coronavirus HKU1 Detected: Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) No negative QC was documented for SARS-CoV-2 and Coronavirus HKU1 No positive QC was documented for the remaining 17 targets on the Respiratory Panel 2.1 December 2022: 12/14/2022: Sample ID: ERC SARS COV 2 [lot number and expiration date not documented] Detected: Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) No negative QC was documented for SARS-CoV-2 No positive QC was documented for the remaining 18 targets on the Respiratory Panel 2.1 130 patients were tested with the BioFire Resp Panel (67 positive) in 2022 including the following 17 patients. Run Date Patient # Result: Result Summary 01/20 /2022 Patient 1 Positive: SARS-CoV-2 and Influenza A H3 02/25/2022 Patient 2 Positive: Coronavirus 229E 03/02/2022 Patient 3 Positive: Human Rhinovirus 03/14 /2022 Patient 4 Positive: Influenza A H3 04/13/2022 Patient 5 Positive: Coronavirus 229E 04/27/2022 Patient 6 Positive: Influenza A H3 05/24/2022 Patient 7 Positive: Parainfluenza Virus 3 06/14/2022 Patient 8 Positive: Human Rhinovirus 07/05/2022 Patient 9 Positive: SARS-CoV-2 08/19/2022 Patient 10 Positive: SARS-CoV-2 09/26 /2022 Patient 11 Positive: Parainfluenza Virus 1 10/04/2022 Patient 12 Positive: Human Rhinovirus 11/03/2022 Patient 13 Positive: Parainfluenza Virus 4 11/22/2022 Patient 14 Positive: Human Rhinovirus 12/08/2022 Patient 15 Positive: Influenza A H1-2009 12/12/2022 Patient 16 Positive: Human Rhinovirus 12/13/2022 Patient 17 Positive: RSV A review of laboratory control documents had the following QC documentation for January to October 2023 January 2023: 1/25/2023: 12 days past the 30-day QC requirement Sample ID: Jan QC - ERC Sample [lot number and expiration not documented] Detected: Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) No negative QC was documented for SARS-CoV-2 No positive QC was documented for the remaining 18 targets on the Respiratory Panel 2.1 February 2023: 2/2/2023: Sample ID: Feb 2023 QC ERC [lot number and expiration not documented] Detected: Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) No negative QC was documented for SARS-CoV-2 No positive QC was documented for the remaining 18 targets on the Respiratory Panel 2.1 March 2023: 3 /30/2023: 14 days past the 30-day QC requirement Sample ID: 328453 [expiration not documented] Detected: Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) No negative QC was documented for SARS-CoV-2 No positive QC was documented for the remaining 18 targets on the Respiratory Panel 2.1 April 2023: No positive or negative QC was documented for the 19 BioFire Respiratory Panel 2.1 targets. May 2023: No positive or negative QC was documented for the 19 BioFire Respiratory Panel 2.1 targets. June 2023: No positive or negative QC was documented for the 19 BioFire Respiratory Panel 2.1 targets. July 2023: No positive or negative QC was documented for the 19 BioFire Respiratory Panel 2.1 targets. August 2023: No positive or negative QC was documented for the 19 BioFire Respiratory Panel 2.1

targets. September 2023: No positive or negative QC was documented for the 19 BioFire Respiratory Panel 2.1 targets. October 2023: No positive or negative QC was documented for the BioFire Respiratory Panel 2.1 56 Patients (23 positive) were tested with the BioFire Respiratory Panel 2.0 from January to October 2023 to include the following 12: Run Date Patient # Result: Result Summary 02/02/2023 Patient 18 Positive: Human Rhinovirus/Enterovirus 02/03/2023 Patient 19 Positive: Parainfluenza Virus 3 02/07/2023 Patient 20 Positive: Coronavirus OC43 02/20/2023 Patient 21 Positive: Coronavirus NL63 03/16/2023 Patient 22 Positive: Human Rhinovirus/Enterovirus 03/20/2023 Patient 23 Positive: Human Metapneumovirus 03 /29/2023 Patient 24 Positive: Human Metapneumovirus 05/24/2023 Patient 25 Positive: Human Rhinovirus/Enterovirus 05/31/2023 Patient 26 Positive: Coronavirus 229E 06/19/2023 Patient 27 Positive: SARS-CoV-2 08/30/2023 Patient 28 Positive: Human Rhinovirus/Enterovirus 09/20/2023 Patient 29 Positive: Human Rhinovirus /Enterovirus B.1. A Review of the laboratory document titled "IQCP Summary of BioFire Gastrointestinal Panel", subsection "External Quality Controls" had the following statement: "External Quality Controls (Positive and Negative) will be assayed with: Each new lot Each new shipment Every 30 days after the lot/shipment is in use" B.2. Review of the BioFire GI Panel menu included the 22 targets available for identification: BACTERIA: Campylobacter (C. jejuni / C. coli / C. upsaliensis) Clostridioides (Clostridium) difficile (toxin A/B) Plesiomonas shigelloides Salmonella Yersinia enterocolitica Vibrio (V. parahaemolyticus / V. vulnificus / V. cholerae) Vibrio cholerae DIARRHEAGENIC ESCHERICHIA COLI/SHIGELLA: Enteroaggregative E. coli (EAEC) Enteropathogenic E. coli (EPEC) Enterotoxigenic E. coli (ETEC) lt/st Shiga-like toxin-producing E. coli (STEC) stx1/stx2 E. coli O157 Shigella/Enteroinvasive E. coli (EIEC) PARASITES: Cryptosporidium Cyclospora cayetanensis Entamoeba histolytica Giardia lamblia VIRUSES: Adenovirus F40/41 Astrovirus Norovirus GI/GII Rotavirus A Sapovirus (I, II, IV, and V) B.3. A review of laboratory control documents had the following QC documentation for 2022: January 2022: No positive or negative QC was documented for the 22 BioFire GI Panel targets. February 2022: No positive or negative QC was documented for the 22 BioFire GI Panel targets. March 2022: No positive or negative QC was documented for the 22 BioFire GI Panel targets. April 2022: No positive or negative QC was documented for the 22 BioFire GI Panel targets. May 2022: No positive or negative QC was documented for the 22 BioFire GI Panel targets. June 2022: 127 days past the 30-day QC requirement: 6/7/2022: Sample ID: 327551; x:12/15/22, GIctrl 1 Detected: Clostridioides (Clostridium) difficile (toxin A/B), Plesiomonas shigelloides, Vibrio, Vibrio cholerae, Enteroaggregative E. coli (EAEC), Shiga-like toxin-producing E. coli (STEC) stx1/stx2, E. coli O157, Shigella/Enteroinvasive E. coli (EIEC), Cryptosporidium, Adenovirus F40/41 Sapovirus. No negative QC was documented for the above. No positive QC was documented for the remaining 9 targets. July 2022: No positive or negative QC was documented for the 22 BioFire GI Panel targets. August 2022: No positive or negative QC was documented for the 22 BioFire GI Panel targets. September 2022: No positive or negative QC was documented for the 22 BioFire GI Panel targets. October 2022: No positive or negative QC was documented for the 22 BioFire GI Panel targets. November 2022: 119 days past the 30-day QC requirement 11/3/2022: Sample ID: QC Sample 06 [lot number and expiration not documented] Detected: Campylobacter, Salmonella, Enteropathic E. coli (EPEC), Enterotoxigenic E. coli (ETEC) lt/st, Cyclospora cayetanensis, Entameoba histolytica, Giardia lamblia, Astrovirus, and Norovirus GI/GII. No negative QC was documented for the above. No positive QC was documented for the remaining 13 targets. December 2022: 11 days past the 30-day QC requirement. 12/14 /2022 Sample ID: QC GI ctrl# 2 [lot number and expiration not documented] Campylobacter, Salmonella, Enteropathic E.coli (EPEC), Enterotoxigenic E. coli

(ETEC) lt/st, Cyclospora cayetanensis, Entameoba histolytica, Giardia lamblia, Astrovirus, and Norovirus GI/GII. No negative QC was documented for the above. No positive QC was documented for the remaining 13 targets. 70 Patients (23 positive) were tested with the BioFire Respiratory Panel 2.0 in 2022 to include the following 10: Run Date Patient # Result: Result Summary 01/18/2022 Patient 30 Positive: Shiga-like toxin-producing E. coli (STEC) 02/22/2022 Patient 31 Positive: Sapovirus 03/02 /2022 Patient 32 Positive: Campylobacter and Sapovirus 04/19/2022 Patient 33 Positive: Clostridium difficil toxin A/B 07/11/2022 Patient 34 Positive: Norovirus GI /GII 08/22/2022 Patient 35 Positive: Shiga-like toxin-producing E. coli (STEC) 09/09 /2022 Patient 36 Positive: Clostridium difficil toxin A/B 10/06/2022 Patient 37 Positive: EAEC 11/01/2022 Patient 38 Positive: Clostridium difficil toxin A/B 12/08 /2022 Patient 39 Positive: Enteropathogenic E. coli (EPEC) A review of laboratory control documents had the following QC documentation for January to October 2023: January 2023: 12 days past the 30-day QC requirement 1/25/2023 Sample ID: Jan QC GIC02 [no lot number or expiration documented.] Detected: Campylobacter, Salmonella, Enteropathic E.coli (EPEC), Enterotoxigenic E. coli (ETEC) lt/st, Cyclospora cayetanensis, Entameoba histolytica, Giardia lamblia, Astrovirus, and Norovirus GI/GII. No negative QC was documented for the above. No positive QC was documented for the remaining 13 targets. February 2023 2/2/2023 Sample ID: FEB 2023 QC - GIC 1 [lot number or expiration documented.] Detected: Clostridioides (Clostridium) difficile (toxin A/B), Plesiomonas shigelloides, Vibrio, Vibrio cholerae, Enteroaggregative E. coli (EAEC), Shiga-like toxin-producing E. coli (STEC) stx1/stx2, E. coli O157, Shigella/Enteroinvasive E. coli (EIEC), Cryptosporidium, Adenovirus F40/41 Sapovirus. No negative QC was documented for the above. No positive QC was documented for the remaining 9 targets. March 2023 No positive or negative QC was documented for the 22 BioFire GI Panel targets. April 2023: 30 days past the 30-day QC requirement 4/3/2023 Sample ID: 10-13-23 329732 lot GI Detected: Campylobacter, Salmonella, Enteropathic E.coli (EPEC), Enterotoxigenic E. coli (ETEC) lt/st, Cyclospora cayetanensis, Entameoba histolytica, Giardia lamblia, Astrovirus, and Norovirus GI/GII. No negative QC was documented for the above targets. No positive QC was documented for the remaining 13 targets. May 2023 No positive or negative QC was documented for the 22 BioFire GI Panel targets. June 2023 No positive or negative QC was documented for the 22 BioFire GI Panel targets. July 2023: 69 days past the 30-day QC requirement. 7/11/2023: Sample ID: nat gi control 2 lot 329732 [no expiration date documented] Detected: Campylobacter, Salmonella, Enteropathic E.coli (EPEC), Enterotoxigenic E. coli (ETEC) lt/st, Cyclospora cayetanensis, Entameoba histolytica, Giardia lamblia, Astrovirus, and Norovirus GI/GII. No negative QC was documented for the above targets. No positive QC was documented for the remaining 13 targets. August 2023 No positive or negative QC was documented for the 22 BioFire GI Panel targets. September 2023 No positive or negative QC was documented for the 22 BioFire GI Panel targets. October 2023 No positive or negative QC was documented for the 22 BioFire GI Panel targets. 60 Patients (18 positive) were tested with the BioFire GI Panel from January to October 2023 to include the following 6: Run Date Patient # Result: Result Summary 04/17/2023 Patient 40 Positive: Sapovirus 06/06/2023 Patient 41 Positive: Campylobacter, Clostridium difficile toxin A/B, and EPEC 06/14 /2023 Patient 42 Positive: Giardia lambia 07/20/2023 Patient 43 Positive: Yersinia enterocolitica 08/31/2023 Patient 44 Positive: Salmonella 10/05/2023 Patient 45 Positive: EPEC 4. In an interview on 1/11/2024 at 13:05 hours, in the laboratory, testing personnel (TP) 1 stated that the laboratory only performed positive QC for SARS-CoV-2 on the BioFire Respiratory Panel 2.1, and that QC records were inconsistent with the 30-day requirement. TP1 also stated that the laboratory personnel did not realize that two levels of QC were available in the shipment box for

	positive and negative testing for the BioFire GI panel, and that QC records were inconsistent with the 30-day QC requirement. TP1 confirmed that the laboratory failed to follow its quality control plan to test positive and negative QC every 30 days for the BioFire Respiratory Panel 2.1 and the BiofFire GI panel.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(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 qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory test menu, quality control records, laboratory policy, and patient test records, the laboratory failed to performed QC every day of patient testing for 18 of 23 patients with either LeukoVue or StrepA testing for records reviewed from August to October 2023. The findings included: 1. Review of the laboratory test menu included the following moderate complexity kit tests: QuickVue+ Strep A Test, for the rapid detection of Group A Streptococcal antigen TechLab Leuko EZ Vue, for the detection of fecal lactoferrin 2.i. Review of laboratory policy titled "Leuko EZ View", section "Quality Control" had the following statement: "B. External control: The reactivity of the LEUKO EZ VUE test should be verified on receipt using the Positive Control and negative control (Diluent). " 2.ii. Review of the laboratory policy titled "Strep A Test", section "Quality Control" had the following statement: "E. External Quality Control External controls are provided and may also be used to ensure that the reagents are performing properly and that you are able to correctly perform the test procedure ... Positive and negative control can be run with each shipment of a new kit lot, and as otherwise required by your laboratory's standard quality control procedures." Surveyor asked, on 1/11/2024 at 12:30 hours, for the individualized quality control plan (IQCP) to support the frequency of positive and negative controls from every day of patient testing to the above. Testing personnel (TP) 1 stated that the laboratory did not have one for the Strep A test or the LeukoVue. 3. Review of quality control documents and patient test records from August to October 2023 for the LeukoVue and Strep A tests had the following days where patients were tested without documentation of QC. 3.i. LeukoVue 4 of 7 days where QC had not been performed for records reviewed in August, September, and October 2023 August 2023: 1 day 8/1/2023: Patient Ticket # 195662 Patient Ticket # 195797 October 2023: 3 days 10/5/2023: Patient Ticket # 23780020 Patient 1 (see crosswalk) Patient Ticket # 232780074 10/23/2023: Patient Ticket # 232960036 Patient Ticket # 232960037 10/24/2023: Patient Ticket # 232970143 3. ii. Review of Strep A QC and Patient testing records for August, September, and October 2023 included the following nine of nine days where QC had not been performed. August 2023: 5 days 8/8/2023: Patient Ticket # 196038 8/16 /2023 Patient Ticket # 196355 8/18/2023 Patient Ticket # 196414 8/23/2023 Patient Ticket # 196617 8/29/2023 Patient Ticket # 196852 September 2023: 1 day 9/20 /2023: Patient Ticket # 197659 October 2023: 3 days 10/9/2023: Patient Ticket # 232820024 10/17/2023: Patient Ticket # 232900049 Patient Ticket # 232900166 10/24 /2023: Patient Ticket # 232970137 4. In an interview on 1/11/2024 at 12:35 hours, in the office, testing personnel (TP) 1 confirmed that QC was not performed each day of patient testing for the Strep A test or the LeukoVue testing.

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 observation, review of manufacturer's instructions, laboratory Quality Control (QC) records (June 2023), patient final reports and confirmed in interview, the laboratory failed to document acceptable QC prior to reporting patient results for 19 of 19 patients reviewed in June 2023. Findings Included: 1. During a tour of the facility on 01/11/2024 at 09:44 a.m., the surveyor observed 1 Abbot Architect i1000 (Serial Number: I1SR54411) in the patient testing area. 2. Review of manufacturer's instructions, "Abbott Architect Folate Instructions for Use" (Reference: 1P74 34-5955/R03), revealed the following: "Quality Control Procedures: ...Each laboratory should establish control ranges to monitor the acceptable performance of the assay. If a control is out of its specified range, the associated test results are invalid and samples must be retested." 3. Review of laboratory QC records in June 2023, revealed the following days Folate was out of QC range and patients were resulted: a. Date Performed: 06/20/2023 Quality Control Level: 2; Lot Number: 35006210 Result: 4.5 ng/mL (Result was flagged as 2 SD out of range) Acceptable QC range: 4.92-6.34 ng/mL QC was NOT repeated, and no troubleshooting steps were documented. b. Date Performed: 06/22/2023 Quality Control Level: 2; Lot Number: 35006210 Result: 4.5 ng/mL (Result was flagged as 2 SD out of range) Acceptable QC range: 4.92-6.34 ng/mL QC was NOT repeated, and no troubleshooting steps were documented. 4. Review of patient final reports revealed the following patient examples and daily totals on the above days for Folate in June 2023: Folate a. Patient 1 (Refer to Patient Reference Sheet) Analysis Date; Time: 06 /20/2023; 13:20 p.m. Result: 13.2 IU/mL Daily Total: 11 b. Patient 4 Analysis Date; Time: 06/22/2023; 11:56 a.m. Result: 17.6 IU/mL (NOTE: Result flagged as "High") Daily Total: 8 5. In an interview on 01/12/2024 at 10:35 p.m., in the laboratory, TP-1 confirmed the laboratory failed to document acceptable QC prior to reporting patient results for 19 of 19 patients reviewed in June 2023.
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 observation, review of manufacturer's instructions, laboratory policy, quality control (QC) documentation in June 2023, patient final reports, and confirmed in interview, the laboratory failed to evaluate patients, since the last acceptable QC, when QC failed to fall within acceptable ranges for 3 of 6 analytes

	reviewed in June 2023. Findings Included: 1. During a tour of the facility on 01/11 /2024 at 09:44 a.m., the surveyor observed 1 Abbot Architect i1000 (Serial Number: I1SR54411) in the patient testing area. 2. Review of manufacturer's instructions, "Abbott Architect Folate Instructions for Use" (Reference: 1P74 34-5955/R03) revealed the following: "Quality Control ...If a control is out of its specified range, the associated test results are invalid and must be retested." Review of manufacturer's instructions, "Abbott Architect Anti-TPO Instructions for Use" (Reference: 2K47-27) revealed the following: "Quality Control ...If a control is out of its specified range, the associated test results are invalid and must be retested." Review of manufacturer's instructions, "Abbott Architect Ferritin Instructions for Use" (Reference: 8C55-18) revealed the following: "Quality Control ...If a control is out of its specified range, the associated test results are invalid and must be retested." 3. Review of laboratory policy, "Quality Control" (Approved by the Laboratory Director on: 02/03/2020) revealed the laboratory failed to have a policy in place for patient evaluation/retesting, since the last acceptable QC, when QC failed to fall within acceptable ranges. 4. Review of quality control documentation for June 2023, revealed the following days calibrations were performed as a corrective action step in QC failures with no patient evaluation documented: a. Folate Quality Control Lot Number: 35006210; Level 2 Expiration Date: 09/30/2023 Result: 4.5 ng/mL (Result was flagged as 2 SD out of range) Calibration Performed: 06/20/2023 b. ATPO Quality Control Lot Number: 35006210; Level 1 Expiration Date: 09/30/2023 Result: 14.77 IU/mL (Result was flagged as 3 SD out of range) Calibration Performed: 06/28/2023 c. Ferritin Quality Control Lot Number: 35006210; Level 2 Expiration Date: 09/30/2023 Result: 120.57 ng/mL (Result was flagged as 3 SD out of range) Calibration Performed: 06/28/2023 5. Review of laboratory, "Monthly Quality Control Review" for June 2023 (Performed by TP-1), revealed the laboratory failed to document patient evaluation since the last acceptable QC when QC failed to fall within acceptable ranges and calibrations were performed. 6. Review of patient final reports revealed the following patient example and daily total of patients for the above analytes in June 2023: a. Folate Patient 1 (Refer to Patient Reference Sheet) Analysis Date; Time: 06/20/2023; 13:22 p.m. Result: 13.2 IU/mL Daily Total: 11 b. ATPO: Patient 2 Analysis Date; Time: 06/27 /2023; 16:15 p.m. Result: 1.2 IU/mL Daily Total: 7 c. Ferritin: Patient 3 Analysis Date; Time: 06/27/2023; 16:21 p.m. Result: 1107.3 ng/mL Daily Total: 5 7. In an interview on 01/12/2024 at 10:35 a.m., in the laboratory, TP-1 confirmed the laboratory failed to evaluate patients since the last acceptable QC when QC failed to fall within acceptable ranges for 3 of 6 analytes in June 2023. Word Key Anti-TPO-Antithyroid peroxidase
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on review of laboratory policy, laboratory proficiency testing results, and laboratory personnel files the laboratory director failed to meet the laboratory director condition for overall management and direction in the laboratory for records reviewed in 2022 and January to October 2023 to include the following standard found D6030.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES

	CFR(s): 493.1407(e)(12) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(12) 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: Based on review of the laboratory's personnel files and staff interview, the laboratory director failed to ensure policies and procedures were established and followed to assess the competency of personnel for records reviewed in 2022 and January to October 2023. Refer to D5209 and D6046.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on review of laboratory records, laboratory policy, and laboratory quality control records, the technical consultant failed to meet the condition requirements to provide the laboratory with technical oversight for records reviewed in 2022 and January through October 2023 to include the standards found at D6042, D6046.
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: Based on review of laboratory quality control records, laboratory policy, and patient results, the technical consultant failed to have a quality control program in place to assure accurate and reliable results for laboratory records reviewed in 2022 and January to October 2023. The findings included: 1. The technical consultant failed to ensure that the laboratory follow its quality control policy to perform a positive and negative QC every 30 days for 2 of 2 panels ran on the BioFire Film Array 2 for records reviewed from January 2022 to October 2023. Refer to D5445. 2. The technical consultant failed to ensure that the laboratory had a step-by-step procedure

	for the establishment and implementation of statistical parameters (mean and standard deviation (S.D.)) for two of two lot roll overs of unassayed control materials put into use on the Architect ci8200 in December 2022 and September 2023. Refer to D5403.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on a review of CMS (Centers for Medicare and Medicaid Services)-209 form, laboratory competency assessments, and confirmed in interview, the technical consultant (TC-1) failed to perform competency assessments for 3 of 3 testing personnel (TP) in 2022 and 2023. Findings Included: 1. Review of CMS-209 form submitted at time of survey, revealed the following 3 testing personnel performing moderate complexity testing: TP-1, TP-2, and TP-3. Further review revealed 1 technical consultant providing assistance to the laboratory: TC-1. 2. Review of laboratory competency assessments for 2022 and 2023 revealed the following competency assessments NOT performed by the TC: 2022 a. TP-1 Annual Competency Assessment: Erythrocyte Sedimentation Rate Date of Hire: 11/2019 Performed on: No documentation Performed by: No documentation The surveyor requested the above documentation for TP-1 and none was provided. b. TP-2 Annual Competency Assessment Date of Hire: 05/2021 Performed on: 05/02/2022 Performed by: TP-1 2023 c. TP-2 Annual Competency Assessment Performed on: 05/02/2023 Performed by: TP-1 d. TP-3 Semi-Annual Competency Date of Hire: 02/2023 Performed on: 07/26/2023 Performed by: TP-1 3. In an interview on 01/11/2024 at 01: 43 p.m., TP-1 confirmed the technical consultant (TC-1) failed to perform competency assessments for 3 of 3 testing personnel (TP) in 2022 and 2023.