

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 34D0242641	<b>(X3) Date Survey Completed</b> 04/24/2024
<b>Name of Provider or Supplier</b> Washington Regional Medical Center	<b>Street Address, City, State</b> 958 Us Highway 64 East, Plymouth, NC	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	A routine recertification survey was conducted April 22-24, 2024. Based on the survey findings, Immediate Jeopardy was identified and the laboratory was notified April 24, 2024 at approximately 1:30 p.m. The following condition level deficiencies were identified during the survey: D2000 - 493.801 Enrollment and testing of samples D5016 - 493.1210 Routine chemistry D6076 - 493.1441 Laboratories performing high complexity testing: laboratory director
<b>D2000</b>	<p><b>ENROLLMENT AND TESTING OF SAMPLES</b> CFR(s): 493.801</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on review of 2021, 2022, and 2023 proficiency testing (PT) records, the absence of 2024 PT records, interview with general supervisor (GS) 04/22/24 and 04/23/24, and telephone interview with an American Proficiency Institute (API) customer service representative 04/29/24, the laboratory failed to enroll in proficiency testing for 2024. Findings: Review of 2021, 2022, and 2023 PT records revealed the laboratory was enrolled with API. There were no 2024 PT records available for review during the survey. During interview 04/22/24 at approximately 1:30 p.m., the GS stated she started trying to enroll in PT for 2024 in August 2023. She stated they have not received any samples for 2024 yet because the bill has not been paid. During interview 04/23/24 at approximately 2:00 p.m., the GS stated she had been notified by</p>

hospital management that the bill was paid. Interview with an API customer service representative 04/29/24 at approximately 3:30 p.m. revealed API had not received payment for the laboratory's 2024 order, and the order had not been processed.

**D3031**

**RETENTION REQUIREMENTS**

CFR(s): 493.1105(a)(3)

Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.

This STANDARD is not met as evidenced by:

Based on review of 2022, 2023, and 2024 laboratory temperature and humidity logs, review of 2022, 2023, and 2024 i-STAT records, and interview with the GS 04/22/24 and 04/24/24, the laboratory failed to retain temperature and humidity logs for 6 of 28 months reviewed and failed to retain i-STAT quality control (QC) records for at least two years. Findings: 1. The laboratory failed to retain temperature and humidity logs for 6 of 28 months reviewed. Review of 2022, 2023 and 2024 laboratory temperature and humidity logs revealed the laboratory failed to retain the following logs from May of 2022 through November of 2022, a period of approximately 6 months: a. "Blood Bank Room Temperature" b. "Blood Bank Reagent Refrigerator" c. "Daily Temperature and Humidity - Side A" d. "Daily Temperature and Humidity - Side B" e. "Daily Temperature Log for Peppermint Patty" (refrigerator) f. "Daily Temperature Log for Lucy" (refrigerator) g. "Daily Temperature Log for Linus" (refrigerator) h. "Daily Temperature Log for Charlie Brown" (refrigerator) Interview with GS 04/22/24 at approximately 3:00 p.m. confirmed the logs were not retained. The GS stated the laboratory had an electronic monitoring system, but they were unable to continue using it and were unable to retrieve the records. 2. The laboratory failed to retain i-STAT QC records for at least two years. Review of 2022, 2023, and 2024 i-STAT records revealed there were no VAS (Value Assignment Sheets) available for review during the survey to determine acceptable ranges for quality control results. During interview 04/24/24 at approximately 11:30 a.m., the GS confirmed that the laboratory had not saved the VAS for each lot number of QC material. She stated they do review their QC results using the VAS for the lot number in use, but the VAS is discarded after the lot number is used up. She stated she thought they might be saved electronically but she was unable to retrieve them.

**D5016**

**ROUTINE CHEMISTRY**

CFR(s): 493.1210

If the laboratory provides services in the subspecialty of Routine Chemistry, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1267, and 493.1281 through 493.1299.

This CONDITION is not met as evidenced by:

Based on review of 2021, 2022, 2023, and 2024 laboratory records 04/22/24-04/24/24, the laboratory failed to monitor and evaluate the ongoing and overall quality of the chemistry testing performed to identify and correct problems and ensure accurate and reliable patient test results. Findings: 1. Procedures not complete for all testing performed (see D5403). 2. Manufacturer's instructions not followed for quality control on the i-STAT (see D5411). 3. Expired reagents used for quality control and patient

testing on the Abbott Architect c4000 and the Abbott Architect ci4100 from April 2022 - April 2024, a period of approximately 2 years with no corrective action documented (see D5417). 4. No validation of the Abbott i-STAT analyzer prior to the initiation of patient testing (see D5421). 5. Calibration verification not performed every 6 months for analytes on the Abbott Architect c4000 and the Abbott Architect ci4100 (see D5439). 6. 2 levels of quality control not tested each day of patient testing on the Abbott i-STAT (see D5447). 7. Instrument comparisons not performed twice a year for analytes tested on the Abbott Architect c4000, the Abbott Architect ci4100, and the Abbott i-STAT (see D5775).

**D5211**

**EVALUATION OF PROFICIENCY TESTING PERFORMANCE**  
CFR(s): 493.1236(a)

The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.

This STANDARD is not met as evidenced by:  
Based on review of 2021, 2022, and 2023 API proficiency testing records and interview with the GS 04/23/24, the laboratory failed to evaluate all ungraded and unacceptable proficiency testing results. Findings: Review of 2021, 2022, and 2023 API proficiency testing records revealed the laboratory failed to evaluate the following ungraded and unacceptable proficiency testing results: a. 2021 Hematology/Coagulation 3rd event - ungraded wet prep sample VKP-03. b. 2022 Hematology/Coagulation 2nd event - unacceptable blood cell identification sample BCI-08 and ungraded wet prep sample VA-02. c. 2022 Hematology/Coagulation 3rd event - ungraded blood cell identification sample BCI-14. d. 2022 Immunology/Immunohematology 1st event - no printed results available for review during the survey. e. 2023 Hematology/Coagulation 3rd event - ungraded wet prep sample VA-03. During interview 04/23/24 at approximately 2:45 p.m., the GS stated she does review the ungraded and unacceptable results, but she doesn't always print the data summary or document the review.

**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 review of laboratory policies/procedures, review of manufacturer's instructions, review of reagent package inserts, observation, and interviews with testing personnel (TP) #3, TP #4, and the general supervisor (GS) 04/23/24 - 04/24/24, the laboratory's blood bank and chemistry procedures were not complete and current for testing performed. Findings: 1. The laboratory procedure "Compatibility Testing Gel Card Test Anti-Igg" was not updated to reflect requirements for Revolutions Per Minute (RPM) and time ranges for the new ORTHO workstation the laboratory started using 05/08/23. Review of blood bank procedure "Compatibility Testing Gel Card Test Anti-Igg" revealed on page 2, "6. Centrifuge the gel card at the preset conditions of 895+RPMs for 10 minutes." Review of "ORTHO workstation" equipment reference guide, Section 7, page 18 revealed, "...1032 rpm 10 rpm...10 minutes 10 sec..." 2. The laboratory procedure "Direct Antiglobulin Test by Gel Card Test Method Anti-IGG" was not updated to reflect requirements for Revolutions Per Minute (RPM) and time ranges for the new ORTHO workstation the laboratory started using 05/08/23. Review of the blood bank procedure "Direct Antiglobulin Test by Gel Card Test Method Anti-IGG" revealed on page 2, "4. Centrifuge the gel card at the preset conditions of 895 25 RPMs for 10 minutes." Review of "ORTHO workstation" equipment reference guide, Section 7, page 18 revealed, "...1032 rpm 10 rpm...10 minutes 10 sec..." Observation of TP #4 during interview at approximately 12:52 p.m. on 04/23/24 showed 1032 rpms for 10 minutes per operator's manual is used for the gel card procedure. TP #4 said she was not sure why the laboratory's procedure has a different range, but this is the range the laboratory uses. During a laboratory tour at approximately 11:00 a.m. on 04/24/24, TP #3 said she didn't notice the ranges were different because the equipment is preset and cannot be changed. During interview at approximately 12:29 p.m. on 04/24/24, the GS confirmed procedures were outdated, equipment ranges do not match, and the maintenance log needs updating. 3. The laboratory procedure "Quality Control Materials" failed to include the analytes tested with each type of control. Review of chemistry procedure "Quality Control Materials" revealed it included the frequency, type and levels of quality control material used but failed to state the analytes tested with each type of control. For example: a. Multiquel-Core Levels 1 and 3 - failed to include the analytes tested. b. Liquichek Cardiac Markers - failed to include the analytes tested. c. Immunoassay Levels 1 and 3 - failed to include the analytes tested. Interview with GS 04/23/24 at approximately 11:00 a.m. confirmed the procedure did not include the analytes tested with each type of control. She stated the analyzer is programmed to perform the correct analytes for each type of control and they did not think it was necessary to include it in the procedure. 2. The laboratory procedure "Calibration" failed to include the type and levels of calibration reagents used for each analyte. Review of chemistry procedure "Calibration" revealed "Calibrations are required whenever a new reagent lot is used, when a calibration interval has expired, or whenever a new method is added. Calibrations will also be performed when indicated by control results, or after specified maintenance and diagnostic procedures." The procedure failed to include the type and levels of calibration reagents used for each analyte. Review of reagent package inserts revealed the package inserts stated the frequency of calibration intervals, but failed to include the type and levels of calibration reagent used for each analyte. For example: a. Reagent package insert for Total Bilirubin stated "CALIBRATION...Calibration is stable for approximately 14 days...Verify calibration with at least two levels of controls according to the established quality control requirements for your laboratory. If control results fall outside acceptable ranges, recalibration may be necessary." b. Reagent package insert

for Creatine Kinase stated "Calibration is stable for approximately 30 days...Verify calibration with at least two levels of controls according to the established quality control requirements for your laboratory. If control results fall outside acceptable ranges, recalibration may be necessary." Interview with GS 04/23/24 at approximately 11:00 a.m. confirmed the procedure did not include the type and levels of calibration reagent used for each analyte. 3. The laboratory procedure "Calibration Verification" failed to include which analytes require a calibration verification every 6 months. Review of chemistry procedure "Calibration Verification" revealed "Calibration verification is performed every 6 months on all tests that do not have a least 3 calibrators that span the reportable range." The procedure failed to include which analytes require a calibration verification. Interview with GS 04/23/24 at approximately 11:00 a.m. confirmed the procedure did not include which analytes require a calibration verification.

**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 review of manufacturer's instructions, review of 2022, 2023, and 2024 i-STAT records, and interview with the GS and TP #3 on 04/23/24, the laboratory failed to follow manufacturer's instructions for quality control on the Abbott i-STAT analyzer. Findings: 1. Review of the "PROCEDURE MANUAL FOR THE i-STAT 1 SYSTEM" (rev. date 4/9/18) revealed on page 16 "...Monthly Procedures Print Electronic Simulator Results Print a copy of the Electronic Simulator results from the Central Data Station. Include the report in the i-STAT QC Log. ..." Review of 2022, 2023, and 2024 i-STAT records revealed the laboratory recorded the results of electronic simulator checks every 8 hours, but the laboratory failed to retain the instrument printouts documenting the checks. 2. Review of the "PROCEDURE MANUAL FOR THE i-STAT 1 SYSTEM" (rev. date 4/9/18) revealed on page 16 "... Monthly Procedures ... Print Control Fluid Analysis Results Print results for any control fluids analyzed from the Central Data Station. ..." Review of 2022, 2023, and 2024 i-STAT records revealed the laboratory routinely printed quality control records and attached the printouts to the log sheet used to document quality control. Review of i-STAT records for January 2024 revealed there were no printouts attached to the log sheets for quality control testing performed 1/3/24, 1/9/24, 1/16/24, 1/23/24, and 1/30/24. 3. Review of the "PROCEDURE MANUAL FOR THE i-STAT 1 SYSTEM" (rev. date 4/9/18) revealed on page 16 "... Periodic Procedures for Cartridges Check Temperature Monitor i-STAT cartridges are shipped refrigerated with a four-window indicator to monitor temperature during transit. Note: All control and calibration verification materials, except for those shipped on dry ice, will also include a four-window indicator to monitor temperature during transit. Action: Fill out the record of receipt and forward materials to refrigerator. ..." Review of 2022, 2023, and 2024 i-STAT records revealed there were no records of transit temperature checks for incoming shipments of cartridges. During interview 4/23/24 at approximately 2:50 p.m., TP #3 stated that she checks the temperature indicator strip included with each

shipment, but she does not document the checks. During interview at approximately 4:00 p.m., the GS stated that they do not keep the temperature indicator strips or document the transit temperature checks for incoming shipments.

**D5417**

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT  
CFR(s): 493.1252(d)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:

Based on review of Centers for Medicare & Medicaid Services (CMS) 116, review of reagent package inserts, review of operators manual, review of 2022, 2023 and 2024 chemistry, endocrinology, and toxicology QC records and interviews with TP #3 and the GS 04/22/24 - 04/24/24, the laboratory performed QC and patient testing on the Abbot Architect ci4100 analyzer and the Abbot Architect c4000 analyzer using expired reagents from April 2022 thru time of survey 04/24/24, a period of approximately 2 years. The laboratory performed approximately 285,140 chemistry, endocrinology and toxicology tests per year. Findings: 1. Review of CMS-116 submitted at time of survey revealed approximately 285,140 chemistry, endocrinology and toxicology tests were performed each year. 2. Review of reagent package inserts revealed the accuracy of assay results cannot be guaranteed if testing is performed utilizing expired reagents. For example: a. Review of reagent package insert for Alkaline Phosphatase (ALKP) revealed "Package insert instructions must be carefully followed. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this package insert....Reagent Handling...Do not use reagents beyond the expiration date." b. Review of reagent package insert for Total Protein (TP) revealed "Package insert instructions must be carefully followed. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this package insert....Reagent Handling...Do not use reagents beyond the expiration date." c. Review of reagent package insert for Total Bilirubin (TBIL) revealed "Package insert instructions must be carefully followed. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this package insert...WARNINGS AND PRECAUTIONS...Do not use components beyond the expiration date." d. Review of reagent package insert for Creatine Kinase (CK) revealed "Package insert instructions must be carefully followed. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this package insert...WARNINGS AND PRECAUTIONS...Do not use components beyond the expiration date." 3. Review of operators manual for the Abbott Architect analyzers revealed "Descriptions of reagent statuses...EXP...The reagent is expired or has exceeded the onboard stability time." 4. Review of 2022, 2023 and 2024 QC records for testing performed on the Abbot Architect ci4100 analyzer revealed reagent status as EXP when QC and patient testing were performed. For example: a. April 2022 QC records revealed the following dates in which analyte reagents were expired: Lactate dehydrogenase (LDH) - 04/10 - 04/29; 20 days. b. October 2022 QC records revealed the following dates in which analyte reagents were expired: Acetaminophen (ACETA) - 10/13 and 10/29 - 10/31; 4 days. (Toxicology) ALKP - 10/06 - 10/08 and 10/17 - 10/18; 5 days. Amylase (AMY) - 10/22 - 10/25; 4 days. Vitamin B12 (B12) - 10/29 - 10/31; 3 days. Cholesterol (CHOL) - 10/28 - 10/31; 4 days. CK - 10/7 - 10/25; 19 days. Bicarbonate (CO2) - 10/23 - 10/25; 3 days. Creatinine (CREA) - 10/07, 10/18, 10/24 - 10/25; 4 days. Direct Bilirubin (DBIL) - 10/10; 1 day. Digoxin (DIG) - 10

/02: 1 day. (Toxicology) Ferritin (FERR) - 10/08 - 10/10; 3 days. Folate (FOL) - 10/29 - 10/30; 2 days. LDH - 10/14 - 10/26; 13 days. Phosphate (PHOS) - 10/29 - 10/30; 2 days. c. May 2023 QC records revealed the following dates in which analyte reagents were expired: Glycosylated hemoglobin (A1c) - 05/01 - 05/03, and 05/08; 4 days. ACETA - 05/01 - 05/08; 8 days. (Toxicology) ALKP - 05/01 - 05/06 and 05/15 - 05/31; 23 days. Alanine transaminase (ALT) - 05/21 - 05/26; 6 days. Aspartate aminotransferase (AST) - 05/13 - 05/31; 19 days. Calcium (CA) - 05/12 - 05/31; 20 days. CHOL - 05/01 - 05/03; 3 days. CK - 05/01 - 05/06; 6 days. Chloride (CL) - 05/27 - 05/29; 3 days. CO2 - 05/19 - 05/22; 4 days. CREA - 05/01 - 05/03 and 05/09 - 05/31; 26 days. Free thyroxine (FT4) - 05/02 - 5/12, 05/15 - 05/19 and 05/23 - 05/24; 18 days. (Endocrinology) Glucose (GLU) - 05/22 - 05/29; 5 days. Potassium (K) - 05/27 - 05/29; 3 days. Lactic Acid (LAC) - 05/28 - 05/29; 2 days. LDH - 05/01 - 05/31; 31 days. Lipase (LIP) - 05/01 - 05/14 and 05/29 - 05/31; 17 days. Low-density lipoprotein (LDL) - 05/01 - 05/03 and 05/29 - 05/31; 6 days. Magnesium (MG) - 05/25 - 05/26; 2 days. Sodium (NA) - 05/27 - 05/29; 3 days. PHOS - 05/12 - 05/31; 20 days. TBIL - 05/20 - 05/22; 3 days. Testosterone (TESTO) - 05/01 - 05/19; 18 days. (Endocrinology) Total prostate-specific antigen (TPSA) - 05/01 - 05/10; 10 days. Triiodothyronine (TT3) - 05/01 - 05/19, 05/23 - 05/24 and 05/31; 23 days. (Endocrinology) Thyroxine (TT4) - 05/01 - 05/19, 05/23 - 05/24 and 05/31; 23 days. (Endocrinology) Uric Acid (UA) - 05/28 - 05/31; 4 days. d. November 2023 QC records revealed the following dates in which analyte reagents were expired: A1c - 11/02 - 11/10 and 11/13 - 11/14; 11 days. AMY - 11/20 - 11/29; 10 days. CK - 11/01 - 11/29; 29 days. CREA - 11/01 - 11/04, 11/10 - 11/22 and 11/28 - 11/29; 19 days. CO2 - 11/23 - 11/28; 5 days. Iron (FE) - 11/01 - 11/29; 29 days. LIP - 11/26 - 11/29; 4 days. LDH - 11/07 - 11/29; 23 days. TESTO - 11/02 - 11/10; 9 days. (Endocrinology) TPSA - 11/05 - 11/10 and 11/13 - 11/14; 8 days. UA - 11/01 - 11/29; 29 days. e. March 2024 QC records revealed the following dates in which analyte reagents were expired: A1c - 03/01 and 03/05 - 03/28; 25 days. ALKP - 03/01 - 03/18; 18 days. AMY - 03/11 - 03/28; 18 days. AST - 03/11 - 03/18; 8 days. CL - 03/01 - 03/02; 2 days. CO2 - 03/01 - 03/03 and 03/18 - 03/28; 14 days. CREA - 03/02 - 03/05 and 03/11 - 03/28; 22 days. K - 03/01 - 03/02; 2 days. LIP - 03/15 - 03/16; 2 days. MG - 03/15 - 03/18; 4 days. NA - 03/01 - 03/02; 2 days. Thyroid stimulating hormone (TSH) - 03/28 - 03/31; 3 days. (Endocrinology) UA - 03/12 - 03/13; 2 days. UREA - 03/04 - 03/05; 2 days. 5. Review of 2022, 2023 and 2024 QC records for testing performed on the Abbot Architect c4000 analyzer revealed reagent status as EXP when QC and patient testing were performed. For example: a. July 2022 QC records revealed the following dates in which analyte reagents were expired: ALKP - 07/02 - 07/09; 8 days. CO2 - 07/07; 1 day. CREA - 07/03 - 07/04, 07/10 - 07/11 and 07/17 - 07/22; 10 days. Oxycodone (OXY) - 07/16 - 07/19; 4 days. (Toxicology) TBIL - 07/02 - 07/09; 8 days. Urine Creatinine (UCREA) - 07/03 - 07/04, 07/10 - 07/11 and 07/17 - 07/22; 10 days. Vancomycin (VANC) - 07/15; 1 day. (Toxicology) Valproic acid (VA) - 07/15; 1 day. (Toxicology) b. April 2023 QC records revealed the following dates in which analyte reagents were expired: Benzodiazepine (BENZ) - 04/01 - 04/10; 11 days. (Toxicology) Opiate (OPI) - 04/09 - 04/27; 19 days. (Toxicology) Cannabis (THC) - 04/27 - 04/30; 4 days. (Toxicology) Urine Albumin (UALB) - 04/27 - 04/30; 4 days. c. October 2023 QC records revealed the following dates in which analyte reagents were expired: Amphetamine (AMP) - 10/26 - 10/31; 6 days. (Toxicology) Barbiturate (BARB) - 10/02 - 10/04; 3 days. (Toxicology) Benzodiazepine (BENZ) - 10/14 - 10/18; 5 days. (Toxicology) CL - 10/01 - 10/02; 2 days. CO2 - 10/13, 10/18 - 10/21, and 10/25 - 10/28; 9 days. CREA - 10/07, 10/11 - 10/12, 10/18 - 10/21 and 10/25 - 10/28; 11 days. DBIL - 10/12 - 10/13, 10/18 - 10/21 and 10/25 - 10/28; 10 days. GLU - 10/02, 10/04 - 10/07, 10/11 - 10/13, 10/18 - 10/20 and 10/27 - 10/31; 16 days. K - 10/01 - 10/02; 2 days. NA - 10/01 - 10/02; 2 days. OPI - 10/21 - 10/31; 11 days.

(Toxicology) OXY - 10/01 - 10/04, 10/06 - 10/08, 10/10 - 10/29; 27 days. (Toxicology) Phencyclidine (PCP) - 10/18 - 10/27; 10 days. (Toxicology) THC - 10/02 - 10/24; 23 days. (Toxicology) UALB - 10/01 - 10/31; 31 days. UCREA - 10/01 - 10/12 and 10/18 - 10/31; 26 days. d. February 2024 QC records revealed the following dates in which analyte reagents were expired: CK - 02/12 and 02/15; 2 days. CO2 - 02/15; 1 day. CREA - 02/14; 1 day. UCREA - 02/13 and 02/14; 2 days. UREA - 02/14 - 02/29; 16 days. e. March 2024 QC records revealed the following dates in which analyte reagents were expired: ALKP - 03/06 - 03/08 and 03/20; 4 days. AST - 03/14 - 03/18, 03/20 - 03/24, 03/28 - 03/31; 14 days. CA - 03/28 - 03/31; 3 days. CO2 - 03/01, 03/18, 03/20 - 03/22 and 03/28; 6 days. Cocaine (COC) - 03/29 - 03/31; 3 days. (Toxicology) CREA - 03/05 - 03/09, 03/14 - 03/18 and 03/21 - 03/23; 13 days. High-density lipoprotein (HDL) - 03/28 - 03/31; 4 days. DBIL - 03/28 - 03/30; 3 days. LIP - 03/28 - 03/31; 4 days. MG - 03/15 - 03/18 and 03/20; 5 days. OPI - 03/29 - 03/31; 3 days. (Toxicology) TBIL - 03/18 and 03/20; 2 days. THC - 03/01 - 03/31; 31 days. (Toxicology) UALB - 03/14 - 03/31; 18 days. UCREA - 03/04 - 03/28; 25 days. 6. Interview with TP #3 04/23/24 at approximately 11:50 a.m. confirmed QC and patient testing was performed when analyte reagents were expired. TP #3 stated they were told that as long as QC was within range patient testing was performed. 7. Interview with GS 04/23/24 at approximately 12:00 p.m. confirmed TP were instructed that patient testing could be performed with expired reagents if QC was within acceptable ranges.

**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 review of 2022 and 2023 Abbott i-STAT records and interview with the GS 04/23/24, the laboratory failed to verify performance specifications for the new i-STAT analyzer received in July 2022. Approximately 82 patients were tested from 07/01/22 - 04/22/24 prior to validation of the analyzer. Review of 2022 and 2023 Abbott i-STAT records revealed the laboratory received a new i-STAT and began patient testing in July 2022. There was no documentation available to indicate that the laboratory had performed any testing to verify the accuracy, precision, reportable range, and manufacturer's reference range for the new analyzer. During interview 04/23/24 at approximately 9:30 a.m., the GS confirmed that the laboratory did not verify the accuracy, precision, reportable range, and manufacturer's reference range of the new i-STAT prior to use for patient testing.

**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 review of laboratory procedure, review of chemistry, endocrinology, and toxicology calibration records, review of calibration verification records, the absence of calibration verification records, and interview with TP #3 and the GS 04/22/24 - 04/24/24, the laboratory failed to perform 6 month calibration verifications on the Abbott Architect ci4100 analyzer and the Abbott Architect c4000 analyzer since January of 2022, a period of approximately 28 months in which calibration verifications were not performed. Findings: Review of laboratory procedure "Calibration Verification" revealed "Calibration verification is performed every 6 months on all tests that do not have at least 3 calibrators that span the reportable range." Review of chemistry, endocrinology, and toxicology calibration records for the Abbott Architect ci4100 analyzer revealed the following 9 analytes required a calibration verification every 6 months: A1c, CL, FE, HDL, K, LIP, NA, Salicylate (SAL), and TSH. Review of chemistry and toxicology calibration records for the Abbott Architect c4000 analyzer revealed the following 5 analytes required a calibration verification every 6 months: CL, Alcohol (ETOH), K, NA, and Tricyclic antidepressants (TCA). Review of January 2022 Abbott Architect ci4100 and Abbott Architect c4000 calibration verification records revealed a calibration verification was performed on CL, K, and NA only, and failed to include all analytes required for each analyzer. There were no records of calibration verification for A1c, FE, HDL, LIP, SAL, and TSH on the Abbott Architect ci4100 in 2022, 2023, or 2024. There were no records of calibration verification for ETOH and TCA on the Abbott Architect c4000 in 2022, 2023, or 2024. Interview with TP #3 on 04/24/24 at approximately 11:00 a. m. confirmed which analytes required calibration. She stated calibration verifications were not performed as required and they did what they could. Interview with the GS 04/23/24 at approximately 4:00 p.m. confirmed calibration verifications had not been performed since January 2022.

**D5447**

**CONTROL PROCEDURES**  
CFR(s): 493.1256(d)(3)(i)(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 quantitative procedure, include two control materials of different

concentrations; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's policies and procedures, review of 2022 and 2023 i-STAT records, and interview with the GS 04/23/24, the laboratory failed to test two levels of control material each day of patient testing for the CG4+ (pH, pCO<sub>2</sub>, pO<sub>2</sub>, lactate) and the cTnI (troponin) cartridges. Approximately 82 patient tests were performed on the i-STAT from 07/01/22 to 04/23/24 when two levels of control material were not tested each day of patient testing. Review of the "Quality Control Materials" procedure revealed "... i-STAT - external controls are performed on the first Tuesday of each month and/or each new lot number on G4 and Troponin. The external simulator is performed every 8 hours." Review of 2022 and 2023 i-STAT records revealed the laboratory had tested two levels of control material on a weekly basis through January 2024 for the CG4+ and the cTnI cartridges. On 02/06/24, the laboratory began testing two levels of quality control material on the first Tuesday of the month. During interview 04/23/24 at approximately 3:20 p.m., the GS confirmed that the laboratory had not established an Individualized Quality Control Plan (IQCP) for the i-STAT. She stated they test two levels of control material on the i-STAT on the first Tuesday of the month, not each day of patient testing.

**D5473**

**CONTROL PROCEDURES**

CFR(s): 493.1256(e)(2)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on review of laboratory policy/procedure, review of 2023 QC records, and interview with the GS 04/22/24 - 04/24/24, the laboratory failed to document QC for the manual differential stain from 09/05/23 - 12/31/23, a period of approximately 3.5 months. Findings: Review of "Quick Slide Stainer Maintenance Log" for September and October 2023, revealed automated stainer, Wright's Giemsa Stain with the Quick Slide Stainer, not in use (NIU) from 09/05/23 - 10/31/23. There was no manual stain QC documented for the Protocol Hema 3 Stain Kit from 09/05/23 - 12/31/23. During interview at approximately 4:32 p.m. on 04/22/24, the GS confirmed no QC documentation was available for manual differential stains from September to December 2023. The GS stated the slide stainer broke and it still has not been repaired due to money issues.

**D5775**

**COMPARISON OF TEST RESULTS**

CFR(s): 493.1281(a)(c)

(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.

This STANDARD is not met as evidenced by:  
Based on review of test menus for the Abbot Architect c4000, the Abbott Architect ci4100, and the Abbott i-STAT analyzers, review of 2022 and 2023 API proficiency testing records, the absence of test comparison records, and interview with GS 04/22/24 - 04/24/24, the laboratory failed to perform a twice a year comparison of test results for the analytes tested on more than one analyzer. Findings: 1. Review of test menus for the Abbott Architect c4000 and ci4100 revealed the following analytes are tested on both analyzers: Albumin (ALB), ALKP, ALT, AST, CA, CL, CO2, CREA, GLU, K, NA, TBIL, Total protein (TP) and UREA. Review of 2022 and 2023 API proficiency testing records revealed: a. In 2022, the laboratory had tested their routine proficiency samples on the Abbott Architect ci4100 and had also tested verification samples for ALB, ALKP, ALT, AST, CA, CL, CO2, CREA, GLU, K, NA, TBIL, TP, and UREA on the Abbott Architect c4000 for each of the three events (Chemistry Core 1st, 2nd, 3rd). b. In 2023, the laboratory did not test verification samples. There were no records available for twice a year comparisons performed between the Abbott Architect c4000 and the Abbott Architect ci4100 during 2023 or 2024. 2. Review of test menus for the Abbott Architect ci4100 and the Abbott i-STAT revealed troponin is tested on both analyzers. There were no records available for twice a year comparisons for troponin tested on the Abbott Architect ci4100 and the Abbott i-STAT during 2022, 2023, or 2024. Interview with GS, 04/24/24 at 10:00 a.m. confirmed the laboratory did not perform twice a year comparison of test results as required.

**D5791**

**ANALYTIC SYSTEMS QUALITY ASSESSMENT**  
CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:  
Based on review of the laboratory's policies and procedures, review of 2024 quality assessment records, and interview with the GS 04/24/24, the laboratory failed to establish written policies and procedures designed to monitor and evaluate the ongoing and overall quality of the analytic systems to identify and correct problems and prevent their recurrence. Review of the laboratory's policies and procedures revealed the laboratory utilized a copy of the hospital's "QUALITY ASSESSMENT PERFORMANCE IMPROVEMENT PLAN FYE 2023-2024". The hospital plan described the processes for collecting data, implementing changes, and monitoring the effectiveness of the changes. The plan did not include laboratory-specific information. Review of 2024 quality assessment records revealed the following laboratory monitors: Blood culture contamination, Emergency Department troponin turn-around-time, "Equipment Checks daily", "Lab Fridge Check daily", "Blood Bank Fridge Check Daily", Blood utilization ratio, and Timely reporting of critical values. The laboratory did not have mechanisms in place to identify the following problems identified in the analytic systems during the survey: 1. Procedure manual not complete and current for the testing performed (see D5403). 2. Expired reagents used for quality control and patient testing on the Abbott Architect c4000 and the Abbott Architect ci4100 (see D5417). 3. No verification of performance specifications for the new Abbott i-STAT received in July 2022 (see D5421). 4. Calibration verification not

performed every 6 months for analytes tested on the Abbott Architect c4000 and the Abbott Architect ci4100 (see D5439). 5. 2 levels of quality control material not tested each day of patient testing for the Abbott i-STAT (see D5447). 6. Stain quality control not documented each day of use for Protocol Hema 3 Stain Kit (see D5473). 7. Instrument comparisons not performed twice a year for analytes tested on the Abbott Architect c4000, the Abbott Architect ci4100, and the Abbott i-STAT (see D5775). During interview 04/24/24 at approximately 11:30 a.m., the GS stated they report their monitors to the hospital quality committee on a monthly basis. She confirmed the laboratory did not have a laboratory-specific quality assessment procedure, and she verified they had not documented any other quality assessment activities.

**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 review of the laboratory's CMS-116 application, review of the CMS database, interview with the TS (technical supervisor) 04/22/24-04/24/24, and the deficiency cited at D6078, the laboratory failed to have a qualified laboratory director in place to provide overall management and direction.

**D6078**

**LABORATORY DIRECTOR QUALIFICATIONS**  
CFR(s): 493.1443

The laboratory director must be qualified to manage and direct the laboratory personnel and performance of high complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R. (a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory director must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2) Be a doctor of medicine, a doctor of osteopathy or doctor of podiatric medicine licensed to practice medicine, osteopathy or podiatry in the State in which the laboratory is located; and (b)(2)(i) Have at least one year of laboratory training during medical residency (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or (b)(2)(ii) Have at least 2 years of experience directing or supervising high complexity testing; or (b)(3) Hold an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution and-- (b)(3)(i) Be certified and continue to be certified by a board approved by HHS; or (b)(3)(ii) Before February 24, 2003, must have served or be serving as director of a laboratory performing high complexity testing and must have at least-- (b)(3)(ii)(A) Two years of laboratory training or experience, or both; and (b)(3)(ii)(B) Two years of laboratory experience directing or supervising high complexity testing. (b)(4) Be serving as a laboratory director and must have previously qualified or could have qualified as a laboratory director under regulations at 42 CFR 493.1415, published March 14, 1990 at 55 FR

9538, on or before February 28, 1992; or (b)(5) On or before February 28, 1992, be qualified under State law to direct a laboratory in the State in which the laboratory is located; or (b)(6) For the subspecialty of oral pathology, be certified by the American Board of Oral Pathology, American Board of Pathology, the American Osteopathic Board of Pathology, or possess qualifications that are equivalent to those required for certification.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's CMS-116 application, review of the CMS database, and interview with the TS (technical supervisor) 04/22/24-04/24/24, the laboratory failed to have a qualified laboratory director in place at the time of the survey. Review of the CMS-116 completed by the laboratory at the time of the survey revealed the person listed as laboratory director on the application is the pathologist who currently serves as the laboratory's TS. Review of the CMS database revealed the pathologist who serves as the laboratory's TS is currently serving as laboratory director for five other laboratories. During interview 4/24/24 at approximately 9:50 a. m., the TS confirmed he is currently serving as laboratory director for five other laboratories.

**D6151**

**GENERAL SUPERVISOR RESPONSIBILITIES**

CFR(s): 493.1463(b)(3)(4)

(3) The director or technical supervisor may delegate to the general supervisor the responsibility for providing orientation to all testing personnel; and (4) Annually evaluating and documenting the performance of all testing personnel.

This STANDARD is not met as evidenced by:

Based on review of personnel records and interview with the GS 04/23/24, the GS failed to retain documentation of competency evaluation for 6 of 7 TP (#1, #3, #4, #5, #6, #7). Review of personnel records revealed the TS (technical supervisor) had delegated the responsibility for performing annual competency evaluations to the GS. Review of personnel records revealed the GS had evaluated the competency of TP #1, TP #3, TP #4, TP #5, TP #6, and TP #7 in 2023, but there were no competency evaluation records available for 2021 or 2022. During interview 04/23/24 at approximately 10:10 a.m., the GS confirmed there were no 2021 or 2022 competency evaluation records for TP #1, TP #3, TP #4, TP #5, TP #6, and TP #7. She stated she performed the 2021 and 2022 evaluations, but the records must have been lost when her office was relocated.