Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D0258220	12/16/2022
Name of Provider or Supplier	**Street Address, City, State**	
Piedmont Henry Hospital, Inc	1133 Eagle'S Landing Parkway, Stockbridge, GA	

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	Full Survey The facility was found to be NOT in compliance with the following 42 CFR Part 493, Requirements for Laboratories for the specialties/subspecialties for which it was surveyed: 493.1240 Pre-Analytic Systems 493.1215 Hematology
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 laboratory policy, laboratory records, and confirmed in staff interview, the laboratory failed to retain documentation 7 of 8 quarterly alarm checks for 2021 and 2022 and of 1 of 1 annual cooler validations for 2021. Findings included: 1. The laboratory policy titled, "Maintenance and QC Overview" (approved by the laboratory director 03/22/2021) stated, "Quarterly Maintenance/QC Procedures A. Perform alarm checks on all refrigerators, freezer, and platelet rotator." 2. Review of laboratory records for 2021 and 2022 revealed one alarm check performed 11/2022 for the fourth quarter of 2022. The laboratory was asked to provide documentation of quarterly alarm check performance for 2021 and the first three quarters of 2022. No documentation was provided. 3. Further review of laboratory records revealed a form titled, "Annual Cooler Validation". The laboratory was asked to provide documentation of performance of cooler validations for 2021. No documentation was provided. 4. During an interview on December 14, 2022 at 2:57 pm in the Blood Bank, the Blood Bank supervisor stated that some records from 2021 and 2022 could not be located. This confirmed the above findings.
D5024	HEMATOLOGY CFR(s): 493.1215

	If the laboratory provides services in the specialty of Hematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1269, and 493. 1281 through 493.1299. This CONDITION is not met as evidenced by: Based on review of the laboratory's policy, manufacturer's instructions, patient test reports, and interviews, the laboratory failed to meet the requirements for Hematology as evidenced by: 1. The laboratory failed to follow their written procedures for testing on the STA-STAGO coagulation analyzer, for D-Dimer, Prothrombin TIme(PT), and Activated Partial Thomboplastin Time(APTT) (see D5401-II) 2. The laboratory failed to follow their written policy and rotate the level of body fluid quality controls tested for two of five months (August 2022-December 14, 2022) (see D5401-III) 3.The laboratory failed to have a written quality control procedure that identified the quality control level and frequency for one of one test systems Beckman Coulter Unicel Dxh 900 (See D5403-I) 4.The laboratory failed to label four of four in use reagent vials with open dates and new expiration dates. (See 5415-I) 5.The laboratory failed to document maintenance for 2 of 2 instruments. (See D5429- II) 6. The laboratory failed to establish the quality control parameters for two of two Beckman Coulter Unicel DxH 900 test systems. (See D5469) 7. The laboratory failed to document manual cell count quality control performance for one of five months (August 2022-December 14, 2022). (See D5543) 8. The laboratory failed to input the laboratory's established mean normal prothrombin time (MNPT) value for one of two STA-Compact Max coagulation analyzers. (See D5545)
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 the College of American Pathologist (CAP) Proficiency Testing (PT) documents for 2021 Hematology and staff interview, the laboratory failed to provide evaluation documentation. Findings: 1. A review of the CAP PT Hemocytometer Fluid Count (HFC) 2021 evaluation reports event A and B, the laboratory failed to provide evaluation documentation for both events. a. Kit HFC-A Evaluation report was not available to review. b. Kit HFC-B Evaluation report was not available to review. 2. Staff interview with Technical Supervisor #1 (CMS 209 form page 2 of 9) on December 15, 2022 at 2:40 pm in the Hospital Administration Conference room confirmed the findings.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on review of the College of American Pathologist (CAP) Proficiency Testing (PT) documents for 2021 for Speciality Microbiology, Subspecialty Gram stain, and

	staff interview, the laboratory failed to provide complete evaluation and corrective action, for 2 out of 5 results for event A, and 3 out of 5 results for event C. Findings: 1. Based on review of the CAP PT 2021 Gram Stain evaluation reports event A, and C the laboratory failed to provide complete evaluation documentation and corrective action documentation for both events. Kit D5-A Gram Stain Evaluation report stated that 2 out of 5 results were unable to analyze, 1 out of 5 was unacceptable and the other 2 results were acceptable. The exception report was started with minimal information documented Kit D5-C Gram Stain Evaluation report stated that 3 out of the 5 were acceptable, 1 out of 5 was unacceptable, and 1 out of 5 was coded with a comment "Lack of Participant or referee consensus". The exception report was started with minimal information documented. 2. Staff interview with the Laboratory Manager on December 16 at 10:24 am in the Hospital Administration Conference room confirmed the aforementioned statements. 33197 II. Based on review of the College of American Pathologist (CAP) Proficiency Testing (PT) Hematology documents for 2021 and staff interview, the lab failed to recognize the difference of the Laboratory Information System (LIS) values and the reported values to CAP kit FH13 event C for 1 of 5 specimens tested for nucleated red blood cell (nRBC) and red blood cell (RBC). Findings: 1. A review of the 2021 CAP PT documents for the FH13-C event revealed: a. 2021 CAP "Results Form Entry" Sample FH13-11 nRBC reported value of 1.44 and RBC reported value of 4.20. The LIS PT Result documented for Sample FH13-11 nRBC reported value space was blank (no value) and RBC reported value of 4.19. b. A review of the nRBC CAP report found the laboratory reported results, when the LIS failed to show any evidence of testing performed. No Corrective Action documentation was available to review for the discrepancies of the values from the CAP "Results Form Entry" verses the LIS lack of results. 2. Interview on 12/16/22 with General Supervisor #2 in the lab at 9:05 AM and an email from the interim lab manager, confirmed the findings.
D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c) (b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities. This STANDARD is not met as evidenced by: Based on record review, written policy and interview with the laboratory manager, the laboratory failed to provide an effective written competency assessment procedure. Findings include: 1. A review of the laboratory competency assessment evaluation records for chemistry, hematology, blood bank, urinalysis, microbiology and coagulation did not include the 6 competency assessment criteria as part of the documentation for review in 2021 and 2022. The laboratory has a competency assessment procedure titled, " Laboratory Competency Assessment, pages 2 of 5" the policy included the 6 competency assessment criteria for technical supervisors (TS) and general supervisors (GS) to follow but departments failed to include in competency evaluation documents. 2. A review of the laboratory competency assessment procedure revealed it failed to include an example of the acceptable competency assessment form, with instructions on how to document the competency assessment criteria. The laboratory policy titled "Laboratory Competency Assessment" section titled "Attachments, list "Leadership Competency Evaluation and

	Orientation Checklist" as examples of documents available for use by the TS and GS. The laboratory failed provide a competency assessment form with the 6 competency assessment criteria for the laboratory departments use. 3. The laboratory manager confirmed on December 15, 2022 at 10:00am in the conference room the laboratory did not have a competency assessment document for TS and GS use.
D5300	PREANALYTIC SYSTEMS CFR(s): 493.1240 Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, 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 preanalytic systems and correct identified problems as specified in 493. 1249 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of the laboratory's policy, manufacturer's instructions, patient test reports, and interviews, the laboratory failed to meet the requirements for the preanalytical system, as evidenced by: 1. The laboratory failed to accurately document the time of collection when specimens were received from outside entities (See D5305). 2. The laboratory failed to ensure patients samples were processed within required time frame according to the manufacturer's instructions and did not have have a written procedure listed for lactate specimen transportation requirement (See D5311-I). 3.The laboratory failed to ensure patients samples were processed (Epoc instrument) and tested according to their policy for the preanalytic phase of testing (See D5311-II).
D5305	TEST REQUEST CFR(s): 493.1241(c) The laboratory must ensure the test requisition solicits the following information: (1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (2) The patient's name or unique patient identifier. (3) The sex and age or date of birth of the patient. (4) The test(s) to be performed. (5) The source of the specimen, when appropriate. (6) The date and, if appropriate, time of specimen collection. (7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable. This STANDARD is not met as evidenced by: Based on review of the laboratory testing records and interview with director of lab services, the laboratory failed to accurately document the time of collection when specimens were received from outside entities during the month of November 2022 as evidence by: In review of the laboratory's testing records, 40 of 40 patients received from the outside entity did not have the accurate collection time. The following are a

	random sampling of patients: a.MRN # 911159843 no collection time from enity on 11/2/2022, beaker collection time: 1656, beaker receive time: 1656; lactic acid, BMP, CBC,procal. b. MRN # 903353520 collection time from entity on 11/3/2022: 1611, beaker collection time 1957, beaker receive time: 1957; cnbc w/diff. c. MRN # 907551928 collection time from enity on 11/7/2022: 0933, beaker collection time 1152, beaker receive time:1205; BMP,procal, latic acid, cbc. d. MRN# 903868439 collection time from entity on 11/30/2022: NA, beaker collection time 1628, beaker received time 1750; cbc w/diff, procal, latic acid. e. MRN# 909503302 collection time from entity on 11/7/2022: 0904, beaker collection time 1404, beaker received time 104; ammonia. In interview with director of lab services on 12-14-2022, @0950 confirmed that the collection times were not accurate in beaker system in comparison with the laboratory's paper testing requestion.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Lactate Testing I. Based on review of the laboratory's policy, manufacturer's instructions, patient test reports, nursing computer instructions, and interviews with the director of lab services, testing person #11 and Nursing, the laboratory failed to ensure patients samples were processed within required time frame according to the manufacturer's instructions and did not have have a written procedure listed for lactate specimen transportation requirement for the month of November 2022 as evidenced by: 1. In review of the manufacturer's instruction Beckman Coulter AU system under for the heading Specimen Collection and preparation states, "Keep the sample on ice and separate the plasma from the cells within 15 minutes of collection. " 2. In review of the laboratory's procedure, "Lactate on Beckman AU" it did not have a time frame to separate the plasma from the cells. It was not in line with the manufacturer's instructions. 3. In review of nursing collection instructions for lactate as a job aid states, "LACID: collect in Gray top, Draw blood without using a tourinquet. Place specimen on ice, Deliver immediately to lab." 4. In review of randomly selected patients, 14 of 30 for the month of November 2022 did not meet the 15 minute separation time frame: a. patient #909435617 collected on 11/15/2022 at 0056 received into laboratory at 0128, 32 minutes b.patient #908728065 collected on 11/15/2022 at 0413 received into the laboratory at 0557, 104 minutes c.patient #908453395 collected on 11/15/2022 at 0844 received into the laboratory at 1050, 126 minutes d. patient #903868439 collection on 11/30/2022 at 1628 received into the laboratory at 1750, 83 minutes e. patient #903673295 collection on 11/12/2022 at 2355 received into the laboratory at 0012, 17 minutes f. patient #911186061 collection on 11/20/2022 at 0515 received into the laboratory at 0541, 26 minutes g. patient #911176734 collection on 11/12/2022 at 2359 received into the laboratory at 0038, 39 minutes h. patient#903366170 collection on 11/13/2022 at 1404 received into the laboratory at 1523, 79 minutes i. patient#90320461 collection on 11/13/2022 at 0603 received into the laboratory at 0620, 17 minutes j. patient #903226273 collection on 11/13/2022 at 0524 received into the laboratory at 0549, 25 minutes k. patient# 903939686

	collection on 11/19/2022 at 1919 received into the laboratory at 1955, 36 minutes l. patient #903226273 collection on 11/13/2022 at 0625 received into the laboratory at 0645, 20 minutes m. patient # 908871264 collection on 11/13/2022 at 1801 received into the laboratory at 1850, 49 minutes n. patient # 903474889 collection on 11/16 /2022 at 1316 received into the laboratory at 1345, 29 minutes 5. In interview with director of lab services on 12/13/2022 at 1206, she was asked how long lactate acid need to be separate from the cells, she stated maybe 3 hours, 2hours maybe 15 minutes.. 6. In interview with testing person #11 on 12/13/2022 at 1324 she stated that it was good 1 hour not on ice. 7. In interview with Nursing on 12/13/2022 at 1345 they stated that they were not sure how long the specimen was good for after being drawn . 8. The laboratory performed an annual volume of 7,588 lactates with 1976 being performed in November 2022. Venous Blood gas II. Based on review of the laboratory's policy, patient test reports, and interviews with the diretor of lab services , the laboratory failed to ensure patients samples were processed (Epoc instrument) and tested according to their policy for the preanalytic phase of testing from October 2022 to the date of the survey as evidenced by: 2. In review of the laboratory's procedure, "Point of Care Testing using the Siemens epoc System" states under the heading Venous , "Samples must be tested within ten minutes of collection." 3. In review of randomly selected patients, 5 of 16 for the month of October 2022 to the date of the survey, did not meet the 10 minute time frame to perform the test, they are as follows: a patient #902526966 collected on 12/11/2022 at 1234, received in laboratory at 1251, 17 minutes total b.patient #9111166573 collected on 12/2/2022 at 1612, received in laboratory at 1623, 11 minutes total c.patient #9111166573 collected on 12/13/2022 at 1600, received in laboratory at 1616, 16 minutes total d.patient #903398365 collected on 10/18/2022 at 1108, received in laboratory at 1218, 70 minutes total e.patient #909354270 collected on 10/262022 at 0243 , received in laboratory at 0257, 12 minutes total 4. In interview with the director of lab services and hospital accreditation nurse on 12-15-2022 at 0930 they confirmed the findings that the laboratory did not meet the 10 minute window.
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: I. Based on observation, review of microbiology laboratory procedures and temperature records, and interview with the microbiology staff, the laboratory failed to follow their procedure. Findings included: 1. During the tour of the microbiology laboratory on 12/13/2022 at approximately 10:30 am, the surveyor observed the Microbiology Thermo Incubator was a non-CO2 incubator and the temperature log form stated a temperature range of 36-38 C. 2. Review of Blood Culture Procedure (BacT-Alert Incubator), PolicyStat ID 12123599, under section V. Procedure, 6. Unload and Work up Positive Bottles (BacT/ALERT 3D), xv., found the following statement: "Place all the plated media except the ANA plate in a biohazard bag and incubate in the CO2 incubator at 35C- 37C." 3. Review of Preventative Maintenance Program policy, PolicyStat ID 9138136, found the following: "Procedures, I. Daily Activities A. Temperature Checks Temperature checks are monitored offsite daily by Vizzia company and reviewed monthly by the Supervisor." 4. Review of the Vizzia

	temperature monitoring system records on 12/15/2022 at 9 am revealed the Microbiology Thermo Incubator temperature range was 36-38 C. 5. During interview on 12/13/2022 at approximately 2 pm, the microbiology General Supervisor stated she does not review the Vizzia temperature charts. The laboratory failed to follow their procedure for PolicyState ID 12123599 and PolicyState ID 9138136. Word Key: ANA=Anaerobic blood agar C=degree Celsius CO2=Carbon dioxide 34051 II. Based on procedure review, observation, and staff interview, the laboratory failed to follow their written procedures for testing on the STA-STAGO coagulation analyzer, for D-Dimer, Prothrombin TIme(PT), and Activated Partial Thomboplastin Time(APTT) Findings: 1. Procedure review of the procedures for D-Dimer, PT, and APTT patient testing list under Specimen: Unacceptable specimens; Samples that are short draws, over draws, clotted or hemolyzed may yield incorrect results. 2. Observed at least four specimens were tested on December 14, 2022 for D-Dimer, PT and APTT, and the plasma was visibly hemolyzed. Patient #: 911228085 was tested for PTT, PT, and D-Dimer Patient # 903242899 was tested for PTT, PT Patient # 903166671 was tested for PTT, PT Patient # 903247277 was tested for PTT, PT Result history and patient report attached to survey 3. Interview with the Laboratoy Manager, in his office on 12 /15/2022 at 4:10 pm, confirmed the aforementioned statements. 41090 III. Based on the laboratory' procedure, record review and interview with staff the laboratory failed to follow their written policy and rotate the level of body fluid quality controls tested for two of five months (August 2022-December 14, 2022). Findings Include: a. A review of the laboratory's procedure Manual Body Fluid Cell Count & Differentials (version effective date 09/16/2016) revealed on pages 3-4, "IV. Quality Control:...B. It is our policy to rotate the level of control to be tested i.e., if Level 1 was counted in the previous run, then count Level 2." b. A review of the Body Fluid Quality Control Log revealed Level 1 quality control documented on: Date Time 9/7/2022 20:00 9/10 /2022 7:10 9/29/2022 1600 10/6/2022 1600 10/24/2022 19:49 No documented performance of Level 2 quality control material for September 2022 through October 2022 was provided. No documented performance for any level quality control material for November 2022 was provided. c. Total manual body fluid cell count volume from 09/19/2022 to 12/13/2022 was 157. d. An interview with the Laboratory Manager on 12/15/2022 at 12:34 PM in the main laboratory confirmed these findings.
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: I. Based on the laboratory's procedure and interview with staff, the laboratory failed to have a written quality control procedure that identified the quality control level and frequency for one of one Beckman Coulter Unicel Dxh 900. Findings Include: a. A review of the laboratory's procedure Beckman Coulter Unicel Dxh 900 (version effective date 5/10/2022) revealed on pages 7-8 "VI. Quality Control ...At least two levels of assayed whole blood controls are run each 24 hours." b. An interview on 12 /14/2022 at 11:17 AM in the main laboratory, Technical Supervisor #1, as listed on the CMS Form 209, stated level one and three of the COULTER Retic-X and 6C Cell Controls are performed on the day shift while level 2 is performed on the evening shift and COULTER Latron CP-X is performed on the night shift. The laboratory's quality control practice was not written in a procedure. c. An interview with the Laboratory Manager on 12/14/2022 at 11:17 AM in the main laboratory confirmed these findings. 46043 II. Based on review of laboratory records, laboratory's immunohematology procedures and staff interview, it was revealed the laboratory failed to have documentation of a policy to ensure annual validation of coolers used to transport blood and blood products. Findings included: 1. Review of laboratory records revealed a form titled, "Annual Cooler Validation". 2. Review of the laboratory's immunohematology procedures revealed the laboratory failed to have documentation of a procedure for annual validation of coolers used to transport blood and blood products for emergency release. 3. During an interview on December 15, 2022 at 12:23 pm, the Blood Bank supervisor stated that she could not locate the procedure for annual cooler validation. This confirmed the above finding.
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: I. Based on observation, manufacturer instructions and interview with staff, the laboratory failed to monitor and document the storage temperature of epoc test cards. Findings included: 1. During tour of the intensive care unit (ICU) on 12/16/2022 at approximately 8:15 am, the surveyor observed epoc test cards stored at ambient temperature. Observation of the epoc test cards found a storage temperature of 15-30 C. No thermometer or other temperature monitoring device was observed in the area. 2. Review of the epoc blood analysis system manufacturer's instructions state "Always store Test Cards in their pouch at room temperature, 15C - 30C." 3. During interview on 12/16/2022 at approximately 8:15 am, the respiratory therapist testing personnel stated temperature is not monitored in the ICU. 4. During interview with the survey team lead on 12/16/2022 at 8:45 am, Biomedical Engineering staff stated the Vissia temperature monitoring system monitors refrigerator and freezer temperatures only. 32494 II. Based on direct observation, review of the FMH Rapid Screen manufaturer's instructions, Ortho Clinical Diagnostics operator's manual, Fetal Bleed Screen

	manufacturer's instructions, and staff interview, it was revealed the laboratory failed to monitor and document temperature and humidity to ensure acceptable temperatures were maintained for immunohematology testing for 12 of the 12 months (January to December 2022). The Findings include: 1. During a tour of the Blood Bank laboratory, the surveyor's observed the Ortho Clinical Diagnostics analyzer for immunohematology testing. Further observation revealed that the laboratory failed to monitor and document temperature and humidity for immunohematology testing. 2. Review of the operator's manual for the Ortho Clinical Diagnostics analyzer (on the actual analyzer) revealed the following: "Operating temperature: 18 degrees to 30 degrees Celsius, Humidity of 15% to 85%." 3. Review of the manufacturer's instructions revealed the laboratory failed to monitor and document room temperature for Fetal Bleed Screen (FMH RapidScreen: 18 degrees to 30 degrees Celsius). 4. Review of the laboratory records revealed the laboratory failed to monitor and document room temperature and humidity for the Blood Bank laboratory for all immunohematology testing. 5. During an interview with the Interim Blood Bank supervisor (CMS-209) on December 14, 2022 at 2:57 PM in the Blood Bank laboratory, confirmed that the room temperature and humidity was not monitored and recorded for January- December 2022. 41090 III. Based on the laboratory's temperature records, direct observation, and interview with staff, the laboratory failed to define storage temperature according to the manufacturer's instructions for two of two areas observed in which reagents were stored. Findings Include: a. A review of the laboratory form DIH2O SYSTEM AND HUMIDITY/TEMP LOG revealed "Month & Year December 2022 ...Chem/Hemo CORE LAB (TEMP) (16-30 C) ... Storage Room (TEMP) (16-30 C)". b. A sampling of reagents observed at room temperature included: 1. Storage Room 12/14/2022 at 10:51 AM: 23 bottles; Beckman Coulter ISE Buffer Solution; Lot # M208670; Store at 2C-25C 17 boxes; GeneXpert Xpert MRSA NxG; Lot # 1000519810; Store at 2C-28C 29 bottles; Beckman Coulter Wash Solution; Lot # M112482; Store at 2C-25C 2. Main Laboratory 12/14/2022 at11:00 AM: 1 box of Beckman Coulter ISE Low Serum Standard; Lot # 2684; Store at 2C-25C 3 boxes; Beckman Coulter ISE Low/High Urine Standard; Lot # 2682; Store at 2C-25C 11 bottles; Beckman Coulter Bicarbonate Calibrator; Lot# 2735; Store at 15C-25C The laboratory's defined room temperature of 16-30C was beyond the stored reagents requirements as listed above (16C-25C). c. An interview with the Laboratory Manager on 12/14/2022 at 11:00 AM in the main laboratory confirmed these findings. Word Key: C=degree Celcius
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: I.Based on the manufacturer's instructions, the laboratory's procedures, direct observation and interview with staff the laboratory failed to label four of four in use reagent vials with open dates and new expiration dates in Hematology. Finding Include: a. A review of COULTER 6C Cell Control (REF A59925,628027) revealed "Storage, Stability, And Disposal ... For opened vial stability refer to the TABLE OF EXPECTED RESULTS for your system". b. A review of COULTER 6C Cell Control

	Table of Expected Results (A63013-AF) revealed "*Assumes that the Instructions for Use section of the package insert is performed a maximum of 18 times within 16 days." c. A review of COULTER Retic-X Cell Control (REF 628028) revealed "Storage, Stability, And Disposal ... For opened vial stability refer to the TABLE OF EXPECTED RESULTS for your system". d. A review of COULTER Retic-X Cell Control (A63007-AE) revealed "*Assumes that the Instructions for Use section of the package insert is performed a maximum of 18 times within 16 days." e. A review of the laboratory's open vial stability job aid found taped to the door of the refrigerator labeled Hematology (PHH Lab DR078859BIN) revealed "Reagent ...Retic-X & 6C Controls ...Open vial stability ...3 Days after opening". f. A review of the laboratory's procedure Beckman Coulter Unicel Dxh 900 (version effective date 5/10/2022) revealed on pages 7-8 "VI. Quality Control ...Coulter 6C Cell and Retic-X Controls ... Pierced vials are stable for 7 days after piercing." g. A sampling of reagents observed on 12/13/2022 at 3:14 PM in the refrigerator Hematology (PHH Lab DR078859BIN) included: 1. COULTER Retic-X Cell Control; Level 3; LOT 173223080; handwritten on the vial "EXP12-26-22" 2. COULTER Retic-X Cell Control; Level 1; LOT 153203080 handwritten on the vial "EXP12-26-22" 3. COULTER6C Cell Control; Level 3; LOT 143194620 handwritten on the vial "EXP12-26-22" 4. COULTER6C Cell Control; Level 1 LOT 123174620 handwritten on the vial "EXP12-26-22" The laboratory failed to label the bottles with open and new expiration dates described by the manufacturer (maximum of 18 times within 16 days). h. An interview with the Laboratory Manager on 12/14/2022 at 11:23 AM in the main laboratory confirmed these findings. 46043 II. Based on direct observation, review of laboratory policy, and confirmed in staff interview, the laboratory failed to ensure reagents stored in secondary containers were labeled with proper identification and expiration dates for 4 of 4 bottles of tissue marking dyes. Findings included: 1. During a tour of the histology department of the laboratory on December 15, 2022 at 12:52 pm, the following bottles of Cancer Diagnostic Tissue Marking Dyes were observed in the grossing area: Location: Under Mopec Maestro Hood, Serial Number MB106E19009 2-ounce bottle Violet; No label present to assess lot number and expiration date Location: Under Mopec Maestro Hood; Serial Number MB106E19019 2-ounce bottle Green; No label present to assess lot number and expiration date 2-ounce bottle Yellow; No label present to assess lot number and expiration date 2-ounce bottle Orange; No label present to assess lot number and expiration date 2. The laboratory policy titled, "Surgical Pathology Specimen Handling and Processing" stated, "All solutions prepared in the Histology Laboratory or poured into secondary container from kit must have the following information on the label: a. Name of reagent b. Date prepared c. Expiration date d. Storage criteria e. Initial of Technologist." 3. During an interview on December 15, 2022 at 1:05 pm in the grossing room, the Histology laboratory supervisor stated that the two-ounce dye bottles in use are refilled from a larger 8-ounce bottle. She confirmed that the laboratory failed to label the secondary containers with the correct lot numbers and expiration dates.
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 direct observation and interview, the laboratory had expired evacuator

	tubes ready for use in the laboratory as evidence by: 1. In direct observation 12-14-2022 at 1315 the surveyor found the following tubes expired ready for use in the laboratory and outpatient center: a. 92 - 6.0 ml BD additive lot #1158522 expiration date: 11-30-222 b.1- 2.2 ml NA citrate lot #1288646 expiration date: 7-31-2022 c.15 - 2.2 ml NA citrate lot #1288646 expiration date: 7-31-2022 2. In interview with the Accreditation Nurse 12-14-2022 at 1315 she confirmed the findings. 34051 II. Based on direct observation on 11/15/2022 in the Urinalysis section, and staff interview, there was a bottle of expired ALBAcheck Monoclonial Control available for use sitting by the Clinitek chemistry strip reader. Findings: 1. Observed in the Urinalysis section by the Clinitek chemistry strip reader, there was a bottle of expired ALBAcheck Monoclonial Control available for use. The reagent had an expiration date of 11-26.2022. 2. Interview with the Hematology Supervisor, and Laboratory Manager, on 11/15/2022, at approximately 2pm in the Urinalysis section confirmed the aforementioned statement. 46043 III. Based on direct observation, review of laboratory policy, and confirmed in staff interview, the laboratory failed to ensure 21 of 21 bottles of tissue marking dyes had not exceeded their expiration dates. Findings included: 1. During a tour of the histology department of the laboratory on December 15, 2022 at 12:52 pm, the following bottles of Cancer Diagnostic Tissue Marking Dyes were observed in the grossing area: Location: Under Mopec Maestro Hood, Serial Number MB106E19009 2-ounce bottle Blue; Lot number 20255; Expiration date 09/30/2022 2-ounce bottle Green; Lot number 20240; Expiration date 08/31/2022 2-ounce bottle Red; Lot number 20234; Expiration date 08/31/2022 2-ounce bottle Yellow; Lot number 20239; Expiration date 08/31/2022 2-ounce bottle Orange; Lot number 20167; Expiration date 06/30/2022 2-ounce bottle Violet; No label present to assess lot number and expiration date 2-ounce bottle Black; Lot number 20034; Expiration date 02/28/2022 Location: Under Mopec Maestro Hood; Serial Number MB106E19019 2-ounce bottle Black; Lot number 20237; Expiration date 08/31/2022 2-ounce bottle Blue; Lot number 20052; Expiration date 02/28/2022 2-ounce bottle Green; No label present to assess lot number and expiration date 2-ounce bottle Red; Lot number 20002; Expiration date 01/31/2022 2-ounce bottle Yellow; No label present to assess lot number and expiration date 2-ounce bottle Orange; No label present to assess lot number and expiration date 2-ounce bottle Violet; Lot number 20232; Expiration date 08/31/2022 Location: In cabinet between the two Mopec Maestro Hoods: 8-ounce bottle Red; Lot number 20211; Expiration date 07/31/2022 Two 8-ounce bottles Orange; Lot number 092203; Expiration date 07/31/2021 8-ounce bottle Yellow; Lot number 20195; Expiration date 07/31/2022 8-ounce bottle Yellow; Lot number 092725; Expiration date 01/31/2022 8-ounce bottle Violet; Lot number 20244; Expiration date 08/31/2022 8-ounce bottle Orange; Lot number 086574; Expiration date 09/30/2021 2. The laboratory policy titled, "Surgical Pathology Specimen Handling and Processing" (approved by the laboratory director 08 /12/2022) stated, "Expired reagents, dyes or chemicals are not to be used for staining techniques." 3. During the tour of the histology grossing area on December 15, 2022 at 1:05pm, the laboratory director confirmed that the tissue marking dyes were expired.
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: I. Based on review of the laboratory maintenance records and staff interview, the laboratory failed to document required monthly maintenance as defined by the manufacturer instructions for the Chemistry analyzer, UniCel DXI for 4 of the 12 months in 2022 (January-April). Findings include: 1. Review of the Unicel DXI (Serial number: 608950) chemistry analyzer's maintenance log revealed the following months in 2022 monthly maintenance performance was not peformed and documented: January 2022 February 2022 March 2022 April 2022 The laboratory failed to perform monthly maintenance as required by the manufacturer instructions for the Unicel DXI analyzer. 2. During an interview with the Chemistry Supervisor (CMS-209) on December 15, 2022, in the Hospital Administration Conference room at 2:45 PM, confirmed the missing maintenance logs, after the review of the maintenance logs, for the above dates. 41090 II. Based on record review and interview with Technical Supervisor #1, the laboratory failed to document maintenance for 2 of 2 instruments in Hematology. Findings Include: a. A review of STAG COMPACT MAINTENANCE CHART #1 S/N 5055060 (September 2022-October 2022) revealed daily maintenance not documented on 11 of 61 days; weekly maintenance not documented on 2 of 8 weeks. The following is a sampling of maintenance not documented: Daily maintenance September 1-3 Weekly maintenance October 1-15. b. A review of Coulter DxH 900 Maintenance Log, DXH 1 (September 2022-October 2022) revealed daily maintenance not documented 13 of 61 days; weekly maintenance not documented 6 of 8 weeks. The following is a sampling of maintenance not documented: Day shift daily maintenance September 21 Evening shift daily maintenance October 27-30 Weekly maintenance (2nd shift) October 1-31. c. An interview with Technical Supervisor #1, as listed on the CMS Form 209, at 2:41 PM in their office confirmed these findings.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on review of the preventative maintenance (PM) records, laboratory policy, interview with staff and electronic mail (email) correspondence, the laboratory failed to perform PM on a centrifuge per the laboratory's PM schedule. Findings included: 1. Review of PM records on 12/13/2022 at approximately 9 am revealed the laboratory performs PM on centrifuges semi-annually (every six months). A centrifuge with serial number A585019 located in the Blood Bank section of the laboratory had PM performed 03/01/2021 and 09/12/2022, an 18 month lapse between the PM. 2. During interview on 12/13/2022 at approximately 9 am, Biomedical Engineering staff stated PM on centrifuges is performed every six months. 3. Review of the Centrifuge Usage policy, PolicyStat ID 9418702, on 12/15/2022 found the following statement under III. Maintenance: "Yearly, biomedical engineering will perform routine preventive maintenance and verification. This should include checking the brushes, timer, speed and for possible electrical leaks. Biomed is also responsible for maintaining and

	checking the tachometer." 4. Email from Biomedical Engineering staff received on 12 /15/2022 stated the following regarding centrifuge with serial number A585019: "11/1 /2020 (Tech I) performed the Incoming Inspection on the Centrifuge putting it into service 11/1/2020 (Tech I) mistakenly set the first PM Schedule Date to generate on 11 /1/2021, (an Annual PM), however the default PM Schedule in Aims (Database) was a Semi-Annual PM. [sic] and therefore Tech I should have set the first scheduled PM date to 5/1/2021. This did not happen meaning that the first Semi-Annual PM would actual start on 11/1/2021. 3/1/2021 (Tech II) Must have realized that the PM was incorrectly set, and manually generated a PM [sic] This would have triggered Aims to advance the PM Schedule date from 11/1/2021 to 5/1/2022. 3/1/2021 (Tech II) mistakenly updated the Next PM Date from 5/1/2022 to 9/1/2022. It appears that (Tech II) tried to correctly adjust the next PM schedule six months from when he manually created the PM that he performed in March, but did not realize that the year had advance to 2022. Had he recognized this the date and schedule would have been correct going forward. In conclusion, one error by Tech I, was caught by Tech II, and PM was performed, but then Tech II overlooked setting the correct year." The laboratory failed to perform centrifuge PM per their written policy (yearly) and per verbal statement and email (six months) for the centrifuge with serial number A585019.
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 review of laboratory procedures, test menu, quality control records, individualized quality control plan (IQCP) and interview with laboratory staff, the laboratory failed to establish IQCPs for laboratory test systems. Findings included: 1. Mono II Rapid Test a. Review of the laboratory procedure Mono II Rapid Test PolicyStat ID 12804664 on 12/14/2022 found the following under section IV. Quality Control: "External Quality Control: External QC must be run on every new lot or shipment and at least very 30 days that the lot is in use." b. Review of the laboratory's test menu on 12/14/2022 found the Mono II Test by Cardinal listed as moderate complexity. c. Review of quality control records titled "RAPID TEST OF THE KITS QUALITY CONTROL LOG (RSV/STREP/MONO)" on 12/14/2022 found the following statement on the log: "Quality control is performed once monthly, additionally per lot, per shipment and recorded below." d. On 12/14/2022, the surveyor requested the laboratory's IQCPs and was provided a binder containing a page with a list of the tests with IQCPs. The list included the Mono II Rapid test and the binder contained a risk assessment for the Mono II Rapid test, but did not contain the quality control plan (QCP) or quality assessment (QA). e. During interview on 12 /14/2022 at 3:15 pm, the laboratory manager confirmed the IQCP for the Mono II Rapid test did not include a QCP and QA and was incomplete. 2. Quik Chek Complete C. Diff Test a. Review of the laboratory procedure Quik Check Complete

	C. Diff PolicyStat ID 11049056 on 12/14/2022 found the following statement under section VI. Quality Control: "2. External Control: Positive Control and negative controls [sic] (Diluent) supplied in the test kit. Controls are run with each new lot number and/or shipment." b. Review of the laboratory's test menu on 12/14/2022 found the C. diff Quik Check Complete Test by Techlab listed as moderate complexity. c. On 12/14/2022, the surveyor requested the laboratory's IQCPs and was provided a binder containing a page with a list of the tests with IQCPs. The list did not include the Quik Chek Complete C. Diff test and no records of an IQCP were found in the binder. d. During interview on 12/14/2022 at 3:15 pm, the laboratory manager confirmed an IQCP for this test was not performed by the laboratory. 3. Determine HIV 1&2 Combo Test a. Review of the laboratory procedure Determine HIV 1&2 Combo PolicyStat ID 9028885 on 12/14/2022 found the following statement under section IV. Quality Control: "B. External Quality Control Alere Determine HIV-1/2 Ag/Ab Combo Controls should be tested under the following circumstances: Each new untrained operator prior to performing tests on patient specimens When opening a new test kit Whenever a new shipment of test kits is received If the temperature of the test storage area falls outside of 2 to 30C (36 to 86F) If the temperature of the testing area falls outside of 15 to 30C (59 to 86F) At periodic intervals indicated by the testing facility" b. Review of the laboratory's test menu on 12/14/2022 found the HIV 1/2 Ag/Ab Combo test by Abbott listed as moderate complexity. c. Review of quality control records titled "RAPID TEST OF THE KITS QUALITY CONTROL LOG (RSV/STREP/MONO) on 12/14/2022 found the following statement on log: "Quality control is performed once monthly, additionally per lot, per shipment and recorded below." HIV 1/2 Ag/Ab Combo quality control for lot number 197235 was documented on this form on 10/04/2022. d. On 12/14/2022, the surveyor requested the laboratory's IQCPs and was provided a binder containing a page with a list of the tests with IQCPs. The list did not include the Determine HIV 1&2 Combo test and no records of an IQCP were found in the binder. e. During interview on 12/14/2022 at 3:15 pm, the laboratory manager confirmed an IQCP for this test was not performed by the laboratory. Word Key: Mono=mononucleosis C. diff=Clostridium difficile HIV=Human Immunodeficiency Virus RSV= Respiratory Syncytial Virus STREP=Streptococcus QC=Quality Control
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 observation, review of laboratory procedures, quality control records and interview with laboratory staff, the laboratory failed to perform quality control on each batch of commercially prepared media. Findings included: 1. During the tour of the microbiology laboratory on 12/13/2022 at approximately 10:30 am, the surveyor observed the laboratory used the following media: BAP (Sheep Blood Agar Plates) CAP (Chocolate Agar Plates) MAC (MacConkey Agar Plates) ANA (Anaerobic Blood Agar Plates) BacT/Alert SA (Aerobic) Bottles BacT/Alert SN (Anaerobic) Bottles BacT/Alert PF (Pediatric) Bottles BacT/Alert FA (Aerobic) Bottles BacT /Alert FN (Anaerobic) Bottles 2. Review of Blood Culture Procedure (BacT-Alert

	Incubator), PolicyStat ID 12123599, found under section III. Equipment and Materials the following: A. BOTTLES 1. BacT/Alert SA (Aerobic) Bottle ... 2. BacT/Alert SN (Anaerobic) Bottle ...3. BacT/Alert PF (Pediatric) Bottles ...4. BacT/Alert FA (Aerobic) Bottles ...5. BacT/Alert FN (Anaerobic) Bottles ..." B. PLATING MEDIA: 1. Includes: a. Blood Agar -Trypticase Soy Agar (TSA) with 5% Sheep Blood b. Brucella Agar -ANA Blood Agar (Anaerobic BAP) c. Chocolate Agar (CHOC) d. MacConkey Agar (MAC) NOTE: Plating media is obtained from [sister facility] Microbiology department and stored in the refrigerator at 2C to 8C until use. QC on the plates is performed at [sister facility]." 3. Review of commercial media quality control forms for Henry Hospital found an area for "Exempt Media Visual inspection on receipt", an area for "Non-Exempt Media Visual inspection on receipt" and an area for "QC for non-Exempt media" for completion. The quality control performed on chocolate agar was documented in the "QC for non-Exempt media". The forms did not contain documentation of a visual inspection or a sterility check. QC documentation was not available for the other types of media used in the laboratory. 4. During interview on 12/14/2022 at 9:30 am, the General Supervisor (GS) of the Microbiology section stated a sister facility performs quality control on the chocolate agar and documents the results on the commercial media quality control forms. The GS stated that no media quality control is performed by the laboratory nor does the laboratory have an individualized quality control plan for microbiology media. The GS further stated she was unsure if the media was shipped to the laboratory from the sister facility or shipped from the vendor. Word Key: QC=Quality Control
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on the laboratory's lack of policies or procedures and interview with Technical Supervisor #1, the laboratory failed to establish the quality control parameters for two of two Beckman Coulter Unicel DxH 900 test systems. Findings Include: a. The laboratory was asked to provide a policy or procedure for establishing quality control parameters. No procedure was provided. b. In an interview on 12/14/2022 at 11:23 AM in the main laboratory, Technical Supervisor #1, as listed on the CMS Form 209, stated the laboratory attempts to gather 10-20 quality control values and establish a mean. The established mean and standard deviation may be changed after comparison to peer group data. In an additional interview on 12/14/2022 at 2:41 PM in Technical Supervisor #1 office they stated the laboratory is currently using the manufacturer's parameters because those established by the laboratory were less than 1 standard deviation from the manufacturer's.

D5543	HEMATOLOGY CFR(s): 493.1269(a)(d) (a) For manual cell counts performed using a hemocytometer-- (a)(1) One control material must be tested each 8 hours of operation; and (a)(2) Patient specimens and control materials must be tested in duplicate. (d) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on the laboratory's procedure, record review and interview with staff, the laboratory failed to document manual cell count quality control performance for one of five months (August 2022-December 14, 2022). Findings Include: a. A review of the laboratory's procedure Manual Body Fluid Cell Count & Differentials (version effective date 09/16/2016) revealed on page 3, "IV. Quality Control: One level of body fluid control is to be tested once every 8 hours of patient testing." b. A review of the Body Fluid Quality Control Log revealed Level 1 quality control documented on: Date Time 9/7/2022 20:00 9/10/2022 7:10 9/29/2022 1600 10/6/2022 1600 10/24 /2022 19:49 No documented performance for any level quality control material for November 2022 was provided. c. A review of body fluid patient reports (sampling) revealed: 1. Sample Number: 903340068; Reported 11/23/2022 at 8:48 AM 2. Sample Number: 903712798; Reported 11/28/2022 at 3:06 PM 3. Sample Number: 903981078; Reported 11/29/2022 at 10:47 AM 4. Sample Number: 903514322; Reported 11/30/2022 at 11:30 AM 5. Sample Number: 903575240; Reported 11/30 /2022 at 9:28 AM 6. Sample Number: 903404529; Reported 11/30/2022 at 10:52 AM 7. Sample Number: 902510415; Reported 11/30/2022 at 11:28 AM d. Total manual body fluid cell count volume from 09/19/2022 to 12/13/2022 was 157. e. An interview with the Laboratory Manager on 12/15/2022 at 12:34 PM in the main laboratory confirmed these findings.
D5545	HEMATOLOGY CFR(s): 493.1269(b)(d) (b) For all nonmanual coagulation test systems, the laboratory must include two levels of control material each 8 hours of operation and each time a reagent is changed. (d) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on record review, instrument input settings, and interview with staff, the laboratory failed to input the laboratory's established mean normal prothrombin time (MNPT) value for one of two STA-Compact Max coagulation analyzers. a. A review of the laboratory's established MNPT revealed: "Inst1: STA-Compact Max 1 ... Instrument Geo Mean = 12.9" b. A review of the instrument input settings for STA-Compact Max 1 revealed "Reference Time 13.0 sec" The laboratory began using the established the MNPT on 07/6/2022. The total volume of the coagulation test from 7/6 /2022 to 12/15/2022 was 13,888. c. An interview with the Laboratory Manager on 12 /15/202 at 2:11 PM in the main laboratory confirmed these findings.
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 quality control records, laboratory list of point of care testing and interview with laboratory staff, the laboratory failed to evaluate/compare the test results from different instruments and methodologies twice a year for two of two years (2021 and 2022). Findings includes: 1. i-STAT a. Review of quality control records on 12/15/2022 revealed the facility has nine i-STAT instruments in various locations in the facility including the Cath Lab, Critical Care Unit (CCU) and Radiology area. b. Review of a listing of i-STAT instruments on 12/15/2022 revealed three i-STAT instruments located in the Cath Lab perform the following tests: potassium, sodium, chloride, total carbon dioxide, ionized calcium, creatinine, glucose, urea, hematocrit and hemoglobin; two i-STAT instruments located in the CCU performed activated clotting time (ACT) testing; and four i-STAT units located in the Radiology area performing creatinine and ACT tests. c. During interview on 12 /16/2022 at 8:52 am, the point of care coordinator stated the laboratory does not perform twice a year comparisons of the testing performed on each individual i-STAT instrument, each individual epoc instrument, or the point of care analytes also performed on the Beckman Coulter analyzer and Nova Prime instrument located in the hospital laboratory. 2. epoc a. Review of quality control records on 12/15/2022 revealed the facility has twenty-four epoc instruments in various locations in the facility including outpatient surgery, intensive care unit (ICU) and respiratory therapy. b. Review of a listing of epoc instruments on 12/15/2022 revealed twenty instruments located in respiratory therapy, three instruments in the in the ICU and one in outpatient surgery that perform the following tests: potassium, sodium, total carbon dioxide, partial carbon dioxide, ionized calcium, pH, partial oxygen, oxygen saturation, hematocrit and hemoglobin. c. During interview on 12/16/2022 at 8:52 am, the point of care coordinator stated the laboratory does not perform twice a year comparisons of the testing performed on each individual i-STAT instrument, each individual epoc instrument, or the point of care also performed on the Beckman Coulter analyzer and Nova Prime instrument located in the hospital laboratory.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on a review of the laboratory's procedure, patient test reports, and an interview with the staff, the laboratory failed to ensure the established reference range was provided on the patient test report for one of two tests reviewed. a. A review of the laboratory's procedure Manual Body Fluid Cell Count & Differentials (version effective date 09/16/2016) revealed on page 9 "XI. Reference Values ...The normal ranges for Spinal Fluid (CSF) are: A. Less than 10 WBC/mm^3 ...B. Less than 5 RBC /mm^3." b. A review of patient reports for CSF Cell Count revealed (sampling): 1.

	Sample Number: 903358738; Reported 12/14/2022 at 1:51 PM ...Reference Range ... RBC, CSF 0-4/mm^3 ...Nucleated Cells, CSF 0-5/mm^3 c. An interview with the Laboratory Manager on 12/15/2022 at 12:34 PM in the main laboratory confirmed these findings.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (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 record review, procedure review and interview with laboratory manager, the laboratory technical supervisor failed to assess testing personnel documenting the 6 competency assessment criteria for 29 of 29 testing personnel in 2021 and 2022. Findings include: 1. A review of the Piedmont Henry Hospital Competency Assessment checklist found the 6 competency assessment criteria were not included on semi-annual and annual competency assessment documents. The laboratory failed to perform semi-annual and annual competency assessments using the 6 competency assessment criteria for 29 of 29 testing personnel in chemistry, hematology, urinalysis, coagulation, and microbiology.The laboratory provided documentation for 8 of 11 testing personnel performing blood bank in 2022. 2. The laboratory policy titled "Laboratory Competency Assessment" stated " I. Assess Competency, E. Each department has developed a competency assessment plan that includes (but) not limited to the following: 1. Direct Observation, 2. Monitoring, recording and reporting of test results, 3. Review of intermediate test results, 4. Assessment, 5. Evaluation of test performance, 6 Problem solving. The laboratory departments failed to provide training documents for 29 of 29 testing personnel that included the 6 competency assessment criteria in 2021 and 2022. 3. The laboratory manager confirmed on December 15, 2022 10:00am in the conference room that the 6 competency assessment criteria were not included on semi-annual and annual training evaluation documents in 2021 and 2022.