Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0482373	09/09/2024
Name of Provider or Supplier	**Street Address, City, State**	
Christus Health-Pine Street	1000 Pine Street, Texarkana, TX	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	An onsite validation survey conducted 09/04/2024 to 09/09/2024 found the laboratory out of compliance with 42 CFR Part 493, Requirements for Laboratories for the following conditions of participation: D5300 - 42 C.F.R. 493.1240 Condition: Preanalytic systems; D5400 - 42 C.F.R. 493.1250 Condition: Analytic systems; D6000 - 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director; D6063 - 42 C.F.R. 493.1421 Condition: Laboratories performing moderate complexity testing; testing personnel;
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of proficiency testing records and confirmed in interview, the laboratory failed to verify the accuracy, at least twice annually, for 13 analytes reviewed in 2022 and 2023, to ensure accurate and reliable results. The findings included: 1. Review of the laboratory proficiency testing records for 2022 and 2023 included the following 13 non-regulated analytes that failed to achieve at least two satisfactory scores annually: 2022: Ammonia Procalcitonin Body Fluid Cholesterol 2023: Ammonia Body Fluid Cholesterol Body Fluid pH (quantitative) Urine Osmolality Body Fluid Chloride Body Fluid Sodium Body Fluid Urea Nitrogen Hemoglobin F, quantitative ACT (activated clotting time) CSF/Body Fluid Manual Cell Counts differentials: for Lymphocytes, Neutrophils, and Monocytes. Body Fluid Microscopy 2. Review of the laboratory proficiency testing policies did not include instructions to ensure that twice annual accuracy assessments for the non-regulated analytes were achieved. 3. In an interview on 9/4/2024 at 12:20 hours, in the conference room, general supervisor (GS) 3 confirmed that the laboratory did not have a mechanism in place to ensure a successful twice annual accuracy assessment

	for non-regulated analytes, and that a successful twice annual accuracy had not been achieved for the above analytes.
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 manufacturer's instructions, review of patient test records and interview of facility personnel, the laboratory failed to ensure that patient specimens collected for Lactate testing were removed from cells within 15 minutes as specified by the manufacturer when using the Beckman DxC 600i, for records reviewed between January 1, 2024 and January 14, 2024. (see D5311)
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: A. Based on review of laboratory policies and procedures, review of patient test records and interview of facility personnel,the laboratory failed to ensure patient specimens collected and tested for Lactate testing were removed from cells within 15 minutes of collection as specified by the the manufacturer when using the Beckman DxC 600i Chemistry analyzer. The laboratory tested and reported 142 patient specimens for Lactate between January 1, 2024 and January 14, 2024. 95 of 142 patient specimens tested and reported exceeded the 15 minute separation of cells from plasma as defined in the laboratory's own written procedure. The findings included: 1. A review of the laboratory's own written policy titled Lactate (LAC): Plasma (dated 05 /01/2009) found on page 2 under the heading storage and Stability: "Tubes of blood are to be kept closed at all times and in a vertical, stopper-up position. Keep samples on ice. Plasma should be physically separated from contact with cells within 15 minutes of sample collection and analyzed without delay." Further review found on page 2 in the section titled SPECIMEN REQUIREMENT: Lactic Acid/Lactate: "Collect: Gray Top (Sodium Fluoride/ Potassium Oxalate). Keep on Ice. Testing Sample: Plasma anticoagulated with sodium fluoride/potassium oxalate. Handling: Specimen shall be collected by the Lab Phlebotomy group or Nursing Staff. Specimen shall be transported on ice and brought to lab immediate for processing. Separate cells from plasma within 15 minutes of collection and process immediately without delay. Unacceptable Conditions: Sodium Heparin Plasma (Our Green Tops) is incompatible

with the method per B/C studies.... Refer to specific Procedure "Limitation and Interfering Substance Section and Procedure Notes sections below. Stability: 15 minutes on the cells if kept in ice." 2. Review of patient test records for Lactate between January 1, 2024 through January 14, 2024 found 95 specimens were received in the laboratory at 15 minutes or later from collection and thus, the plasma was not removed from the cells within the time required. 28 of the 95 patient results reported on samples that exceeded the 15 minute time limit for separation follows: Patient: C00201R Collected: 01/01/24 - 0540 Received: 01/01/24 - 0630 Elapsed time: 50 minutes Patient: C00417S Collected: 01/01/24 - 0351 Received: 01/01/24 - 0639 Elapsed time: 168 minutes Patient: C00649R Collected: 01/02/24 - 1159 Received: 01 /02/24 - 1313 Elapsed time: 74 minutes Patient: C01141S Collected: 01/02/24 - 2050 Received: 01/02/24 - 2155 Elapsed time: 55 minutes Patient: C00866S Collected: 01 /03/24 - 1350 Received: 01/03/24 - 1413 Elapsed time: 23 minutes Patient: C011708 Collected: 01/03/24 - 2045 Received: 01/03/24 - 2112 Elapsed time: 27 minutes Patient: C00986S Collected: 01/04/24 - 1649 Received: 01/04/24 - 1739 Elapsed time: 50 minutes Patient: C01224R Collected: 01/04/24 - 2220 Received: 01/04/24 - 2255 Elapsed time: 35 minutes Patient: C00953S Collected: 01/05/24 - 1605 Received: 01 /05/24 - 1650 Elapsed time: minutes Patient: C01157S Collected: 01/05/24 - 2125 Received: 01/05/24 - 2252 Elapsed time: 87 minutes Patient: C00809T Collected: 01 /06/24 - 1514 Received: 01/06/24 - 1541 Elapsed time: 27 minutes Patient: C 00251S Collected: 01/06/24 - 0001 Received: 01/06/24 - 0039 Elapsed time: 38 minutes Patient: C00636S Collected: 01/07/24 - 1354 Received: 01/07/24 - 1434 Elapsed time: 40 minutes Patient: C00829S Collected: 01/07/24 - 1735 Received: 01/07/24 - 1852 Elapsed time: 77 minutes Patient: C00334S Collected: 01/08/24 -0133 Received: 01 /08/24 - 0252 Elapsed time: 89 minutes Patient: C00890S Collected:01/08/24 - 1243 Received: 01/08/24 - 1330 Elapsed time: 47 minutes Patient: C00234R Collected: 01 /09/24 - 0252 Received: 01/09/24 - 0322 Elapsed time: 30 minutes Patient: C00338S Collected: 01/09/24 - 0130 Received: 01/09/24 - 0221 Elapsed time: 51 minutes Patient: C00333R Collected: 01/10/24 - 0543 Received: 01/10/24 - 0627 Elapsed time: 44 minutes Patient: C01152 S Collected: 01/10/24 - 1925 Received: 01/10/24 - 2020 Elapsed time: 55 minutes Patient: C00994S Collected: 01/11/24 - 1425 Received: 01/11/24 - 1529 Elapsed time: 64 minutes Patient: C00254 Collected: 01/11 /24 - 0035 Received: 01/11/24 - 0058 Elapsed time: 23 minutes Patient: C01001S Collected: 01/12/24 - 1627 Received: 01/12/24 - 1757 Elapsed time: 90 minutes Patient: C01041S Collected: 01/12/24 - 1715 Received: 01/12/24 - 1737 Elapsed time: 21 minutes Patient: C00911S Collected: 01/13/24 - 2010 Received: 01/13/24 - 2038 Elapsed time: 28 minutes Patient: C01041S Collected: 01/13/24 - 2255 Received: 01 /13/24 - 2343 Elapsed time: 48 minutes Patient: C00416R Collected: 01/14/24 - 0450 Received: 01/14/24 - 0613 Elapsed time: 74 minutes Patient: C00742S Collected: 01 /14/24 - 1423 Received: 01/14/24 - 1502 Elapsed time: 39 minutes 3. During interview of the Compliance officer conducted September 5, 2024 at 11:14 AM, it was confirmed that patient specimens tested for Lactate were not always removed from cells within 15 minutes of collection. B. Based on review of laboratory policies and procedures, review of patient test records and interview of facility personnel,the laboratory failed to ensure patient specimens collected and tested for Ammonia testing were removed from cells within 10 minutes as specified by the the manufacturer when using the Beckman DxC 600i Chemistry analyzer. Receipt of 15 of 23 patients specimens tested and reported for Ammonia between January 1, 2024 and January 14, 2024 exceeded the 10 minute separation of plasma from cells as defined in their own written procedure. The findings included: 1. Review of the laboratory's own written policy titled Ammonia (AMM) (dated 05/09) found on page 2 under the heading Storage and Stability: "Tubes should be filled completely, mixed gently by inversion, placed on ice, centrifuged immediately for 10 minutes at an RCF of 1500G and

	analyzed within 30 minutes." Further review found under SPECIMEN REQUIREMENT: AMMONIA/KEEP ON ICE "Collect: Green Top (Sodium Heparin Anticoagulated Plasma) on ice. Testing Sample: Sodium Heparin Plasma. Handling: Specimen shall be collected by the Lab Phlebotomy group or Nursing Staff. Specimen will be transported on ice and brought to lab immediate for processing. Specimen should be centrifuged within 10 minutes of collection. Notify Tech work department for processing ASAP. Unacceptable Conditions: Hemolyzed samples are not recommended because lysed red blood cells may elevate ammonia concentration in the sample. Lipemic samples greater than 1+ (visual turbidity) should be ultracentrifuged and the analysis performed on the infranate. Stability: 30 minutes, if specimen has remained tightly capped, stored in an upright position, and centrifuged within 10 minutes of collection." 2. Review of patient test records found the laboratory tested and reported 23 patient specimens for Lactate between January 1, 2024 through January 14, 2024. Of the 23 patient results reported, 15 specimens were received in the laboratory at 10 minutes or later from collection and thus, the plasma was not removed from the cells within the time required as follows. Patient: C00125R Collected: 01/01/24 - 0021 Received: 01/01/24 - 0211 Elapsed time: 50 minutes Patient: C00202R Collected: 01/01/24 - 0540 Received: 01/01/24 - 0625 Elapsed time: 45 minutes Patient: C00309S Collected: 01/01/24 - 0305 Received: 01/01/24 - 0317 Elapsed time: 12 minutes Patient: C00628S Collected: 01/01/24 - 1144 Received: 01/01/24 - 1155 Elapsed time: 11 minutes Patient: C00816S Collected: 01 /01/24 - 1608 Received: 01/01/24 - 1626 Elapsed time: 18 minutes Patient: C00127R Collected: 01/02/24 - 0301 Received: 01/02/24 - 0314 Elapsed time: 13 minutes Patient: C00159R Collected: 01/02/24 - 0218 Received: 01/02/24 0230 Elapsed time: 12 minutes Patient: C00130R Collected: 01/03/24 - 0137 Received: 01/03/24 - 0215 Elapsed time: 43 minutes Patient: C00133R Collected: 01/04/24 - 0350 Received: 01 /04/24 - 0411 Elapsed time: 21 minutes Patient: C00874R Collected: 01/04/24 - 1355 Received: 01/04/24 - 1422 Elapsed time: 27 minutes Patient: COO394R Collected: 01 /06/24 - 0745 Received: 01/06/24 0818 Elapsed time: 33 minutes Patient: C00045R Collected: 01/07/24 - 0300 Received: 01/07/24 - 0317 Elapsed time: 17 minutes Patient: C00098R Collected: 01/07/24 - 0047 Received: 01/07/24 0234 Elapsed time: 144 minutes Patient: C00961S Collected: 01/09/24 - 1450 Received: 01/09/24 - 1504 Elapsed time: 13 minutes Patient: C01039S Collected: 01/12/24 - 1715 Received: 01 /12/24 - 1337 Elapsed time:22 minutes 3. During interview of the Compliance officer conducted September 5, 2024 at 11:14 AM, it was confirmed that patient specimens tested for Ammonia were not always removed from cells within 10 minutes of collection.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on the review of laboratory Individual Quality Control Plan (IQCP), laboratory policy, laboratory quality control (QC) records, patient test records and interviews, the laboratory failed to meet the applicable analytic system requirements to monitor and

	evaluate the overall quality of the analytc system to identify and correct problems for records reviewed in 2023 and 2024. The findings included: 1. The laboratory failed to follow its quality control plan to perform weekly external for GN ID and GP ID Cards used in the identification of gram negative and gram positive bacteria isolated from culture in microbiology for 15 of 17 weeks reviewed in January 2024 through April 2024. (See D5401 I) 2. The laboratory failed to follow its quality control plan for the testing of external QC every 31 days for three of three kit tests used in microbiology patient testing for records reviewed from May 2023 to April 2024. (See D5401 II) 3. The laboratory failed to perform and document quality control procedures for 24 of 24 months when testing patient specimens for Activated Clotting Time (ACT) using the Hemochron Whole Blood Coagulation System. (See D5445) 4. The laboratory failed to test at least two levels of Hematology quality control materials when testing 169 patient specimens for Complete Blood Counts (CBC) using the Sysmex XN-10 and XN-450 between August 11- 12, 2023. (See D5447) 5. The laboratory failed to define the acceptability criteria accurately for analytes in each lot for five of five BIO RAD quality controls used to ensure the quality of results in Chemistry and Immunology between January 1, 2024 and May 31, 2024. (See D5469) 6. The laboratory failed to ensure QC was acceptable every 8 hours of operation that prothrombin time (PT) patient testing was performed on the Sysmex CS-2500 coagulation analyzer, for records reviewed in January 2023 and February 2023. (See D5481) 7. The laboratory failed to test body fluid QC in duplicates for 40 of 40 days where patient testing occurred for records reviewed in March, November, and December 2023. (See D5543)
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 review of the laboratory Individual Quality Control Plan (IQCP) for the VITEK 2 Systems, quality control records, patient test records, and confirmed in interview, the laboratory failed to perform 15 of 17 weekly quality control for GN ID and GP ID Cards used in the identification of gram negative and gram positive bacteria isolated from culture for records reviewed in January 2024 through April 2024. The findings included: 1. Review of the laboratory IQCP, section "Quality Control Plan" for the VITEK 2 System included the following quality control frequency for the GN ID and GP ID cards, approved by the laboratory director 9/19 /2023: " ... Two levels of external controls or knowns performed with each lot /shipment and weekly thereafter" 2. Review of the microbiology form titled "Microbiology Vitek QC Log" included the following dates of QC for the GPID and the GNID: In January 2024 the GNID QC was performed and acceptable on 1/22 /2024. QC for the GPID was performed and acceptable on 1/23/2024 and 1/29/2024. During the period from 1/1/2024 and 1/23/2024, where weekly QC was not performed, 20 patients had bacterial ID's performed on the Vitek to include the following five patients: WD0007547748, WD0007548670, WD0007556582, WD0007525264, WD0007578834. In March 2024, the next acceptable QC was performed on 3/22/2024 for the GPID and GNID. During the period from 1/30/2024, seven days after the initial QC, to 3/22/2024 included 45 patients with bacterial ID's

performed on the Vitek to include the following five patients: WD0007624224, WD0007639073, WD0007644933, WD0007654346, WD0007612112. In April 2024, no weekly quality control was performed for the Vitek Bacterial GNID and GPID cards. During the period from 3/29/2024, seven days after the initial QC, to 4/30/2024 included 12 patients with bacterial ID's performed on the Vitek to include the following five patients: WD0007745508, WD0007731771, WD0007764632, WD0007764913, WD000778251. 3. In an interview on 9/5/2024 at 09:55 hours, in the conference room, the general supervisor (GS)1 confirmed that weekly QC had not been performed on the vitek for the GNID and GPID cards. II. Based on review of laboratory Individualized Quality Control Plans (IQCP), quality control (QC) records, patient test records, and confirmed in interview, the laboratory failed to follow its quality control plan for the testing of external QC every 31 days for three of three kit tests used in microbiology patient testing for records reviewed from May 2023 to April 2024. The findings included: 1.A. Review of the laboratory IQCP for the "ImmunoCard STAT Giardia/Cryptosporidium Kit Rapid", signed by the laboratory director 1/5/2024, included the following instructions under section "Quality Control Plan": "Two levels of external controls or known's [sic] performed with each lot /shipment and every 31 days thereafter." 1.B Review of the laboratory IQCP for the "Leuko EZ Vue" for stool lactoferrin testing, signed by the laboratory director on 12 /30/2015, included the following instructions under section "Quality Control Plan": "Two levels of external controls or known's [sic] performed with each lot/shipment and every 31 days thereafter." 1.C. Review of the laboratory IQCP for the MRSA Screen PBP2a, signed by the laboratory director on 02/12/2016, included the following instructions under the section "Quality Control Plan": "Two levels of external controls or known's [sic] performed with each lot/shipment and every 31 days thereafter." 2. Review of the microbiology QC forms, and patient testing, from May 2023 to April 2024 identified six months where QC intervals exceeded 31 days, and patients tested during these lapses. In May 2023, the ImmunoCard STAT Giardia /Cryptosporidium and Leuko EZ view kits QC was conducted on 5/6/2023 with the next acceptable QC performed on 6/26/2023. During the period from 6/6/2023 (31 days after the initial QC) until the next acceptable QC on 6/26/2023, the following 25 patients were tested: Date Patient Accession Test Performed 06/07/2023 23: M0036951R Stool Lactoferrin 06/07/2023 23:M0036993R Stool Lactoferrin 06/07 /2023 23:M0036951R Giardia/Cryptosporidium 06/09/2023 23:M0037393S Stool Lactoferrin 06/09/2023 23:M0037363S Giardia/Cryptosporidium 06/11/2023 23: M0037850R Stool Lactoferrin 06/11/2023 23:M0037850R Giardia/Cryptosporidium 06/12/2023 23:M0038138R Giardia/Cryptosporidium 06/13/2023 23:M0037755R Stool Lactoferrin 06/13/2023 23:M0038181S Stool Lactoferrin 06/13/2023 23: M0038195R Stool Lactoferrin 06/13/2023 23:M0038181S Giardia/Cryptosporidium 06/13/2023 23:M0038195R Giardia/Cryptosporidium 06/14/2023 23:M0038457S Stool Lactoferrin 06/14/2023 23:M0038472S Giardia/Cryptosporidium 06/17/2023 23: M0038981R Stool Lactoferrin 06/17/2023 23:M0038981R Giardia/Cryptosporidium 06/18/2023 23:M0039078S Stool Lactoferrin 06/18/2023 23:M0039107S Stool Lactoferrin 06/19/2023 23:M0039105R Giardia/Cryptosporidium 06/20/2023 23: M0039378R Stool Lactoferrin 06/20/2023 23:M0039378R Giardia/Cryptosporidium 06/22/2023 23:M0039663R Stool Lactoferrin 06/22/2023 23:M0039663R Giardia /Cryptosporidium 06/23/2023 23:M0039714R Stool Lactoferrin 06/23/2023 23: M0039891R Stool Lactoferrin 06/23/2023 23:M0039714R Giardia/Cryptosporidium 06/24/2023 23:M0040081R Stool Lactoferrin 06/24/2023 23:M0040081R Giardia /Cryptosporidium In July 2023, the Leuko EZ Vue QC was performed on 7/5/2023 with the next acceptable QC performed on 8/7/2023. During the period from 8/5/2023 (31 days after the initial QC) until the next acceptable QC on 8/7/2023, the following patient was tested. Date Patient Accession Test Performed 08/06/2023 23:

	M0047725R Stool Lactoferrin In August 2023, the ImmunoCard STAT Giardia /Cryptosporidium and Leuko EZ view kits QC was conducted on 8/7/2023 with the next acceptable QC performed on 9/23/2023. During the period from 9/7/2023 (31 days after the initial QC) until the next acceptable QC on 9/23/2023, the following 10 patients were tested: Date Patient Accession Test Performed 09/07/2023 23: M0054080S Stool Lactoferrin 09/08/2023 23:M0054423R Stool Lactoferrin 09/13 /2023 23:M0055402R Giardia/Cryptosporidium 09/14/2023 23:M0055569R Stool Lactoferrin 09/14/2023 23:M0055629S Stool Lactoferrin 09/14/2023 23:M0055569R Giardia/Cryptosporidium 09/15/2023 23:M0055716R Stool Lactoferrin 09/15/2023 23:M0055716R Giardia/Cryptosporidium 09/16/2023 23:M0055905R Stool Lactoferrin 09/17/2023 23:M0056155S Stool Lactoferrin In September 2023 the ImmunoCard STAT Giardia/Cryptosporidium QC was conducted on 9/23/2023 with the next acceptable QC performed on 12/16/2023. During the period from 10/24/2023 (31 days after the initial QC) until the next acceptable QC on 12/16/2023, the following 5 patients were tested. Date Patient Accession Test Performed 12/04/2023 23:M0069641S Giardia/Cryptosporidium 12/06/2023 23:M0071172R Giardia /Cryptosporidium 12/11/2023 23:M0072036R Giardia/Cryptosporidium 12/11/2023 23:M0072211R Giardia/Cryptosporidium 12/13/2023 23:M0072547R Giardia /Cryptosporidium In October 2023, the Leuko View kit QC was conducted on 10/06 /2023 with the next acceptable QC performed on 11/16/2024. During the period from 11/06/2023 (31 days after the initial QC) until the next acceptable QC on 11/16/2024, the following four patients were tested: Date Patient Accession Test Performed 11/07 /2023 23:M0064159S Stool Lactoferrin 11/10/2023 23:M0066059R Stool Lactoferrin 11/12/2023 23:M0066350R Stool Lactoferrin 11/15/2023 23:M0067191S Stool Lactoferrin In February 2024 the ImmunoCard STAT Giardia/Cryptosporidium and Leuko EZ, and PBP2 MRSA QC was conducted on 2/03/2024 with the next acceptable QC performed on 03/15/2024. During the period from 03/05/2024 (31 days after the initial QC) until the next acceptable QC on 03/15/2024, the following 11 patients were tested: Date Patient Accession Test Performed 03/08/2024 24: M0012730R MRSA PBP2a 03/10/2024 24:M0013546R Stool Lactoferrin 03/10/2024 24:M0013546R Giardia/Cryptosporidium 03/11/2024 24:M0013641S Stool Lactoferrin 03/11/2024 24:M0013711R Stool Lactoferrin 03/11/2024 24:M0013727R Stool Lactoferrin 03/11/2024 24:M0013711R Giardia/Cryptosporidium 03/12/2024 24:M0013884R Stool Lactoferrin 03/12/2024 24:M0014032S Stool Lactoferrin 03/13 /2024 24:M0014077R Stool Lactoferrin 03/13/2024 24:M0014156R Giardia /Cryptosporidium 3. In an interview on 9/5/2024 at 15:25, in microbiology, the general supervisor (GS)1 confirmed that monthly QC had not been performed on a monthly, 31-day, cycle and patient testing had occurred when QC exceeded the 31 days.
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 policy, patient transfusion records, provider comments, and confirmed in interview, the laboratory failed to include instructions, to the laboratory blood bank, when adult patients were identified by the provider to have sickle cell disease, for one of one patient reviewed, and transfused, in 2023. The findings included: 1. Review of the laboratory procedure "Administration of Blood and Blood Components", section "C. Orders" stated the following: "1. A LIP order is required to initiate any blood or blood component transfusion and will indicate conditions that need special handling; the blood bank will prepare the product appropriately to the clinical indication." 2. Review of patient transfusion records included the following patient, order, and comment entered by the provider: 2/1/2023 Patient WR18444296 Order products: Red Blood Cells / 6 / -4 Comments: Sickle Cell Disease (Y/N) Y RBC Units W036522111438 and W03523006053 crossmatched and transfused to the patient 2/1/2023. 6/10/2023 Patient WR18444296 Order products: Red Blood Cells / 2 Comments: Sickle Cell Disease (Y/N) Y RBC Units W036523043556 and W036523045196 were crossmatched and transfused to the patient 6/10/2023. 11/25/2023 Patient WR18444296 Order products: Red Blood Cells / 2 Comments: Sickle Cell Disease (Y/N) Y RBC units W036523087331 and W036523100512 were crossmatched and transfused to the patient 11/25/2023. 3. Review of the laboratory procedure "Administration of Blood and Blood Components", section "D. Special Needs", subsection "8. Hemoglobin S" failed to addressed child and adult populations with known sickle cell disease, identified by the provider. 4. In an interview on 9/5/2024 at 14:10 hours, in the conference room, technical supervisor (TS)4 confirmed the laboratory policy for the administration of blood products did not include an assessment for adults with known sickle cell disease. Key: LIP: Licensed independent practitioner
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on surveyor observation, laboratory policy, and confirmed in interview, the laboratory failed to label four of four coplin jars with stain used for the differentiation of morphological cell types in peripheral blood and bome marrow observed on 9/6 /2024. The findings included: 1. On 9/6/2024 surveyor observed four unlabeled coplin jars containing four different colored solutions; a light blue, red, dark blue, and blue. Surveyor asked about the contents and testing personnel (TP) 6 indicated it was the

	Easy III staining for differential, changed weekly, the fourth coplin jar was Deionized water (blue in color). The primary containers for the stain were located on the shelf above the staining area and included the following information: Easy III, Fixative: Lot 34972, exp 9/15/2025 (light blue in color) Easy III, Solution I: Lot 32411, exp 1/25 /2025 (red in color) Easy III, Solution II: Lot 33363, exp 5/9/2025 (dark blue in color) 2. Review of the laboratory policy titled "Easy III Step Stain" did not include instructions on the labeling the coplin jars to include the identity of the substance and storage requirements, the stains preparation and expiration dates. 3. In an interview on 9/6/2024 at 09:35 hours, in the laboratory, TP6 confirmed that the coplin jars for the aliquot of the Easy III step stain solutions were not labeled stating they used to have a way to label them, but they didn't anymore.
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: Review of the Individualized Quality Control Policy (IQCP) for Activated Clotting Time (ACT), quality control (QC) records and interview of facility personnel found the laboratory failed to perform and document quality control procedures for 24 of 24 months when testing patient specimens for ACT using the Hemochron Whole Blood Coagulation System. The findings included: 1. Review of the laboratory's IQCP found on page 2 of 6 under the heading Summary of In-house Data: "Current QC: 2 levels of liquid controls are processed with each new lot/ new shipment of reagent tubes as recommended by the manufacturer and every 31 days thereafter. Electronic control is run daily in Cath lab or prior to processing each patient sample in ICU (at least every 8 hours during testing). All QC is logged on manual log sheet and forwarded to the POCC for monthly review." 2. Review of the Hemochron Response Tracking Charts for the two analyzers between August 2022 through May 2024 found: Serial Number HR0863 (previously located in ICU): Review of 10 months of tracking charts between August 2022 and May 2023 (when it was moved from the ICU to the CATH lab) found no documentation of quality control results performed at least once every 31 days. Continued review of tracking charts found that this analyzer was used in the CATH lab between October 2023 and May 2024. There was no documentation of quality control results tested at least once every 31 days found on 8 of 8 tracking charts. Serial number HR4244: Review of 14 months of tracking charts between August 2022 and September 2023 (removed from service) found no documentation of quality control results. 3. Review of patient test records found one of five patients was tested for ACT between November 17, 2022 and November 5, 2023 without quality control procedures being performed. 4. During interview of the Point of Care Coordinator conducted September 4, 2024 at 2:38 PM, she confirmed that the laboratory did not perform and document quality control procedures at least once every 31 days as defined in their own IQCP procedure dated December 14, 2016.

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 upon review of the Laboratory's written policies and procedures, quality control records, patient test records and interview of facility personnel, the laboratory failed to test at least two levels of Hematology quality control materials when testing 169 patient specimens for Complete Blood Counts (CBC) using the Sysmex XN-10 and XN-450 between August 11- 12, 2023. The findings included: 1. Review of the laboratory's written policy titled CBC: Sysmex XN-10 (dated 11/1/2022) found on page 9 of 21 under the heading QUALITY CONTROL: " quality control is performed in order to monitor an analyzer's performance over time. XN CHECK is the material used to monitor the performance of the XN-Series analyzer. Quality control should be run in accordance with regulatory agency requirements. XN control levels: 3 will be run on the 1st shift." Review of the laboratory's written policy titled CBC: Sysmex XN-450 (dated 11/1/2022) found on page 9 of 21 under the heading QUALITY CONTROL: " quality control is performed in order to monitor an analyzer's performance over time. XN CHECK is the material used to monitor the performance of the XN-Series analyzer. Quality control should be run in accordance with regulatory agency requirements. XN control levels: 3 will be run on the night shift." 2. Review of the Sysmex Insight quality control records for XN CHECK lot 3198 (used between July 19, 2023 and September 6, 2023) found no quality controls tested between August 11-12, 2023 on the XN-450 or the XN-10. 3. Review of Lab Specimen logs for August 11-12, 2023 found 169 patients tested . (See CBC Logs). 4. During interview of the Laboratory Administrative Director conducted September 6, 2024 at 10:22 AM, she confirmed there were no quality control results available for review for August 11-12, 2024 and provided a list of patients tested.
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 review of policies and procedures, the BIO-RAD quality control instructions for use, quality control records, and interview with facility personnel, the laboratory failed to define the acceptability criteria accurately for analytes in each lot for 5 of 5 quality controls used to ensure the quality of results in Chemistry and Immunology between January 1, 2024 and May 31, 2024. The findings included: 1. Review of policy Gen 900 Quality Management program found on page 8 of 13 under the heading Moderate and Highly Complexity Test Methods QC (Non-Waved Tests): "Two levels of controls must be verified as acceptable within +/- 2SD." 2. Based on review of the Bio-Rad instructions for use, the instructions stated: "Liquid control is intended for use as an assayed quality control material to monitor the precision of laboratory testing procedures for the analytes listed in this package insert." And "ASSIGNMENT OF VALUES - The mean and corresponding plus/minus 3SD ranges in the Assignment of Values Data Charts (available separately) were derived from replicate analyses and are specific for this lot of product." 2. Based on review of quality control records, the laboratory used the following BIO-RAD controls to ensure the quality of results between January 1 and May 31, 2024 and had calculated the acceptable limits defined as 2 standard deviation (SD) for the following assays as follows: Liquichek Spinal Fluid Control Levels 1 and 2 lot 56530 expiration 2024-09-30 Glucose Level 1 Mean: 60.1 Low limit of acceptability: 49.5 High Limit of acceptability: 70.7 Liquichek Immunoassay Plus Control lot 85340 expiration 2024-11-30 Free T4 Level 1 Mean: 0.810 Low limit of acceptability: 0.67 High Limit of acceptability: 0.95 Liquichek Ethanol/ Ammonia lot 54390 Expiration 2024-10-31 Ammonia Level 1 Mean: 81.2 Low limit of acceptability: 62.65 High Limit of acceptability: 99.75 Liquichek Cardiac Markers Plus Control lot 67690 Expiration 2025-08-31 Troponin I Level 1 Mean: 34.3 Low limit of acceptability: 15.34 High Limit of acceptability: 53.26 Liquichek Pediatric Control lot 74900 expiration 2025-03-31 Bilirubin (Direct) Level 2 Mean: 5.37 Low limit of acceptability: 4.28 High Limit of acceptability: 6.46 The formula used by the laboratory results in an aceptable range of +/- 6 SD. 3. Based on review of the Bio-Rad controls Assignment of Values charts, the 2 SD acceptable limits should have been calculated as follows: Liquichek Spinal Fluid Control Levels 1 and 2 lot 56530 expiration 2024-09-30 Glucose Level 1 Mean: 60.1 Low limit of acceptability: 56.5 High Limit of acceptability: 63.7 Liquichek Immunoassay Plus Control lot 85340 expiration 2024-11-30 Free T4 Mean: 0.810 Low limit of acceptability: 0.71 High Limit of acceptability: 0.91 Liquichek Ethanol/ Ammonia lot 54390 Expiration 2024-10-31 Ammonia Level 1 Mean: 81.2 Low limit of acceptability: 68.86 High Limit of acceptability: 93.54 Liquichek Cardiac Markers Plus Control lot 67690 Expiration 2025-08-31 Troponin I Level 1 Mean: 34.3 Low limit of acceptability: 15.34 High Limit of acceptability: 53.26 Liquichek Pediatric Control lot 74900 expiration 2025-03-31 Bilirubin (Direct) Level 2 Mean: 5.37 Low limit of acceptability:5.01 High Limit of acceptability: 5.37 4. During interview of the Core Lab Lead Tech conducted September 5, 2024 at 2:10 PM, she confirmed that she calculated the standard deviation by subtracting the Mean value from the high range (As listed on the chart)to obtain her 1 SD value. She then entered the Mean and 1 SD into the analyzer to calculate the 2 SD range for acceptability.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: Based on review of laboratory policy, laboratory quality control records, and confirmed in interview, the laboratory failed to ensure QC was acceptable every 8 hours of operation that prothrombin time (PT) patient testing was performed on the Sysmex CS-2500 coagulation analyzer, for records reviewed in January 2023 and February 2023. The findings included: 1. Review of the laboratory policy titled "Coag Quality Management (QM) Program", section "QC/Patient Data Review" stated the following: "1. QC Results: Shift review of routine controls is done by a technologist at least once every 6 to 8 hours. 2 levels of control must be within acceptable limits prior to reporting patient data." 2. Review of laboratory Sysmex CS-2500 coagulation analyzer QC records for January and February 2023 included the following nine failed PT QC events and 25 patients tested when quality control was out of the laboratory's established acceptability limits: Control Test Lot Number Expiration [Acceptability Criteria] Citrol 3 PT Lot 556561 Exp 2/1/2025 [42.5 - 48.5] Day and Time Result; Next acceptable QC 01/06/2023 at 18:40 49.0 sec; QC not within acceptability limits until 01/07/2023 at 13:25 01/07/2023 at 00:47 49.1 sec; QC not within acceptability limits until 01/07/2023 at 13:25 01/07/2023 at 12:10 49.9 sec; QC not within acceptability limits until 01/07/2023 at 13:25 01/07/2023 at 19:32 49.2 sec; QC not within acceptability limits until 01/08/2023 at 01:01 01/21/2023 at 12:14 48.7 sec; QC not within acceptability limits until 01/21/2023 at 18:21 The following 18 patients had PT testing performed in the above time periods where QC was outside of acceptable limits: Patient WD# PT Result Date Time Verified WD0006814909 11.9 sec 01/06 /2023, 19:37 WD0006814842 10.8 sec 01/06/2023, 19:38 WD0006783328 11.4 sec 01 /06/2023, 21:47 WD0006815138 10.9 sec 01/06/2024, 23:42 WD0006815096 12.9 sec 01/06/2023, 23:19 WD0006815120 10.1 sec 01/07/2023, 3:11 WD0006815179 11.4 sec 01/07/2023, 2:54 WD0006815310 11.8 sec 01/07/2023, 7:27 WD0006815286 11.8 sec 01/07/2023, 7:29 WD0006815278 11.5 sec 01/07/2023, 7: 26 WD0006815351 10.0 sec 01/07/2023, 7:29 WD0006815617 10.5 sec 01/07/2023, 13:11 WD0006815922 11.1 sec 01/07/2023, 20:13 WD0006815948 10.6 sec 01/07 /2023, 21:11 WD0006816086 11.3 sec 01/07/2023, 23:00 WD0006844435 11.3 sec 01 /21/2023, 15:30 WD0006844500 14.0 sec 01/21/2023, 16:44 WD0006844542 11.3 sec 01/21/2023, 17:37 Control Test Lot Number Expiration [Acceptability Criteria] Citrol 3 PT Lot 556561, Exp 2/1/2025 [42.5 - 48.5] Day, Time: Result 02/18/2023 at 00:52 49.1 sec; QC not within acceptability limits until 02/18/2023 at 06:19 02/18 /2023 at 12:23 48.8 sec; QC not within acceptability limits until 02/18/2023 at 18:36 02/19/2023 at 01:08 50.7 sec; reran on 2/19/2023 at 01:18 02/19/2023 at 01:18 50.7 sec; QC not within acceptability limits until 02/19/2023 at 01:35 The following 7 patients had PT testing performed in the above time periods where QC was outside of acceptable limits: Patient WD# PT Result Date, Time Verified WD0006901235 11.3 sec 02/18/2023, 01:04 WD0006901201 11.7 sec 02/18/2023, 02:04 WD0006901250 11.7 sec 02/18/2023, 03:12 WD0006901607 11.4 sec 02/18/2023, 13:30 WD0006901664 10.8 sec 02/18/2023, 13:51 WD0006901847 9.5 sec 02/18/2023, 18: 00 WD0006902100 10.5 sec 02/19/2023, 01:18 3. In an interview on 9/6/2024 at 10: 00 hours, in the conference room, technical supervisor (TS) 4 confirmed quality control had been outside of acceptable limits on the Sysmex CS-2500 for prothrombin time testing.
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 review of laboratory policy, laboratory body fluid cell count quality control and patient worksheets, and confirmed in interview, the laboratory failed to test body fluid QC in duplicates for 40 of 40 days where patient testing occurred for records reviewed in March, November, and December 2023. The findings included: 1. Review of the laboratory policy titled "Body Fluids - Cell Count and Differential", section "Quality Control" stated the following: "1. Charge both sides of the hemocytometer counting chamber and count both sides. 2. Count the number of red or white cells in all nine primary squares (i.e., the entire area of one side of the counting chamber). 3. The counts must agree within 10% to be considered a valid count." 2. Review of the laboratory worksheet titled "Shift Worksheet Body Fluid/CSF Cell Count & Diff" included a space at the top of the worksheet for documentation of QC white blood cell (WBC) and red blood cell (RBC) control results. Worksheets reviewed for March, November, and December 2023 only included one WBC and RBC count to determine QC acceptability each day of patient testing to include the following 54 patients with body fluid cell counts performed: Day of Test - Patient Accession March 2023: 24 Patients 03/01/2023 - 0301:BF00004R 03/02/2023 - 0302: BF00009R 03/03/2023 - 0303:BF00009S 03/05/2023 - 0305:BF00002S 03/09/2023 - 0308:BF00003R 03/10/2023 - 0310:BF00009S 03/11/2023 - 0311:BF00006R, 0311: BF00007R 03/13/2023 - 0313:BF00004R, 0311:BF00014R, 0311:BF00015R 03/14 /2023 - 0314:BF00002S, 0314:BF00003R, 0314:BF00006R 03/18/2023 - 0318: BF00003R 03/21/2023 - 0321:BF00015S 03/23/2023 - 0323:BF00001S, 0323: BF00015R 03/24/2023 - 0324:BF00001S, 0324:BF00002R 03/27/2023 - 0326: BF00010R, 0327:BF00002S, 0327:BF00008R 03/31/2023 - 0331:BF00012R November 2023: 14 Patients 11/07/2023 - 1107:BF00007S 11/10/2023 - 1110: BF00005R 11/14/2023 - no patient identifier 11/15/2023 - 1115:BF00008R 11/16 /2023 - 1116:BF00003R 11/18/2023 - 1117:BF00008R 11/21/2023 - 1121:BF00001R, 1121:BF00009R 11/22/2023 - 1121:BF00010S 11/27/2023 - 1127:BF00009R 11/28 /2023 - 1128:BF00007S 11/29/2023 - 1129:BF00008R 11/30/2023 - 1130:BF00006S, 1201:BF00011S December: 16 Patients 12/02/2023 - 1201:BF00013R 12/03/2023 - 1203:BF00001R 12/04/2023 - 1204:BF00008R 12/05/2023 - 1205:BF00004S 12/06 /2023 - 1206:BF00007R, 1206:BF00009R 12/09/2023 - 1209:BF00001S 12/13/2023 - 1213:BF00010R 12/14/2023 - 1214:BF00006R, 1214:BF00007S 12/19/2023 - 1219: BF00001R 12/20/2023 - 1220:BF00006S 12/26/2023 - 1226:BF00003S 12/28/2023 - 1228:BF00002S, 1228:BF00003R 12/29/2023 - 1229:BF00002R 3. In an interview on 9/6/2024 at 09:32 hours, in the laboratory, testing personnel (TP)6 stated body fluid cell count QC was only counted once on once side of the hemocytometer.
D5555	IMMUNOHEMATOLOGY CFR(s): 493.1271(c)(f) (c) Blood and blood products storage. Blood and Blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section.

	This STANDARD is not met as evidenced by: Based on review of laboratory policy, blood bank temperature charts, temperature wheels for the continuous monitoring system, and confirmed in interview, the laboratory failed to perform the alarm activation check in 2023 for the one of one blood bank refrigerator used in the storage of red blood cells (RBC) at 1-6 (degrees) Celsius (C). The findings include: 1. Review of the laboratory policy titled "Refrigerator Maintenance/Quality Control (QC), section "Annually" included the following instructions: "Perform Manual Check of Temperature Activation at least annually, or if the high and low alarm checks show a problem. Low Alarm Activation (1.5(degrees) C) 1. Hill an 8 oz glass half full of chilled water at 4C. 2. Crush ice to 1 /8 inch particles in a separate container. 3. Remove the sensors from the upper solution bottle. 4. Slowly add crushed ice about one teaspoon every 15 to 25 seconds to provide a temperature drop of 0.5C/min. 6. Log the low alarm activation temperature. High Alarm Activation 1. Slowly add warm water to the ice slurry at a rate to provide a temperature rise of 0.5C/min., constantly stirring the thermometers. 2. Log the high alarm activation temperature." 2. Review of the blood bank form titled "Blood Bank Refrigerators/Blood Supply Inventory" and the temperature wheels for the continuous monitoring system for January to December 2023, included the following days where an alarm check was documented but a temperature change was not detected through the continuous monitoring system: January 2023: Quarterly: Alarm Test Performed: Date: 1/2/2023 Review of the continuous monitoring wheel chart from 12/30/2022 to 1/6/2023 did not include record of the temperature change. April 2023: Quarterly: Alarm Test Performed: Date: 4/3/2023 Review of the continuous monitoring wheel chart from 3/31/2023 to 4/7/2023 did not include record of the temperature change. July 2023: Quarterly: Alarm Test Performed: Date: 7/3 /2023 Review of the continuous monitoring wheel chart from 6/30/2023 to 7/7/2023 did not include record of the temperature change. October 2023: Quarterly: Alarm Test Performed: Date: 10/2/2023 Review of the continuous monitoring wheel chart from 09/29/2023 to 10/6/2023 did not include record of the temperature change. 3. In an interview on 9/5/2024 at 12:15 hours, in the conference room, technical supervisor (TS) 4 stated that laboratory practice was to perform the alarm activation check quarterly, however, the laboratory did not perform the alarm activation check in 2023.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based upon review of policies and procedures, manufacturer's instructions, quality control records, patient test records, and interview of facility personnel, the laboratory director failed to provide overall management and direction for records reviewed in 2023 and 2024. The findings included: 1. The laboratory director failed to ensure that testing personnel tested patient specimens for Lactate as specified by the manufacturer to obtain accurate and reliable results. (See D6014) 2. The laboratory director failed to establish and maintain a quality control program for the specialties of microbiology, hematology, and chemistry for records reviewed in 2023 and 2024. (See D6020) 3. The laboratory director failed to ensure that pertinent information on the limitation for the identification Escherichia coli results on the Verigene Gram-Negative Blood Culture Nucleic Acid Test (BC-GN) was included on the patient test results for 27 of

	27 patients reviewed from December 1, 2022 to April 30, 2023. (See D6026) 4. The laboratory director failed to ensure 8 of 19 testing personnel performing the Rupture of Membrane (ROM) had documentation of minimum education and initial training for performing moderate complexity testing in Immunology. (see D6065 and D6066)
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based upon review of manufacturer's instructions, patient test records and interview of facility personnel, the laboratory director failed to ensure that testing personnel tested patient specimens for Lactate as specified by the manufacturer to obtain accurate and reliable results. (See D5311)
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based upon review of policies and procedure, manufacturer's instructions, quality control records, patient test records and interview of facility personnel found the laboratory director failed to establish and maintain a quality control program for the specialties of microbiology, hematology, and chemistry for records reviewed in 2023 and 2024. 1. The laboratory failed to perform 15 of 17 weekly quality control for GN ID and GP ID Cards used in the identification of gram negative and gram positive bacteria isolated from culture for records reviewed in January 2024 through April 2024. (See D5401 I) 2. The laboratory failed to follow its quality control plan for the testing of external QC every 31 days for three of three kit tests used in microbiology patient testing for records reviewed from May 2023 to April 2024. (See D5401 II) 3. The laboratory failed to perform and document quality control procedures for 24 of 24 months when testing patient specimens for ACT using the Hemochron Whole Blood Coagulation System. (See D5445) 4. the laboratory failed to test at least two levels of Hematology quality control materials when testing 169 patient specimens for Complete Blood Counts (CBC) using the Sysmex XN-10 and XN-450 between August 11 - 1, 2023. (See D5447) 5. The laboratory failed to define the acceptability criteria accurately for analytes in each lot for 5 of 5 quality controls used to ensure the quality of results in Chemistry and Immunology between January 1, 2024 and May 31, 2024. (See D5469) 6. The laboratory failed to ensure QC was acceptable every 8

	hours of operation that prothrombin time (PT) patient testing was performed on the Sysmex CS-2500 coagulation analyzer, for records reviewed in January 2023 and February 2023. (See D5481) 7. The laboratory failed to test body fluid QC in duplicates for 40 of 40 days where patient testing occurred for records reviewed in March, November, and December 2023. (See D5543)
D6026	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(8) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(8) Ensure that reports of test results include pertinent information required for interpretation. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, patient final reports, and interview, the laboratory director failed to ensure that pertinent information on the limitation for the identification Escherichia coli results on the Verigene Gram-Negative Blood Culture Nucleic Acid Test (BC-GN) was included on the patient test results for 27 of 27 patients reviewed from December 1, 2022 to April 30, 2023. The findings included: 1. Review of the Luminex "Verigene Gram-Negative Blood Culture Nucleic Acid Test (BC-GN) Package Insert" included the following foot note for Escherichia coli as one of the Bacterial Genera and Species the BC-GN detects and identifies: "BC-GN will not distinguish Escherichia coli from Shigella spp. (S. dysenteria, S. flexneri, S. boydii, and S. sonnei)." 2. Review of patient reports did not include the statement for patients where E.coli was identified from positive blood cultures on the Luminex Verigene, to include the following 27 patients: Date of Testing Patient WD# 12/08/2022 WD0006757678 12/13/2022 WD0006766661 12/13/2022 WD0006769947 12/17/2022 WD0006776702 12/23/2022 WD0006787196 12/28 /2022 WD0006794655 12/29/2022 WD0006794655 01/01/2023 WD0006802144 01 /16/2023 WD0006831531 01/18/2023 WD0006836795 01/28/2023 WD0006848345 01/31/2023 WD0006861090 02/01/2023 WD0006862387 02/02/2023 WD0006867212 02/10/2023 WD0006886097 02/16/2023 WD0006894117 02/22 /2023 WD0006906838 02/26/2023 WD0006914808 03/02/2023 WD0006925077 03 /04/2023 WD0006931190 03/14/2023 WD0006947709 03/22/2023 WD0006967855 03/24/2023 WD0006969364 03/23/2023 WD0006967947 03/20/2023 WD0006981781 04/04/2023 WD0006992200 04/05/2023 WD0006994511 3. In an interview on 9/4/2024 at 16:15 hours, in the conference room, general supervisor (GS) 3 confirmed the footnote was not included on patient reports for the interpretation the identification of E.coli on the Verigene Gram-Negative Blood Culture Nucleic Acid test.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel

	have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on review of the CMS Report 209 Laboratory Personnel Report, personnel records and interview of facility personnel the laboratory director failed to ensure eight of nineteen testing personnel performing the Rupture of Membrane (ROM) had documentation of minimum education and initial training for performing moderate complexity testing in Immunology. (see D 6065 and D 6066)
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on review of the CMS Report 209 Laboratory Personnel Report, personnel records and interview of facility personnel eight of nineteen testing personnel performing the Rupture of Membrane (ROM) failed to have documentation of education and initial training for performing moderate complexity testing in Immunology. (see D 6065 and D 6066)
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on review of the CMS Report 209 Laboratory Personnel Report, personnel records and interview of facility personnel seven of nineteen testing personnel performing the Rupture of Membrane (ROM) + procedure failed to have documentation of minimum education for performing moderate complexity testing in Immunology. The findings included: 1. Review of the CMS report 209 Laboratory Personnel Report identified 63 testing personnel. 2. Review of personnel records found no documentation of education to ensure seven of nineteen testing personnel performing the ROM+ procedure met the minimum education requirements for performing moderate complexity testing: Testing person 42 (hire date 06/01/1998)

	had no documentation of education available for review. The laboratory provided a Quick Confirm License Report as documentation of education. Testing person 43 (hire date 05/21/2019) had no documentation of education available for review. The laboratory provided a Quick Confirm License Report as documentation of education. Testing person 44 (hire date 06/14/1999) had no documentation of education available for review. The laboratory provided a Quick Confirm License Report as documentation of education. Testing person 49 (hire date 06/01/1987) had no documentation of education available for review. The laboratory provided a Quick Confirm License Report as documentation of education. Testing person 50 (hire date 08/13/2007) had no documentation of education available for review. The laboratory provided a Quick Confirm License Report as documentation of education. Testing person 51 (hire date 01/22/2024) had no documentation of education available for review. The laboratory provided a Quick Confirm License Report as documentation of education. Testing person 60 (hire date 01/24/2022) had no documentation of education available for review. The laboratory provided a Quick Confirm License Report as documentation of education. 3. During interview of the Administrative lab director conducted September 4, 2024 at 2:01 PM, she confirmed that education records were not available for review for the seven testing personnel.
D6066	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(4)(ii) Have documentation of training appropriate for the testing performed prior to analyzing patient specimens. This STANDARD is not met as evidenced by: Based on review of the CMS Report 209 Laboratory Personnel Report, personnel records and interview of facility personnel one of nineteen testing personnel performing the Rupture of Membrane (ROM) + procedure failed to have documentation of initial training for performing moderate complexity testing in Immunology. The findings included: 1. Review of the CMS report 209 Laboratory Personnel Report identified 63testing personnel. 2. Review of personnel records found no documentation of training for testing person 58 (hire date 03/21/2022). 3. During interview of the Administrative lab director conducted September 4, 2024 at 2:01 PM, she confirmed that initial training records were not available for review for testing person 58.
D6085	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3) The laboratory director must ensure that the test methodologies selected have the capability of providing the quality of results required for patient care. This STANDARD is not met as evidenced by: Based on review of laboratory blood bank transfusion records, provider comments, laboratory policy, and confirmed in interview, the laboratory director failed to ensure a protocol for special components for a patient with sickle cell disease, identified and communicated by the provider, that was transfused six of six RBC components in 2023. Refer to D5403.