Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0055388	09/15/2023
Name of Provider or Supplier	**Street Address, City, State**	
Odessa Texas Hospital Company, Llc	520 East 6th Street, Odessa, 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	The laboratory was surveyed and failed to meet the following conditions of the CLIA regulations found at CFR 42 493.1 through 493.1780 during an onsite validation inspection: 493.1240 Condition: Preanalytic systems; 493.1250 Condition: Analytic systems; 493.1441 Condition: Laboratories performing high complexity testing; laboratory director; 493.1487 Condition: Laboratories performing high complexity testing; testing personnel.
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, Quality Control (QC) records, and confirmed in interview, the laboratory failed to retain all package inserts for infectious diseases QC material tested on the Roche COBAS e801 analyzer for 11 of 11 sets of lot numbers in December 2022 and January through June 2023. Findings included: 1. Review of the laboratory's policy titled "Records & Specimen Retention Policy" revealed: "Procedure ... B. Laboratory Record Retention ... TYPE OF RECORD RETENTION PERIOD Quality Control Records 2 Years" 2. Review of infectious diseases QC records tested on the Roche COBAS e801 analyzer in December 2022 and January through June 2023 revealed the laboratory failed to retain the package insert for the following analytes' QC lots: Analyte: HBc Ab IGM; lot# 582186 Analyte: HBs Ab Total; lot# 583920 Analyte: HIV AG-AB; lot# 608350 Analyte: HBc Ab, Total; lot# 574636 Analyte: HCV Ab, Total; lot# 613466 Analyte: Syphilis Ab, Total; lot# 582585 Analyte: Syphilis Ab, Total; lot# 610594 Analyte: Syphilis Ab, Total; lot# 582583 Analyte: Syphilis Ab, Total; lot# 610593 Analyte: HAV Ab, IgM; lot# 612520 Analyte: HAV Ab, IgM; lot# 661373 The laboratory was asked to provide the

	above package inserts, and none were provided. The laboratory did not establish their own QC ranges and used the QC ranges from the manufacture's packge insert for acceptability. Without the package inserts QC ranges could not be verified. 3. During an interview on 09/14/2023 at 10:40 am, the General Supervisor- 4 (as designated on the CMS 209 form) confirmed the laboratory failed to retain all infectious diseases QC material package inserts tested on the Roche COBAS e801 analyzer. Word Key: HBc Ab- Hepatitis B core antibody IgM- Immunoglobulin M HBs AB- Hepatitis B surface antibody HIV AG-AB- Human Immunodeficiency Virus Antigen-Antibody HCV Ab- Hepatitis C antibody HAV Ab- Hepatitis A antibody CMS- Center for Medicare & Medicaid Services
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 a review of the laboratory's policies, the laboratory's records, and staff interview, the laboratory failed to have documentation of performing twice annual accuracy assessments in 2022 for one non-regulated analyte tested on the Siemens Vista chemistry analyzer. Findings include: 1. A review laboratory's policy titled 'Proficiency Testing Policy' revealed the following: "Proficiency testing is a useful tool for the verification of the reliability of methodologies, technical skills, and reagent systems employed for patient sample analysis. Materials for proficiency testing are currently obtained from the College of American (CAP) and American Proficiency Institute (API) and consist of the number of samples per survey and number of surveys per year as required by CLIA '88 guidelines. The current CAP activity Menu reflects the testing performed at ORMC laboratory. (There are no tests at ORMC at this time that do not have PT offered by CAP or API)" 2. A review of the laboratory's proficiency testing records revealed the laboratory failed to have documentation of the analyte Ammonia being tested in any of the 3 API chemistry events in 2022. 3. Further review of the laboratory's records revealed the laboratory failed to have documentation of performing twice annual accuracy assessments for Ammonia in 2022. 4. A review of the laboratory's test records revealed the laboratory performed a total of 549 Ammonia tests in 2022. 5. An interview with technical consultant #1 for chemistry (as indicated on the CMS 209 form) on 9/12/23 at 11:30 a. m. in the laboratory, after review of the records, confirmed the above findings.
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 upon review of Cobas manufacturer's instructions, patient test records,

	laboratory policies and procedures and interview of facility personnel, the laboratory failed to follow the manufacturer's instructions for the storage, processing and analysis of patient samples tested for Lactate, Ammonia, Homocysteine, Progesterone, Human Chorionic Gonadotropin (HCG) and Estradiol. (See D5311)
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 direct observation, review of patient final reports, and confirmed in staff interview, the laboratory failed to ensure specimen collection time was correctly entered into the laboratory information system (LIS) for 16 of 36 patients prior to testing in May and June 2023. Findings Included: 1. During a tour of the facility on 09 /13/2023 at 01:25 p.m., the surveyor observed 2 Radiometer ABL90 Flex Analyzers in patient test areas for blood gas analysis. East Campus Serial Number (SN): 092R0427N0036 West Campus SN: 092R0427N0033 2. Review of blood gas patient final reports for May and June 2023 revealed the following information: May 2023 a. 05/15/2023 Patient Account Number (ACCT): OD0006770671 Collection Time: 05/15 /2023 10:00 a.m. Received Time: 05/15/2023 9:59 a.m. The received time was documented prior to the collection time. The laboratory failed to document the correct collection time into the LIS. b. 05/15/2023 Patient Account Number (ACCT): OD0006771638 Collection Time: 05/15/2023 2:05 p.m. Received Time: 05/15/2023 2: 04 p.m. The received time was documented prior to the collection time. The laboratory failed to document the correct collection time into the LIS. c. 05/15/2023 Patient Account Number (ACCT): OD0006770705 Collection Time: 05/15/2023 2:30 p.m. Received Time: 05/15/2023 2:29 p.m. The received time was documented prior to the collection time. The laboratory failed to document the correct collection time into the LIS. d. 05/18/2023 Patient Account Number (ACCT): OD0006773493 Collection Time: 05/18/2023 12:11 p.m. Received Time: 05/18/2023 12:10 p.m. The received time was documented prior to the collection time. The laboratory failed to document the correct collection time into the LIS. e. 05/30/2023 Patient Account Number (ACCT): OD0006794812 Collection Time: 05/30/2023 9:45 a.m. Received Time: 05/30/2023 9:44 a.m. The received time was documented prior to the collection time. The laboratory failed to document the correct collection time into the LIS. June 2023 f. 06/04/2023 Patient Account Number (ACCT): OD0006803886 Collection Time: 06/04/2023 5:02 p.m. Received Time: 06/04/2023 5:01 p.m. The received time was documented prior to the collection time. The laboratory failed to document the correct collection time into the LIS. g. 06/06/2023 Patient Account Number (ACCT):

	OD0006782007 Collection Time: 06/06/2023 9:27 a.m. Received Time: 06/06/2023 9: 25 a.m. The received time was documented prior to the collection time. The laboratory failed to document the correct collection time into the LIS. h. 06/08/2023 Patient Account Number (ACCT): OD0006811806 Collection Time: 06/08/2023 6:42 p.m. Received Time: 06/08/2023 6:41 p.m. The received time was documented prior to the collection time. The laboratory failed to document the correct collection time into the LIS. i. 06/12/2023 Patient Account Number (ACCT): OD0006734974 Collection Time: 06/12/2023 9:25 a.m. Received Time: 06/12/2023 9:24 a.m. The received time was documented prior to the collection time. The laboratory failed to document the correct collection time into the LIS. j. 06/14/2023 Patient Account Number (ACCT): OD0006819007 Collection Time: 06/14/2023 1:19 p.m. Received Time: 06/14/2023 1:18 p.m. The received time was documented prior to the collection time. The laboratory failed to document the correct collection time into the LIS. k. 06 /16/2023 Patient Account Number (ACCT): OD0006823835 Collection Time: 06/16 /2023 4:50 p.m. Received Time: 06/16/2023 4:49 p.m. The received time was documented prior to the collection time. The laboratory failed to document the correct collection time into the LIS. l. 06/17/2023 Patient Account Number (ACCT): OD0006842645 Collection Time: 06/17/2023 7:45 a.m. Received Time: 06/17/2023 7: 44 a.m. The received time was documented prior to the collection time. The laboratory failed to document the correct collection time into the LIS. m. 06/17/2023 Patient Account Number (ACCT): OD0006825749 Collection Time: 06/17/2023 8:03 a.m. Received Time: 06/17/2023 8:02 a.m. The received time was documented prior to the collection time. The laboratory failed to document the correct collection time into the LIS. n. 06/17/2023 Patient Account Number (ACCT): OD0006825749 Collection Time: 06/17/2023 8:07 a.m. Received Time: 06/17/2023 8:05 a.m. The received time was documented prior to the collection time. The laboratory failed to document the correct collection time into the LIS. o. 06/17/2023 Patient Account Number (ACCT): OD0006824338 Collection Time: 06/17/2023 9:28 a.m. Received Time: 06/17/2023 9:26 a.m. The received time was documented prior to the collection time. The laboratory failed to document the correct collection time into the LIS. p. 06 /17/2023 Patient Account Number (ACCT): OD0006825764 Collection Time: 06/17 /2023 11:06 a.m. Received Time: 06/17/2023 11:05 a.m. The received time was documented prior to the collection time. The laboratory failed to document the correct collection time into the LIS. 3. During an interview with testing person 1 (TP-1) on 09 /14/2023 at 9:30 a.m. in the respiratory therapy office, TP-1 confirmed the laboratory failed to ensure specimen collection time was correctly entered into the LIS for 16 of 36 patients prior to testing in May and June 2023.
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: I. Based on review of the manufacturer's instructions of the Cobas Lactate Gen.2 assay, review of patient test records from February 2023, and staff interview, the laboratory failed to ensure 167 of 272 samples were centrifuged within 15 minutes of

collection as required by the manufacturer. The finding include: 1. A review of the manufacturer's instructions for the Cobas Lactate Gen.2 assay (2020-07, V 1.0 English) under the section titled "Specimen collection and preparation" revealed: "Centrifuge within 15 minutes of collecting the specimen." 2. A review of patient test records from February 2023 identified the laboratory performed testing on 272 patient samples. Of these, 167 were tested when the time from collection to receipt was 15 minutes or longer, and thus, the sample could not be centrifuged within the time limit set by the manufacturer. Examples are: a) Patient: 0206:C011281S collection: 02/06 /2023 1100 received: 02/06/2023 1124 elapsed time: 24 minutes b) Patient: 0208: C01985S collection: 02/08/2023 2100 received: 02/08/2023 2139 elapsed time: 39 minutes c) Patient: 0209:C01871S collection: 02/09/2023 2036 received: 02/09/2023 2130 elapsed time: 54 minutes d) Patient: 0210:C00934S collection: 02/10/2023 0845 received: 02/10/2023 0928 elapsed time: 43 minutes e) Patient: 0210:C01736S collection: 02/10/2023 1933 received: 02/10/2023 2009 elapsed time: 36 minutes f) Patient: 0211:C01652S collection: 02/11/2023 0020 received: 02/11/2023 0122 elapsed time: 62 minutes g) Patient: 0212:C01247S collection: 02/12/2023 1656 received: 02/12/2023 1725 elapsed time: 29 minutes h) Patient: 0213:C00943R collection: 02/13/2023 0932 received: 02/13/2023 1021 elapsed time: 49 minutes i) Patient: 0213:C01845S collection: 02/13/2023 1850 received: 02/13/2023 2014 elapsed time: 84 minutes j) Patient: 0214:C02113S collection: 02/14/2023 1753 received: 02/14/2023 2133 elapsed time: 220 minutes k) Patient: 0215:C00984S collection: 02/15/2023 0845 received: 02/15/2023 1018 elapsed time: 93 minutes l) Patient: 0217:C01469S collection: 02/17/2023 1613 received: 02/17/2023 1644 elapsed time: 31 minutes m) Patient: 0218:C0878S collection: 02/18/2023 0835 received: 02/18/2023 0919 elapsed time: 44 minutes n) Patient: 0219:C00204R collection: 02/19/2023 0340 received: 02/19/2023 0440 elapsed time: 60 minutes o) Patient: 0220:C00109R collection: 02/20/2023 0345 received: 02/20/2023 0438 elapsed time: 53 minutes p) Patient: 0221:C00885S collection: 02/21/2023 0845 received: 02/21/2023 0917 elapsed time: 32 minutes q) Patient: 0225:C01508S collection: 02/25/2023 1810 received: 02/25/2023 1909 elapsed time: 59 minutes r) Patient: 0226:C01676S collection: 02/26/2023 2030 received: 02/26/2023 2253 elapsed time: 143 minutes s) Patient: 02278:C00360R collection: 02/28/2023 0331 received: 02/28/2023 0425 elapsed time: 54 minutes 3. A interview with technical consultant #3 (chemistry) on 09/12/2023 at 4:30 pm in her office revealed lactic acid samples were collected and brought to the laboratory for centrifugation. She stated that it was difficult to get samples to the laboratory within 15 minutes as required. This confirmed the findings. II. Based on a review of the manufacturer's instructions for the Cobas Ammonia II assay, review of patient test records from January 2023 to March 2023, and staff interview, the laboratory failed to ensure samples were tested within 60 minutes of collection for 7 of 69 tests performed. The findings include: 1. A review of the manufacturer's instructions for the Cobas Ammonia II assay (2020-02, V 1.0 English) under the section titled "Specimen collection and preparation" revealed: "Perform analysis within 60 minutes of venipuncture, or freeze separated plasma immediately." 2. A review of patient test records from January 2023 to March 2023 identified 7 of 69 patient samples which were received by the laboratory at or more than 60 minutes after collection, and thus, could not have been tested or separated as required by the manufacturer. They were: a) Patient: 0119:C01348S collected: 01/19/2023 1149 received: 01/19/2023 1305 elapsed time: 76 minutes b) Patient: 0121:C00968S collected: 01/21/2023 1115 received: 01/21/2023 1252 elapsed time: 97 minutes c) Patient: 0131:C00210R collection: 01/31/2023 0526 received: 01/31/2023 0626 elapsed time: 60 minutes d) Patient: 0210:C00294R collection: 02/10/2023 0423 received: 02/10/2023 0544 elapsed time: 81 minutes e) Patient: 0210:C01544S collection: 02/10/2023 1620 received: 02/10/2023 1730

elapsed time: 70 minutes f) Patient: 0213:C00137R collection: 02/13/2023 0359 received: 02/13/2023 0509 elapsed time: 70 minutes g) Patient: 0320:C00290R collection: 03/20/2023 0500 received: 03/220/2023 0610 elapsed time: 70 minutes 3. A interview with the laboratory manager on 09/13/2023 at 10:15 am in her office - after her review of the records - confirmed the findings. III. Based on a review of the manufacturer's instruction for the Cobas Homocysteine Enzymatic Assay, review of the laboratory's instructions for the collection of samples, review of patient test records from January 2023 to March 2023, and staff interview, the laboratory failed to ensure samples were centrifuged 'immediately' as required by the manufacturer. The findings include: 1. A review of the manufacturer's instructions for the Cobas Homocysteine Enzymatic Assay (2020-05, V1.0 English) under the section titled "Specimen collection and preparation" revealed: "It is important to centrifuge blood samples immediately after collection to separate the plasma from the blood cells." 2. A review of the laboratory's policy titled "Handling & Transporting Specimens" (Origination date: 6/97, Last Revised: 6/13/22) failed to provide instructions to phlebotomists to centrifuge homocysteine samples immediately after collection. 3. A review of patient test records from January 2023 to March 2023 revealed the laboratory performed homocysteine testing on 34 patient samples. Further review of the records revealed the time from collection to receipt in the laboratory (when the samples would be centrifuged) varied from 1 to 412 minutes. Examples are: a) Patient: 0102:C01878S collection: 01/02/2023 2346 received: 01/03/2023 0104 elapsed time: 78 minutes b) Patient: 0125:C00595S collection: 1/25/2023 0205 received: 01/25/223 0303 elapsed time: 58 minutes c) Patient: 0129:C01241S collection: 01/29/2023 1700 received: 01/29/2023 1815 elapsed time: 75 minutes d) Patient: 0130:C01706S collection: 01/30/2023 1315 received: 01/30/2023 1633 elapsed time: 198 minutes e) Patient: 0131:C00990R collection: 01/31/2023 0204 received: 01/30/2023 0856 elapsed time: 412 minutes f) Patient: 0210:C00536S collection: 02/10/2023 0024 received: 02/10/2023 0130 elapsed time: 66 minutes g) Patient: 0225:C01539S collection: 02/25/2023 1830 received: 02/25/2023 1908 elapsed time: 38 minutes h) Patient: 0317:C01417S collection: 03/17/2023 1720 received: 03/17/2023 1747 elapsed time: 27 minutes. 3. A interview with technical consultant #3 (chemistry) on 09/12/2023 at 4:30 pm in her office revealed homocysteine samples were collected and brought to the laboratory for centrifugation. She stated the laboratory was unaware the samples needed to be centrifuged immediately. This confirmed the findings. IV. Based on review of the manufacturer's instructions for the Cobas Elecsys Progesterone III assay, review of the manufacturer's instructions for the Cobas Elecsys HCG STAT assay, review of the manufacturer's instructions for the Cobas Elecsys Estradiol III assay, review of the laboratory's policies, review of patient test records from June 2023, and staff interview, the laboratory failed to document the temperature of samples received from couriers in the laboratory to ensure the samples were maintained at manufacturer's required temperatures. The findings include: 1. A review of the manufacturer's instructions for the Cobas Elecsys Progesterone III assay (2020-10, V 3.0 English) under the section titled "Specimen collection and preparation" revealed: "Stable for 1 day at 20 - 25C." 2. A review of the manufacturer's instructions for the Cobas Elecsys HCG STAT assay (2021-09, V 1.0 English) under the section titled "Specimen collection and preparation" revealed: "Stable for 5 days at 20 - 25C." 3. A review of the manufacturer's instructions for the Cobas Elecsys Estradiol III assay (2021-07, V 4.0 English) under the section titled "Specimen collection and preparation" revealed: "Stable for 24 hours at 20 - 25C." 4. A review of the laboratory's policy titled "Contract Account Specimen Handling & Requirements" (Origination Date: 10/9/15, Last Revised: 10/03/19) under the section titled "Procedure" revealed: "The courier must maintain the proper transport temperatures. Specimen temperatures should be

	documented by the courier on the transport form." 5. A review of the laboratory's courier transport forms from June 2023 revealed the laboratory received 13 samples by courier during the month. A column in the form had the heading of "Temp" where the courier was to enter the temperature of the samples. For each of the 13 samples reviewed, the courier had documented "RT" as the temperature. 6. A review of patient test records of the samples delivered by courier in June 2023 revealed the following tests were performed: a) Patient: 0605:C00729R Test date: 06/05/2023 Tests: Progesterone HCG Estradiol b) Patient: 0606:C00987R Test date: 06/06/2023 Tests: Progesterone Estradiol c) Patient: 0606:C00988R Test date: 06/06/2023 Test: HCG d) Patient: 0606:C00989R Test date: 06/06/2023 Test: Progesterone e) Patient: 0608: C0844R Test date: 06/08/2023 Test: HCG f) Patient: 0612:C01077R Test date: 06/12 /2023 Test: HCG g) Patient: 0612:C01284R Test date: 06/12/2023 Tests: Progesterone HCG Estradiol h) Patient: 0615:C0073R Test date: 06/15/2023 Tests: Progesterone Estradiol i) Patient: 0617:C00778R Test date: 06/16/2023 Tests: Progesterone HCG j) Patient: 0619:C00870R Test date: 06/19/2023 Tests: Progesterone HCG Progesterone k) Patient: 0627:C00755R Test date: 06/27/2023 Tests: Progesterone Estradiol l) Patient: 0627:C0070R Test date: 06/27/2023 Tests: Progesterone Estradiol m) Patient: 0628:C00767R Test date: 06/28/2023 Test: HCG 7. The laboratory was asked to provide documentation of the actual temperature of the samples during and upon receipt to ensure they were maintained within the manufacturer's required range of 20 - 25C. No documentation was provided. 8. An interview with the processor on 09/12/2023 at 9:15 am in the laboratory revealed the courier delivered samples to the laboratory in coolers. She stated for room temperature samples the cooler contained the samples only. She stated the cooler did not contain a thermometer and a temperature check was not performed on samples. 9. An interview with the laboratory manager on 09/12/2023 at 9:30 am in the laboratory revealed she did not know what exact temperature range the courier company meant by documenting "RT" other than that it meant room temperature. This confirmed the findings.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of the laboratories policies and procedures, quality control records, patient test records, and interview of facility personnel, the laboratory failed to meet the applicable analytic systems requirements. (See D5411, D5417, D5423, D5471 and D5783)
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 laboratory policy, patient final reports and confirmed in interview, the laboratory failed to follow its own policy for specimen storage prior to testing for 5 of 15 patients randomly reviewed in 2023. (January-June 2023) Findings included: 1. Review of laboratory policy, "ROM Plus: Fetal Membrane Rupture Test" (Reviewed by the Laboratory Director on: 07/27/2020) stated the following: "Specimens (Collection and handling) ...2. Samples are transported ASAP to the laboratory. 3. Run the patient sample as soon as possible. 4. If sample is not run within 30 minutes and sample storage is necessary, place in the refrigerator for up to 6 hours." 2. Review of random patient final reports from 2023 (January-June 2023) determined the following patient specimens tested after 30 minutes: a. 02/02/2023 ACCT: OD0006601405 Collection Time: 02/02/2023 12:00 a.m. Received Time: 02 /02/2023 12:32 a.m. Time Elapsed: 32 minutes b. 02/18/2023 ACCT: OD0006628762 Collection Time: 02/18/2023 10:20 p.m. Received Time: 02/18/2023 11:36 p.m. Time Elapsed: 1 hour and 16 minutes c. 03/09/2023 ACCT: OD0006662803 Collection Time: 03/09/2023 11:36 p.m. Received Time: 03/09/2023 12:36 a.m. Time Elapsed: 1 hour d. 04/23/2023 ACCT: OD0006733182 Collection Time: 04/23/2023 2:10 a.m. Received Time: 04/23/2023 3:40 a.m. Time Elapsed: 1 hour and 30 minutes e. 05/27 /2023 ACCT: OD0006793475 Collection Time: 05/27/2023 3:55 p.m. Received Time: 05/27/2023 4:28 p.m. Time Elapsed: 33 minutes 3. In an interview with TP-21 on 09/13/2023 at 10:14 a.m., TP-21 was asked if the above patients were placed in the refrigerator prior to testing. TP-21 stated the specimens were not placed in the refrigerator. This confirmed the laboratory failed to follow its own policy for specimen storage prior to testing for 5 of 15 patients randomly reviewed in 2023. (January-June 2023) 45469 II. Based on a review of laboratory policy, laboratory maintenance logs, and interview, the laboratory failed to confirm the dispense volume, monthly, for two MTS dispensers, a 0.5mL and a 1.0mL dispenser, for nine of nine random months reviewed from October 2021 to April 2023. The findings included: 1. Review of the laboratory policy titled "MTS Dispenser Operation, Cleaning and Calibration", section "Calibration Check" had the following instructions: " 1. A calibration check will be done each month and after repairs. 2. Dispense 10 times into a clean, dry 10 mL graduated cylinder and record volume. Acceptable volumes for 0.5 mL dispenser; 4.75 to 5.25 milliliters after 10 deliveries 1.0 mL dispenser: 9.50 - 10.50 mL (after 10 deliveries) 3. Calibration of the dispenser is set by the manufacturer and cannot be adjusted by the user. In the event the dispenser does not meet the required specification during the calibration check, contact Ortho Clinical Diagnostics and ask for Technical Support. 4. Document volumes on the monthly QC form." 2. Review of the laboratory form titled "Odessa Regional Medical Center Blood Bank QA/Maintenance Log" had the following nine months where the calibration check dispense volume was not recorded for the 1.0 mL MTS dispenser and the 0.5 mL MTS dispenser: October 2021: Maintenance performed on 10/28/2021 December 2021: Maintenance performed on 12/30/2021 February 2022: Maintenance performed on 3/3/2022 May 2022: Maintenance performed on 5/12/2022 and 5/26 /2022 July 2022: Maintenance performed on 7/28/2022 September 2022: Maintenance performed on 9/29/2022 January 2023: Maintenance performed on 1/30/2023 March 2023: Maintenance performed on 3/30/2023 April 2023: Maintenance performed on 4 /27/2023 3. In an interview on 9/13/2023 at 12:30 P.M., in the conference room, the technical supervisor (TS) 5 confirmed that the calibration check dispense volumes for the MTS 1.0 mL dispenser and the MTS 0.5mL dispenser had not been documented as part of monthly maintenance. KEY: mL - milliliter MTS - Micro Typing System

D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: I. Based on review of the manufacturer's instructions for the Cobas Elecsys total PSA assay, review of patient test records from January 2023 to June 2023, and staff interview, the laboratory failed to follow the manufacturer's instructions for 6 of 41 samples. The findings include: 1. A review of the manufacturer's instructions for the Cobas Elecsys total PSA assay (2020-10, V 1.0 English) under the section titled "Intended use" revealed: "This immunoassay, a quantitative in vitro diagnostic test for total (free + complexed) prostate-specific antigen (tPSA) in human serum and plasma, is indicated of the measurement of total PSA in conjunction with digital rectal examination (DRE) as an aid in the detection of prostate cancer in men aged 50 years or older." 2. A review of patient test records from January 2023 to March 2023 identified 6 of 41 tests were performed on patients under the age of 50 years. They were: a) Patient: 0217:C01077R Test date: 02/17/2023 Age: 31 years b) Patient: 0226: C00800R Test date: 02/26/2023 Age: 48 years c) Patient: 0302:C009872R Test date: 03/02/2023 Age: 49 years d) Patient: 0408:C00568R Test date: 04/08/2023 Age: 43 years e) Patient: 0414:C00713R Test date: 04/14/2023 Age: 43 years f) Patient: 0615: C00903R Test date: 06/03/2023 Age: 18 years 3. An interview with the laboratory manager on 09/13/2023 at 1:55 pm in the conference room revealed the laboratory was unaware of the manufacturer's age requirements for the assay. This confirmed the findings. 41687 II. Based on a review of the Cobas ISE indirect Na-K-Cl for Gen.2 instructions for use, a random review of the laboratory's patient test records, and staff interview, the laboratory failed to ensure patient's specimens were not hemolyzed prior to running potassium testing on the Cobas c503 chemistry analyzers for three of ten patient samples reviewed between February 1, 2023 to March 1, 2023. Findings include: 1. A review of the Cobas ISE indirect Na-K-Cl for Gen.2 instructions for use (2022-06, V 2.0) revealed the following: "For specimen collection and preparation only use suitable tubes or collection containers. Serum: Use serum free of hemolysis and gross lipemia, collected by standard venipuncture technique." 2. A random review of the laboratory's patient test records from February 1, 2023 to March 1, 2023 revealed the following 3 patients' potassium tests, run on the Cobas c503 chemistry analyzers, were resulted and the laboratory noted that the specimens were hemolyzed: Patient ID: OD0006596035 Run on 2/1/23 Potassium result: 4.7 Laboratory noted: Specimen hemolyzed, results affected Patient ID: OD0006596134 Run on 2/1/23 Potassium result: 4.7 Laboratory noted: Specimen hemolyzed, results affected Patient ID: OD0006641070 Run on 3/1/23 Potassium result: 4.5 Laboratory noted: Specimen hemolyzed, results affected 3. An interview with technical consultant #1 for chemistry (as indicated on the CMS 209 form) on 9/14/23 at 10:00 a.m. in the laboratory, after review of the records, confirmed the above findings. 47301 III. Based on direct observation, a review of laboratory records, a review of the manufacturer's instructions for the Sysmex CS-2500, and confirmed in staff interview, the laboratory failed to follow manufacturer's instructions for verifying the prothrombin time (PT) reference interval for 1 of 1 events (October 2022). Findings included: 1. During a tour of the laboratory on 09/12/2023 at 09:15 am, two Sysmex CS-2500 instruments (serial numbers 24352 and 24345) were observed. 2. A review of the Sysmex CS-

	2500 System Installation Package Rev 2.0 7/7/2017, stated "V. Reference Interval, Verification of Reference Procedures, Requirements: Donors must be from a healthy population (no known pathological condition; no presurgical or hospitalized patients)". 3. Review of laboratory records revealed a verification study for the PT reference interval was completed on 10/19/2022. 4. A request was made for documentation of healthy population determinants required by the manufacturer. No documentation was provided. 5. During an interview on 09/13/2023 at 10:14 am, in the laboratory, Technical Consultant #2 (as listed on the submitted CMS 209) stated that participant samples are obtained from chart reviews where samples collected from both clinic and hospitalized patients. This confirmed the above findings. Word Key: CMS: Centers for Medicare and Medicaid Services
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on review of Roche COBAS Pro operator's guide, environmental logs, and in interview with staff, the laboratory failed define a room humidity range in accordance with manufacturer's specifications and failed to ensure the room humidity did not exceed manufacturer's instructions for 21 of 31 days in 2022 (December) and 86 of 181 days in 2023 (January through June). Findings included: 1. Review of the Roche COBAS Pro operator's guide on page 245 revealed: "Environmental conditions during operation The following environmental conditions must be fulfilled during operation. Specifications ... Ambient humidity 30-85%" 2. Review of the laboratory's environmental logs for the "Chemistry Area" from December 2022 through June 2023 defined room humidity as "Lower Limit 0%" and "Upper Limit 65%" not 30-85% as required by the manufacturer. The following was a random sampling of days the room humidity exceeded manufacturer's requirements: 12/13/2022: 27% 12/14/2022: 25% 12/15/2022: 21% 12/16/2022: 21% 12/25/2022: 12% 12/26/2022: 10% 12/27/2022: 12% 01/06/2023: 21% 01/07/2023: 20% 01/08/2023: 22% 01/09/2023: 23% 01/10 /2023: 22% 01/20/2023: 23% 01/21/2023: 18% 01/22/2023: 18% 01/26/2023: 22% 02 /02/2023: 18% 02/03/2023: 23% 02/04/2023: 23% 02/12/2023: 17% 02/13/2023: 17% 03/12/2023: 25% 03/13/2023: 24% 03/14/2023: 24% 03/28/2023: 25% 03/29/2023: 22% 04/19/2023: 24% 04/20/2023: 24% 04/21/2023: 23% 04/22/2023: 21% 04/23 /2023: 21% 04/30/2023: 23% 05/01/2023: 23% 05/07/2023: 21% 05/12/2023: 22% 06 /15/2023: 28% 06/16/2023: 22% 3. During an interview on 09/12/2023 at 4:26 pm, the Technical Consultant-1 (as designated on the CMS 209 form), after review of records, confirmed the above findings. Word Key: CMS- Center for Medicare & Medicaid Services
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 review of the manufacturer's instructions for the STAT-Site M Ketone test, surveyor observation of test strips currently in use in laboratory and staff interview, it was revealed the laboratory failed to document the opened date and/or the revised expiration date on 1 of 1 containers for the test strips currently in use. The findings include: 1. A review of the manufacturer's instructions for the STAT-Site M Ketone test under the section titled "Storage and Handling" revealed: "Write the date opened on the container label where indicated. Once you open the container, Test Strips must be used within 30 days." 2. Surveyor observation of the test strips currently in use in the laboratory on 09/13/2023 at 4:00 pm revealed 1 container of test strips were opened and in use: Lot: 202887 expiration date: 2024-01-31 5 of 10 strips remaining No documentation of open date or revised expiration date was seen. 3. An interview with the chemistry supervisor on 09/13/2023 at 4:05 pm in the laboratory revealed she did not know when the container was opened. This confirmed the findings.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies, surveyor's observation, a review of patient test records, and staff interview, the laboratory failed to ensure two of two subculture broths had not exceeded their expiration dates prior to using them for patient testing. Findings include: 1. A review of the laboratory's policy titled 'Reagent Policy' revealed the following: "All reagents are used within their indicated expiration date. Expired reagent should be discarded." 2. Surveyor observation of the microbiology laboratory on 9/13/23 at 3:50 p.m. revealed the following 2 subculture broths had exceeded their expiration date: Hardy Diagnostics Thio w/ Indicator Lot: 151385 Expiration date: 9/10/23 Hardy Diagnostics Lim Broth, SML Lot: 523619 Expiration date: 8/29/23 3. Further observation of the microbiology laboratory revealed the expired subculture broths were used for testing the following 5 patient samples: Patient ID: OD0006959662 - Abscess Culture Thio set up on 9/11/23 Patient ID: OD0006967699 - Wound Culture Thio set up on 9/12/23 Patient ID: OD0006968911 - Wound Culture Thio set up on 9/13/23 Patient ID: OD0006968556 - Group B Culture Screen Lim Broth set up on 9/13/23 Patient ID: OD0006968374 - Wound Culture Thio set up on 9/13/23 4. An interview with the technical supervisor for Bacteriology on 9/14/23 at 9:30 a.m. in the laboratory, after review of the records, confirmed the above findings.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces

	a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on a review of the manufacturer's instructions for use, the laboratory's records from 2022 and 2023, the laboratory's test records, and staff interview, the laboratory failed to have documentation of establishment studies on cord blood specimens for total bilirubin testing on the Siemens Vista chemistry analyzers and the Cobas e503 chemistry analyzers. Findings include: 1. A review of the Siemens Vista Systems instructions for use (K1167) revealed the following: "Recommended specimen types: serum and plasma (lithium heparin and EDTA)." 2. A review of the Cobas Bilirubin Total Gen.3 instructions for use (2020-02, V1.0) revealed the following: "Only the specimens listed below were tested and found acceptable. Serum Plasma: Li-heparin, K2-EDTA plasma" 3. A review of the laboratory's records revealed the laboratory performed verification studies for total bilirubin testing on the following: - 2 Siemens Vista analyzers (Serial numbers: DV331355 and DV331358) in November 2016 - 2 Cobas e503 analyzers (Serial numbers: 22D4-06 and 22D4-07) in December 2022 3. Further review of the laboratory's records revealed the laboratory failed to have documentation of establishment studies on cord blood specimens for total bilirubin testing on the 2 Siemens Vistas and the 2 Cobas e503 analyzers. 4. A review of the laboratory's test records revealed the laboratory performed 77 total bilirubin tests on cord blood samples in 2022 and 49 total bilirubin tests on cord blood samples in 2023. 5. An interview with technical consultant #1 for chemistry (as indicated on the CMS 209 form) on 9/14/23 at 10:00 a.m. in the laboratory, after review of the records, confirmed the above findings.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions, maintenance logs, and interview, the laboratory failed to document the performance of monthly maintenance performed on the Vitek 2 used for the ID and sensitivities for gram positive, gram negative, and yeast cultures for five out of 13 months reviewed. Findings follow. A. Review of the Vitek 2 Instrument Preventative Maintenance Checklist showed the following monthly maintenance duties: "Print instrument QC Print instrument status report Clean DensiCHEK Clean external surfaces Check dispensette volume Clean drip pan Clean vacuum chamber Clean vacuum seal Clean waste trays Change tips/saline Clean carousels Clean boats". B. Review of the Vitek 2 Instrument Preventative Maintenance Checklist from June 2022 - June 2023 showed no documentation of the

	monthly maintenance performed for five out of 13 months: 1. Feb 2023 2. March 2023 3. April 2023 4. May 2023 5. June 2023 C. Interview with technical supervisor #6 (as listed on the CMS form 209) on August 12, 2023 at 4:05 PM acknowledged they forgot to document the maintenance.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of manufacturer instructions, calibration records, and interview with facility personnel, the laboratory failed to perform calibration verification procedures at least every six months for two of two coagulation assays reviewed, D-Dimer and Fibrinogen. The findings included: 1. Based on review of the Siemens Health Diagnostics Sysmex CS-2500 System - Installation Package Rev 2.0, on page 31, the instructions stated the following: "Calibrated Assays 1. Calibration required with lot number change 2. Calibration/Verification required every 6 months per CLIA 3. Calibration may be required after major preventive maintenance or replacement of critical parts." 2. Based on review of the calibration records for Sysmex CS-2500 analyzer A, Fibrinogen was calibrated on 9/20/2022 and again on 6/19/2023, an interval of 8 months and 30 days. D-Dimer was calibrated on 9/20/2022 and again on 6 /29/2023, an interval of 9 months and 9 days. 3. Based on review of the calibration records for Sysmex CS-2500 analyzer B, Fibrinogen was calibrated on 12/13/2021 and again on 9/20/2022, an interval of 9 months and 7 days. D-Dimer was calibrated on 12/13/2021 and again on 9/20/2022, an interval of 9 months and 7 days. 4. In an interview at 15:53 hours on 9/13/2023 in the hematology section of the laboratory, Technical Consultant 1 (as listed on CMS-209 Laboratory Personnel Report) stated the laboratory had some challenges obtaining reagents and that is why calibrations had not been performed at least every 6 months.
D5471	CONTROL PROCEDURES CFR(s): 493.1256(e)(1)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
I. Based on manufacturer's instructions, laboratory's policies and procedures, quality control records, and interview, the laboratory failed to perform external quality control (QC) on the Gram Positive (GP) identification cards on the Biomerieux Vitek 2 for 12 out of 12 shipments and lots reviewed for 21 out of 21 months. Findings follow. A. Review of the package insert Vitek 2 GP, rev 043900-03 03/2019, for the Vitek 2 Gram-Positive identification card stated: "Quality Control Quality control organisms and their expected results are listed in the Vitek 2 GP Quality Control Tables. Process these according to the procedure for test isolates outlined in this document ... Frequency of Testing Currently, it is recommended that you use your most stringent inspecting agency's guidelines for frequency of identification product testing. Common practice is to perform QC upon receipt of shipment of the test kits. Reactions must follow Instructions for Use results. If the results do not meet the criteria, subculture for purity and repeat the test. If discrepant results are repeated, perform an alternate identification method and contact bioMerieux ... Streamlined Quality Control ...As there are no substrates that are consistently sensitive to degradation during shipping conditions, streamlined quality control may be conducted by testing two strains: one that is mostly positive and the other, which is mostly negative for reactions on GP. (See GP Quality Control tables for more details.) Comprehensive Quality Control Customers who do not qualify for streamlined quality control testing are required to perform comprehensive quality control testing, which entails demonstration of a positive and negative reaction for each substrate of an identification product. In order to qualify initially for streamlined quality control testing, the CLSI M50-A standard requires that the user perform and document either of the following: Verification testing to show that performance is equivalent to the manufacturer's claims. Comprehensive quality control testing of at least three lots over at least three different seasons. Refer to the complete CLSI M50-A standard for information regarding continued qualification and further details of requirements and responsibilities for both the user and the manufacturer related to streamlined quality control testing. GP Quality Control Tables: Enterococcus casseliflavus ATCC 700327 (for streamlined or comprehensive quality control) Streptococcus salivarius ssp. Thermophilus ATCC 1928 (for comprehensive quality control) Kocuria kristinae ATCC BAA-752 (for comprehensive quality control) Listeria monocytogenes ATCC BAA-751 (for comprehensive quality control) Streptococcus pneumoniae ATCC 49619 (for comprehensive quality control) Staphylococcus saprophyticus ATCC BAA-750 (for streamlined or comprehensive quality control) Staphylococcus sciuri ATCC 29061 (for comprehensive quality control) Streptococcus equi ssp. Zooepidemicus ATCC 43079 (for comprehensive quality control) Enterococcus saccharolyticus ATCC 43076 (for comprehensive quality control) ..." B. Review of the laboratory's policy and procedure titled Vitek 2 Procedure, policy number Lab 8.1520 revised 08/21/2020, under Quality Control stated, "New Lot of MIC/ID Panels QC is performed on each new lot of MIC or ID panels before or concurrent with initial use with appropriate QC organisms, after that MIC QC is done weekly. Control results are reviewed for acceptability before reporting patient results. When QC

results are not acceptable, corrective action is taken ..." C. Review of the QC Cumulative Report for the Vitek 2 from 09/15/2021 - 06/30/2023 showed no QC for ID panels performed using known organisms. D. Review of the reagent tracking log titled Vitek 2 Systems Web showed from 09/15/2021 - 06/30/2023 the lab received 12 shipments/lots of GP ID panels as listed by received date, Lot number, and Expiration date: Received Lot Number Expiration 1. 11/12/21 2421858103 12/28/22 2. 12/23/21 2422002103 05/21/23 3. 02/09/22 2422035503 06/23/23 4. 03/22/22 2422088403 08 /15/23 5. 05/27/22 2422149503 10/15/23 6. 06/29/22 2422174503 11/09/23 7. 08/16 /22 2422247403 01/21/24 8. 11/19/22 2422324503 04/07/24 9. 12/21/22 2422364403 05/17/24 10. 02/28/23 2422430403 07/22/24 11. 03/16/23 2422438203 07/30/24 12. 06/02/23 2422527503 10/27/24 E. Random review of patient testing showed the following patients were tested by the GP ID panel as listed by requisition number, culture type, and Vitek testing date: Req # Culture type Date Organism 1. 03726624 Wound 03/01/23 Enterococcus faecalis 2. 03725629 Urine 03/01/23 Enterococcus faecalis 3. 03746979 Body Fluid 03/09/23 Staphylococcus warneri 4. 03973158 Urine 05/13/23 Methicillin resistant Staph aureus 5. 04015081 Urine 05/27/23 Strep gallolyt ss gallolyt 6. 04023094 Respiratory 05/31/23 Streptococcus pneumoniae 7. 04066881 Urine 06/14/23 Strep agalactiae - (group b) 8. 04096952 Abscess 06/23/23 Streptococcus viridans group 9. 04104375 Wound 06/24/23 Strep agalactiae - (group b) 10. 04104043 Wound 06/25/23 Strep pyogenes -group a F. Interview with technical supervisor #6 (as listed on the CMS form 209) on August 13, 2023 at 9:30 AM confirmed they were not performing QC for the ID panels. He also verified there was no documentation in the laboratory showing comprehensive QC was performed to support streamlined QC for the GP, GN, and YST ID panel cards. G. Query on the analyzer showed 488 GP, GN, and YST ID panels were performed from 09/15/2021 - 06/30/2023. II. Based on manufacturer's instructions, laboratory's policies and procedures, quality control records, and interview, the laboratory failed to perform external quality control on the Gram Negative (GN) identification cards on the Biomerieux Vitek 2 for 20 out of 20 shipments and lots reviewed for 21 out of 21 months. Findings follow. A.Review of the package insert Vitek 2 GN, rev 044066-04 03/2020, for the Vitek 2 Gram-Negative identification card stated: "Quality Control Quality control organisms and their expected results are listed in the Vitek 2 GN Quality Control Tables. Process these according to the procedure for test isolates outlined in this document ... Frequency of Testing Currently, it is recommended that you use your most stringent inspecting agency's guidelines for frequency of identification product testing. Common practice is to perform QC upon receipt of shipment of the test kits. Reactions must follow Instructions for Use results. If the results do not meet the criteria, subculture for purity and repeat the test. If discrepant results are repeated, perform an alternate identification method and contact bioMerieux ... Streamlined Quality Control ...As there are no substrates that are consistently sensitive to degradation during shipping conditions, streamlined quality control may be conducted by testing two strains: one that is mostly positive and the other which is mostly negative for reactions on GN. (See GN Quality Control tables for more details.) Comprehensive Quality Control Customers who do not qualify for streamlined quality control testing are required to perform comprehensive quality control testing, which entails demonstration of a positive and negative reaction for each substrate of an identification product. In order to qualify initially for streamlined quality control testing, the CLSI M50-A standard requires that the user perform and document either of the following: Verification testing to show that performance is equivalent to the manufacturer's claims. Comprehensive quality control testing of at least three lots over at least three different seasons. Refer to the complete CLSI M50-A standard for information regarding continued qualification and further details of requirements and responsibilities for both the user and the manufacturer related to

streamlined quality control testing. GN Quality Control Tables: Enterobacter hormaechei ATCC 700323 (for streamlined or comprehensive quality control) Stenotrophomonas maltophilia ATCC 17666 (for streamlined or comprehensive quality control) Acintobacter baumannii ATCC BAA-747 (for comprehensive quality control) Elizabethkingia meningoseptica ATCC 13253 (for comprehensive quality control) Klebsiella oxytoca ATCC 700324 (for comprehensive quality control) Ochrobactrum anthropi ATCC BAA-749 (for comprehensive quality control) Proteus vulgaris ATCC 6380 (for comprehensive quality control) Pseudomonas aeruginosa ATCC 9721 (for comprehensive quality control) Pseudomonas aeruginosa ATCC BAA-1744 (for comprehensive quality control) Note: Pseudomonas aeruginosa ATCC BAA-1744 may contain two morphologically distinct colony types; however, either will provide proper expected reactions when tested for quality control. For 7.01 Software Users Shigella sonnei ATCC 25931 (for comprehensive quality control) For 8.01 or Higher Software Users Escherichia coli ATCC 25922 (for comprehensive quality control) ..." B. Review of the laboratory's policy and procedure titled Vitek 2 Procedure, policy number Lab 8.1520 revised 08/21/2020, under Quality Control stated, "New Lot of MIC/ID Panels QC is performed on each new lot of MIC or ID panels before or concurrent with initial use with appropriate QC organisms, after that MIC QC is done weekly. Control results are reviewed for acceptability before reporting patient results. When QC results are not acceptable, corrective action is taken ..." C. Review of the QC Cummulative Report for the Vitek 2 from 09/15/2021 - 06/30/2023 showed no QC for ID panels performed using known organisms. D. Review of the reagent tracking log titled Vitek 2 Systems Web showed from 09/15 /2021 - 06/30/2023 the lab received 20 shipments/lots of GN ID panels as listed by received date, Lot number, and Expiration date: Received Lot Number Expiration 1. 10/26/21 2411709203 08/01/22 2. 11/30/21 2411793203 10/24/22 3. 12/07/21 2411810503 11/10/22 4. 01/25/22 2411847503 12/17/22 5. 02/09/22 2411863103 01 /02/23 6. 02/23/22 2411870403 01/09/23 7. 03/22/22 2411891403 01/30/23 8. 05/18 /22 2411954403 04/03/23 9. 06/28/22 2411982103 05/01/23 10. 08/02/22 2412024403 06/12/23 11. 09/07/22 2412078403 08/05/23 12. 11/01/22 2412129503 09/25/23 13. 11/09/22 2412157403 10/23/23 14. 12/21/22 2412181503 11/16/23 15. 02/06/23 2412223403 12/28/23 16. 02/28/23 2412257503 01/31/24 17. 03/16/23 2412264103 02/07/24 18. 04/21/23 2412283503 02/26/24 19. 05/31/23 2412325403 04/08/24 20. 06/13/23 2412353203 05/06/24 E. Random review of patient testing showed the following patients were tested by the GN ID panel as listed by requisition number, culture type, and Vitek testing date: Req # Culture type Date Organism 1. 03726624 Wound 03/01/23 Citrobacter freundii 2. 03725629 Urine 03/02/23 Pluralibacter gergoviae 3. 03725629 Urine 03/03/23 Escherichia coli 4. 03749702 Respiratory 03/09/23 E coli-ESBL 5. 03973158 Urine 05/13/23 Escherichia coli 6. 03987198 Urine 05/18/23 Escherichia coli 7. 04015081 Urine 05/27/23 Escherichia coli 8. 04066881 Urine 06/14/23 Escherichia coli 9. 04096952 Abscess 06/22/23 Proteus mirabilis 10. 04104375 Wound 06/24/23 Proteus mirabilis 11. 04102698 Urine 06/25/23 Proteus mirabilis, Escherichia coli 12. 04111222 Urine 06/28/23 Escherichia coli F. Interview with technical supervisor #6 (as listed on the CMS form 209) on August 13, 2023 at 9:30 AM confirmed they were not performing QC for the ID panels. He also verified there was no documentation in the laboratory showing comprehensive QC was performed to support streamlined QC for the GP, GN, and YST ID panel cards. G. Query on the analyzer showed 488 GP, GN, and YST ID panels were performed from 09/15/2021 - 06/30/2023. III. Based on manufacturer's instructions, laboratory's policies and procedures, quality control records, and interview, the laboratory failed to perform external quality control on the Yeast (YST) identification cards on the Biomerieux Vitek 2 for 8 out of 8 shipments and lots reviewed for 21 out of 21 months. Findings follow. A. Review of the package insert

Vitek 2 YST, rev 043908-02 10/2016, for the Vitek 2 Yeast identification card stated: "Quality Control Quality control organisms and their expected results are listed in the Vitek 2 YST Quality Control Tables. Process these according to the procedure for test isolates outlined in this document Note: Staphylococcus epidermidis ATCC 12228 needs to be tested at a McFarland Standard No. 0.5 to 0.63. All other QC strains are tested at a McFarland Standard No. 1.80 to 2.20 ... Frequency of Testing Currently, it is recommended that you use your most stringent inspecting agency's guidelines for frequency of identification product testing. Common practice is to perform QC upon receipt of shipment of the test kits. Reactions must follow Instructions for Use results. If the results do not meet the criteria, subculture for purity and repeat the test. If discrepant results are repeated, perform an alternate identification method and contact bioMerieux ... Streamlined Quality Control Streamlined quality control may be used to confirm acceptable performance of the YST card after shipping/storage. This methodology may be performed with the YST card by following the instructions for quality control testing as described in the YST Instructions for Use and meeting the criteria stated in CLSI M50-A Quality Control for Commercial Microbial Identification Systems. Testing may be conducted using Candida albicans ATCC 14053 and evaluating the performance of the NAGA1 well. Testing at bioMerieux, Inc has shown that the NAGA1 well is the most liable well on the YST card and Candida albicans ATCC 14053 is the most sensitive strain for detecting degradation of this well with a false negative reaction. (See YST Quality Control table for more details). Comprehensive Quality Control Customers who do not qualify for streamlined quality control testing are required to perform comprehensive quality control testing, which entails demonstration of a positive and negative reaction for each substrate of an identification product. In order to qualify initially for streamlined quality control testing, the CLSI M50-A standard requires that the user perform and document either of the following: Verification testing to show that performance is equivalent to the manufacturer's claims. Comprehensive quality control testing of at least three lots over at least three different seasons. Refer to the complete CLSI M50-A standard for information regarding continued qualification and further details of requirements and responsibilities for both the user and the manufacturer related to streamlined quality control testing. YST Quality Control Tables: Candida albicans ATCC 14053 (for streamlined or comprehensive quality control) Candida glabrata ATCC MYA-2950 (for comprehensive quality control) Candida lusitaniae ATCC 34449 (for comprehensive quality control) Candida utilis ATCC 9950 (for comprehensive quality control) Kloeckera japonica ATCC 58370 (for comprehensive quality control) Prototheca wickerhamii ATCC 16529 (for comprehensive quality control) Sporobolomyces salmonicolor ATCC MYA-4550 (for comprehensive quality control) Trichosporon mucoides ATCC 204094 (for comprehensive quality control) Oligella ureolytica ATCC 43534 (for comprehensive quality control) Staphylococcus epidermidis ATCC 12228 (for comprehensive quality control) Zygosaccharomyces parabailii ATCC MYA-4549 (for comprehensive quality control) ..." B. Review of the laboratory's policy and procedure titled Vitek 2 Procedure, policy number Lab 8.1520 revised 08/21/2020, under Quality Control stated, "New Lot of MIC/ID Panels QC is performed on each new lot of MIC or ID panels before or concurrent with initial use with appropriate QC organisms, after that MIC QC is done weekly. Control results are reviewed for acceptability before reporting patient results. When QC results are not acceptable, corrective action is taken ..." C. Review of the QC Cumulative Report for the Vitek 2 from 09/15/2021 - 06/30/2023 showed no QC for ID panels performed using known organisms. D. Review of the reagent tracking log titled Vitek 2 Systems Web showed from 09/15/2021 - 06/30/2023 the lab received 8 shipments/lots of YST ID panels as listed by received date, Lot number, and Expiration date: Received Lot Number Expiration 1. 11/08/21 2431580403 03/25/22 2. 11/20/21 2431580403 03/25

	/22 3. 01/14/22 2431991203 05/10/23 4. 01/18/22 2431991203 05/10/23 5. 02/23/22 2432022503 06/10/23 6. 04/27/22 2432091503 08/18/23 7. 10/12/22 2432261103 02/04/24 8. 02/28/23 2432419403 07/01/24 E. Random review of patient testing showed the following patients were tested by the YST ID panel as listed by requisition number, culture type, and Vitek testing date: Req # Culture type Date Organism 1. 03722926 Urine 03/01/23 Candida dubliniensis 2. 03747194 Respiratory 03/09/23 Candida tropicalis 3. 04025391 Respiratory 06/01/23 Candida dubliniensis F. Interview with technical supervisor #6 (as listed on the CMS form 209) on August 13, 2023 at 9:30 AM confirmed they were not performing QC for the ID panels. He also verified there was no documentation in the laboratory showing comprehensive QC was performed to support streamlined QC for the GP, GN, and YST ID panel cards. G. Query on the analyzer showed 488 GP, GN, and YST ID panels were performed from 09/15/2021 - 06/30/2023.
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 the manufacturer's instructions, manufacturer product information, laboratory's policy and procedure, quality control (QC) records, and interview, the laboratory failed to ensure the QC met the laboratory's and manufacturer's criteria for acceptability prior to reporting patient testing for one of five QC events tested over 12 months on the Luminex Verigene used for blood culture identification of gram positive (BC-GP) organisms. Findings follow. A. Review of the Verigene Gram Positive Blood Culture Nucleic Acid Test package insert, 89-30000-00-782 Rev A 11/2019, under Assay controls stated, "External Controls It is highly recommended that known culture-confirmed blood culture specimens positive for each of the BC-GP panel organisms be tested routinely as defined by the user's laboratory's standard operating procedures on a rotating basis using 3-4 smaller groups of organisms, and/or under the following circumstances: Instrument installation, test validation, and when troubleshooting is necessary; During performance verification of receipt of a new set/lot of consumables; When the integrity of consumables or the device is in question." B. Review of the Microbiologics Quality Control Sets product information, 14-0045-C, showed Pools 1-3 are for the Verigene Gram-Positive Blood Culture QC Set as listed by pool and organisms in each pool: Pool Organisms Pool 1 S. epidermidis, S. lugdunensis, E. faecium, L. monocytogenes Pool 2 S. pyogenes, S. agalactiae, S. anginosus Pool 3 S. aureus, E. faecalis, S. pneumoniae C. Review of the laboratory's policy and procedure titled Verigene-Blood Culture Panels, Policy Number Lab 9.118 revised 11/01/2020, under Quality Control stated, "If any level of control fails, patient testing may not be performed until corrective action has occurred, acceptable results are obtained and testing has been repeated ... New Lot of Shipment of Reagents-Microbiologics control panels must be processed prior to putting a new lot or shipment of reagent into use ..." D. Review of the QC records on the Verigene for Processor A1 from 06/17/2022 - 06/21/2023 showed the QC run performed on 04/07/2023 failed for the organism Streptococcus agalactiae using QC pool 2. The next successful QC run for Streptococcus agalactiae was performed on 06/29/2023 using QC pool 2. E. Review of the BC-GP patient instrument print-outs from 04/07/2023 - 06/29/2023 showed patient testing was performed as listed by the Sample ID and

	Analysis completed date: Sample ID Analysis date 1. 20139 06/08/23 2. 372533 06/05 /23 3. 19308 06/05/23 4. 362358 06/04/23 5. 366561 06/03/23 6. 357868 05/31/23 7. 346618 05/20/23 8. 326297 05/23/23 9. 18309 05/22/23 10. 324438 05/22/23 11. 297272 05/15/23 12. 276542 05/07/23 13. 233486 04/26/23 14. 220922 04/21/23 15. 209725 04/21/23 16. 196845 04/18/23 17. 14293 04/17/23 18. 14551 04/18/23 19. 184800 04/12/23 20. 180206 04/10/23 F. Interview with technical supervisor #6 (as listed on the CMS form 209) on August 14, 2023 at 10:55 AM acknowledged the QC "got out of his sight", that he "didn't notice it was out," and "all patients are also run on the Vitek" [from a culture. The Verigene gives the physician a preliminary report while waiting on the culture.]
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 a review of laboratory policy, laboratory alarm check records, 7 day temperature chart recorders, and confirmed in interview, the laboratory failed to ensure that the chart recorder for the continuous monitoring system registered the temperature change when internal temperature probes were manipulated with warm and cold water during quarterly testing of the continuous monitoring system, for four blood product storage units, during five of six quarterly tests from February 2022 to May 2023. The findings included: 1. Review of the laboratory blood bank policy titled "Alarm Testing", section "Procedure" had the following instructions: "Alarm Function Testing is performed quarterly. 1. Ensure the alarm circuits are operating and the alarm is switched "On". Place an easy to read mercury thermometer inside a blood bag and immerse with the thermocouple into the container. ensure the temperature is 1 - 6 degrees Celsius (C). 2. For low activation: place the container with the thermocouple and thermometer in a pan containing A slush of ice and water colder than 0 degrees C. To achieve this temperature, add several spoonfuls of table salt, along with ice. The temperature should be -4 degrees C or colder. 3. Close the refrigerator door to avoid changing the temperature of the storage compartment. 4. Allow the container to remain in the pan of cold slush, and periodically agitate until the alarm sounds. Record this temperature as the low activation on the recorder chart. (record initials& date) 5. Remove the container from the slush bath. Allow the fluid to return to normal temperature, and note the temperature at which the audible or visible alarm stops. 6. For high activation: place the container with the thermal coupler and thermometer in a pan containing water at 12 - 15 degrees C. Keep refrigerator door closed. Allow the fluid in the container to warm slowly, with occasional agitation. Record temperature at which the alarm sounds as the high activation temperature on the chart. (Record initials & date) 7. Remove the container from warm pan, and note temperature at which audible or visible alarm ceases. 8. Record the date, identity of the refrigerator, the low temperature activation, the high temperature activation, and the initial of the person performing the test on the recorder chart and the monthly QC form, located in the Blood Bank Quality Control Manual." Section "NOTES" had the following statement: "3. When the temperature of the activation are checked, the

	temperature change should occur slowly enough that measurements and recording are accurate. Too rapid a change in temperature may give the false impression that the alarm does not sound until an inappropriate temperature is registered." Section "Thermo Freezer Alarm Testing" had the following instructions: "1. Fill an 8oz container half full of chilled water. (4C) and crushed ice. 2. Remove the Thermo sensor from the solution bottle, and rubber band the probe to the test thermometer (NBS certified) then insert into the container of slush. the sensor and the thermometer must be at the same level. 3. Slowly add room temperature water to the container, to provide a temperature rise of no more than 0.5 C per minute. 4. Stir the test thermometer and sensor in a circular motion, keeping the ends in the lower liquid. 5. Record the high alarm activation. 6. Record the reaction of the remote monitor during this test procedure. 7. Record all results on the monthly QC form in the maintenance manual." 2. A review of the laboratory quarterly "Blood Bank Alarm Checks" form from February 2022 to May 2023 had the following five instances where the alarm function testing did not reflect on the continuous monitoring chart recorders on the equipment tested in the corresponding time frame: May 2022: 5/26/2022 Thermo Refrigerator #1: S/N 1112516701170901 Low Alarm Temp: External: 1.4 High Alarm Temp: External: 5.5 Thermo Refrigerator #2: S/N 01152676C1140129 Low Alarm Temp: External: 1.4 High Alarm Temp: External: 5.5 Thermo Freezer: S/N 01122862011211214 Low Alarm Temp: External: N/A High Alarm Temp: External: -19.9 Platelet Rotator: 0961489 Low Alarm Temp: External: 21 High Alarm Temp: External: 23.5 The time frame of 7-day chart recorders reviewed: 5/23/2022 - 5/30 /2022 August 2022: 8/31/2022 Thermo Refrigerator #1: S/N 1112516701170901 Low Alarm Temp: External: 1.4 High Alarm Temp: External: 5.5 Thermo Refrigerator #2: S/N 01152676C1140129 Low Alarm Temp: External: 1.4 High Alarm Temp: External: 5.5 Thermo Freezer: S/N 01122862011211214 Low Alarm Temp: N/A High Alarm Temp: External: -19.9 Platelet Rotator: 0961489 Low Alarm Temp: External: 21 High Alarm Temp: External: 23.5 The time frame of 7-day chart recorders reviewed: 8/29/2022 - 9/5/2022 November 2022: 11/21/2022 Thermo Refrigerator #1: S/N 1112516701170901 Low Alarm Temp: External: 1.4 High Alarm Temp: External: 5.5 Thermo Refrigerator #2: S/N 01152676C1140129 Low Alarm Temp: External: 1.4 High Alarm Temp: External: 5.5 Thermo Freezer: S/N 01122862011211214 Low Alarm Temp: N/A High Alarm Temp: External: -19.9 Platelet Rotator: 0961489 Low Alarm Temp: External: 21 High Alarm Temp: External: 23.5 The time frame of 7-day chart recorders reviewed: 11/14/2022 - 11/21 /2022 and 11/21/2022 - 11/28/2022 February 2023: 2/28/2023 Thermo Refrigerator #1: S/N 1112516701170901 Low Alarm Temp: External: 1.4 High Alarm Temp: External: 5.5 Thermo Refrigerator #2: S/N 01152676C1140129 Low Alarm Temp: External: 1.4 High Alarm Temp: External: 5.5 Thermo Freezer: S/N 01122862011211214 Low Alarm Temp: N/A High Alarm Temp: External: -19.9 Platelet Rotator: 0961489 Low Alarm Temp: External: 21 High Alarm Temp: External: 23.0 The time frame of 7-day chart recorders reviewed: 2/27/2023 - 3/6 /2023 May 2023: 5/30/2023 Thermo Refrigerator #1: S/N 1112516701170901 Low Alarm Temp: External: 1.4 High Alarm Temp: External: 5.5 Thermo Refrigerator #2: S/N 01152676C1140129 Low Alarm Temp: External: 1.4 High Alarm Temp: External: 5.5 Thermo Freezer: S/N 01122862011211214 Low Alarm Temp: N/A High Alarm Temp: External: -19.8 Platelet Rotator: 0961489 Low Alarm Temp: External: 21.0 High Alarm Temp: External: 23.5 The time frame of 7-day chart recorders reviewed: 5/29/2023 - 6/5/2023 3. In an interview on 9/13/2023 at 09:20 A.M., in the office, the technical supervisor (TS) 5 confirmed that the low and high-temperature activations were not reflected on the chart recorders of the continuous monitoring system.

D5783

CORRECTIVE ACTIONS
CFR(s): 493.1282(b)(2)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.

This STANDARD is not met as evidenced by:
I. Based on review of the manufacturer's instructions, manufacturer product information, laboratory's policy and procedure, quality control (QC) records, and interview, the laboratory failed to evaluate patient testing back to the last successful QC run when they obtained a QC failure for one organism in one of five QC events tested over 12 months on the Luminex Verigene used for blood culture identification of gram positive (BC-GP) organisms. Findings follow. A. Review of the Verigene Gram Positive Blood Culture Nucleic Acid Test package insert, 89-30000-00-782 Rev A 11/2019, under Assay controls stated, "External Controls It is highly recommended that known culture-confirmed blood culture specimens positive for each of the BC-GP panel organisms be tested routinely as defined by the user's laboratory's standard operating procedures on a rotating basis using 3-4 smaller groups of organisms, and/or under the following circumstances: Instrument installation, test validation, and when troubleshooting is necessary; During performance verification of receipt of a new set /lot of consumables; When the integrity of consumables or the device is in question." B. Review of the Microbiologics Quality Control Sets product information, 14-0045-C, showed Pools 1-3 are for the Verigene Gram-Positive Blood Culture QC Set as listed by pool and organisms in each pool: Pool Organisms Pool 1 S. epidermidis, S. lugdunensis, E. faecium, L. monocytogenes Pool 2 S. pyogenes, S. agalactiae, S. anginosus Pool 3 S. aureus, E. faecalis, S. pneumoniae C. Review of the laboratory's policy and procedure titled Verigene-Blood Culture Panels, Policy Number Lab 9.118 revised 11/01/2020, under Quality Control stated, "If any level of control fails, patient testing may not be performed until corrective action has occurred, acceptable results are obtained and testing has been repeated ... New Lot of Shipment of Reagents-Microbiologics control panels must be processed prior to putting a new lot or shipment of reagent into use ..." D. Review of the QC records on the Verigene for Processor A1 from 06/17/2022 - 06/21/2023 showed the QC run performed on 04/07 /2023 failed for the organism Streptococcus agalactiae using QC pool 2. The last successful QC run for Streptococcus agalactiae was performed on 02/14/2023 using QC pool 2. E. Review of the BC-GP patient instrument print-outs from 02/14/23 - 04 /07/23 showed patient testing was performed as listed by the Sample ID and Analysis completed date: Sample ID Analysis date 1. 947731 02/16/23 2. 963850 02/18/23 3. 7020 02/20/23 4. 979403 02/22/23 5. 8006 02/25/23 6. 8316 02/28/23 7. 060366 03/02 /23 8. 037818 03/05/23 9. 48066 03/13/23 10. 10230 03/13/23 11. 12394 03/14/23 12. 111336 03/22/23 13. 108541 03/22/23 14. 118197 03/25/23 15. 012069 03/27/23 16. 012456 03/30/23 17. 144194 03/31/23 18. 153991 04/03/23 19. 160163 04/04/23 20. 166326 04/05/23 F. Interview with technical supervisor #6 (as listed on the CMS form 209) on August 14, 2023 at 10:55 AM acknowledged the QC "got out of his sight", that he "didn't notice it was out," and "all patients are also run on the Vitek" [from a culture. The Verigene gives the physician a preliminary report while waiting on the culture.] 41687 II. Based on a review of the laboratory's policies, the chemistry

quality control records from January 2023 on the Cobas c503 chemistry analyzer, patient test records, and staff interview, the laboratory failed to have documentation of evaluating patient results tested prior to a control failure back to the last successful quality control run for one of three times in January 2023. Findings include: 1. A review of the laboratory's policy titled 'Quality Control Policy & Equipment Maintenance Policy' revealed the following: "Acceptable Results Must: - Be within +/- 2 SD Corrective Actions: - Repeat analysis with fresh control material - Verify that the controls were mixed correctly and adequately - Verify the correct lot number of controls, reagent and calibrator has been used - Replace reagents and reanalyze - Verify instrument performance by performing appropriate mechanical checks/ troubleshooting - Verify instrument performance by analyzing assayed controls if available as patient results - Verify methodology performance by analyzing a previously tested patient sample and comparing results to the previously run values" 2. A review of the laboratory's quality control records for the Cobas c503 chemistry analyzers from January 2023 revealed the following time where the quality control (QC) results failed: Date: 1/25/23 Level 1 failed for Calcium on Cobas c503 (SN: 22D4-06) * Laboratory noted: Line B Calcium reran X2. Calcium Level 1, Recalibrated, QC still out 3. A review of patient test records from January 2023 identified the following 32 patient samples that were tested prior to the quality control failure and the laboratory failed to have documentation of evaluating the results per the laboratory's policy: - Patients tested for Calcium on the Cobas c503 analyzer (SN: 22D4-06) between 1/24/23 11:05 (passing QC) and 1/25/23 10:30 (QC failure) Patient ID: OD0006573430 Patient ID: OD0006556823 Patient ID: OD0006577001 Patient ID: OD0006587869 Patient ID: OD0006587901 Patient ID: OD0006587943 Patient ID: OD0006588016 Patient ID: OD0006584510 Patient ID: OD0006588313 Patient ID: OD0006588552 Patient ID: OD0006588537 Patient ID: OD0006588610 Patient ID: OD0006588677 Patient ID: OD0006588651 Patient ID: OD0006588768 Patient ID: OD0006572614 Patient ID: OD0006575153 Patient ID: OD0006564660 Patient ID: OD0006574701 Patient ID: OD0006585640 Patient ID: OD0006586812 Patient ID: OD0006587000 Patient ID: OD0006582415 Patient ID: OD0006587406 Patient ID: OD0006587059 Patient ID: OD0006564181 Patient ID: OD0006584064 Patient ID: OD0006586069 Patient ID: OD0006587901 Patient ID: OD0006588834 Patient ID: OD0006588842 Patient ID: OD0006540785 4. An interview with technical consultant #1 for chemistry (as indicated on the CMS 209 form) on 9/14/23 at 10:00 a. m. in the laboratory, after review of the records, confirmed the above findings. 47301 III. Based on a review of the laboratory's coagulation corrective action form and confirmed in staff interview, the laboratory failed to evaluate patient test results back to the last acceptable quality control (QC) run for 5 of 120 days (January 2023 - April 2023). Findings included: 1. A review of the laboratory's" Instrument / Control Corrective Action Form" revealed the following: a) 01/01/2023 PTT Level 3 failure. Corrective action: New CaCl/FSL QC IN 01/01/2023 at 0023 QC OUT 01/01/2023 at 0822 QC IN 01/01/2023 at 0919 Patients tested since last acceptable QC: Sample ID 747825 01/01/2023 at 0135 Sample ID 747948 01/01/2023 at 0227 Sample ID 748010, 01/01/2023 at 0254 Sample ID 747932, 01/01/2023 at 0258 Sample ID 747342, 01/01/2023 at 0552 b) 01/14/2023 PT Level 1 failure. Corrective action: Changed Innovin QC IN 01/14/2023 at 0106 QC OUT 01/14/2023 at 0724 QC IN 01 /14/2023 at 0804 Patients tested since last acceptable QC: Sample ID 808882, 01/14 /2023 at 0130 Sample ID 808994, 01/14/2023 at 0137 Sample ID 809150, 01/14/2023 at 0321 Sample ID 808509, 01/14/2023 at 0339 Sample ID 808925, 01/14/2023 at 0340 Sample ID 808261, 01/14/2023 at 0341 Sample ID 808275, 01/14/2023 at 0455 Sample ID 808840, 01/14/2023 at 0548 Sample ID 808694, 01/14/2023 at 0549 Sample ID 809436, 01/14/2023 at 0602 Sample ID 809486, 01/14/2023 at 0644 c) 03 /05/2023 PT Level 1 failure. Corrective action: Changed Innovin QC IN 03/05/2023

	at 0058 QC OUT 03/05/2023 at 0753 QC IN 03/05/2023 at 0849 Patients tested since last acceptable QC: Sample ID 043420, 03/05/2023 at 0212 Sample ID 043797, 03/05 /2023 at 0540 Sample ID 042981, 03/05/2023 at 0612 Sample ID 043938, 03/05/2023 at 0630 d) 04/02/2023 PT Level 3 failure. Corrective action: Changed Innovin QC IN 04/02/2023 at 0828 QC OUT 04/02/2023 at 1514 QC IN 04/02/2023 at 1616 Patients tested since last acceptable QC: Sample ID 155305, 04/02/2023 at 0957 e) 04/03/2023 PTT Level 3 failure. Corrective action: Changed Innovin QC IN 04/03/2023 at 0041 QC OUT 04/03/2023 0854 QC IN 04/03/2023 0944 Patients tested since last acceptable QC: Sample ID 157862, 04/03/2023 at 0304 Sample ID 158042, 04/03 /2023 at 0322 Sample ID 157631, 04/03/2023 at 0540 2.During an interview on 09/13 /2023 at 01:25 pm in the laboratory, after review of the above records, Technical Consultant #2 (as listed on the submitted CMS 209) confirmed the above findings. Word Key: CaCL: Calcium chloride FSL: Dade Actin FSL activated PTT reagent PTT: Partial thromboplastin
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on review of instrument print-outs and interview, the laboratory failed to document who performed the patient testing on the Luminex Verigene used for blood culture identification of gram positive (BC-GP) and gram-negative (BC-GN) organisms performed for 56 out of 85 instrument print-outs reviewed. A. Review of the BC-GP and BC-GN patient instrument print-outs from the Verigene from 06/22 /23 - 02/20/23 showed the "performed by" defaulted to "administrator" and the tech initials who performed the test was not documented on 56 out of 85 patient instrument print-outs reviewed. BC-GP Sample ID Analysis date 1. 20139 06/08/23 2. 372533 06 /05/23 3. 19308 06/05/23 4. 362358 06/04/23 5. 19283 05/31/23 6. * 05/27/23 7. 326297 05/23/23 8. 18309 05/22/23 9. 324438 05/22/23 10. 297272 05/15/23 11. 17281 05/12/23 12. 276542 05/07/23 13. 16149 05/04/23 14. 220922 04/21/23 15. 209725 04/21/23 16. 14416 04/17/23 17. 200067 04/16/23 18. 160163 04/04/23 19. 153991 04/03/23 20. 144194 03/31/23 21. 012456 03/30/23 22. 012069 03/27/23 23. 118197 03/25/23 24. * 03/22/23 25. 111336 03/22/23 26. 010780 03/17/23 27. 12394 03/14/23 28. 037818 03/05/23 29. 030633 03/02/23 30. 8316 02/28/23 31. 7961 02/25 /23 32. 979403 02/22/23 33. 7020 02/20/23 34. 6931 02/20/23 35. 963850 02/18/23 36. * 02/17/23 37. 947731 02/16/23 * sample IDs were illegible BC-GN Sample ID Analysis date 1. 21625 06/22/23 2. 20842 06/15/23 3. 20213 06/10/23 4. 16569 05/08 /23 5. 16575 05/08/23 6. 268277 05/06/23 7. 265979 05/05/23 8. 15683 04/29/23 9. 237936 04/26/23 10. 15274 04/25/23 11. 14354 04/16/23 12. 175378 04/08/23 13. 012180 03/28/23 14. 10922 03/18/23 15. 8716 03/03/23 16. 024239 03/01/23 17. 8459 02/28/23 18. 986165 02/24/23 19. 973322 02/22/23 B. Interview with technical supervisor #6 (as listed on the CMS form 209) on August 13, 2023 at 4:30 PM confirmed not all the instrument print-outs had the initials of the tech who performed the test.

D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based upon review of the laboratory policies and procedures, manufacturer instructions for use, quality control records patient test records personnel records and interview of facility personnel the laboratory director failed to provide oversight and direction. (See D6093 and D6102)
D6087	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(iii) The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based upon review of Cobas manufacturer's instructions, patient test records, laboratory policies and procedures and interview of facility personnel, the laboratory failed to follow the manufacturer's instructions for the storage, processing and analysis of patient samples tested for Lactate, Ammonia, Homocysteine, Progesterone, Human Chorionic Gonadotropin (HCG) and Estradiol. (See D5311)
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based upon surveyor's observations, review of policies and procedures, manufacturer instructions, quality control records, patient test records and staff interview, the Laboratory Director failed to ensure a quality control (QC) plan was established and maintained for Bacteriology and Chemistry. (See D5471)
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must 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:

	Review of personnel Records and interview of facility personnel found that the laboratory director failed to ensure that one of fifteen testing personnel had the appropriate education prior to performing high complexity testing. (See D 6171)
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: Based on a review of the CMS-209 Laboratory Personnel Report, laboratory personnel records and interview of facility personnel, the laboratory failed to ensure one of fifteen testing personnel met the minimum education requirements for performing high complexity testing . (See D6171)
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry 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; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling,

	handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations. This STANDARD is not met as evidenced by: Based upon review of the laboratory's submitted CMS Form 209, review of the personnel records, and interview of facility personnel, the laboratory failed to have documentation of foreign education equivalency for one of fifteen testing personnel performing high complexity testing. The findings included: 1. Review of the CMS Form 209 (signed by the laboratory director August 30, 2023) found the laboratory identified 89 testing personnel with 15 testing personnel performing high complexity testing. 2. Review of the laboratory's personnel records found no documentation of foreign equivalency evaluation of education obtained outside the Unites States for testing person 15 (hired August 5, 2022). 3. During Interview of the laboratory administrative director conducted September 13, 2023 at 1:48 PM, she confirmed she did not have a foreign equivalency evaluation available for review for testing person 15.