Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0660553	12/04/2024
Name of Provider or Supplier	**Street Address, City, State**	
Starr County Memorial Hospital	128 N Fm 3167, Rio Grande City, 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 found to be in compliance with the Conditions of the CLIA regulations found at 42 CFR 493.1 through 493.1780, and recertification is recommended. Standard level deficiencies were cited.
D3015	REQUIREMENTS FOR TRANSFUSION SERVICES CFR(s): 493.1103 A facility that provides transfusion services must meet all of the requirements of this section and document all transfusion-related activities. This STANDARD is not met as evidenced by: Based on a review of the facility's policies, patient transfusion records, and staff interview, the facility failed to follow its own policy for documenting patient vitals during a transfusion for three of ten random transfusions reviewed in 2023 and 2024. Findings include: 1. A review of the facility's policy titled 'Blood Product Administration' revealed the following: "- Take baseline vitals before starting transfusion and record in Transfusion Record. After blood has started infusing, stay with the patient for at least 15 minutes to check for a transfusion reaction. Repeat vital signs at 15 minutes and at one hour after the start of transfusion, and hourly thereafter for the duration of the transfusion, and then at the ed of the transfusion." 2. A random review of patient transfusion records from 2023 and 2024 revealed the follow 3 transfusions were missing patient vital sign documentation at 15 minutes, per the facility's policy: - Patient #: 10491735 Unit #: W03622307728200L Baseline vitals taken: 5/19/23 at 01:10 Next time vials were taken: 5/19/23 at 01:45 Elapsed time: 35 minutes - Patient #: 10532672 Unit #: W041124017845005 Baseline vitals taken: 2/16 /24 at 17:30 Next time vitals were taken: 2/16/24 at 18:00 Elapsed time: 30 minutes - Patient #: 10532672 Unit #: W04112401521400P Baseline vitals taken: 2/17/24 at 11: 05 Next time vitals were taken: 2/17/24 at 11:45 Elapsed time: 40 minutes 3. In an interview on 12/4/24 at 11:30 a.m. in the conference room, after review of the records, the technical consultant confirmed the above findings.

D3021	REQUIREMENTS FOR TRANSFUSION SERVICES CFR(s): 493.1103(c)(1) Blood and blood products storage and distribution. If a facility stores or maintains blood or blood products for transfusion outside of a monitored refrigerator, the facility must ensure the storage conditions, including temperature, are appropriate to prevent deterioration of the blood or blood product. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies, the Blood Bank Alarm Checks for 2023 and 2024, a review of the chart recorder graphs, surveyor observation, and staff interview, the laboratory failed to ensure the changes in temperature were recorded on the chart recorder graphs when the Blood Bank refrigerator temperatures fell outside of the acceptable range during nine of ten alarm checks performed in 2023 and 2024. Findings include: 1. A review of the laboratory's policy titled 'Blood Bank Alarm Check' revealed the following: "The blood bank refrigerator is equipped with an alarm to sound off should the temperature of the refrigerator not be within the specified range. This alarm must be checked quarterly to ensure that it is working properly. Temperature range is +1 to +6 ." 2. A review of the Blood Bank Alarm Checks for 2023 and 2024 revealed the laboratory performed the alarm checks on the following days: - 1/10/23 Beeps at 1.5C and 5.5C - 4/18/23 Beeps at 1.5C and 5.5C - 7/11/23 Beeps at 1.5C and 5.5C - 10/4/23 Beeps at 1.5C and 5.5C - 12/5/23 Beeps at 1.5C and 5.5C - 1/7/24 Beeps at 1.5C and 5.5C - 4/5/24 Beeps at 1.5C and 5.5C - 7/6/24 Beeps at 1.5C and 5.5C - 10/2/24 Beeps at 1.6C and 5.5C - 12/2/24 Beeps at 1.5C and 5.5C 3. A review of the chart recorder graphs for the dates above revealed the following nine alarm checks found no change in temperatures were recorded on the chart recorder graphs: - 1/10/23 - 4/18/23 - 7/11/23 - 10/4/23 - 1/7/24 - 4/5/24 - 7/6/24 - 10/2/24 - 12/2/24 4. Testing person #7 was asked on 12/4/24 at 11:20 a.m. to perform an alarm check. Surveyor observation of the Blood Bank refrigerator revealed the alarm sounded and the temperatures were recorded on the chart recorder graphs when the temperatures fell outside of the acceptable range. 5. In an interview on 12/4/24 at 11:25 a.m. in the conference room, after review of the records, the technical consultant confirmed the above findings. Key: C = Degrees Celsius
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: Based on a review of the laboratory's policies, a review of the laboratory's Incoming Specimen Logs, and staff interview, the laboratory failed to define the acceptability criteria for 11 of 11 specimens received at "Room Temp" from January to November 2024. Findings include: 1. A review of the laboratory's policies revealed the laboratory failed to have documentation of a policy defining the acceptability criteria for specimens received at "Room Temp". 2. A review of the laboratory's Incoming

	Specimen Logs from January to November 2024 revealed the following patient's specimens were documented as received at "Room Temp", with no defined acceptability criteria: Date: 1/6/24 Patient #: 10526306 Date: 7/3/24 Patient #: 10553698 Date: 7/26/24 Patient #: 10557355 Date: 7/29/24 Patient #: 10557656 Date: 8/14/24 Patient #: 10560082 Date: 8/19/24 Patient #: 10560744 Date: 10/15/24 Patient #: 10570263 Date: 10/22/24 Patient #: 10571344 Date: 10/22/24 Patient #: 10571343 Date: 10/22/24 Patient #: 10571357 Date: 11/14/24 Patient #: 10575037 3. In an interview on 12/4/24 at 3:10 p.m. in the conference room, after review of the records, the technical consultant confirmed the above findings.
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on the review of the manufacturer's instructions for the Siemens' Dimension Lactic Acid assay, review of patient test records from November 16, 2024 to November 20, 2024, and staff interview, the laboratory's quality assurance plan failed to identify that collection times for ----- of ------ lactic acid tests were not being recorded correctly and, therefore, the laboratory could not ensure samples were processed in the required timeframe. The findings included: 1. A review of the manufacturer's instructions for the Siemens' Dimension Lactic Acid assay (Issue date: 2019-04-01) under the section titled "Specimen Collection and Handling" identified: '.....followed by the immediate chilling of the specimen and separation of the cells within 15 minutes." 2. A review of patient test records from November 16, 2024 to November 20, 2024 identified 18 of 30 lactic acid tests where the recorded collection time was identical to the recorded time the sample was received in the laboratory despite the samples being collected in various parts of the hospital and transported to the lab. They were: Order: 76355 Date: 11/16/2024 Documented collection time: 0611 Documented received time: 0611 Order:76584 Date: 11/16/2024 Documented collection time: 1255 Documented received time: 1255 Order:76661 Date: 11/16/2024 Documented collection time: 1648 Documented received time: 1648 Order:76693 Date: 11/16/2024 Documented collection time: 2014 Documented received time: 2014 Order:77124 Date: 11/167/2024 Documented collection time: 2107 Documented received time: 2107 Order:77586 Date: 11/18/2024 Documented collection time: 1450 Documented received time: 1450 Order:77257 Date: 11/18/2024 Documented collection time: 0017 Documented received time: 0017 Order:77733 Date: 11/18/2024 Documented collection time: 1853 Documented received time: 1853 Order:77719 Date: 11/18/2024 Documented collection time: 1812 Documented received time: 1812 Order:77792 Date: 11/19/2024 Documented collection time: 0439 Documented received time: 0439 Order:78153 Date: 11/19/2024 Documented collection time: 1248 Documented received time: 1248 Order:78089 Date: 11/19/2024 Documented collection time: 1125 Documented received time: 1125 Order:78000 Date: 11/19/2024 Documented collection time: 0922 Documented received time: 0922 Order:78930 Date: 11/20/2024 Documented collection time: 1347 Documented received time: 1347 Order:78949 Date: 11/20/2024 Documented collection time: 1448 Documented received time: 1448 Order:79059 Date: 11/20/2024 Documented collection time: 1745 Documented received time: 1745 Order:78843 Date: 11/20/2024 Documented collection time: 1245 Documented received time: 1245 Order:78936 Date: 11/20/2024

	Documented collection time: 1545 Documented received time: 1545 3. The technical consultant confirmed that samples were collected throughout the hospital and then brought to the laboratory where they were received into the LIS during an interview conducted on 12/04/2024 at 1600 hours in the conference room. She stated the received time was used as the collection time inappropriately. She then agreed that without the correct collection time, the laboratory could not ensure samples for lactic acid testing were processed within 15 minutes as required by the manufacturer.
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 a review of the ASI Color Mono II Test Instructions for Use, a review of the laboratory's Mono Logs, and staff interview, the laboratory failed to ensure the patient's samples used for Infectious Mononucleosis antibody testing were rotated for the correct time for 105 of 118 patient test records reviewed from March 2023 to March 2024. Findings include: 1. A review of the ASI Color Mono II Test Instructions for Use (6004-450, Rev 12/2018) revealed the following: "Gently rotate the card for 2 minutes." 2. A review of the Mono Logs from March 2023 to March 2024 revealed the laboratory documented the rotation time as 8 minutes, not 2 minutes per the manufacturer's requirements, for the following patients: Patient #s for patients tested using the ASI Color Mono II Test from 3/2/23 to 3/14/24: 10480278, 10480299, 10480537, 10480616, 10480987, 10482038, 10482050, 10482067, 10483058, 10483259, 10483312, 10484061, 10484126, 10484199, 10483692, 10485101, 10486194, 10486021, 10486356, 10486487, 10486535, 10486957, 10486987, 10488039, 10488266, 10488297, 10488297, 10488750, 10489156, 10489158, 10489483, 10490233, 10491389, 10491616, 10491884, 10492449, 10492574, 10492678, 10492736, 10486451, 10490468, 10493413, 10493581, 10493579, 10493908, 10494028, 10494328, 10494574, 10496088, 10495825, 10496465, 10496297, 10497528, 10497593, 10500456, 10503729, 10506555, 10507996, 10508106, 10509012, 10509017, 10508928, 10509835, 10510491, 10511532, 10511880, 10517492, 10512495, 10513438, 10516123, 10516782, 10518142, 10518152, 10518515, 10518906, 10518266, 10520854, 10521032, 10521134, 10521202, 10521988, 10522324, 10522348, 10523229, 10523277, 10523367, 10523599, 10524538, 10524874, 10525299, 10525300, 10526058, 10526300, 10526310, 10526827, 10534330, 10534536, 10534608, 10534977, 10535637, 10535852, 10535902, 10536023, 10536786, 10536798 3. In an interview on 12/4/24 at 3:00 p.m. in the conference room, after review of the records, the technical consultant confirmed the above findings. II. Based on a review of the Medline Mono Test Cassette Instructions for Use, surveyor observation, a review of the Sorvall Legend X1 centrifuge settings, a review of the laboratory's Mono Logs, and staff interview, the laboratory failed to ensure the patient's samples were centrifuged at the correct speed and time for Infectious Mononucleosis antibody testing for 66 of 66 patient test records reviewed from March to December 2024. Findings include: 1. A review of the Medline Mono Test Cassette Instructions for Use revealed the following: "Serum or Plasma: - centrifuged at 1500 x g for ten minutes at room temperature." 2. Surveyor observation of the laboratory on 12/4/24 at 3:00 p.m.

	revealed the laboratory used one Thermo Scientific Sorvall Legend X1 centrifuge (serial number: 41870083) to centrifuge all laboratory specimens. 3. A review of the Thermo Scientific Sorvall Legend X1 centrifuge's settings revealed the following pre-programmed settings for patient specimens: 1. 1620 RPM 5 minutes 2. 3500 RPM 10 minutes 3. 3500 RPM 4 minutes 4. 1500 RPM 15 minutes 5. 3000 RPM 15 minutes *There was not a pre-programmed setting that matched the requirements for the Medline Mono Test Cassette of 1500 RPM for 10 minutes. 4. A review of the laboratory's Mono Logs from March to December 2024 revealed the laboratory failed to centrifuge the following patient samples at the correct speed and time: Patient #s for patients tested using the Medline Mono Test Cassette Test from 3/15/24 to 12/3 /24: 10537052, 10537346, 10537349, 10537347, 10539097, 10539102, 10539100, 10539103, 10539107, 10539135, 10539172, 10539773, 10539940, 10540600, 10540801, 10541148, 10542413, 10543489, 10543932, 10544897, 10545878, 10546114, 10546322, 10546836, 10547152, 10547470, 10547607, 10548404, 10549220, 10550864, 10551141, 10552035, 10552494, 10552842, 10554000, 10548483, 10559997, 10560049, 10560178, 10560306, 10560469, 10560654, 10560657, 10562499, 10562606, 10565746, 10565961, 10566960, 10569471, 10570041, 10570556, 10570805, 10571620, 10571724, 10571724, 10572298, 10572706, 10572095, 10573817, 10573819, 10575288, 10576190, 10576851, 10577004, 10577517, 10577798 5. In an interview on 12/4/24 at 3:00 p.m. in the conference room, after review of the records, the technical consultant confirmed the above findings. Key: RPM = Revolutions per minute
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on a review of the laboratory's records and staff interview, the laboratory failed to have documentation of performing two of four verification studies (accuracy and precision) for Infectious Mononucleosis (Mono) testing using the Medline Mono Test Cassette in March 2024. Findings include: 1. A review of the laboratory's records revealed the laboratory started Mono testing using the Medline Mono Test Cassette on 3/15/24. 2. Further review of the laboratory's records revealed the laboratory failed to have documentation of an accuracy and precision study for Mono testing using the Medline Mono Test Cassette. 3. In an interview on 12/4/24 at 10:20 a.m. in the conference room, after review of the records, the technical consultant confirmed the above findings.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a

	function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies, the maintenance records for the Sorvall Cell Washer from 2023 to 2024, the laboratory's records, and staff interview, the laboratory failed to ensure the cell washer: a) delivered the proper amount of saline to the blood bank tubes for 640 of 640 days between March 2023 to November 2024. b) was spinning at the appropriate revolutions per minute (RPMs) for four of four times quarterly maintenance was performed in 2024. Findings include: 1. A review of the laboratory's policy titled 'Cell Washer Preventative Maintenance' revealed the following: "Daily: Check saline fill volume - Using the CALIBRATE key and a graduated cylinder, make sure that the washer delivers 54 mls of saline to the 12x75 tubes. Every 3 months: Check motor speed - Set the power to ON and press the HOLD key. Allow the motor to accelerate to speed. Shine a stroboscope or tachometer through the viewport in the cover to verify the speed. RPM 3400 - 3600" 2. A review of the Maintenance for Sorvall Cell Washer records revealed the following: a) From March 2023 to November 2024, the laboratory performed the daily saline volume check and for all 640 days, the saline volume was documented below 54 mls. b) In 2024, the laboratory performed the quarterly RPM checks on the following dates and the RPMs were below the acceptable range of 3400 - 3600: - Date: 3/2/24 3000 RPM - Date: 6/5/24 3000 RPM - Date: 9/24/24 3000 RPM - Date: 12/3/24 3000 RPM 3. A review of the laboratory's records revealed the laboratory estimated performing 4,500 immunohematology tests annually. 4. In an interview on 12/4/24 at 11:15 a.m. in the conference room, after review of the records, the technical consultant confirmed the above findings. Key: mls = milliliters ***NOTE: This is a repeat deficiency from the survey performed on 2/15/23***
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 the laboratory's calibration verification records for the ABL90 blood gas analyzers from 2023 and 2024 and staff interview, the laboratory failed to have documentation of performing calibration verifications every six months for 2 of 2 analyzers. The findings included: 1. A review of the laboratory's calibration verification records for the ABL90 blood gas analyzers (serial number 092R0348N017 and 092R0348N020) determined calibration verification records were performed on following times: a) 092R0348N017 April 2023 July 2023 (4 months later) March 2024 (8 months later) October 2024 (7 months later) Tests: pH, TCO2, pO2, tHb, SO2, Ca+ b) 092R0348N020 April 2023 July 2023 (4 months later) March 2024 (8 months later) October 2024 (7 months later) Tests: pH, TCO2, pO2, tHb, SO2, Ca+ 2. The technical consultant confirmed the findings in an interview conducted on 12/03/2024 at 1525 hours in the conference room.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of the laboratory's quality control records, a review of the laboratory's Mono Logs, and staff interview, the laboratory failed to have documentation of running a negative and positive quality control each day of patient testing for 54 of 54 days from March to December 2024 on the Medline Mono Test Cassette. Findings include: 1. A review of the laboratory's quality control records from March to December 2024 revealed the following days the laboratory failed to have documentation of running a negative and positive control when patients were tested: 3/15/24, 3/18/24, 3/29/24, 3/30/24, 3/31/24, 4/3/24, 4/4/24, 4/9/24, 4/10/24, 4 /12/24, 4/19/24, 4/28/24, 4/30/24, 5/6/24, 5/12/24, 5/13/24, 5/15/24, 5/17/24, 5/20/24, 5/22/24, 5/28/24, 6/3/24, 6/13/24, 6/15/24, 6/21/24, 6/25/24, 6/27/24, 7/5/24, 7/15/24, 8/14/24, 8/15/24, 8/16/24, 8/18/24, 8/28/24, 8/29/24, 9/17/24, 9/18/24, 9/24/24, 10/10 /24, 10/14/24, 10/17/24, 10/19/24, 10/23/24, 10/24/24, 10/28/24, 10/30/24, 11/7/24, 11 /10/24, 11/15/24, 11/21/24, 11/26/24, 11/27/24, 12/2/24, 12/3/24 2. A review of the laboratory's Mono Logs from March to December 2024 revealed the following patient's samples were run on days when the laboratory failed to have documentation of running a negative and positive control: 10537052, 10537346, 10537349, 10537347, 10539097, 10539102, 10539100, 10539103, 10539107, 10539135, 10539172, 10539773, 10539940, 10540600, 10540801, 10541148, 10542413, 10543489, 10543932, 10544897, 10545878, 10546114, 10546322, 10546836, 10547152, 10547470, 10547607, 10548404, 10549220, 10550864, 10551141, 10552035, 10552494, 10552842, 10554000, 10548483, 10559997, 10560049, 10560178, 10560306, 10560469, 10560654, 10560657, 10562499, 10562606, 10565746, 10565961, 10566960, 10569471, 10570041, 10570556, 10570805, 10571620, 10571724, 10571724, 10572298, 10572706, 10572095, 10573817, 10573819, 10575288, 10576190, 10576851, 10577004, 10577517, 10577798 3. In an

	interview on 12/4/24 at 3:00 p.m. in the conference room, after review of the records, the technical consultant confirmed the above findings.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on review of the laboratory's test menu, review of the laboratory's records from 2023 and staff interview, the laboratory failed to have documentation of performing instrument comparisons for 2 of 2 tests. The findings included: 1. A review of the laboratory's test menu determined the laboratory performed Strep A and C. diff testing on the following two analyzers in 2023: a) Cephid Gene Xpert b) Meridian Bioscience Revogene 2. A review of the laboratory's records determined the laboratory failed to have documentation of performed twice annual instrument comparisons for the tests in 2023. 3. The technical consultant confirmed the findings in an interview conducted on 12/03/2024 at 1130 hours in the conference room.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: Based on review of the laboratory's hematology/coagulation temperature and humidity records from January 2024 to November 2024, and staff interview, the laboratory failed to have documentation of performing corrective actions for 6 of 334 days when temperature or humidity was documented outside the laboratory's acceptable ranges. The findings included: 1. A review of the laboratory's temperature and humidity records from January 2024 to November 2024 determined the laboratory had the following acceptable ranges for temperature and humidity: a) temperature 20 - 25C b) humidity 30 - 85% 2. Further review of the records determined the following times where the documented temperature or humidity was out of range, and the facility failed to have documentation of performing corrective actions: January 17, 2024 humidity: 28% January 18, 2024 humidity: 24% May 4, 2024 temperature: 26C May 5, 2024 temperature: 26C May 7, 2024 temperature: 25.1C November 29, 2024 humidity: 29% 3. The technical consultant confirmed the findings in an interview conducted on 12/04/2024 at 1615 hours in the conference room.
D5813	TEST REPORT CFR(s): 493.1291(g) The laboratory must immediately alert the individual or entity requesting the test and, if applicable, the individual responsible for using the test results when any test result

	indicates an imminently life-threatening condition, or panic or alert values. This STANDARD is not met as evidenced by: Based on review of the laboratory's Abnormal Laboratory Values protocol, review of patient test records from October 16, 2024 to December 4, 2024, and staff interview, the laboratory failed to have documentation of the notification of 6 of 6 panic values for white blood cell counts. The findings included: 1. A review of the laboratory's Abnormal Laboratory Values protocol (effective date: July 2014) under the section titled "Policy" determined: "The following laboratory test values listed in the table below are to be reported to the patient's primary nurse and to the patient's primary physician. Upon notification, the laboratory staff will document on the report form [the] following: a. Names of the patient's primary physician and patient's primary nurse b. Date and time when the patient's primary physician and patient's primary nurse were notified." 2. Further review of the protocol determined the laboratory had the following panic ranges defined for white blood cell counts: Less than 2 Higher than 28 3. A sampling of patient test records from October 16, 2024 to December 4, 2024 determined the facility failed to have documentation of the notification of 6 of 6 panic values. They were: a) Date: 10/16/2024 Order: 54599 WBC: 38.6 b) Date: 10/19 /2024 Order: 56716 WBC: 1.5 c) Date: 11/07/2024 Order: 70251 WBC: 1.3 d) Date: 11/14/2024 Order: 75167 WBC: 29.1 e) Date: 11/15/2024 Order: 75601 WBC: 1.5 f) Date: 12/04/2024 Order: 88470 WBC: 1.7 4. The technical consultant confirmed the finding in an interview conducted on 12/04/2024 at 1755 hours in the laboratory. Key: WBC: white blood cell
D6045	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(7) (b) The technical consultant is responsible for-- (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; This STANDARD is not met as evidenced by: Based on a review of the laboratory's records, the laboratory's personnel records, and staff interview, the technical consultant failed to have documentation of training for the following: a) five of nine testing personnel for Methicillin-resistant Staphylococcus aureus (MRSA) testing on the Cepheid GeneXpert in 2023. b) eight of eight testing personnel for Clostridioides difficile (C. diff) testing on the Cepheid GeneXpert in 2023. c) one of one testing personnel for Streptococcus A (Strep A) testing on the Cepheid GeneXpert in 2023. d) six of six testing personnel for Infectious Mononucleosis (Mono) testing using the Medline Mono Test Cassette in 2024. Findings include: 1. A review of the laboratory's records revealed the laboratory began testing using the following new methodologies: a) MRSA testing on the Cepheid GeneXpert in July 2023. b) C. diff testing on the Cepheid GeneXpert in March 2023. c) Strep A testing on the Cepheid GeneXpert in March 2023. d) Mono testing using the Medline Mono Test Cassette in March 2024. 2. A review of the laboratory's personnel records revealed the technical consultant failed to have documentation of training for testing personnel prior to patient testing for the following: a) MRSA testing on the Cepheid GeneXpert: - Testing person #5 - Testing person #6 - Testing person #8 - Testing person #14 - Testing person #15 b) C. diff testing on the Cepheid GeneXpert: - Testing person #1 - Testing person #2 - Testing

	person #4 - Testing person #5 - Testing person #7 - Testing person #8 - Testing person #14 - Testing person #15 c) Strep A testing on the Cepheid GeneXpert: - Testing person #7 d) Mono testing using the Medline Mono Test Cassette: - Testing person #2 - Testing person #5 - Testing person #7 - Testing person #8 - Testing person #14 - Testing person #15 3. In an interview on 12/4/24 at 2:00 p.m. in the conference room, after review of the records, the technical consultant confirmed the above findings.
D6055	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing whenever test methodology or instrumentation changes. The individual's performance must be reevaluated to include the use of the new test methodology or instrumentation prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on a review of the laboratory's records, the laboratory's personnel files, and staff interview, the technical consultant failed to evaluate and document the competency of the following testing personnel performing testing using new methodologies, prior to patient testing: a) nine of nine testing personnel for Methicillin-resistant Staphylococcus aureus (MRSA) testing on the Cepheid GeneXpert in 2023. b) eight of eight testing personnel for Clostridioides difficile (C. diff) testing on the Cepheid GeneXpert in 2023. c) one of one testing personnel for Streptococcus A (Strep A) testing on the Cepheid GeneXpert in 2023. d) six of six testing personnel for Infectious Mononucleosis (Mono) testing using the Medline Mono Test Cassette in 2024. Findings include: 1. A review of the laboratory's records revealed the laboratory began testing using the following new methodologies: a) MRSA testing on the Cepheid GeneXpert in July 2023. b) C. diff testing on the Cepheid GeneXpert in March 2023. c) Strep A testing on the Cepheid GeneXpert in March 2023. d) Mono testing using the Medline Mono Test Cassette in March 2024. 2. A review of the laboratory's personnel files revealed the technical consultant failed to evaluate and document the competency of the following testing personnel using the new methodologies, prior to patient testing: a) MRSA testing on the Cepheid GeneXpert: - Testing person #1 - Testing person #2 - Testing person #4 - Testing person #5 - Testing person #6 - Testing person #7 - Testing person #8 - Testing person #14 - Testing person #15 b) C. diff testing on the Cepheid GeneXpert: - Testing person #1 - Testing person #2 - Testing person #4 - Testing person #5 - Testing person #7 - Testing person #8 - Testing person #14 - Testing person #15 c) Strep A testing on the Cepheid GeneXpert: - Testing person #7 d) Mono testing using the Medline Mono Test Cassette: - Testing person #2 - Testing person #5 - Testing person #7 - Testing person #8 - Testing person #14 - Testing person #15 3. In an interview on 12/4/24 at 2:00 p.m. in the conference room, after review of the records, the technical consultant confirmed the above findings.
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens.

	This STANDARD is not met as evidenced by: Based on a review of the laboratory's Centers for Medicaid and Medicare services (CMS) 209 form, personnel records, and staff interview, the technical supervisor failed to provide documentation of performing four of fifteen initial competency assessments for testing personnel performing high complexity testing in 2024. Findings include: 1. A review of the laboratory's CMS 209 form revealed the laboratory employed fifteen testing personnel performing high complexity immunohematology testing. 2. A review of the laboratory's personnel records revealed the technical consultant performed the initial competency assessments for immunohematology for the following 4 testing personnel: - Testing person #9 initial competency assessment performed 4/20/24 - Testing person #10 initial competency assessment performed 6/18/24 - Testing person #11 initial competency assessment performed 2/15/24 - Testing person #13 initial competency assessment performed 5/28 /24 3. In an interview on 12/4/24 at 11:30 a.m. in the conference room, after review of the records, the technical consultant confirmed the above findings.