Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0660553	08/04/2021
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 found to be out of compliance based on the following CONDITION LEVEL DEFICIENCY: D6063 - 42 C.F.R. 493.1412 Condition: Testing Personnel; moderate complexity Noted deficiencies and plans of correction were discussed with the laboratory representative at the exit conference. The facility representative was given an opportunity to provide evidence of compliance with noted deficiencies and no such evidence was provided prior to survey exit. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider /supplier, the State Survey Agency (SA) should be notified immediately.
D5213	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1) The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: Based on review of the laboratory's College of American Pathologists' (CAP) proficiency testing records, and staff interview, it was revealed the laboratory failed to have documentation of evaluating proficiency testing results not graded by the proficiency testing agency. The findings were: 1. A review of a sampling of the laboratory's College of American Pathologists' proficiency testing records from 2020 and 2021 revealed the following results which were returned as not graded by the proficiency testing agency: a) FHC9-C Hematology Auto Differential Blood Cell ID Specimen BCP-26 Specimen BCP-27 Specimen BCP-28 Specimen BCP-29 Specimen BCP-30 b) D-A 2021 Bacteriology Survey MIC Educational Ampicillin Specimen: D-

	01 Daptomycin Specimen: D-01 Erythromycin Specimen: D-01 Linezolid Specimen: D-01 Penicillin Specimen: D-01 Rifampin Specimen: D-01 Vancomycin Specimen: D-01 2. The laboratory was asked to provide documentation of evaluating the identified results returned as not graded by the proficiency testing agency. No documentation was provided. 3. An interview with the technical consultant on 08/03/2021 at 1100 hours in the conference room - after her review of the records- confirmed the findings.
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 review of the manufacturer's instructions, review of the patient test records, and staff interview, it was revealed the facility failed to follow manufacturer's instructions for: A) patient age limitation for the Dimension TPSA Flex cartridge, and B) specimen stability for blood gas samples tested on the ABL800 Flex analyzer. The findings include: A) TPSA Flex cartridge 1. A review of the manufacturer's instructions for the Dimension Total Protein specific Antigen (TPSA) Flex cartridge (2019-07-29 L PN 755451.001 US) under the section titled "Intended Use" revealed: The TPSA method for the Dimension clinical chemistry system with the heterogeneous immunoassay module is an in vitro diagnostic test intended to quantitatively measure total prostate specific antigen (PSA) in human serum and plasma: 1. As an aid in the detection of prostate cancer when used in conjunction with digital rectal exam (DRE) in men 50 years or older..." 2. A review of patient test records from January 1, 2021 to August 3, 2021 identified 13 of 236 patients who were under the age of 50 years old and had samples tested using the assay. They were: ID number Age (years) 10364681 41 10385024 19 10386421 46 10388193 28 10392442 47 10396003 49 10396251 27 10396614 35 10397803 41 10398493 47 10399812 45 10400350 47 10400353 48 3. An interview with the technical consultant on 08/03/2021 at 1500 hours in the laboratory confirmed the findings. b) Blood Gas on ABL800 1. A review of the manufacturer's instructions for the Seimen's ABL800 analyzer revealed samples for blood gas analysis were required to be tested within 30 minutes of collection. 2. A sampling of patient test records from July 29, 2021 to August 3, 2021 identified 1 of 20 blood gas samples which were tested and reported by laboratory more than 30 minutes after collection. It was: ID: 10400174 collected: 08/02 0445 am received: 08/02 0515 am resulted: 08/02 0522 am elapsed time: 37 minutes 3. An interview with the technical consultant on 08/03/2021 at 1624 hours in the conference room confirmed the findings.
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: A. Based on review of the Laboratoy's Bacteriology Safety policy, review of laboratory's maintenance records and interview with the staff it was determined the laboratory failed to follow its own policy for disinfection of work areas. The findings were: 1. Review of the Diagnostic Microbiology Procedures, Laboratory Safety, General Precautions section 4 revealed "Always carry out terminal disinfection and sterilization after completing your work. Wipe of all work areas with a disinfectant solutions(sic), such as 10% bleach." 2. Review of the laboratory's maintenance records revealed no documentation for performing disinfection of work areas. 3. In an interview on 08/03/2021 at 1000 hours in the conference room testing person #2 (as documented on CMS Form 209, signed by the laboratory director on 08/03/2021) stated that the laboratory does not document workspace disinfection. This confirmed the findings. B. Based on review of the laboratory's policies and procedures, review of patient's Wet Mount testing records from 08/22/2020 to 03/29/2021 and interview with the staff it was determined that the laboratory failed to have written procedures for performing Wet Mount testing for presence of Trichomonas and fungi (yeast). The findings were: 1. Review of the laboratory's patient testing records revealed that the laboratory was performing and reporting Wet Mount results. There were 44 patients tested from 08/22/2020 to 03/29/2021. Refer to Wet Mount Alias List. 2. Review of the laboratory's policies and procedures revealed that there was no written policy /procedure for performing Wet Mount testing. 3. In an interview on 08/03/2021 at 1430 hours in the conference room Technical Consultant and Testing Person #2 (as documented on CMS Form 209, signed by the laboratory director on 08/03/2021) stated they were not aware of a written policy/procedure for performing Wet Mounts. This confirmed the findings.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the laboratory's Parasitology Procedure, review of the laboratory's patient records for July 2021 and interview with the staff it was determined the

	laboratory failed to establish written protocols for referral of samples to a reference laboratory if parasites are seen on direct smear. The findings were: 1. Review of the Parasitology procedure revealed Under Section IV, subsection 2" If ova or parasites are seen on direct smear, preserve in PVA and proceed with trichrome stain". No written protocol was found for referral to a reference laboratory of parasitology samples positive for parasites from direct smear. 2. Review of patient parasitology July 2021 reports for specimens containing parasites on direct smear revealed specimens were sent to a reference laboratory for trichrome stain and identification of parasites. A sampling of the most recent specimens sent to reference laboratory included: Patient ID Date Test 10400332 07/29/2021 Ova and Parasite 10395283 07 /02/2021 Ova and Parasites 3. In an interview on 08/03/2021 at 1000 hours in the conference room testing person #2 (as documented on CMS Form 209, signed by the laboratory director on 08/03/2021) stated that the laboratory does not perform trichrome stain and samples with direct smears positive for presence of parasites are sent to reference laboratory for parasite identification, bur was unaware of a policy addressing the referal. This confirmed the findings.
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 random review of the laboratory's temperature logs for 2019, 2020, and 2021, review of manufacturer's package inserts for BD Bactec Blood Culture bottles, Meridian Bioscience Revogene Strep A, GBS LB and CDiff assays testing cartridges, and interview with the staff it was determined the laboratory failed to maintain appropriate temperature conditions for storage of supplies per manufacturer requirements for 36 of 36 instances reviewed. The findings were: 1. Review of BD Bactec Blood Culture vials package insert revealed the bottles' storage temperature requirement to be 2-25C. 2. Review of the package inserts for Meridian Bioscience Revogene Strep A Assay (for Streptococcus Group A detection), GBS LB Assay (for Streptococcus Group B) and CDiff Assay (for Clostridium difficile) testing cartridges' revealed the cartridges' storage temperature requirements to be 2-25C. 3. Further review of the laboratory's temperature logs for 2019, 2020 and 2021 revealed the laboratory's temperature was out of manufacturer's required range for storage of above supplies on multiple days. A sampling of those dates included: 10/01/2019 temperature recorded was 26C 10/02/2019 temperature recorded was 27C 10/13/2019 temperature recorded was 26C 10/24/2019 temperature recorded was 29C 10/30/2019 temperature recorded was 26C 11/03/2019 temperature recorded was 27C 11/13/2019 temperature recorded was 27C 11/21/2019 temperature recorded was 26C 11/22/2019 temperature recorded was 28C 11/24/2019 temperature recorded was 26C 11/31/2019 temperature recorded was 27C 12/06/2019 temperature recorded was 27C 12/13/2019 temperature recorded was 28C 12/19/2019 temperature recorded was 27C 12/23/2019 temperature recorded was 27C 12/25/2019 temperature recorded was 26C 08/04/2020 temperature recorded was 26C 08/05/2020 temperature recorded was 26C 08/12/2020

	temperature recorded was 27C 08/13/2020 temperature recorded was 28.4C 08/15 /2020 temperature recorded was 28C 11/05/2020 temperature recorded was 26C 11/06 /2020 temperature recorded was 26C 11/13/2020 temperature recorded was 26C 11/15 /2020 temperature recorded was 26C 11/29/2020 temperature recorded was 28C 02/04 /2021 temperature recorded was 26C 02/05/2021 temperature recorded was 26.1C 02 /06/2021 temperature recorded was 26.1C 02/10/2021 temperature recorded was 26.2 C 02/20/2021 temperature recorded was 26.7C 03/01/2021 temperature recorded was 28C 05/10/2021 temperature recorded was 25.6C 06/20/2021 temperature recorded was 26.5C 06/21/2021 temperature recorded was 26.C 06/22/2021 temperature recorded was 26.8C 4. In an interview on 08/03/2021 at 1500 hours in the conference room the Technical Consultant (as documented on CMS Form 209, signed by the laboratory director on 08/03/2021) stated that she was not aware of the storage temperature requirements' upper limit of 25C as the charts show the upper limit to be 27C. This confirmed the findings.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of the laboratory's verification studies, review of patient test records and staff interview, it was revealed the laboratory failed to have documentation of verifying patient normal ranges for 3 of 3 assays. The findings were: 1. A review of the laboratory's verification studies revealed the laboratory failed to have documentation of verifying patient normal ranges for the following assays: a) Total prostate specific antigen (studies approved 11/2019) b) C- reactive protein (studies approved 9/2020) c) Ferritin (studies approved 9/2020) 2. A review of patient test records revealed the following patient normal ranges were currently in use by the laboratory: a) Total prostate specific antigen 0.13 - 4.00 b) C-reactive protein 0.00 - 0.90 c) Ferritin 8 - 252 females 26 - 388 males 3. The laboratory was asked to provide documentation of verifying the patient normal ranges currently in use. No documentation was provided. 4. An interview with the technical consultant on 08/04 /2021 at 1030 hours in the conference room - after her review of the records- confirmed the 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 for the Siemens CS-2500 analyzer,

	review of maintenance records from July 2020 to July 2021, and staff interview it was revealed the laboratory failed to have documentation of performing required maintenance. The findings include: 1. A review of the manufacturer's instructions for the Siemens CS-2500 analyzer revealed the following maintenance was required to be performed daily: a) rinse probe b) discard used cuvettes c) dispose of waste d) check and discard trap chamber fluid e) shut down 2. A review of the laboratory's maintenance records from July 2020 to July 2021 identified the following days were required maintenance was not documented: a) July 2020 July 3 missing b, c, d July 18 missing a, b, c, d, e b) September 2020 July 10 missing a, e July 17 missing b, c, d c) October 2020 October 3 missing a, b, c, d, e October 4 missing a, b, c, d, e October 10 missing a, b, c, d, e October 24 missing b, c, d d) November 2020 November 1 missing b, c, d November 15 missing a, b, c, d, e November 24 missing b, c, d November 29 missing b, c, d e) December 2020 December 8 missing b, c, d December 24 missing b, c, d f) January 2021 January 14 missing b, c, d g) February 2021 February 10 missing b, c, d February 25 missing b, c, d February 26 missing b, c, d h) March 2021 March 23 missing b, c, d i) April 2021 April 15 missing b, c, d j) May 2021 May 2 missing b, c, d May 15 missing b, c, d May 23 missing b, c, d May 25 missing b, c, d May 29 missing b, c, d k) June 2021 June 26 missing b, c, d l) July 2021 July 20 missing b, c, d 3. An interview with the technical consultant on 08/04 /2021 at 1300 hours in the laboratory - after her review of the records- confirmed the findings.
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on review of the laboratory's BD Bactec Blood Culture System's operators manual, random review of the Bactec maintenance logs for May, June and July of 2021 and interview with the staff, it was revealed the laboratory failed to document function checks in 21 of 92 records reviewed. The findings were: 1. Review of the BD Bactec operator's manual revealed under section II DAILY MAINTENANCE Subsection A, 2) "Retrieve or print daily maintenance report" and "Record temperatures and LED results on Daily Maintenance Report". 2. In addition, upon review of the tables describing each Task and Instructions it was revealed the tasks to be performed included: Test Red button Test Green button Verify Temperature Repeat the steps above for each drawer in the system (the laboratory had 2 drawers A and B) Test Alarm button Test Status button Note: The tasks of testing Alarm button and testing Status button ensure that the visual and audible alerts function properly to alert the staff of when a blood culture turns positive for microbial growth. Blood culture is used to detect microorganisms causing septicemia. 3. Review of the laboratory's BD Bactec's Daily Maintenance Reports for May June and July of 2021 revealed missing at least one annotation of the required function checks on the following days: 05/15/2021 - no audible alarm checked 05/16/2021 - no audible alarm checked 05/19/2021 - no internal function checks for either drawer A or B checked 05 /20/2021 - no audible alarm checked 05/21/2021 - no audible alarm checked 05/24 /2021 - no audible alarm checked 05/28/2021 - no audible alarm checked 05/29/2021 - no audible alarm checked 06/01/2021 - no audible alarm checked 06/02/2021 - no

	audible alarm checked 06/23/2021 - no internal function checks for drawer B, no audible alarm checked 06/24/2021 - no audible alarm checked 07/03/2021 - no audible alarm checked 07/04/2021 - no audible alarm checked 07/05/2021 - no audible alarm checked 07/07/2021 - no audible alarm checked 07/08/2021 - no audible alarm checked 07/10/2021 - no internal LEDs or audible alarm checked 07/16 /2021 - none of the function checks were documented 07/18/2021 - no audible alarm checked 07/22/2021 - no audible alarm checked 4. In an interview on 08/03/2021 at 1130 hours in the laboratory Testing Person #2 (as documented on CMS Form 209, signed by the laboratory director on 08/03/2021) stated the techs must have missed documenting function checks because they were in a hurry. This confirmed the findings
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's patient records for Parasitology Ova and Parasites testing, review of Quality Control (QC) records from September of 2020 to July of 2021, review of BD BBL Dobell & O'Connor Iodine Stain droppers manufacturer's package insert, review of the laboratory's Quality Control policies and interview with the staff it was determined that the laboratory failed to test Iodine staining material for intended reactivity each day of use for 173 of 173 days testing was performed. The findings were: 1. Review of the laboratory's patient records for Parasitology testing revealed that there were 261 Ova and Parasites tests performed between 09/01/2020 and 07/13/2021. Refer to Ova and Parasites Alias List. 2. Review of the laboratory's Quality Control (QC) records from September of 2020 to July of 2021 revealed there was no documentation of QC performance on day of testing for BD BBL Dobell & O'Connor Iodine Stain droppers. 3. Review of BD BBL Dobell & O'Connor Iodine Stain droppers manufacturer's package insert under User Quality Control revealed "Quality Control requirements must be performed in accordance with applicable local, state and/or federal regulations or accreditation requirements and your laboratory's standard Quality Control procedures." 4. Review of the laboratory's Quality Control policies revealed no mention of the QC requirements for Iodine droppers. 5. In an interview on 08/04/2021 at 1300 hours in the laboratory Testing Person #2 (as documented on CMS Form 209, signed by the laboratory director on 08/03/2021) stated she was not aware of QC requirements for Iodine droppers. This confirmed the findings.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics

	of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on random review of the laboratory's media Quality Control (QC) records for 2021, review of Individualized Quality Control Plans (IQCPs) for 2019, 2020, 2021, review of Bacteriology QC policies and procedures and interview with the staff it was determined the laboratory failed to check each new batch/lot of LIM Broth media for its ability to support growth and its selectivity for Group B Streptococcus. The findings were: 1. Review of the laboratory's media QC records for 2021 revealed the laboratory did not have documentation of checking each new batch of LIM broth media for its ability to select for Group B Streptococcus before or concurrent with the its initial use. The batches of LIM Broth media included: LIM Broth received 07/07 /2021 Lot# 1097572 Exp. Date 01/13/2022 LIM Broth received 10/27/2020 Lot# 0218664 Exp. Date 05/18/2021 2. Review of the laboratory's Bacteriology IQCP for media revealed the laboratory did not develop IQCP for LIM Broth media. 3. Review of the laboratory's Bacteriology QC policies and procedures revealed they did not address LIM Broth's ability to support growth and its selectivity for Group B Streptococcus. 4. In an interview on 08/04/2021 at 1430 hours in the conference room the Technical Consultant (as documented on CMS Form 209, signed by the laboratory director on 08/03/2021) stated that the laboratory did not develop IQCP for LIM Broth. This confirmed the findings.
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 random review of the laboratory's temperature records for bacteriology for 2019,2020, and 2021 and interview with the staff it was revealed that the laboratory failed to document corrective action for 7 of 7 instances when laboratory room temperatures were outside of laboratory's defined acceptable range of 20-27C. The findings were: 1. Based on review of the laboratory's temperature records it was revealed the acceptable range for the room temperature was defined as 20-27C. 2. Random review of the laboratory's temperature records for 2019, 2020, and 2021 revealed laboratory's room temperature was out of range on the following days: 10/24 /2019 temperature recorded was 29C 11/22/2019 temperature recorded was 28C 12/13 /2019 temperature recorded was 28C 08/13/2020 temperature recorded was 28.4C 08 /15/2020 temperature recorded was 28C 11/29/2020 temperature recorded was 28C 03 /01/2021 temperature recorded was 28C 3. Further review of the records revealed no corrective action documented on the days the temperature was out of laboratory defined range. 4. In an interview on 08/03/2021 at 1500 hours in the conference room the Technical Consultant (as documented on CMS Form 209, signed by the laboratory director on 08/03/2021) confirmed that there was no corrective action for the days the room temperature was out of laboratory's defined acceptable range.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)

	The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of the laboratory's Quality Assurance (QA) reports for 2019, 2020, and 2021, review of the laboratory's QA policies and interview with the staff it was determined the laboratory director failed to document review of QA as per laboratory's policy in 31 of 31 reports reviewed. The findings were: 1. Review of the laboratory's Quality Assurance Plan signed into effect by laboratory director on 03/30 /12, under section Quality Assurance Records revealed "All records are dated and initialed by the staff performing the review, by the Technical Consultant, and by the Laboratory Director." 2. Review of the monthly QA reports for all of 2019 and 2020, and January through July of 2021 revealed there was no documentation of review by laboratory director for 31 of 31 reports reviewed. 3. In an interview on 08/04/2021 at 1500 hours in the conference room the Technical Consultant (as documented on CMS Form 209, signed by the laboratory director on 08/03/2021) stated that she provides monthly reports to the Laboratory Director for review and sign off. However, she could not provide the completed documents with evidence of evaluation. This confirmed the findings.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on surveyor's observations, review of Bacteriology Quality Control (QC) policy, and interview with the staff it was determined the laboratory director failed to ensure laboratory procedures reflect current laboratory policies. The findings were: 1. Review of the Bacteriology QC policy revealed it contained Vitek QC requirements. The last documented review of the policy was on 01/14/2016. 2. Surveyor's observations on 08/03/2021 at 0940 hours revealed there was no Vitek instrument in the laboratory. 3. In an interview on 08/03/2021 at 1000 hours in the conference room testing person #2 (as documented on CMS Form 209, signed by the laboratory director on 08/03/2021) stated that the laboratory has discontinued the Vitek a long time ago but could not remember exactly when. This confirmed the findings.

D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on review of the laboratory's submitted CMS 209, review of personnel records and staff interview, it was revealed the laboratory failed to have documentation of education to qualify 1 of 18 testing personnel (refer to D6065).
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted Form CMS 209, review of the laboratory's personnel records, and staff interview, it was revealed the laboratory failed to have documentation of education to qualify 1 of 18 testing personnel to perform moderate complexity testing. The findings include: 1. A review of the laboratory's submitted Form CMS 209 revealed the laboratory identified 18 testing personnel. 2. A review of the laboratory's personnel records revealed the laboratory failed to have documentation of education to qualify 1 of 18 testing personnel who performed moderate complexity testing. Testing personnel number 14 (as listed on Form CMS 209) did not have documentation of education and was employed by the laboratory from July 2020 to May 2021. 3. The laboratory was asked to provide documentation of education for testing personnel number 14. No documentation was provided. 4. An interview with the technical consultant on 08/03/2021 at 1100 hours in the conference room - after her review of the records- confirmed the findings.
D6066	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(4)(ii) Have documentation of training appropriate for the testing performed prior to analyzing patient specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted Form CMS 209, review of the

	laboratory's personnel records, and staff interview, it was revealed the laboratory failed to have documentation of training for 1 of 18 testing personnel. The findings include: 1. A review of the laboratory's submitted Form CMS 209 revealed the laboratory identified 18 testing personnel. 2. A review of the laboratory's personnel records revealed the facility failed to have documentation of training for testing personnel number 16 as listed on Form CMS 209. Testing personnel number 16 was evaluated as performing moderate complexity testing in the specialties of hematology, chemistry, urine analysis, immunohematology and syphilis serology and was employed by the laboratory from July 2020 to April 2021. 3. The laboratory was asked to provide documentation of training for testing personnel number 16. No documentation was provided. 4. An interview with the technical consultant on 08/03 /2021 at 1100 hours in the conference room - after her review of the records- confirmed the findings.