Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0976385	01/27/2023
Name of Provider or Supplier	**Street Address, City, State**	
Monty Nicholas Heinen, Md	3448 Highway 190, Eunice, LA	

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	A Certification survey was performed at Monty Nicholas Heinen, MD, CLIA # 19D0976385, on January 27, 2023. Monty Nicholas Heinen was found not in compliance with the following CONDITION LEVEL DEFICIENCIES: 42 CFR 493.1201 CONDITION: Bacteriology 42 CFR 493.1403 CONDITION: Laboratories performing moderate complexity testing; Laboratory Director 42 CFR 493.1409 CONDITION: Laboratories performing moderate complexity testing; Technical Consultant
D5002	BACTERIOLOGY CFR(s): 493.1201 If the laboratory provides services in the subspecialty of Bacteriology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1261, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on observation by surveyor, record review, and interview with personnel, the laboratory failed to ensure quality laboratory services for the subspecialty of Bacteriology. Findings: 1. The laboratory failed to establish complete quality control (QC) procedures that included frequency of performance for Bacteriology testing. Refer to D5403. 2. The laboratory failed to ensure supplies, test kits, and controls did not exceed their expiration dates. Refer to D5417 I. 3. The laboratory failed to ensure quality controls utilized for Bacteriology testing were not expired. Refer to D5417 II. 4. The laboratory failed to perform maintenance for the Cepheid GeneXpert system as required for Bacteriology testing for one (1) of three (3) dates in June 2022. Refer to D5429. 5. The laboratory failed to follow their established procedure of testing quality control material following instrument repair for one (1) of three (3) service dates reviewed. Refer to D5433. 6. The laboratory failed to perform quality control (QC) for the Cepheid GeneXpert analyzer weekly per policy. Refer to D5445. 7. The laboratory failed to document corrective actions performed when the room temperature was not

	maintained within acceptable range per laboratory policy for 111 of 235 days reviewed. Refer to D5785 I. 8. The laboratory failed to document corrective actions performed when the refrigerator temperature was not maintained within acceptable range per laboratory policy for seven (7) of 235 days reviewed. Refer to D5785 II. 9. The laboratory's quality assessment monitors failed to correct issues identified within the analytic system. Refer to D5793.
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 policies and interview with personnel, the laboratory failed to establish complete quality control (QC) procedures that included frequency of performance for Bacteriology testing. Findings: 1. Review of the laboratory's "Quality Control" policy revealed "At least once each day patient specimens are assayed or examined perform the following for: Each qualitative procedure, include a negative and positive control material." 2. Review of the laboratory's Individualized Quality Control Plan (IQCP) revealed the laboratory will perform controls every Monday, new lot, new shipment. 3. In interview on January 27, 2023 at 10:26 am, the Technical Consultant confirmed the laboratory's QC procedures did not define the frequency of performance.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: I. Based on observation by surveyor and interview with personnel, the laboratory failed to ensure supplies, test kits, and controls did not exceed their expiration dates. Findings: 1. Observation by surveyor during the laboratory tour on January 27, 2023

	at 9:11 am revealed the following expired items: a) SAS Pregnancy Urine tests, Lot 0091011, Expiration date: August 2022, Quantity: three (3) cassettes b) SAS Pregnancy Urine tests, Lot 0101203, Expiration date: October 2022, Quantity: fifteen (15) cassettes c) UroSwab, Lot 191871, Expiration date: 2021/11, Quantity six (6) tubes d) LBM Urisponge, Lot 1915090, Expiration date: 2021-10-31, Quantity: three (3) tubes e) HemaScreen Specific Gold Positive/Negative controls, Lot 1121122, Expiration date: 2022-11-30, Quantity: one (1) box f) Cepheid Xpert CT/NG Control Panel, Lot 8188-55, Expiration date: 2022-12-31, Quantity: nine (9) positive swabs and eleven (11) negative swabs 2. In interview on January 27, 2022 at 9:14 am, the Technical Consultant confirmed the identified items were expired. II. Based on observation by surveyor, review of quality control records, and interview with personnel, the laboratory failed to ensure quality controls utilized for Bacteriology testing were not expired. Findings: 1. Observation by surveyor during laboratory tour on January 27, 2023 at 9:11 am revealed the following expired items: a) Cepheid Xpert CT/NG Control Panel, Lot 8188-55, Expiration date: 2022-12-31, Quantity: nine (9) positive swabs and eleven (11) negative swabs 2. Review of the laboratory's quality control records for January 2023 revealed on January 5, 2023 the test results for Patient ID 80988 were reported following the use of the identified expired quality control material. 3. In interview on January 2, 2023 at 9:14 am, the Technical Consultant confirmed expired quality controls were utilized on the identified date for Bacteriology testing.
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 observation by surveyor, review of the laboratory's maintenance logs, patient test records, and interview with personnel, the laboratory failed to perform maintenance for the Cepheid GeneXpert system as required for Bacteriology testing for one (1) of three (3) dates in June 2022. Findings: 1. Observation by surveyor during the laboratory tour on January 27, 2023 at 9:11 am revealed the laboratory utilizes the Cepheid GeneXpert for Bacteriology testing of Chlamydia trachomatis and Neisseria gonorrhoeae. 2. Review of the laboratory's 2022 maintenance logs for the Cepheid GeneXpert revealed the following required tasks: a) Daily Maintenance: Clean work area Close all module doors Discard used cartridges b) Weekly Maintenance: Power down the GeneXpert instrument Power down the GeneXpert computer c) Monthly Maintenance: Archive tests Purge tests Replace fan filters d) Quarterly Maintenance: Clean plunger rod and cartridge bays Clean instrument surfaces e) Yearly Maintenance: Check annual instrument maintenance f) As Necessary: Print system log report Back up database 3. Further review of the "GeneXpert System Maintenance Log" for June 2022 and patient test records revealed the laboratory did not perform the following maintenance in June: June 30, 2023: Daily maintenance Week of June 27, 2023: Weekly maintenance (last performed June 17, 2023) 4. Further review of patient test logs for June 30, 2023 revealed the following patients were reported without documented instrument maintenance performed: Patient ID 063022130718 Patient ID 063022130614 Patient ID 063022130524 Patient ID 063022130120 Patient ID 063022130024 Patient ID 063022125933 5. In interview on January 27, 2023 at 11:19 am, the Technical

	Consultant confirmed maintenance was not documented for the identified date in June 2022.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, maintenance records, quality control records, and interview with personnel, the laboratory failed to follow their established procedure of testing quality control material following instrument repair for one (1) of three (3) service dates reviewed. Findings: 1. Review of the laboratory's "Quality Control" procedure revealed "Quality Control is also conducted when: a complete change of reagents is introduced; major preventative maintenance is performed; or any critical part that may influence test performance is replaced." 2. Review of the service report for December 9, 2021 revealed the following statement "Instrument is ready for customer QC process." 3. Review of the laboratory's quality control records from 2021 through 2023 revealed the laboratory did not have documentation of external quality controls performed following the module replacement on December 9, 2021. 4. In interview on January 27, 2023 at 12:18 pm, the Technical Consultant confirmed external quality controls were not performed per their policy following the repair on December 9, 2021.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, quality control records, patient logs, and interview with personnel, the laboratory failed to perform quality control (QC) for the Cepheid GeneXpert analyzer weekly per policy. Findings: 1. In interview on January 27, 2023 at 9:04 am, the Technical Consultant stated the laboratory performs external controls once a month on the Cepheid GeneXpert analyzer. 2. Review of the laboratory's Individualized Quality Control Plan (IQCP) revealed the laboratory will perform controls every Monday, new lot, new shipment. 3. Review of the laboratory's "Quality Control" policy revealed "At least once each day patient specimens are

	assayed or examined perform the following for: Each qualitative procedure, include a negative and positive control material." 4. Review of the quality control records for December 2021 through January 2023 revealed the laboratory performed QC monthly, new lot, and new shipment, not every Monday as stated in the laboratory's IQCP. 5. In further interview on January 27, 2023 at 10:26 am, the Technical Consultant confirmed external controls were not tested weekly as stated in the IQCP.
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: I. Based on review of the laboratory's temperature logs and interview with personnel, the laboratory failed to document corrective actions performed when the room temperature was not maintained within acceptable range per laboratory policy for 111 of 235 days reviewed. Findings: 1. Review of the laboratory's temperature logs revealed the acceptable room temperature range as 22-28 degrees Celsius. 2. Further review of the laboratory's temperature logs for 2022 and January 2023 revealed the room temperature was documented as outside of acceptable limits without documented corrective actions for the following 111 dates: January 4, 2022 documented temperature of 20.8 degrees Celsius January 5, 2022: documented temperature of 21.5 degrees Celsius January 7, 2022: documented temperature of 21.5 degrees Celsius January 10, 2022: documented temperature of 20.6 degrees Celsius January 11, 2022: documented temperature of 20.5 degrees Celsius January 12, 2022: documented temperature of 21.2 degrees Celsius January 14, 2022: documented temperature of 20.5 degrees Celsius January 17, 2022: documented temperature of 19.2 degrees Celsius January 18, 2022: documented temperature of 20.8 degrees Celsius January 19, 2022: documented temperature of 21.5 degrees Celsius January 21, 2022: documented temperature of 21.5 degrees Celsius January 26, 2022: documented temperature of 21.9 degrees Celsius January 27, 2022: documented temperature of 21.8 degrees Celsius January 28, 2022: documented temperature of 19.2 degrees Celsius January 31, 2022: documented temperature of 21.4 degrees Celsius February 1, 2022: documented temperature of 21.2 degrees Celsius February 2, 2022: documented temperature of 21.0 degrees Celsius February 7, 2022: documented temperature of 20 degrees Celsius February 8, 2022: documented temperature of 19.2 degrees Celsius February 9, 2022: documented temperature of 20.1 degrees Celsius February 11, 2022: documented temperature of 21.1 degrees Celsius February 14, 2022: documented temperature of 21.3 degrees Celsius February 15, 2022: documented temperature of 20.9 degrees Celsius February 16, 2022: documented temperature of 20.3 degrees Celsius February 21, 2022: documented temperature of 21.9 degrees Celsius February 22, 2022: documented temperature of 20 degrees Celsius February 24, 2022: documented temperature of 21.2 degrees Celsius February 28, 2022: documented temperature of 21.4 degrees Celsius March 3, 2022: documented temperature of 21.5 degrees Celsius March 9, 2022: documented temperature of 20.1 degrees Celsius March 10, 2022: documented temperature of 20.5 degrees Celsius March 11, 2022: documented temperature of 21.2 degrees Celsius March 14, 2022: documented temperature of 21.0 degrees Celsius March 16, 2022: documented temperature of 21.2 degrees Celsius March 24, 2022: documented temperature of 20.3 degrees Celsius March 25, 2022: documented temperature of 20.0

degrees Celsius March 29, 2022: documented temperature of 21.8 degrees Celsius March 30, 2022: documented temperature of 21.0 degrees Celsius April 1, 2022: documented temperature of 21.8 degrees Celsius April 4, 2022: documented temperature of 21. 8 degrees Celsius April 7, 2022: documented temperature of 21.9 degrees Celsius April 11, 2022: documented temperature of 20.2 degrees Celsius April 20, 2022: documented temperature of 21.0 degrees Celsius April 25, 2022: documented temperature of 21.5 degrees Celsius April 28, 2022: documented temperature of 21.2 degrees Celsius April 29, 2022: documented temperature of 21.0 degrees Celsius May 2, 2022: documented temperature of 21.4 degrees Celsius May 5, 2022: documented temperature of 21.0 degrees Celsius May 6, 2022: documented temperature of 21.2 degrees Celsius May 19, 2022: documented temperature of 21.5 degrees Celsius May 20, 2022: documented temperature of 21.9 degrees Celsius May 28, 2022: documented temperature of 21.9 degrees Celsius May 30, 2022: documented temperature of 21.9 degrees Celsius July 7, 2022: documented temperature of 21.8 degrees Celsius July 12, 2022: documented temperature of 21.8 degrees Celsius July 14, 2022: documented temperature of 21.5 degrees Celsius July 18, 2022: documented temperature of 21.8 degrees Celsius July 20, 2022: documented temperature of 20.1 degrees Celsius July 22, 2022: documented temperature of 21.7 degrees Celsius July 25, 2022: documented temperature of 21.8 degrees Celsius July 28, 2022: documented temperature of 21.2 degrees Celsius August 3, 2022: documented temperature of 20.4 degrees Celsius August 4, 2022: documented temperature of 21.8 degrees Celsius August 9, 2022: documented temperature of 21.7 degrees Celsius August 11, 2022: documented temperature of 21.8 degrees Celsius August 22, 2022: documented temperature of 21.2 degrees Celsius August 24, 2022: documented temperature of 21.3 degrees Celsius August 26, 2022: documented temperature of 21.9 degrees Celsius August 30, 2022: documented temperature of 21.4 degrees Celsius September 1, 2022: documented temperature of 21.9 degrees Celsius September 7, 2022: documented temperature of 21.1 degrees Celsius September 8, 2022: documented temperature of 21.9 degrees Celsius September 12, 2022: documented temperature of 21.8 degrees Celsius September 15, 2022: documented temperature of 21.5 degrees Celsius September 22, 2022: documented temperature of 20.7 degrees Celsius September 26, 2022: documented temperature of 21.2 degrees Celsius September 29, 2022: documented temperature of 21.2 degrees Celsius October 3, 2022: documented temperature of 21.9 degrees Celsius October 10, 2022: documented temperature of 21.8 degrees Celsius October 13, 2022: documented temperature of 21.6 degrees Celsius October 14, 2022: documented temperature of 21.9 degrees Celsius October 17, 2022: documented temperature of 21.6 degrees Celsius October 19, 2022: documented temperature of 21.8 degrees Celsius October 24, 2022: documented temperature of 21.8 degrees Celsius October 25, 2022: documented temperature of 21.8 degrees Celsius October 27, 2022: documented temperature of 21.8 degrees Celsius October 31, 2022: documented temperature of 21.2 degrees Celsius November 8, 2022: documented temperature of 21.2 degrees Celsius November 9, 2022: documented temperature of 21.5 degrees Celsius November 14, 2022: documented temperature of 21.8 degrees Celsius November 15, 2022: documented temperature of 21.8 degrees Celsius November 30, 2022: documented temperature of 21.2 degrees Celsius December 1, 2022: documented temperature of 20.8 degrees Celsius December 2, 2022: documented temperature of 21.2 degrees Celsius December 5, 2022: documented temperature of 20.7 degrees Celsius December 8, 2022: documented temperature of 21.9 degrees Celsius December 9, 2022: documented temperature of 21.2 degrees Celsius December 19, 2022: documented temperature of 21.7 degrees Celsius December 21, 2022: documented temperature of 21.7 degrees Celsius December 22, 2022: documented temperature of 21.8 degrees Celsius December 27, 2022: documented temperature of

	21.8 degrees Celsius January 2, 2023: documented temperature of 21.9 degrees Celsius January 5, 2023: documented temperature of 21.8 degrees Celsius January 9, 2023: documented temperature of 21.9 degrees Celsius January 10, 2023: documented temperature of 21.8 degrees Celsius January 13, 2023: documented temperature of 21.9 degrees Celsius January 16, 2023: documented temperature of 21.7 degrees Celsius January 19, 2023: documented temperature of 21.5 degrees Celsius January 24, 2023: documented temperature of 21.1 degrees Celsius January 25, 2023: documented temperature of 21.4 degrees Celsius January 26, 2023: documented temperature of 21.5 degrees Celsius 3. In interview on January 27, 2023 at 11:05 am, the Technical Consultant confirmed the laboratory did not have documentation of performance of corrective actions for unacceptable temperatures for the identified days. II. Based on review of the laboratory's temperature logs and interview with personnel, the laboratory failed to document corrective actions performed when the refrigerator temperature was not maintained within acceptable range per laboratory policy for seven (7) of 235 days reviewed. Findings: 1. Review of the laboratory's temperature logs revealed the acceptable refrigerator temperature range as 2-8 degrees Celsius. 2. Further review of the laboratory's temperature logs for 2022 and January 2023 revealed the refrigerator temperature was documented as outside of acceptable limits without documented corrective actions for the following seven (7) dates: January 4, 2022: documented temperature of 8.4 degrees Celsius January 19, 2023: documented temperature of 8.8 degrees Celsius January 20, 2023: documented temperature of 8.2 degrees Celsius January 23, 2023: documented temperature of 8.1 degrees Celsius January 24, 2023: documented temperature of 8.5 degrees Celsius January 25, 2023: documented temperature of 8.2 degrees Celsius January 26, 2023: documented temperature of 8.9 degrees Celsius 3. In interview on January 27, 2023 at 11:05 am, the Technical Consultant confirmed the laboratory did not have documentation of performance of corrective actions for unacceptable temperatures for the identified days.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on observation by surveyor, record review, and interview with personnel, the laboratory's quality assessment monitors failed to correct issues identified within the analytic system. Findings: 1. Review of the laboratory's "Quality Management Plan" revealed "The Laboratory Medical Director acting as the head of the Quality Assurance team, with the assistance of the designated Quality Assurance Manager will, on an annual basis, prepare a report of Quality Assurance activities which have occurred during the previous year. The Quality Assurance Review shall be completed by April 1 for the preceding year and available for presentation to the Quality Assurance Committee, the management group and/or the Board of Directors. The Quality Assurance Review shall include the following areas: Review of Quality Assurance Monitors for the previous year Performance on proficiency testing Safely and safety training updates Staff competency and training Review of HIPAA Compliance and activities Areas of improvement Goals for upcoming year

	Certification and licensing activities 2. Observation by surveyor, review of records, and interview with personnel revealed the laboratory did not identify the following issues with the analytic system: a) The laboratory failed to establish complete quality control (QC) procedures that included frequency of performance for Bacteriology testing. Refer to D5403. b) The laboratory failed to ensure supplies, test kits, and controls did not exceed their expiration dates. Refer to D5417 I. c) The laboratory failed to ensure quality controls utilized for Bacteriology testing were not expired. Refer to D5417 II. d) The laboratory failed to perform maintenance for the Cepheid GeneXpert system as required for Bacteriology testing for one (1) of three (3) dates in June 2022. Refer to D5429. e) The laboratory failed to follow their established procedure of testing quality control material following instrument repair for one (1) of three (3) service dates reviewed. Refer to D5433. f) The laboratory failed to perform quality control (QC) for the Cepheid GeneXpert analyzer weekly per policy. Refer to D5445. g) The laboratory failed to document corrective actions performed when the room temperature was not maintained within acceptable range per laboratory policy for 111 of 235 days reviewed. Refer to D5785 I. h) The laboratory failed to document corrective actions performed when the refrigerator temperature was not maintained within acceptable range per laboratory policy for seven (7) of 235 days reviewed. Refer to D5785 II.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on observation by surveyor, record review, and interview with personnel, the Laboratory Director failed to provide overall management and direction for the laboratory. Findings: 1. The Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Refer to D6014. 2. The Laboratory Director failed to ensure that a complete quality control program was established to assure the quality of laboratory testing. Refer to D6020. 3. The Laboratory Director failed to ensure that a quality assessment (QA) program was maintained to assure the quality of laboratory services provided and to identify failures as they occur. Refer to D6022. 4. The Laboratory Director failed to ensure that the laboratory performed required maintenance. Refer to D6023. 5. The Laboratory Director failed to ensure corrective actions were taken and documented when deviations from laboratory's policies occurred. Refer to D6024. 6. The Laboratory Director failed to ensure one (1) of three (3) Testing Personnel met state of Louisiana licensure requirements for moderate complexity testing. Refer to D6029.
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results.

	This STANDARD is not met as evidenced by: Based on observation by surveyor, record review, and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Findings: 1. The laboratory failed to ensure supplies, test kits, and controls did not exceed their expiration dates. Refer to D5417 I. 2. The laboratory failed to ensure quality controls utilized for Bacteriology testing were not expired. Refer to D5417 II.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on observation by surveyor, record review, and interview with personnel, the Laboratory Director failed to ensure that a complete quality control program was established to assure the quality of laboratory testing. Findings: 1. The laboratory failed to establish complete quality control (QC) procedures that included frequency of performance for Bacteriology testing. Refer to D5403. 2. The laboratory failed to follow their established procedure of testing quality control material following instrument repair for one (1) of three (3) service dates reviewed. Refer to D5433. 3. The laboratory failed to perform quality control (QC) for the Cepheid GeneXpert analyzer weekly per policy. Refer to D5445.
D6022	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on observation by surveyor, record review, and interview with personnel, the Laboratory Director failed to ensure that a quality assessment (QA) program was maintained to assure the quality of laboratory services provided and to identify failures as they occur. Refer to D5793.
D6023	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(6) 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)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system; This STANDARD is not met as evidenced by: Based on observation by surveyor, record review, and interview with personnel, the Laboratory Director failed to ensure that the laboratory performed required maintenance. Findings: 1. The laboratory failed to perform maintenance for the Cepheid GeneXpert system as required for Bacteriology testing for one (1) of three (3) dates in June 2022. Refer to D5429. 2. The laboratory failed to follow their established procedure of testing quality control material following instrument repair for one (1) of three (3) service dates reviewed. Refer to D5433.
D6024	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(7) 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)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified, This STANDARD is not met as evidenced by: Based on review of policies, temperature logs, and interview with personnel, the Laboratory Director failed to ensure corrective actions were taken and documented when deviations from laboratory's policies occurred. Refer to D5785 I and D5785 II.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure one (1) of three (3) Testing Personnel met state of Louisiana licensure requirements for moderate complexity testing. Refer to D6064.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409

	The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on observation by surveyor, record review, and interview with personnel, the Technical Consultant failed to provide technical oversight of the laboratory for moderate complexity testing. Findings: 1. The Technical Consultant failed to provide technical and scientific oversight to the laboratory. Refer to D6036. 2. The Technical Consultant failed to ensure the quality control program was established to assure the quality of laboratory testing. Refer to D6042. 3. The Technical Consultant failed to ensure corrective actions were taken and documented when deviations form the laboratory's policies occurred. Refer to D6043. 4. The Technical Consultant failed to perform annual competency assessments in 2021 and 2022 for testing personnel performing microscopic Microbiology testing. Refer to D6054.
D6036	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413 The technical consultant is responsible for the technical and scientific oversight of the laboratory. This STANDARD is not met as evidenced by: Based on observation by surveyor, record review, and interview with personnel, the Technical Consultant failed to provide technical and scientific oversight to the laboratory. Findings: 1. The laboratory failed to ensure supplies, test kits, and controls did not exceed their expiration dates. Refer to D5417 I. 2. The laboratory failed to ensure quality controls utilized for Bacteriology testing were not expired. Refer to D5417 II. 3. The laboratory failed to perform maintenance for the Cepheid GeneXpert system as required for Bacteriology testing for one (1) of three (3) dates in June 2022. Refer to D5429. 4. The laboratory failed to follow their established procedure of testing quality control material following instrument repair for one (1) of three (3) service dates reviewed. Refer to D5433.
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Technical Consultant failed to ensure the quality control program was established to assure the quality of laboratory testing. Findings: 1. The laboratory failed to establish complete quality

	control (QC) procedures that included frequency of performance for Bacteriology testing. Refer to D5403. 2. The laboratory failed to perform quality control (QC) for the Cepheid GeneXpert analyzer weekly per policy. Refer to D5445.
D6043	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(5) (b) The technical consultant is responsible for-- (b)(5) Resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications; This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Technical Consultant failed to ensure corrective actions were taken and documented when deviations form the laboratory's policies occurred. Refer to D5785 I and D5785 II.
D6054	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 at least annually, after the first year. This STANDARD is not met as evidenced by: Based on review of the laboratory's CMS 209 (Laboratory Personnel Report) form, personnel records, test menu, and interview with personnel, the Technical Consultant failed to perform annual competency assessments in 2021 and 2022 for testing personnel performing microscopic Microbiology testing. Findings: 1. Review of the laboratory's CMS 209 form and test menu revealed the Laboratory Director (physician) performs wet prep, potassium hydroxide (KOH) and fern testing microscopically. 2. Review of the personnel records for the Laboratory Director revealed no documentation of an annual competency assessment performed in 2021 and 2022 for the identified microscopic Microbiology testing. 3. In interview on January 27, 2023 at 12:34 pm, the Technical Consultant confirmed no performance of the 2021 and 2022 annual competency assessments for the testing personnel (Laboratory Director) performing microscopic Microbiology testing.
D6064	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(a) Each individual performing moderte complexity testing must possess a current license issued by the State in which the laboratory is located, if such licensing is required. This STANDARD is not met as evidenced by: Based on review of personnel records and interview with personnel, the laboratory failed to maintain documentation that one (1) of three (3) of Testing Personal met the state of Louisiana licensure requirement. Findings: 1. In interview on January 27, 2023 at 11:13 am the Technical Consultant stated Testing Personnel 3 was no longer employed as of May 2022. 2. Review of personnel records revealed the laboratory did not have documentation of a Louisiana Board of Medical Examiners (LSBME)

	license for laboratory testing for 2022 for Testing Personnel 3. 3. In further interview on January 27, 2023 at 11:13 am, the Technical Consultant confirmed the laboratory did not have documentation of a 2022 LSBME license for previously employed Testing Personnel 3.