Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0976385	09/10/2018
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 - 19D0976385 on September 10, 2018. Monty Nicholas Heinen, MD was found not in compliance with the following CONDITION LEVEL DEFICIENCIES: 42 CFR 493.1250 CONDITION: Analytic Systems 42 CFR 493.1403 CONDITION: Laboratories performing moderate complexity testing, Laboratory Director 42 CFR 493.1409 CONDITION: Laboratories performing moderate complexity testing, Technical Consultant
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: I. Based on observation, record review, and interview with personnel, the laboratory failed to report Urine Drug Screen (UDS) test results as preliminary results and failed to confirm all UDS test results as required by the manufacturer. Findings: 1. Observation by the surveyor on September 10, 2018 revealed the laboratory utilized the UScreen Drugs of Abuse Cup System for Urine Drug Screen (UDS) testing and reporting of Amphetamine (AMP), Barbiturates (BAR), Benzodiazepines (BZO), Cocaine (COC), Methylenedioxymethamphetamine (MDMA), Methamphetamine (MET), Methadone (MTD), Morphine (MOP), Morphine 200 (OPI), Marijuana (THC), Oxycodone (OXY), Phencyclidine (PCP), Tri-cyclic Antidepressants (TCA), and Buprenorphine (BUP) in patient urine samples. 2. Review of the UScreen Drugs of Abuse Cup System package insert revealed "This assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS is the preferred confirmatory method. Gas Chromatography/Mass Spectrometry (GC/MS) is the preferred

	confirmatory method. Clinical consideration and professional judgement should be applied to any drug test result, particularly when preliminary positive results are indicated. " 3. Review of a random selection of Patient UDS Final Reports from April 31, 2018 through September 4, 2018 revealed the following patients failed to be reported as preliminary test results for UDS testing and failed to be confirmed by GC /MS as required by the manufacturer: Patient 188 on April 31, 2018; all results negative. Patient 189 on May 1, 2018; all results negative. Patient 190 on June 12, 2018; all results negative. Patient 191 on July 2, 2018; all results negative. Patient 192 on August 6, 2018; all results negative. Patient 193 on September 4, 2018; all results negative. Review of the Task 1 and 3 Forms submitted to the surveyor on September 10, 2018 revealed the laboratory performs 1000 UDS tests annually. 4. Interview with Personnel 2 on September 10, 2018 confirmed that patient urine drug screen test results were not reported as preliminary results and confirmed the laboratory does not confirm results as required by the manufacturer. II. Based on observation, record review, and interview with personnel, the laboratory failed to document the internal control for Urine Drug Screen (UDS) testing for each patient. Findings: 1. Observation by the surveyor on September 10, 2018 revealed the laboratory utilized the UScreen Drugs of Abuse Cup System for Urine Drug Screen (UDS) testing and reporting of Amphetamine (AMP), Barbiturates (BAR), Benzodiazepines (BZO), Cocaine (COC), Methylenedioxymethamphetamine (MDMA), Methamphetamine (MET), Methadone (MTD), Morphine (MOP), Morphine 200 (OPI), Marijuana (THC), Oxycodone (OXY), Phencyclidine (PCP), Tri-cyclic Antidepressants (TCA), and Buprenorphine (BUP) in patient urine samples. 2. Review of the UScreen Drugs of Abuse Cup System package insert revealed under "Reading the Results" for "Invalid" results states "If a color band is not visible in the control "C" region or a color band is only visible in the test "T" region, the test is invalid." The package insert goes on to state that another test is to be performed and if the same results are obtained then the laboratory is to contact the distributor from whom they purchased the product. 3. Review of a random selection of Patient UDS Test Records from April 31, 2018 through September 4, 2018 revealed the laboratory failed to document the internal control for each patient to ensure accurate and reliable UDS test results: Patient 188 on April 31, 2018; all results negative. Patient 189 on May 1, 2018; all results negative. Patient 190 on June 12, 2018; all results negative. Patient 191 on July 2, 2018; all results negative. Patient 192 on August 6, 2018; all results negative. Patient 193 on September 4, 2018; all results negative. Review of the Task 1 and 3 Forms submitted to the surveyor on September 10, 2018 revealed the laboratory performs 1000 UDS tests annually. 4. Interview with Personnel 2 on September 10, 2018 confirmed the laboratory failed to document internal controls for any of the patients tested.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on observation, record review and interview with personnel, the laboratory

	failed to ensure the quality of testing within the analytic systems. Findings: 1. The laboratory failed to ensure that "all reagents and PACs must be at 22 to 28 degrees Celsius prior to use" for the BD Affirm VPIII Microbial Identification Test System for twenty one (21) of fifty seven (57) patient test days . Refer to D5413. 2. The laboratory failed to have complete Individualized Quality Control Plan (IQCP) to support the reduction of quality control material testing for the BD Affirm VPIII Microbial Identification and Cepheid Xpert patient testing. Refer to D5445. 3. The laboratory's Quality Assurance monitors failed to identify and correct quality issues in Bacteriology, Mycology and Parasitology. Refer to D5793.
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 observation, record review and interview with personnel, the laboratory failed to ensure that all reagents and PACs must be at 22 to 28 degrees Celsius prior to use for the BD Affirm VPIII Microbial Identification Test System as required by the manufacturer for twenty one (21) of fifty seven (57) patient test days . Findings: 1. Observation by the surveyor on September 10, 2018 during the laboratory tour revealed the laboratory utilized the BD Affirm VPIII Microbial Identification Test System for the identification of Trichomonas vaginalis (T.vag), Garderella vaginalis (Gard vag), and Candida. 2. Review of BD Affirm VPIII Microbial Identification Test System Package insert revealed "all reagents and PACs must be at 22 to 28 degrees Celsius prior to use" . Further review of the package insert revealed the temperature requirements are needed for accurate and reliable test results. 3. Review of Temperature Records and Patient Test Records for BD Affirm VPIII Microbial Identification Test System from May 1, 2018 through August 22, 2018 revealed the laboratory documented temperatures outside the 22 to 28 degrees Celsius for the following days affecting the following patient test results: May 7, 2018 documented 21 degrees Celsius; patients 17 - 20 were tested and reported May 8 2018 documented 21 degrees Celsius; patients 21 - 26 were tested and reported May 10, 2018 documented 21 degrees Celsius; patients 27 - 32 were tested and reported May 14, 2018 documented 21 degrees Celsius; patients 33 - 37 were tested and reported May 15, 2018 documented 21 degrees Celsius; patients 38 - 49 were tested and reported May 17, 2018 documented 21 degrees Celsius; patients 50 - 54 were tested and reported May 18, 2018 documented 21 degrees Celsius; patients 55 - 70 were tested and reported May 21, 2018 documented 21 degrees Celsius; patients 71 - 80 were tested and reported May 22, 2018 documented 21 degrees Celsius; patients 81 - 82 were tested and reported May 25, 2018 documented 21 degrees Celsius; patients 83 - 88 were tested and reported May 29, 2018 documented 21 degrees Celsius; patients 89 - 101 were tested and reported July 6, 2018 documented 21 degrees Celsius; patients 102 - 108 were tested and reported July 23, 2018 documented 21 degrees Celsius; patients 109 - 118 were tested and reported July 26, 2018 documented 21 degrees Celsius; patients 119 - 124 were tested and reported July 30, 2018 documented 21

	degrees Celsius; patient 125 was tested and reported July 31, 2018 documented 21 degrees Celsius; patients 126 - 143 were tested and reported August 2, 2018 documented 21 degrees Celsius; patients 144 - 161 were tested and reported August 6, 2018 documented 21 degrees Celsius; patients 162 - 169 were tested and reported August 7, 2018 documented 21 degrees Celsius; patients 170 - 174 were tested and reported August 20, 2018 documented 21 degrees Celsius; patients 175 - 181 were tested and reported August 21, 2018 documented 21 degrees Celsius; patients 182 - 187 were tested and reported 4. Interview with personnel 2 on September 10, 2018 confirmed that patients are to be ran when all the reagents and PACs are between 22 to 28 degrees Celsius. Personnel 2 also confirmed that patients were tested and reported when the laboratory documented temperatures outside of 22 to 28 degrees Celsius.
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 observation, record review, and interview with personnel, the laboratory failed to have complete Individualized Quality Control Plan (IQCP) to support the reduction of quality control material testing for the BD Affirm VPIII Microbial Identification and Cepheid Xpert patient testing. Findings: 1. Observation by the surveyor during the tour of the laboratory on September 10, 2018 revealed the laboratory maintained: a) BD Affirm VPIII Microbial Identification Test System for the identification of Trichomonas vaginalis (T.vag), Gardnerella vaginalis (Gard vag) and Candida testing. b) Cepheid Xpert testing for the identification of Neisseria gonorrhoeae (NG) and Chlamydia trachomatis (CT). 2. Review of the Laboratory's IQCP for the BD Affirm VPIII and Cepheid Xpert test systems revealed the laboratory failed to maintain: a) A complete Risk Assessment that identifies and evaluates potential failures and sources of errors in all five components: Specimen, Test System, Reagents, Environment and Testing Personnel. b) Manufacturer Requirements: Operators Manual and package inserts c) In house quality control data to support the length of reduction in quality control frequency. d) Pertinent Literature to support the reduction of quality control. 3. Review of a random selection of patient records from October 10, 2017 through September 5, 2018 revealed the following sixteen (16) patient samples were tested and reported without establishing a complete Individualized Quality Control Plan that supports the reduction of quality control for the BD Affirm VPIII and Cepheid Xpert Test Systems. a) For the Cepheid Xpert Test System On October 10, 2017: Patient 1. On January 9, 2018: Patient 2 On April 3, 2018: Patient 3. On May 3, 2018: Patient 4. On June 7, 2018: Patient 5. On July 3, 2018: Patient 6. On August 7, 2018: Patient 7. On September 8, 2018: Patient 8. b) For the BD Affirm VPIII Test System On October 11, 2017: Patient 9. On January 8, 2018: Patient 10 On April 4, 2018: Patient 11. On May 2, 2018: Patient 12. On June 6, 2018: Patient 13. On July 2, 2018: Patient 14. On August 3, 2018: Patient 15. On

	September 5, 2018: Patient 16. Review of the Task 1 and 3 form filled out by the laboratory and submitted to the surveyor on September 10, 2018 revealed the laboratory performs the following annual volumes: T.vag - 2400, Gard vag - 2400, Candida - 2400, NG - 2760, and CT 2760. 4. Interview with personnel 2 on September 10, 2018 confirmed the laboratory failed to have complete IQCP studies for the BD Affirm VPIII and Cepheid Xpert Test systems.
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 record review, and interview with personnel, the laboratory's Quality Assurance monitors failed to identify and correct quality issues in Bacteriology, Mycology and Parasitology. Findings: 1. A review of patient test records and quality control records indicated problems with the analytic system as follows: a) The laboratory failed to ensure that "all reagents and PACs must be at 22 to 28 degrees Celsius prior to use" for the BD Affirm VPIII Microbial Identification Test System for twenty one (21) of fifty seven (57) patient test days . Refer to D5413. b) The laboratory failed to have complete Individualized Quality Control Plan (IQCP) to support the reduction of quality control material testing for the BD Affirm VPIII Microbial Identification and Cepheid Xpert patient testing. Refer to D5445. 2. The laboratory has a Quality Assurance Policy that identified specific monitors that were routinely performed by the laboratory; however, the monitors failed to identify any of the deficiencies identified with the analytic systems. 3. Interview with personnel 2 on September 10, 2018 confirmed the laboratory failed to identify the deficiencies cited above.
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, 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 laboratory personnel performed testing as required for accurate and reliable results. Refer to D6014. 2. The Laboratory Director failed to ensure that quality control programs were 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 established and maintained to assure the quality of laboratory services provided. Refer to D6021.
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 record review and interview with personnel, the Laboratory Director failed to ensure laboratory personnel performed testing as required for accurate and reliable results. Findings: 1. The laboratory failed to ensure that "all reagents and PACs must be at 22 to 28 degrees Celsius prior to use" for the BD Affirm VPIII Microbial Identification Test System for twenty one (21) of fifty seven (57) patient test days . Refer to D5413. 2. Interview with Personnel 2 on September 10, 2018 confirmed the laboratory failed to maintain the reagents and PACs between 22 - 28 degrees Celsius as required by the manufacturer.
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, record review, and interview with personnel, the Laboratory Director failed to ensure that quality control programs were established to assure the quality of laboratory testing. Findings: 1. The laboratory failed to have complete Individualized Quality Control Plan (IQCP) to support the reduction of quality control material testing for the BD Affirm VPIII Microbial Identification and Cepheid Xpert patient testing. Refer to D5445. 2. Interview with Personnel 2 on September 10, 2018 confirmed the laboratory failed to have complete IQCP for the BD Affirm VPIII Microbial Identification and Cepheid Xpert patient testing.
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 observation, record review and interview with laboratory personnel, the Laboratory Director failed to ensure that a quality assessment (QA) program was established and maintained to assure the quality of laboratory services provided. Findings: 1. Review of the laboratory's policy and procedure manual revealed the laboratory had a Quality Assurance Policy however, the monitors failed to identify any of the deficiencies identified with the preanalytic and analytic system as follows: a) The laboratory failed to ensure that "all reagents and PACs must be at 22 to 28 degrees Celsius prior to use" for the BD Affirm VPIII Microbial Identification Test System for twenty one (21) of fifty seven (57) patient test days . Refer to D5413. b) The laboratory failed to have complete Individualized Quality Control Plan (IQCP) to support the reduction of quality control material testing for the BD Affirm VPIII Microbial Identification and Cepheid Xpert patient testing. Refer to D5445. 2. The laboratory has a Quality Assurance Policy that identified specific monitors that were routinely performed by the laboratory; however, the monitors failed to identify any of the deficiencies identified with the analytic systems. 3. Interview with personnel 2 on September 10, 2018 confirmed the laboratory failed to identify the deficiencies cited above.
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, record review, and interview with personnel, the Technical Consultant (Personnel 2) failed to meet the qualifications and provide technical oversight of the laboratory. Findings: 1. The Technical Consultant failed to provide technical and scientific oversight for the laboratory. Refer to D6036.
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, record review and interview with personnel, the Technical Consultant failed to provide technical and scientific oversight for the laboratory. Findings: 1. Review of the FORM CMS 209 submitted to the surveyor on September 10, 2018 revealed that personnel 2 fulfilled the duties for Technical Consultant. 2. Observation, record review and interview with personnel revealed the Technical Consultant failed to address the following problems identified in the laboratory: a) The laboratory failed to ensure that "all reagents and PACs must be at 22 to 28 degrees Celsius prior to use" for the BD Affirm VPIII Microbial Identification Test System for twenty one (21) of fifty seven (57) patient test days . Refer to D5413. b) The laboratory failed to have complete Individualized Quality Control Plan (IQCP) to support the reduction of quality control material testing for the BD Affirm VPIII Microbial Identification and Cepheid Xpert patient testing. Refer to D5445. 3. Review of the Laboratory's Policy and Procedure Manual revealed the laboratory establish a

	Quality Assurance Plan that covered all phases of testing; however the Technical Consultants failed to identify and correct the problems cited above. Refer to D5793. 3. Interview with personnel 2 on September 10, 2018 revealed that he was recently hired and also confirmed the laboratory failed to identify the deficiencies cited above.