

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D0976385	(X3) Date Survey Completed 11/20/2024
Name of Provider or Supplier Monty Nicholas Heinen, Md	Street Address, City, State 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 Recertification survey was performed at Monty Nicholas Heinen, MD, CLIA # 19D0976385 on November 20, 2024. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's CMS-209 (Laboratory Personnel Report) form, policies, and proficiency testing records; as well as interview with personnel, the laboratory failed to ensure proficiency testing samples were rotated among all testing personnel performing provider performed microscopy (PPM) testing for five (5) of five (5) events reviewed. Findings: 1. Review of the laboratory's CMS-209 form revealed the following two (2) personnel performed provider performed microscopy (PPM) testing to include KOH, wet prep, and fern testing: a) Personnel 1 b) Personnel 3 2. Review of the laboratory's policy "Laboratory Quality Management Plan" section "Proficiency testing" revealed "The laboratory must introduce proficiency testing test specimens into its routine workflow and process them using pre-examination and examination protocols generally applied to the processing of patient specimens, including repeat analysis." 3. Review of proficiency testing records for KOH, wet prep, and fern testing in 2023 and 2024 revealed Personnel 1 performed all testing for the following events and Personnel 3 did not participate in any events: a) 2023 Hematology/Coagulation - 1st Event b) 2023 Hematology/Coagulation - 2nd Event c) 2023 Hematology/Coagulation - 3rd Event d) 2024 Hematology/Coagulation - 1st Event b) 2024 Hematology/Coagulation - 2nd Event 4. In interview on November 20,</p>

2024 at 10:31 a.m., the Technical Consultant confirmed Personnel 1 was the only testing personnel that participated in the proficiency testing events identified above.

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, review of the laboratory's temperature records, and interview with personnel, the laboratory failed to define acceptable room temperature limits within the manufacturer's required range for laboratory supplies stored in one (1) of one (1) rooms. Findings: 1. Observation by surveyor during the laboratory tour on November 20, 2024 at 9:40 a.m. revealed the following testing supplies stored in the laboratory: a) GeneXpert Xpert CT/NG - Lot 1001448217, Expiration date: 08/30/2026 - Manufacturer's storage requirements 2 - 28 degrees Celsius 2. Review of the laboratory's room temperature logs for June 2024 through November 2024 revealed the laboratory defined the acceptable temperature limits as 15 - 30 degrees Celsius which exceeded the manufacturer's upper temperature limit. 3. In interview on November 20, 2024 at 1 p.m., the Technical Consultant confirmed the acceptable temperature limits defined by the laboratory exceeded the manufacturer's temperature limits.

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:

****Repeat deficiency from previous survey January 27, 2023**** I. Based on observation, review of laboratory maintenance logs, and interview with personnel, the laboratory failed to ensure weekly maintenance was performed on the Cepheid GeneXpert as required by the manufacturer for two (2) of twenty-six (26) weeks reviewed. Findings: 1. Observation by surveyor during the laboratory tour on November 20, 2024 at 9:40 a.m. revealed the laboratory utilized a Cepheid GeneXpert analyzer for chlamydia and gonorrhea testing. 2. Review of the laboratory's "GeneXpert Maintenance Log" revealed the following required weekly tasks: a) Weekly Maintenance: - Power down the GeneXpert Instrument - Power down the GeneXpert Computer 3. Further review of the laboratory's Cepheid maintenance logs from June 2024 through November 2024 revealed the laboratory failed to perform weekly maintenance for the following weeks: - September 2 - September 6, 2024 - October 7 - October 11, 2024 4. In interview on November 20, 2024 at 1:53 p.m., the Technical Consultant confirmed the weekly maintenance was not performed as

identified above. II. Based on observation, review of laboratory maintenance logs, and interview with personnel, the laboratory failed to ensure monthly maintenance was performed on the Cepheid GeneXpert as required by the manufacturer for two (2) of five (5) months reviewed. Findings: 1. Observation by surveyor during the laboratory tour on November 20, 2024 at 9:40 a.m. revealed the laboratory utilized a Cepheid GeneXpert analyzer for chlamydia and gonorrhea testing. 2. Review of the laboratory's "GeneXpert Maintenance Log" revealed the following required monthly tasks: a) Monthly Maintenance: - Archive Tests - Purge tests - Replace fan filters 3. Further review of the laboratory's Cepheid maintenance logs from June 2024 through October 2024 revealed the laboratory failed to perform monthly maintenance for the following months: - September 2024 - October 2024 4. In interview on November 20, 2024 at 1:53 p.m., the Technical Consultant confirmed the monthly maintenance was not performed as identified above.

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, record review, and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Refer to D5413.

D6016

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)(i)

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)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:
Based on record review and interview with personnel, the Laboratory Director failed to ensure proficiency samples are tested as required. Refer to D2007.

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, review of laboratory policies and records, as well as interview with personnel, the Laboratory Director failed to ensure that the laboratory performed required maintenance. Findings: 1. The laboratory failed to ensure weekly maintenance was performed on the Cepheid GeneXpert as required by the manufacturer for two (2) of twenty-six (26) weeks reviewed. Refer to D5429 I. 2. The laboratory failed to ensure monthly maintenance was performed on the Cepheid GeneXpert as required by the manufacturer for two (2) of five (5) months reviewed. Refer to D5429 II.

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 to the laboratory. Findings: 1. The laboratory failed to ensure proficiency testing samples were rotated among all testing personnel performing provider performed microscopy (PPM) testing for five (5) of five (5) events reviewed. Refer to D2007. 2. The laboratory failed to define acceptable room temperature limits within the manufacturer's required range for laboratory supplies stored in one (1) of one (1) rooms. Refer to D5413. 3. The laboratory failed to ensure weekly maintenance was performed on the Cepheid GeneXpert as required by the manufacturer for two (2) of twenty-six (26) weeks reviewed. Refer to D5429 I. 4. The laboratory failed to ensure monthly maintenance was performed on the Cepheid GeneXpert as required by the manufacturer for two (2) of five (5) months reviewed. Refer to D5429 II.

D6051

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(8)(v)

The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples.

This STANDARD is not met as evidenced by:

Based on review of the CMS-209 (Laboratory Personnel Report) form and personnel records as well as interview with laboratory personnel, the Technical Consultant failed to ensure all testing personnel were assessed through testing previously analyzed specimens, internal blind samples, or external proficiency samples for one (1) of four (4) testing personnel reviewed. Findings: 1. Review of the laboratory's CMS-209 form revealed the following testing personnel: Personnel 1 Personnel 3 Personnel 4 Personnel 5 2. Review of the laboratory's 2024 personnel records for Personnel 5 revealed a six (6) month competency assessment and an annual competency assessment performed, but the laboratory did not have documentation to support the performance of blind sample testing. 3. In interview on November 20, 2024 at 11:19 a.

m., the Technical Consultant stated Testing Personnel 5 did perform blind sample testing by performing a split sample analysis with other testing personnel, but he did not have documentation as identified above.