Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0976385	10/27/2021
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 Recertification survey was performed on October 27, 2021 at Monty Nicholas Heinen, CLIA ID # 19D0672917. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedure manual, personnel records and interview with personnel, the laboratory failed to establish competency policy for two (2) of six (6) personnel performing microscopic procedures. Findings: 1. Review of the Laboratory Personnel Report (209) provided at the time of the survey revealed two (2) providers performing microscopic procedures. 2. Review of the laboratory's personnel records revealed no evaluation of competency performed for two (2) of six (6) personnel listed as testing personnel performing direct wet prep. 3. Further review of laboratory policy and procedure revealed the laboratory had no policy addressing competency assessment of providers performing microscopic procedures to include, but not limited to: frequency of competency assessment, process for competency evaluation, who is responsible for competency assessment. 4. Interview with technical consultant on October 27, 2021 at 10:42am confirmed the laboratory did not have a policy for competency evaluation of providers performing microscopic procedures.
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 manufacturer instructions as well as interview with personnel, the laboratory failed to include manufacturer limitations established by Cepheid Gene Xpert in the laboratory procedure manual. Findings: 1. Observation during laboratory tour on October 27, 2021 revealed a Cepheid Gene Xpert in use for patient testing. 2. Review of the assay instructions for use for Cepheid Gene Xpert CT/NG Assay under limitations revealed the following limitations: a) "Xpert CT/NG performance has not been evaluated in patients less than 14 years of age." b) "Xpert CT/NG performance has not been evaluated in patients with history of hysterectomy." 3. Review of the laboratory procedure revealed use of the manufacturer instructions as laboratory policy. 4. Interview with Technical Consultant on October 27, 2021 at 11:00am revealed the laboratory was unaware of the manufacturer limitations. The Technical Consultant confirmed the laboratory was not actively screening patients to meet manufacturer limitations. 5. Review of the laboratory's application indicated an annual test volume of 300 CT/NG on Cepheid Gene Xpert.
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 record review and interview with personnel, the Laboratory Director failed

	to ensure complete policies and procedures for assessing personnel competency. Refer to D5209
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) 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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure that a complete procedure manual was available to personnel to include manufacturer limitations established by Cepheid Gene Xpert for CT/NG assay. Refer to D5403