

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D1063408	(X3) Date Survey Completed 08/08/2018
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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
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a surveyor's review of laboratory's temperature records and interview with the testing person, the laboratory failed to follow the laboratory's temperature policy for laboratory testing. FINDINGS: 1. The laboratory's temperature policy requires the refrigerator temperature to be between 2 to 8 degree Celsius. 2. On August 8, 2018 at approximately 3:30 PM the testing person confirmed surveyor's findings that the laboratory failed to take and document corrective action from March 2018 through the survey date when the temperature of the refrigerator was out of acceptable ranges for 44 days. 3. Approximately 400 patient samples were tested and reported during the above time frames.</p>
D5441	<p>CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g)</p> <p>(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1)</p>

Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on surveyor's review of the laboratory's Quality Control (QC) Plan, QC records, Beckman Dickinson (BD) Affirm VP III manufacturer's operations manual and an interview with the testing person, the laboratory failed to follow the laboratory's established QC procedure for the BD Affirm VP III microbial identification test. FINDINGS: 1. The laboratory's written QC procedure established the frequency of testing the external Trivalent control materials once per month and with each new lot and/or shipment of PAC test cassettes. 2. The testing person confirmed on August 8, 2018 at approximately 3:30 PM, the laboratory failed to perform the external control material (Trivalent Swab) monthly and for each new lot of Probe Analysis Card (PAC) test cassettes, prior to use for patient testing in July, August, December 2017 and from May through August 2018. 3. Approximately 50 patients were tested and reported for Gardnerella, Candida and Trichomonas during the above time frames. PLEASE NOTE: THIS IS A RECITED DEFICIENCY FROM THE SURVEY CONDUCTED ON APRIL 17, 2017.

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 surveyor's findings and confirmed in an interview with the testing person, the laboratory director failed to provide overall management of the laboratory. The laboratory director failed to ensure that the laboratory: 1. Maintained the plan of correction from the survey conducted on 4/17/2017; 2. QC program for Affirm testing was maintained, refer to D6020; 3. Testing personnel had their annual competency evaluation, refer to D6054.

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 surveyor's review of the laboratory's QC records and an interview with the testing person, the laboratory director failed to ensure that the quality control program

was maintained to assure quality testing for bacteriology, mycology and parasitology testing. Refer to D5441, D5413.

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 a surveyor's review of competency assessment records and confirmed in an interview with the testing person, the laboratory director, acting as the technical consultant, failed to ensure that competency assessment for the two testing persons was performed in calendar year 2017.