

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0857736	(X3) Date Survey Completed 04/03/2018
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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
D1001	<p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a lack of laboratory quality control (QC) records and an interview with the laboratory director, the laboratory failed to test QC material when a new bottle of Siemens' 10 SG Urine reagent strips are opened. Findings Include: It was confirmed by the laboratory director on April 3, 2018, at approximately 11:45 am that the laboratory failed to follow the manufacturer's instruction for the Siemens' 10 SG Urine reagent strips and test a positive and negative controls prior to patient testing. Approximately 1140 patient tests were performed for urinalysis and results reported for 2017.</p>
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on no proficiency test verification records and an interview with the laboratory director, the laboratory failed to verify the accuracy of urine microscopy test procedure. Findings Include: On April 4, 2018, at approximately 11:50 AM and confirmed by the laboratory director, the laboratory failed to perform twice annual verification for the urine microscopy procedure performed from the date of the last</p>

survey April 19, 2016, through the date of this survey. Approximately 300 patient specimens were tested and reported for the urine microscopy procedure performed.

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 a review of the laboratory's procedure manual and an interview with the laboratory director, the laboratory failed to have a complete procedure manual for urine colony counts. Findings Include: It was confirmed by the laboratory director at approximately 11:30 am that the laboratory failed to include sterility checks for each new lot/shipment of the Uricult media in their procedure manual.

D5477

CONTROL PROCEDURES

CFR(s): 493.1256(e)(4)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on a lack of documentation and an interview with the laboratory director, the laboratory failed to perform quality control testing (QC) for the Uricult Media from April 10, 2016, through the date of this survey. Findings Include: 1) It was confirmed by the laboratory director on April 3, 2018, at approximately 11:30 am that the laboratory failed to perform the sterility check for each new lot/shipment of the Uricult Media. 2) The IQCP addresses QC for the Uricult media but failed to address

the sterility checks for the Uricult media. 3) Approximately 300 patient specimens were tested and results reported for Urine colony counts during this time. THIS SURVEY IS A RE-CITATION FROM THE LAST SURVEY OF APRIL 19, 2016.

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 a review of QC records, and an interview with the laboratory director, the laboratory director failed to ensure that the QC program for urine colony counts was maintained to assure quality of laboratory services. Refer to: D5477 THIS SURVEY IS A RE-CITATION FROM THE LAST SURVEY OF APRIL 19, 2016.

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 surveyor's review of laboratory procedures and no records for twice a year verification and an interview with the laboratory director, the laboratory director failed to have a complete procedure for the sterility check of the Uricult media and perform twice annual verification in year 2016 for colony counts. Refer to: D5403 & D5217