

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D2138618	(X3) Date Survey Completed 06/04/2019
Name of Provider or Supplier Mark Kirschenbaum Medical Pc	Street Address, City, State 2361 Nostrand Avenue - Ste 101, Brooklyn, NY	
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
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on lack of proficiency testing (PT) records and an interview with the lab manager, the laboratory failed to enroll in Health & Human Services (HHS) approved PT program for the specialty Bacteriology/throat cultures for the calendar year 2018 and 2019.</p>
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>

This STANDARD is not met as evidenced by:
Based on surveyor's review of laboratory temperature records and an interview with the laboratory manager, the laboratory failed to follow the manufacturer's instructions for monitoring and maintaining incubator temperatures for incubating throat cultures. FINDINGS: 1. The laboratory manager confirmed on June 4, 2019 at approximately 2:30 PM, the surveyor's findings that the laboratory failed to record the incubator temperatures from September 10, 2018 through June 4, 2019. 2. The manufacturer of the throat culture SSA media used for testing requires that the incubation temperature to be in the range of 35-37 degree Celsius. 3. Approximately 40 specimens were tested and reported for throat culture during the above time period.

D5471

CONTROL PROCEDURES

CFR(s): 493.1256(e)(1)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on surveyor's review of the bacteriology Quality Control (QC) documentation and an interview with the laboratory manager, the laboratory failed to check each new batch, lot number and shipment of 0.04 bacitracin discs for positive and negative reactivity from September 10, 2018 through June 6, 2019. FINDINGS: 1. The laboratory manager confirmed on June 4, 2019 at approximately 2:00 PM, surveyor's findings that the laboratory failed to check each new batch, lot number and shipment of the bacitracin discs for positive and negative reactivity in September 10, 2018 through June 6, 2019. The current lot in use 0.04 bacitracin disc lot #8338541 expiration date 6/30/2020 contain ten vials in the same lot/shipment since patient testing was implemented on September 10, 2018. 2. Approximately 40 patients' specimens were tested and reported for throat culture during this time-period.

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 surveyor's review of bacteriology Quality Control (QC) documentation and an interview with the laboratory manager, the laboratory failed to perform QC as required from September 10, 2018 through June 4, 2019. FINDINGS: The laboratory manager confirmed on June 4, 2019 at approximately 2:00 PM, that the laboratory

failed to: 1. Perform and document the sterility for the SSA Media lots; a. SSA media lot # 81586561 expiration date 9/7/18 and #90606801 expiration date 6/1/19 2. Approximately 40 specimens were tested and reported for throat culture during the above time period.

D6015

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(4)

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) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed.

This STANDARD is not met as evidenced by:

Based on the surveyor's review of laboratory records and an interview with the laboratory manager, the laboratory director failed to enroll the laboratory in a HHS PT program for bacteriology /throat culture in calendar year 2018 and 2019. FINDINGS: The laboratory manager confirmed on June 6, 2019 at approximately 2:30 PM, that the laboratory initiated bacteriology/throat culture testing in September 10, 2018 but did not enroll in a PT program for 2018 and 2019. Refer to D2000.

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 QC records and confirmed in an interview with the laboratory manager, the laboratory director failed to ensure that the QC program for bacteriology/throat culture testing was maintained to assure the quality of laboratory services. Refer to: D5413, D5471 and D5477.