

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0115425	(X3) Date Survey Completed 01/08/2019
Name of Provider or Supplier Efrem Greenfield Md	Street Address, City, State 16 Pocono Road, Suite 111, Denville, NJ	
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
D5002	<p>BACTERIOLOGY CFR(s): 493.1201</p> <p>If the laboratory provides services in the subspecialty of Bacteriology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1261, and 493.1281 through 493.1299.</p> <p>This CONDITION is not met as evidenced by: Based on surveyor review of the Quality Control (QC) records and interview with the Laboratory Director (LD) the laboratory failed to ensure that the quality systems for the analytical phases of bacteriology testing were monitored from 3/3/15 to the date of survey. The findings include: 1. The laboratory failed to ensure that quality control on media was performed. Cross Refer to D5477. 2. The laboratory failed to ensure that quality control on bacitracin discs was done. Cross Refer to D5471.</p>
D5471	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(1)(g)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Quality Control (QC) records and interview with the Laboratory Director (LD), the laboratory failed to check each lot number and</p>

shipment of Bacitracin Discs (BD) for positive and negative reactivity from 3/3/15 to the date of the survey. The findings include: 1. The LD stated that he obtained patients samples that were positively identified as streptococcal bacteria to show current lot of BD inhibits growth of group A streptococci . 2. There was no documented evidence that QC was performed on BD. 3. The 3/3/15 Allegation of Compliance (AOC) stated "When Bacitracin discs arrives I will take a positive rapid strep specimen and plate the patient specimen and corroborate positive symmetry of positive Bacitracin sensitivity of same specimen " 4. The 2/15/17 AOC stated "Bacitracin discs lot should be checked for efficacy using a know GP A B strep organism to check for zone of inhibition upon incubation with above agar plate" 5. The LD confirmed on 1/8/19 at 12:20 pm that QC was not performed. Note: This was cited in previous surveys 3/3/15 and 2/15/17.

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 surveyor review of Quality Control (QC) records and interview with the Laboratory Director (LD), the laboratory failed to check each batch of Throat culture media for its ability to support growth and select or inhibit organisms from 2/15/17 to the date of the survey. The findings include: 1. The Allegation Of Compliance stated "Agar plates for throat CX should be checked upon arrival for contamination by visual inspection for crack in agar/plastic, growth on agar and sample plate should be put in incubation for 24 hours for check of sterility" 2. There was no evidence that the laboratory checked the media's ability to support growth and select or inhibit organisms. 3. The LD confirmed on 1/8/19 at 10:50 AM the laboratory did not perform QC. Note: This was previous cited on 2/15/17.

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 surveyors review of the laboratory's records and interview with the Laboratory Director (LD), the LD failed to provide overall management and direction to the laboratory to ensure that laboratory testing is performed satisfactorily and in compliance with the CLIA regulations from 3/3/15 and 2/25/17 to the date of the survey. 1. The LD failed to follow the Allegation of Compliance for surveys conducted 3/3/15 and 2/15/17. 2. The LD failed to submit PT results within the required time frame. Cross refer to D6017. 3. The LD failed to establish a QC

program for bacteriology Testing. Cross refer to D6020 Note: This deficiency was cited on 3/3/15 and 2/15/17.

D6017

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

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)(ii) Ensure that results are returned within the timeframes established by the proficiency testing program.

This STANDARD is not met as evidenced by:
Based on surveyor review of the Proficiency Testing (PT) records and interview with the Laboratory Director (LD), the LD failed to ensure that the American Proficiency Institute (AIP) Bacteriology 2nd 2018 PT event was returned within the required time frame by the provider. The findings include: 1. The laboratory did not submit in time and scored zero for the event. 2. The LD stated that the initial samples sent from AIP were damaged during shipping, so the laboratory ordered new samples from the provider. 3. The LD stated that the laboratory missed the deadline to send PT results for evaluation due to the delayed shipping and holidays. 4. The laboratory did not perform a self-evaluation, to ensure that a passing grade was achieved. 5. The LD confirmed on 1/8/19 at 1:00 PM the PT results were not returned within the required time frame.

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 review of the Quality Control (QC) records and interview with the Laboratory Director (LD), the LD failed to establish a QC program for throat culture Testing from 3/3/15 to the date of survey. The LD confirmed on 1/8/19 at 1:00 pm that a QC program was not established. Note: This deficiency was cited on 2/15/17 and 3/3/15.