

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D1013902	(X3) Date Survey Completed 03/21/2019
Name of Provider or Supplier Ica Pediatrics	Street Address, City, State 359 Avenue U, 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
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 the surveyor's review of bacteriology Quality Control (QC) records and an interview with the laboratory director/testing person, the laboratory failed to check each new batch, lot number and shipment of 0.04 bacitracin disks for positive and negative reactivity from June 7, 2017 through to the date of this survey FINDINGS: 1. On March 21, 2019 at approximately 11:00 AM, the laboratory director/testing person confirmed the surveyor's findings that the laboratory failed to have documentation of bacitracin disk quality control testing from June 7, 2017 through to the date of this survey 2. Approximately 2400 patients specimens were tested and reported for throat culture testing during this time period.</p>
D5477	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g)</p> <p>(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</p>

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 the surveyor's review of records and confirmed in an interview with the laboratory director/testing person at the time of this survey, the laboratory failed to perform and document sterility checks for each new lot of Selective Strep Agar (SSA) Media from June 7, 2017 through the date of this survey. Approximately 2400 patient specimens were tested and reported for throat culture testing during this time period.

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 the surveyor's review of the laboratory's quality control (QC) records, and confirmed in an interview with the laboratory director/testing person, at the time of this survey, the laboratory director failed to ensure that the QC program for bacteriology testing was maintained to assure quality of laboratory services. Refer to: D5471 and D5477