

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0161435	(X3) Date Survey Completed 01/26/2018
Name of Provider or Supplier Shaker Pediatrics Pc	Street Address, City, State 10 Century Hill Drive Suite 5, Latham, 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
D5291	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.</p> <p>This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's Quality Assessment (QA) policies /procedures and an interview with and confirmed by the laboratory supervisor, the laboratory failed to follow the laboratory's written QA policy and perform general laboratory systems QA reviews yearly for bacteriology testing in calendar years 2016 and 2017.</p>
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor's review of the laboratory's Quality Control Plan (QCP) for the bacitracin disks and confirmed in an interview with the laboratory supervisor, the laboratory personnel failed to follow the laboratory's QCP for bacitracin disks used for throat culture testing. FINDINGS: The laboratory supervisor confirmed on 01/26 /2018 at approximately 11:00 AM that the laboratory personnel did not follow the</p>

established QCP for the bacitracin disks and perform quality control weekly using a positive and negative organism to check the reactivity of the disks.

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 the surveyors review of quality control (QC) records for Selective Strep Agar (SSA) used to throat culture testing and confirmed in an interview with the laboratory supervisor on 01/26/2018, the laboratory failed to check and document the physical characteristics of the SSA media and failed to perform the sterility check on each new batch (shipment) or lot number of SSA media in calendar years 2016, 2017 through to 01/26/2018. Approximately 500 patients throat culture tests were performed and read from 01/01/2016 through 01/26/2018.