

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0716005	(X3) Date Survey Completed 09/19/2023
Name of Provider or Supplier Navesink Pediatrics	Street Address, City, State 55 N Gilbert St, Tinton Falls, 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
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 of the media when compromised and report any deterioration in the media to the manufacturer. (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, the Procedure Manual and interview with Testing Personnel (TP), the laboratory failed to check each new lot number and shipment of Selective Strep Agar (SSA) media for its ability to inhibit specific organisms from 5/18/21 to the date of the survey. The findings include: 1. The laboratory failed to use at least one organism to confirm the SSA inhibitory characteristic. 2. The TP #9 as listed on CMS-209 form confirmed on 9/19/23 at 11:30 am the laboratory did not perform the above mentioned QC on SSA media.</p>