

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D0215893	(X3) Date Survey Completed 11/29/2023
Name of Provider or Supplier Pediatric Group/Pediatrics In Severna Park	Street Address, City, State 692-A Ritchie Hwy, Severna Park, MD	
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
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 laboratory procedure manual and record review and interview with the technical consultant (TC), the laboratory did not ensure that the procedure for sub-culturing bacteriology quality control (QC) organisms accurately reflected the current practice in the laboratory. Findings: 1. The laboratory maintains QC organisms for bacteriology testing by growing the organism on agar plates and then sub-culturing the organisms to new agar plates to extend their life. 2. During an interview at 11:40 AM on the day of the survey, the TC stated that they "verbally" told the testing personnel that they could sub-culture the bacteriology QC organisms monthly instead of weekly. 3. The procedure, "Stock Culture Policy" states that, "The first week of each month, the three stock organisms should be plated to three separate Urine plates - Just the red Blood Agar side." and "New sub plates should be plated each of the 4 weeks from the stock culture plate." 4. Review of the "Stock Organism Sub-Culturing Worksheet" from 03/06/2023 to 09/07/2023 showed that the QC organisms were sub-cultured nine times in six months, not weekly. 5. During an interview on 11/29/2023 at 12:30 PM, the TC confirmed that the "Stock Culture Policy" in the laboratory procedure manual was not current and needed to be updated.</p>