

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0669731	(X3) Date Survey Completed 06/22/2020
Name of Provider or Supplier Pediatric Place Llc	Street Address, City, State 2800 S Seacrest Blvd Ste 150, Boynton Beach, FL	
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
D0000	An announced recertification survey was conducted at Seitz Pediatrics on 6/22/20. The laboratory was not in compliance with 42 Code of Federal Regulations (CFR), Part 493, requirements for clinical laboratories.
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 record review and interview with laboratory personnel, the laboratory did not document quality control procedures for uricult urine cultures. The findings included: During an interview with testing person A at 10:20 a.m. on 6/22/20, she said that quality control for uricult media should be documented in the patient log when a new lot or shipment was used. Review of the patient log at that time revealed that there were no quality control entries for uricult media in 2018 through the present to indicate that positive and negative control organisms were tested to check the media for its ability to support growth, or that the physical condition of the media had been checked.</p>