

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D0421883	(X3) Date Survey Completed 05/16/2018
Name of Provider or Supplier Naperville Pediatric Associates	Street Address, City, State 1012 95th St - Ste 7, Naperville, IL	
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 review of laboratory records, direct observations, and interview with the laboratory director (LD); the laboratory failed to test each lot and/or shipment of culture media for the ability to support growth, inhibit growth, and document the results. Findings Include: 1. Direct observation of laboratory testing supplies during a tour of the laboratory with the office manager on 5-16-2018 at 9:45am identified Uricult CLED+Polymyxin/MacConkey culture paddles used for urine cultures. 2. Review of the laboratory policy and procedure manual identified the policy, "Quality Assurance Manual", which indicates under the section "For Urine Screens for the detection of Urinary Infections" that Uricult paddles will be tested for accuracy with a UriCult Control kit (Catalog # Uri-Kit). 3. Review of the package insert for the Gibson Bioscience UriCult Control kit found it contained a Escherichia coli (ATCC 25922) and a sterile matrix. 4. Review of the quality control testing log, "UriCult Paddles for Urine Screen", found each lot of Uricult paddles were tested with E.Coli and sterile water. 5. No quality control records were found for 8 of 8 lots of CLED+Polymyxin/MacConkey Uricult paddles for positive growth on the CLED+Polymyxin media and inhibition of growth on the MacConkey media. a. CLED+Polymyxin/MacConkey Uricult paddle Lot #'s: 1710252, 1725469, 1735024, 1750125, 1771404, 1784761, 1805628, and 1827867 6. Review of 6 of 6 patient test</p>

results for urine cultures found no documented control results verifying that CLED+Polymyxin/MacConkey Uricult paddles have the ability to support growth and the ability to inhibit growth for both media types on the paddle. Urine Cultures a. Patient ID - P1, Test Date: 04-25-2018 b. Patient ID - P2, Test Date: 04-24-2018 c. Patient ID - P3, Test Date: 01-04-2018 d. Patient ID - P4, Test Date: 11-01-2017 e. Patient ID - P5, Test Date: 05-12-2017 f. Patient ID - P6, Test Date: 09-19-2016 7. Interview with the LD on 05-16-201 at 12:15 PM confirmed that each lot of CLED+Polymyxin/MacConkey Uricult culture paddles were not tested for the ability to support growth on the CLED+Polymyxin side and the ability to inhibit growth on the MacConkey prior or concurrent to patient testing.