

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D0211985	(X3) Date Survey Completed 01/31/2019
Name of Provider or Supplier Olney Pediatrics	Street Address, City, State 18111 Prince Philip Dr, Ste 311, Olney, 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
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory (lab) did not ensure that testing personnel attested that proficiency testing was performed in the same manner as patient samples. Findings: 1. The laboratory is enrolled in a proficiency test program. Unknown samples are shipped to the lab by the proficiency test provider for testing. The test results are reported to the provider and the provider then evaluates and scores the labs performance; 2. The proficiency test records for 2018 and 2017 bacteriology proficiency test events 1, 2 and 3 (for both years) did not include signed statements attesting to the routine integration of the samples into the patient workload using the laboratory's routine methods (either by pen or electronic signature); and 3. These findings were confirmed with lab staff during interview with staff on the day of survey.</p>
D5211	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory (lab) did not ensure that the proficiency test results evaluated by the proficiency test provider are reviewed by the</p>

lab director and that the reviews are documented. Findings: 1. The laboratory is enrolled in a proficiency test program. Unknown samples are shipped to the lab by the proficiency test provider for testing. The test results are reported to the provider and the provider then evaluates and scores the labs performance; 2. The results of the 2018 bacteriology proficiency test events 1, 2 and 3 were not reviewed, signed and dated by the lab director; and 3. These findings were confirmed with lab staff during interview with staff on the day of survey.

D5445

CONTROL PROCEDURES
CFR(s): 493.1256(d)(1)(2)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--
(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on observation of the written procedure manual and interview with lab staff, the lab did not have an Individualized Quality Control Plan (IQCP) for The Uricult and Selective Strep Agar plates (SSA) the laboratory (lab) uses for patient testing.
Findings: 1. The laboratory uses commercially prepared test media (Uricult and SSA) to test for harmful bacteria in patient specimens. The sources of these specimens are throat for SSA and urine for Uricult; 2. The lab documents the conditions of the media upon arrival in the lab for quality control purposes; and 3. It was observed during review that the lab did not have an IQCP showing that the documentation made during receipt was as effective as checking each shipment of media with quality control organisms to demonstrate growth and chemical reactivity; 4. On the day of survey this was confirmed during interview of lab staff.