

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  21D0211985	<b>(X3) Date Survey Completed</b>  09/27/2021
<b>Name of Provider or Supplier</b>  Olney Pediatrics	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5423</b>	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2)</p> <p>Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance.</p> <p>This STANDARD is not met as evidenced by: Based on review of the product insert and laboratory testing logs and interview with the testing person (TP) and laboratory director (LD), the laboratory failed to establish performance specifications for testing specimen types that were not validated by the manufacturer using the McKesson Consult Diagnostics Strep A Dipstick, a FDA-cleared test system. Findings: 1. The laboratory used the McKesson Consult Diagnostics Strep A Dipstick for rapid antigen testing to aid in the diagnosis of Group A Streptococcus (GAS) infection. The testing complexity was categorized as CLIA waived when used with throat swab specimens. 2. The "Limitations" section of the Strep A Dipstick product insert stated that "The test should be used for the detection of Strep A antigen in throat swab specimens only." 3. Review of the patient logs for GAS rapid and culture testing from 01/02/2020-06/30/2021 identified that penile specimens were tested on 06/26/2020 and 07/16/2020 and rectal specimens were tested on 02/07/2020 and 03/21/2021 using the Strep A Dipstick rapid antigen test kit. 4. The laboratory modified a FDA-cleared test system by testing specimen types that were not validated or approved by the manufacturer. A modified FDA-cleared or</p>

approved test system becomes a high complexity test. The laboratory did not establish performance specifications for accuracy, precision, analytical sensitivity and analytical specificity for testing the unapproved specimen types, penile and rectal, using the McKesson Consult Diagnostics Strep A Dipstick. 5. During the exit interview on 09/27/2021 at 11:45 AM, the TP and LD confirmed that the laboratory tested penile and rectal specimens using the McKesson Consult Diagnostics Strep A Dipstick, which was approved for use with throat swab specimens only.

**D6051**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(8)(v)

The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples.

This STANDARD is not met as evidenced by:  
Based on review of the laboratory personnel report and proficiency testing (PT) records and interview with the laboratory director (LD), testing of the microbiology PT samples was not rotated among all the testing personnel (TP) for evaluation of each individual's competency for evaluating patient throat culture testing results. Findings: 1. The laboratory personnel report (form CMS-209) listed five TP that evaluated results for patient throat culture testing. 2. Review of eight microbiology PT events from 2019-2021 showed that only a single TP was performing all the throat culture PT. 3. During the exit interview on 09/27/2021 at 11:50 AM, the LD confirmed that testing of the throat culture PT samples was not rotated among all TP for evaluation of individual competency.

**D6054**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:  
Based on review of the laboratory personnel report and personnel competency records and interview with the laboratory director (LD), the technical consultant (TC) failed to perform annual competency assessments of the testing personnel (TP) evaluating patient throat culture testing results. Findings: 1. The laboratory personnel report (form CMS-209) listed four TP (other than the LD) that evaluated results for patient throat culture testing. 2. The personnel files for these four TP did not include annual competency assessments of evaluating patient throat culture testing results. 3. During the exit interview on 09/27/2021 at 11:50 AM, the LD confirmed that annual competency assessments of the four TP evaluating throat culture testing results was not being performed.