

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D0212960	(X3) Date Survey Completed 08/22/2023
Name of Provider or Supplier White Oak Pediatrics	Street Address, City, State 903 Russell Avenue Suite 301, Gaithersburg, 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
D2006	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)</p> <p>The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing.</p> <p>This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and the procedure manual and interview with the laboratory director (LD), the laboratory did not have written procedures stating that staff who perform the throat culture proficiency testing (interpretation) for reporting to the proficiency test provider, to not discuss their results with other staff who may also have performed the test prior to submission of their test results. Findings: 1. The procedure manual did not include procedures stating that proficiency testing results interpreted by the primary testing person (testing person who is reporting the test results to the proficiency test provider) are not to be discussed with staff who may also be performing the testing, prior to submission of their test results to the proficiency test provider. 2. During the afternoon of the survey on August 14, 2023, the laboratory director confirmed that the laboratory did not have written procedures or documentation to show that the primary testing person did not discuss results with other staff prior to submission of their results to the proficiency test provider.</p>
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</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.

This STANDARD is not met as evidenced by:

Based on review of proficiency testing (PT) records and the procedure manual and interview with the laboratory director (LD), the laboratory did not document the identity of the testing person for each Proficiency test sample that was tested. Findings: 1. The attestation statement from the 2022 1st and 2nd PT event for throat cultures was signed by Testing Person # 1 and Testing Person # 2, but the description of what samples each person tested (Interpreted) was not written on the statement. 2. The attestation statement from the 2022 MLE-M3 PT event for throat cultures was signed by Testing Person # 1 and Testing Person #2 along with four other individuals, but the identification of samples each person tested or processed (prepared cultures for) was not written on the attestation statement. 3. The laboratory did not have the attestation statement for the 1st and 2nd proficiency test event in 2023 for throat culture testing. 4.. During the afternoon of the survey on August 14, 2023, the laboratory director confirmed that the laboratory did not have written procedures or documentation to show who performed the proficiency testing and that the primary did not discuss results with other staff prior to submission to the proficiency test provider.

D5211

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
CFR(s): 493.1236(a)

The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.

This STANDARD is not met as evidenced by:

Based on review of proficiency test records (PT), the laboratory did not have documentation that the laboratory director reviewed the results of the proficiency test provider's evaluation of the laboratory's performance for the 1st proficiency test event in 2023 for throat culture testing.

D6030

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(12)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

This STANDARD is not met as evidenced by:

Based on review of competency check records performed for testing staff (for throat culture testing), the laboratory director did not document if those competency checks were made by observation of throat and urine culture testing or by proficiency testing, or review of urine and throat culture testing records, as needed to show how competency was assessed.