

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D0212960	(X3) Date Survey Completed 11/09/2021
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
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 review of proficiency testing (PT) records and interview with the laboratory director (LD), the laboratory failed to attest to the routine integration of throat culture PT samples into the patient workload using the laboratory's routine methods in four out of six PT testing events reviewed. Findings: 1. Throat culture PT records from Medical Laboratory Evaluation (MLE) modules 1-3 (M1-M3) from 2020 and 2021 were reviewed. 2. MLE supplied the laboratory with a "Test Result Form" for each module which included an "Attestation Statement", to be signed by the LD or designee and the testing personnel (TP) that performed the testing, indicating that the PT was performed in the same manner as patient testing. 3. The "Attestation Statement" was not signed by the LD or designee for the 2021 MLE-M2 PT event. 4. The "Attestation Statement" was not signed by the TP who performed the testing for the 2020 MLE-M2, 2020 MLE-M3, and 2021 MLE-M3 PT events. 5. During the survey on 10/27/2021 at 11:30 AM, the LD confirmed that the attestation statements for performing PT in the same manner as patient testing were not consistently signed by laboratory personnel.</p>
D2010	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2)</p> <p>The laboratory must test samples the same number of times that it routinely tests patient samples.</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 failed to test throat culture PT samples the same number of times that it routinely tested patient samples.
 Findings: 1. Records from the 2020 3rd PT event for throat cultures included a worksheet documenting that all five PT samples were evaluated by five different testing personnel (TP). 2. The worksheet did not include a date that each TP evaluated the PT samples or a statement that the PT samples were tested by a single individual and then reviewed by the other TP after the PT results were submitted to the PT provider as part of the TP competency assessments. 3. The procedure manual did not include any procedures stating that routine patient throat cultures were to be reviewed by multiple TP prior to releasing test results. 4. During the survey on 10/27/2021 at 11:30 AM, the laboratory director confirmed that the PT records indicated that multiple TP evaluated the PT samples prior to results submission to the PT provider.

D3000

FACILITY ADMINISTRATION
 CFR(s): 493.1100

Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe.

This CONDITION is not met as evidenced by:
 Based on interview with the laboratory director (LD) and review of instrument data, the laboratory failed to report severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) negative test results on 117 of 117 days reviewed from 06/01/2021 through 10/27/2021. Findings: 1. The laboratory tested patient specimens for SARS-CoV-2 using the Quidel Sofia 2 analyzer. 2. During the survey on 10/27/2021 at 11:30 AM, the LD confirmed that the laboratory was only reporting positive results to the Maryland Department of Health (MDH) and was not reporting negative results. 3. Patient test results from the Quidel Sofia 2 analyzer were electronically transferred to an Excel worksheet that was received via email on 11/09/2021 at 9:32 PM. 4. The Sofia 2 analyzer data was reviewed from 06/01/2021-10/27/2021, during which 689 valid tests were performed. Of 689 valid tests performed, 670 resulted in negative detection. 5. Data review revealed that 65 of 65 tests performed on 22 days in 06/2021 were negative, 79 of 80 tests performed on 23 days in 07/2021 were negative, 98 of 101 tests performed on 24 days in 08/2021 were negative, 243 of 254 tests performed on 26 days in 09/2021 were negative, and 185 of 189 tests performed on the 22 days that were reviewed in 10/2021 were negative. 6. In an email received on 11/09/2021 at 9:32 PM, the LD stated that staff have been instructed to report all positive and negative SARS-CoV-2 results to MDH.

D5217

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
 CFR(s): 493.1236(c)(1)

At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.

This STANDARD is not met as evidenced by:

Based on review of the procedure manual and proficiency testing (PT) records and interview with the laboratory director (LD), the laboratory failed to verify the accuracy of rectal culture testing. Findings: 1. The procedure manual included a procedure titled "Rectal Cultures" that gave instructions for collecting rectal swabs and performing testing to screen for group A streptococcus. 2. Review of PT records showed that the laboratory was only enrolled in PT for throat cultures and not for any additional bacteriology testing. 3. There were no records of any alternative PT or split samples performed twice annually to verify the accuracy of the rectal culture testing. 4. During the survey on 10/27/2021 at 11:30 AM, the LD confirmed that the laboratory did not verify the accuracy of the rectal culture testing twice annually.

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 procedure, personnel report and proficiency testing (PT) records and interview with the laboratory director (LD), testing of the throat culture 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 procedure titled "Personnel Assessment" stated that "PT samples will be performed by all employees on a rotating basis." 2. The laboratory personnel report (form CMS-209) listed seven TP that evaluated results for patient throat culture testing. 3. Throat culture PT records from Medical Laboratory Evaluation (MLE) modules 1-3 (M1-M3) from 2020 and 2021 were reviewed. 4. MLE supplied the laboratory with a "Test Result Form" for each module which included an "Attestation Statement", to be signed by the TP that performed the testing. 5. Event 2020 MLE-M1 contained the signatures of five TP. 6. Event 2020 MLE-M3 contained no signatures, but included a worksheet indicating that 5 TP evaluated the PT samples. 7. Events 2020 MLE-M2 and 2021 MLE-M3 contained no signatures and no additional documentation identifying which TP performed the PT. 8. Events 2021 MLE-M1 and 2021 MLE-M2 contained a single signature from the same individual performing the PT for both events. 9. During the survey on 10/27/2021 at 11:30 AM, the LD confirmed that testing of the throat culture PT samples was not documented as being 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 laboratory failed to provide documentation of annual competency assessments of the testing personnel (TP) evaluating patient throat cultures for 2019 and 2020. Findings: 1. The laboratory personnel report (form CMS-209) listed six TP (other than the LD) that evaluated results for patient throat culture testing. 2. Laboratory records for the competency assessments of the six TP evaluating throat cultures were reviewed for 2021, but were missing for 2019 and 2020. 3. During the survey on 10/27/2021 at 11:30 AM, the LD confirmed that documentation of the annual competency assessments for the six TP performing throat cultures was missing for 2019 and 2020.