

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D0212960	(X3) Date Survey Completed 04/30/2019
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
D5445	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on record review, observation and interview, the lab did not perform quality control procedures for the selective strep agar plates and "Uricult" media used for bacteriology testing. Findings: 1. The laboratory receives bacteriology test media into the lab, and uses quality control checks, performed by the manufacturer to show that the media reacts as expected; 2. In order for the lab to use the manufacturer's quality control checks, the lab is required to document receipt of the culture media, observe the media for physical defects, contamination and drying, and document these activities for each lot and shipment of culture media received; 3. The last quality control check performed by the lab, for the selective strep agar was conducted on April 3, 2018 (lot 1803608) with an assigned expiration date of May 28, 2018, further quality checks have not been recorded as of the date of survey; 4. Prior to the April 3, 2018 media quality control check for the selective strep agar, the last quality control check was performed almost one year ago on March 9, 2017 (lot 7068632) with an assigned expiration date of July 18, 2017; 5. Selective strep agar plates were observed in the lab. The lot number of the plates were 1905830 and 1904500. The quality control checks were not documented on the lab's media check worksheet for these two lots; 6. The last quality control check performed by the lab for the "Uricult" test media</p>

was on June 3, 2018 for lot number 1810955 that had an assigned expiration date of August 26, 2018, no other receipt was recorded even though it was observed that the lab was using "Uricult" media lot 1875031 (expiration date August 16, 2019) and this media quality control check was not documented; and 7. The lab's records for receipt (quality control) of the "Uricult" media did not include checking the physical characteristics of the media and initials of the person performing the quality control checks in 2018 and 2017.

D5781

CORRECTIVE ACTIONS

CFR(s): 493.1282(b)(1)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on record review and interview with the laboratory (lab) director, the lab did not document corrective action for bacteriology testing when the bacteriology incubator performed outside established operating parameters. Findings: 1. The laboratory documents daily temperature readings for the bacteriology incubator on a log; 2. The temperature reading observed on 8/15/18 was 27.8 degree Fahrenheit, and the comment "unplugged"; 3. The lab did not document further corrective actions or investigations concerning (but not limited to) how the plug was pulled, if any patients were affected, and if so, steps taken to ensure reliable testing; and 4. When additional documentation was requested from the lab director, during interview on the day of survey, the lab director was unable to provide the additional records.

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 record review and interview with the laboratory (lab) director acting as technical consultant, the lab director did not ensure that staff responsible for observing throat cultures and interpreting the results, participated in testing proficiency samples to evaluate competency. Findings: 1. The lab participates in three proficiency test events each year for bacteriology. Each event contains 5 samples of unknown value, the samples are tested (results observed) and reported to the proficiency test provider for evaluation. The proficiency test provider scores the lab based on its performance and reports the score as a percentage of passing or acceptable responses; 2. The lab did not rotate the proficiency test challenges to all 6 providers who perform throat culture testing. Only one individual performed the proficiency testing in all of 2018

and the first event of 2019; 3. The labs written procedures state that "PT procedures will be performed by all employees on a rotating basis"; and 3. This was confirmed with the lab director during interview on the day of survey.