

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 34D0240591	<b>(X3) Date Survey Completed</b> 07/14/2022
<b>Name of Provider or Supplier</b> White Oak Pediatric Associates, Pa	<b>Street Address, City, State</b> 4414 Lake Boone Trail Suite 103, Raleigh, NC	
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>D1001</b>	<p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e)</p> <p>Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions for the BD Veritor System SARS-CoV-2 test and interview with laboratory director (LD) 7/14/22, the laboratory failed to provide fact sheets to patients and providers. Findings: Review of manufacturer's instructions, page 14, revealed "CONDITIONS OF AUTHORIZATION FOR THE LABORATORY...Authorized laboratories using your product must include with test result reports, all authorized Fact Sheets.". Interview with LD at approximately 9:45 a. m. confirmed fact sheets were not included with test result reports for the SARS-CoV-2 testing performed. She stated she was unaware it was required.</p>
<b>D5403</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or</p>

control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:

Based on review of laboratory procedures and review of hematology quality control (QC) records 7/14/22, the laboratory procedures for performance of QC for complete blood cell (CBC) testing on the Medonic hematology analyzer failed to include the type and levels of QC reagent used and the corrective actions to take when QC results fail to meet the laboratory's criteria of acceptability. The laboratory utilizes multiple procedures and/or manufacturer's instructions for the performance of QC on the Medonic hematology analyzer. 1. The procedures and instructions fail to state the specific type and levels of QC reagent used by the laboratory. Findings: Review of procedure "Quality Control and Calibrations Procedures Laboratory General Policy" revealed "All quality control materials utilized are recommended by the instruments', systems', and methods' manufacturers and/or have established assay values for the instruments, systems and methods being performed.". The procedure fails to state the specific type and levels of QC reagent used by the laboratory. Review of manufacturer's "Daily Startup Sequence" instructions revealed how to run controls and also the use of low, normal and high control levels but fails to state the name (type) of controls used. 2. The procedures and instructions fail to include the corrective actions to take when QC results fail to meet the laboratory's criteria of acceptability. Findings: Review of procedure "Quality Control and Calibrations Procedures Laboratory General Policy" revealed "Patient controls are acceptable if their results have been established during a run when commercial controls of known values have been acceptable." The procedure fails to include corrective actions to take when QC results are unacceptable. Review of manufacturer's "Daily Startup Sequence" instructions revealed "When control results are acceptable, the daily startup sequence is complete.". The instructions fail to include corrective actions to take when QC results are unacceptable. Review of hematology QC records revealed when QC samples have unacceptable results the only corrective action taken is to repeat the QC sample until an acceptable result is achieved. For example: a. 10/14/21, Normal and High controls were ran 5 times until the QC result was acceptable. b. 3/24/22 and 3/25/22, High controls were ran 3 times until the QC result was acceptable. c. 4/29/22, High control was ran 3 times until the QC result was acceptable. d. 4/30/22, High control was ran 11 times until the QC result was acceptable.

**D6053**

**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 semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Based on review of testing personnel (TP) training and competency records, and interview with LD 7/14/22, the technical consultant (LD) failed to ensure competency

assessments for 2 of 5 TP were performed semiannually their first year of testing. Findings: Review of TP training and competency records revealed TP #1 began testing in November of 2020. Records also revealed no competency assessment was performed the first year and the first competency assessment performed was in July of 2022, approximately 18 months after testing began. Review of TP training and competency records revealed TP #5 began testing in August of 2021. Records also revealed one competency assessment was performed the first year of testing in July of 2022. Exit interview with LD at approximately 2:00 p.m. confirmed competency assessments for TP #1 and TP #5 were not performed semiannually as required the first year of testing.