

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  37D1022550	<b>(X3) Date Survey Completed</b>  03/28/2024
<b>Name of Provider or Supplier</b>  South Pointe Pediatrics	<b>Street Address, City, State</b>  1615 S Eucalyptus Ave Suite 210, Broken Arrow, OK	
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>D0000</b>	The recertification survey was performed on 03/28/2024. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the laboratory director at the conclusion of the survey.
<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 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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the hematology policy and procedure manual, and interview with the laboratory director, the laboratory failed to have a complete written procedure for one of one procedures reviewed. Findings include: (1) On 03/28/2024 at</p>

09:05 am, the laboratory director stated the following: (a) CBC (Complete Blood Count) testing was performed using the Medonic M-Series analyzer; (b) Three levels of QC (quality control) materials were tested each day of patient testing; (c) The manufacturer's provided ranges were used to determine acceptability of QC results. (2) A review of the procedure titled, "Quality Control - Medonic M-Series" identified the procedure did not include instructions for how the laboratory verified the stated values of new lot numbers of QC materials before they were put into use; (3) The findings were reviewed with the laboratory director who stated on 03/28/2024 at 01:30 pm, the CBC procedure had not included all of the required information.

**D5429**

**MAINTENANCE AND FUNCTION CHECKS**  
CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:  
Based on a review of records, manufacturer's instructions, and interview with the laboratory director, the laboratory failed to ensure the manufacturer's instructions were followed for performing maintenance procedures during the review period of March 2023 through January 2024. Findings include: (1) On 03/28/2024 at 09:05 am, the laboratory director stated CBC (Complete Blood Count) testing was performed using the Medonic M-Series analyzer; (2) A review of the manufacturer's instruction manual titled, "Medonic M-series User's Manual", Chapter 8, section 8-1 required the following daily cleaning procedures: (a) Clean the aspiration and pre-dilute probes using and alcohol wipe; (b) Remove possible traces of salt crystals or blood at the top of the aspiration and pre-dilute probes, probe rinse cup, and around top of sampling device probe inlet (if applicable) using a paper tissue with a disinfecting solution. (3) A review of maintenance logs identified the daily cleaning had not been documented as performed between March 2023 through January 2024; (4) The records were reviewed with the laboratory director who stated on 03/28/2024 at 01:00 pm, the daily cleaning had not been documented as performed.