

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2059871	(X3) Date Survey Completed 08/05/2022
Name of Provider or Supplier Ari Brown Pediatrics,Pa	Street Address, City, State 925 Westbank Drive, Suite 100, Austin, TX	
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
D0000	Noted deficiencies were discussed with the laboratory representatives at the exit conference. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended.
D5411	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.</p> <p>This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions, calibration records, and interview, the laboratory failed to print the post-calibration report for the CBC (Complete Blood Count) tested on the Medonic M Series for one of three calibrations reviewed. Findings follow. A. Review of the M-Series Calibration Instructions quick guide, (PN207053C R09.30.19) stated on page 2, "Keep all important calibration documents together in a safe location: Five calibration runs Pre-Calibration Log Calibration assay insert/M-Series barcode insert/product description insert Post calibration report Post Calibration Control Results". B. Review of the calibration records showed the 1/20 /2022 post calibration report, that listed the target values used in the calibration, was not available for review. On August 3, 2022 at 1355 hours, the post calibration report was requested but not provided. C. Interview with the technical consultant on August 3, 2022 at 1355 hours in the office confirmed the findings and stated there were two different prompts that allowed you to print the calibration report, and once another calibration is performed, the report cannot be retrieved.</p>
D5415	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p>

Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:

Based on review of manufacturer's instructions, observation and interview, the laboratory failed to label the CBC (Complete Blood Count) control material with the open date and open expiration for three of three control vials in use in the laboratory tested on the Medonic M series. Findings follow. A. Review of the package insert for the Boule Con-Diff Tri Level controls (201043L R03.31.15) under Storage and Stability stated, "Open vial stability 14 days after opening when returned to refrigerator after each run." B. During a tour of the laboratory on August 3, 2022 at 1305 hours, the surveyor observed the Boule Con-Diff low, normal, and high control vials in use in the laboratory, Lot 22203, closed vial expiration 8/10/2022, were not labeled with the open date and open vial expiration. C. Interview with the office manager on August 3, 2022 at 1305 hours in the laboratory confirmed the findings and added when looking back on the calendar, the controls would have been opened last week.