

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0700623	(X3) Date Survey Completed 03/01/2023
Name of Provider or Supplier Childersburg Primary Care	Street Address, City, State 33637 Us Hwy 280, Childersburg, AL	
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 a review of the American Proficiency Institute (API) Proficiency Testing (PT) records and an interview with Testing Personnel #1, the Laboratory Director failed to sign the attestation statements for three of three events in 2022. The findings include: 1. A review of the API PT records revealed the no signature by the Laboratory Director (or designee) on attestation statements for the following surveys: a) 2022 Hematology 1st Event. b) 2022 Hematology 2nd Event. c) 2022 Hematology 3rd Event. 2. During an interview on March 1, 2023, at 9:55 AM, Testing Personnel #1 confirmed the above findings.</p>
D5437	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a)</p> <p>Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b) (3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.</p>

This STANDARD is not met as evidenced by:

Based on a review of the Hematology calibration records, the Medonic User Manual, and an interview with Testing Personnel #1, the Laboratory failed to perform calibrations on the Medonic Hematology analyzer every six months as per the manufacturer's instructions. The laboratory failed to perform two of two calibrations due in 2022. The findings include: 1. A review of the Hematology calibration records revealed the Medonic was last calibrated 12/21/2021. There was no documentation of calibrations performed in 2022. 2. A further review of the Medonic User Manual revealed on page 59, "It is recommended to calibrate the instrument every six months." 3. During an interview on March 1, 2023, at 10:05 AM, Testing Personnel #1 confirmed the two calibrations due in 2022 were not performed.