

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2129843	(X3) Date Survey Completed 11/19/2024
Name of Provider or Supplier Wildflower Pediatrics	Street Address, City, State 11609 Anderson Mill Road, 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	The laboratory was surveyed and found to be in compliance with the Conditions of the CLIA regulations found at 42 CFR 493.1 through 493.1780, and recertification is recommended. Standard level deficiency was cited.
D2006	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)</p> <p>The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing.</p> <p>This STANDARD is not met as evidenced by: Based on review of the proficiency testing records, data logs, manufacturer's instructions, maintenance logs, and interview, the laboratory failed to test proficiency samples in the same manner as patient testing when it performed a monthly cleaning prior to five of five proficiency testing (PT) events on the Medonic M-series for the Complete Blood Count (CBC). Findings follow. A. Review of the American Proficiency Institute (API) Hematology testing events from the 1st, 2nd and 3rd events of 2023, and 1st and 2nd events from 2024 against the Medonic All Sample Summary Report (data logs) showed for each event a monthly cleaning was performed on the analyzer prior to the performance of PT. Review of the PT instrument print-outs showed PT was performed on the following dates: 03/16/2023, 07/12/2023, 11/14/2023, 03/14/2024, 07/16/2024. B. Review of the Medonic M-series User's Manual, Art no 1504472 02/2016, Section 8: Cleaning, Maintenance & Transport at 8.2 Monthly Cleaning stated, "This section describes the cleaning</p>

procedure to be used to secure the correct function of the instrument on a monthly basis. The Monthly Cleaning procedure takes approximately 10 minutes, instructions are follows: 1. Clean the aspiration probes using an alcohol wipe. 2. Fill a cup with 10 ml 2% hypochlorite (Bottle #2 from Boule Cleaning Kit) and one cup with 18 ml diluent. (Recommend use of dispense function for obtaining diluent, see Section 5.5: Dispense Function.) 3. Aspirate the hypochlorite as a pre-dilute sample. 4. Run 2 blank samples by aspirating diluent as a pre-diluted sample. 5. Perform a background check, in pre-dilute mode, to verify all values are within range. See Section 5.3 for more details. Clot Prevention: This process will decrease the risk of debris material building up in the instrument system. This should be performed at least once a month or every 1000 samples. This procedure will take 15 minutes to complete." C. Review of the Medonic M Series Maintenance Log showed the monthly cleaning was performed on the following dates as PT: 03/16/2023, 07/12/2023, 11/14/2023, 03/14/2024, 07/16/2024. D. Interview with testing personnel #1 on November 19, 2024 at 1520 hours stated she performed the monthly cleaning prior to performing PT.