

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0306156	(X3) Date Survey Completed 10/25/2023
Name of Provider or Supplier Selma Pediatrics Pc	Street Address, City, State 1225 Medical Center Parkway, Selma, 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
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> <p>This STANDARD is not met as evidenced by: Based on a review of the Medonic Hematology analyzer calibration records, the Medonic User's Manual and an interview with the Laboratory Director, the laboratory failed to perform and document quality controls (QC) following calibration as per manufacturer's instructions. This was noted for two out of five calibrations performed from April 2022 to the date of the current survey, 10/25/2023. The findings include: 1. A review of the Medonic Hematology records revealed calibrations and QC as follows: A) Calibration 3/21/2023 at 07:39 AM with QC performed at 7:27 AM only. B) Calibration 10/20/2023 at 08:45 AM with QC performed at 07:30 AM only. 2. A review of the Medonic M Series User's Manual on page 62 in the Calibration Section revealed, "...17. It is recommended to run controls after calibration to verify that all parameters have been calibrated correctly. ...". 3. During an interview on 10/25/2023 at 3:30 PM, the above noted findings were reviewed and confirmed with the Laboratory Director.</p>
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 a review of Personnel records and an interview the Laboratory Director, the Technical Consultant failed to assess competency at least semi annually in the first year of patient testing for the Medonic M Series Hematology Analyzer. This was noted for one out of six new Testing Personnel since the date of the last survey, April 19, 2022, to the date of the current survey, October 25, 2023. The findings include: 1. A review of Personnel records revealed Testing Personnel #8 to have an initial training date of 2/20/23. No evidence of a six month competency assessment was available for review. 2. During an interview on 10/25/2023 at 3:30 PM, the Laboratory Director confirmed the above findings.

D6054

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 annually, after the first year.

This STANDARD is not met as evidenced by:

Based on a review of Personnel records and an interview with the Laboratory Director, the Technical Consultant failed to assess competency of Testing Personnel at least annually for the Medonic M Series Hematology Analyzer. This was noted for four out of seven Testing Personnel eligible for annual assessment from the date of the last survey, January 27, 2022, to the date of the current survey, October 11, 2023. The findings include: 1. A review of Personnel records revealed the following: A) Testing Personnel #1 had an annual competency assessment dated 1/7/2023 only. No evidence of an annual competency assessment for 2022 was available for review. B) Testing Personnel #2 had an annual competency assessment dated 1/7/2022 only. No evidence of an annual competency assessment for 2023 was available for review. C) Testing Personnel #4 had an initial training date of 7/27/2022 and a six month competency assessment dated 1/9/2023. No evidence of an annual competency assessment for 2023 was available for review. D) Testing Personnel #5 had an initial training date of 5/23/2022 and a six month competency assessment dated 1/23/2023. No evidence of an annual competency assessment for 2023 was available for review. 2. During an interview on 10/25/2023 at 3:30 PM, the Laboratory Director confirmed the above findings.