

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0306156	(X3) Date Survey Completed 04/19/2022
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
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the 2019 - 2022 Medonic M Series Hematology calibration records, and an interview with the Laboratory Director, the laboratory failed to retain the manufacturer's assay sheets (package insert) for one of seven calibrations reviewed. The findings include: 1. A review of the 2019 - 2022 Medonic M Series Hematology records revealed no manufacturer's assay sheet (package insert) for the calibrator utilized during the 10/15/2021 calibration of the instrument. 2. During the exit summation on 4/19/2022 at 4:00 PM, the above noted findings were reviewed and confirmed with the Laboratory Director. .</p>
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on a review of accuracy verification documentation for Fungal Cultures performed on ACU-DTM (Dermatophyte Test Medium) and an interview with the Laboratory Director, the surveyor determined the laboratory failed to verify the accuracy of Fungal Cultures the second half of 2019 and 2021. This was noted in two out of three years of accuracy verification records reviewed. The findings include: 1.</p>

A review of 2019-2021 accuracy verification records for Fungal Cultures performed on ACU-DTM revealed the laboratory performed "split sample" testing for "Growth" or "No Growth" with a reference laboratory, and compared the results twice a year. However, the surveyor noted records for only one accuracy verification comparison in 2019 (5/24/2019), and one in 2021 (4/20/2021). 2. During an interview on 4/19/2022 at 1:23 PM, the Laboratory Director confirmed the above noted findings. .

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(b)

The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

Based on a review of environmental records, and an interview with the Laboratory Director, the laboratory failed to ensure temperature and humidity records were retained and accessible on the day of the survey. The laboratory was unable to locate 2019 and 2020 (two of four years) records for room temperature and humidity, and incubator temperatures. Monthly refrigerator temperature records (2019-2021) for the laboratory were mixed with general monthly records, and the laboratory was unable to collate and organize the records for review during the survey. The findings include: 1. A review of the poorly organized monthly records revealed the laboratory recorded room temperature and humidity, and incubator temperatures on one sheet annually, however the staff were unable to locate the sheets for 2019 and 2020. The laboratory was unable to provide 2019-2020 documentation demonstrating the Medonic was operated within the manufacturer's environmental specification, or documentation of the urine and fungal culture incubation temperatures. 2. A review of temperature requirements for the Hematology controls and ACU-DTM (Dermatophyte Test Medium) revealed storage requirements of 2-8 degrees Celsius, or 35-46 degrees Fahrenheit. The laboratory used "Vaccine Logs" to document the temperatures in which these laboratory items were stored. These records were mixed with vaccine logs for three other refrigerators, and in folders with individual monthly records for 2019-2022. The surveyor requested the laboratory refrigerator temperatures, however the laboratory failed to provide these records during the survey period. 3. During the exit summation with the Laboratory Director on 4/19/2022 at 4:00 PM, the laboratory was unable to provide the above noted environmental records. The surveyor explained CLIA did not specify how a laboratory should store their records, however a laboratory should utilize a mechanism to allow accessibility to the records requested during the on-site survey. .

D5437

CALIBRATION AND CALIBRATION VERIFICATION
CFR(s): 493.1255(a)

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.

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 controls after two of two 2019 calibrations, as per manufacturer's instructions. The findings include: 1. A review of the Medonic Hematology records revealed calibrations and QC as follows: A) Calibration 9/24 /2019 at 08:12 AM with QC performed 7:26 to 7:28 AM only B) Calibration 12/5 /2019 at 10:57 AM with QC performed 8:38 to 8:40 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 the exit summation on 4/19/2022 at 4:00 PM, the above noted findings were reviewed and confirmed with the Laboratory Director. SURVEYOR ID# 32558 Licensure and Certification Surveyor