

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2042515	(X3) Date Survey Completed 04/02/2024
Name of Provider or Supplier Bee Caves Pediatrics,Pa	Street Address, City, State 2501 Rr 620 South, Suite 220, Lakeway, 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.
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 review of the manufacturer's instructions, the laboratory's policy and procedure, calibration records, pre-survey paperwork, and interview, the laboratory failed to follow the user's manual for performing calibrations for the Medonic M-Series Complete Blood Count (CBC) for one of four calibrations reviewed from July 2022 - January 2024. Findings follow. A. Review of the Medonic M-Series User's Manual, May 2009 Article # 1504248, under 7.2 Calibration stated, "Follow the instructions below to calibrate: ... Step 9 If all parameters have acceptable CVs proceed to the next step, if not rerun calibration following steps above. Step 10 The new calibration factor can be entered in three ways. The recommended method is to select the [USE CAL] button which will automatically calculated the new calibration factor using target range from assay values [hand written instructions stated, 'have to</p>

push for all 6 parameters, will only ask for ID & code for first value'] (other 2 options marked out)... Step 11 In the first and second methods the calibration factor is automatically calculated once either the [USE CAL] button is pressed or target value is entered. Step 12 Once calibration factor has been entered using one of the methods above, operator will be prompted to enter a 4-digit Operator ID... and Authorization Code (REQUIRED) before the new value can be changed or updated. NOTE: Authorization Code prompt is displayed only once per calibration sequence when [USE CAL], [TARGET VALUE], or [NEW CAL FACTOR] buttons are pressed. Step 13 Authorized operator can update or change calibration factor by inputting the Authorization Code [2576]. Step 14 Perform steps 9-12 for RBC, MCV, PLT, HGB, WBC, and MPV parameters. To move to the next parameter press [NEXT]. Step 15 It is recommended to not change preset calibration factors for RDW%... Step 16 Once parameters are calibrated, press [EXIT] and a screen will be displayed asking operator if a calibration report is wanted, [SEND], [PRINT], or [EXIT] can be selected. It is recommended that calibration reports be printed and archived in case it may be needed for future reference [with the handwritten instructions 'must completely exit out of calibration menu before this will pop up'] (Pop up stated, 'Do you want a calibration report? Print')." The laboratory failed to perform steps 13-16. B. Review of the laboratory's policy and procedure titled CBC Medonic M-Series, approved 01/12/2021, at Calibration stated, "Calibration of the Medonic M-Series should occur at least once every 6 months or any time quality control values indicate that the instrument is 'out' of calibration or following major maintenance procedures or parts replacement. Whole blood calibration material is available commercially and ready to use. Refer to manufacturer's package insert for specific instructions on storage and mixing and Section 7.2 of the User's manual for operational instructions." C. A Review of the calibration records from July 2022 - January 2024, as listed by date performed, revealed: 1. 07/22/2022: The post calibration report showed RBC, MCV, PLT, MPV, HGB, and WBC were successfully calibrated on 07/22/2022. 2. 01/24/2023: The pre-calibration report showed the last calibration was on 07/22/2022. The post calibration report showed only RBC was calibrated on 01/24/2023. MCV, PLT, MPV, HGB, and WBC still showed the last calibration was on 07/22/2022 (elapsed time of 6 months). 3. 07/26/2023: The pre-calibration report showed RBC was calibrated on 01/24/2023. MCV, PLT, MPV, HGB, and WBC showed the last calibration was on 07/22/2022. The post-calibration report showed RBC, MCV, PLT, MPV, HGB, and WBC were successfully calibrated on 07/26/2023 (elapsed time of 12 months for MCV, PLT, MPV, HGB, and WBC). 4. 01/31/2024 The post calibration report showed RBC, MCV, PLT, MPV, HGB, and WBC were successfully calibrated on 01/31/2024. D. Review of the CMS-116 showed a CBC annual test volume of 1770. E. Interview with the Technical Consultant (as listed on the CMS-209) on April 2, 2024 at 1400 hours in the patient room verified the findings after a review of the records. KEY: RBC = Red Blood Cell Count MCV = Mean Corpuscular Volume PLT = Platelet MPV = Mean Platelet Volume HGB = Hemoglobin WBC = White blood cell count RDW = Red cell Distribution Width

D5807

TEST REPORT
CFR(s): 493.1291(d)

Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

This STANDARD is not met as evidenced by:

Based on review of patient test reports, pre-survey paperwork, and interview, the laboratory failed to provide the reference ranges for the Throat Culture Screen for Group A Streptococcus for five of five test reports for in-house throat cultures reviewed from March 2023 - March 2024. Findings follow. A. Review of 5 in-house throat culture test reports from 03/13/2023 - 03/12/2024 showed no reference ranges on the patient test report, as listed by accession number and collection date: 1. #1608033, 03/13/2023 2. #1726026, 08/02/2023 3. #1838131, 12/06/2023 4. #1889369, 02/05/2024 5. #1921422, 03/12/2024 B. Review of the CMS-116 showed a throat culture annual test volume of 701. C. Interview with Technical Consultant (as listed on the CMS-209) on April 2, 2024 at 1635 hours in the patient room acknowledged they should be able to fix that.