

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0362833	(X3) Date Survey Completed 02/21/2023
Name of Provider or Supplier Bloom Pediatrics	Street Address, City, State 2055 E 14 Mile Road, Birmingham, MI	
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
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: . Based on observation, record review, and interview with the Technical Consultant (TC), the laboratory failed to monitor the room temperature and humidity for the west laboratory for the hematology testing with the Beckman Coulter AcT diff2 analyzer for 6 (8/09/2022 to 2/14/2023) of 6 months in use. Findings include: 1. During a tour of the west laboratory on 2/14/2023 at 9:08 am, the surveyor observed a Beckman Coulter AcT diff2 analyzer was in use. 2. A record review of the laboratory's temperature monitoring logs revealed a lack of documentation for the room temperature and humidity of the west laboratory for 6 (8/09/2022 to 2/14/2023) of 6 months in use. 3. An interview on 2/14/2023 at 9:18 am, the TC confirmed the laboratory was not monitoring the room temperature and humidity for the west laboratory.</p>
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p>

This STANDARD is not met as evidenced by:
. Based on observation and interview with the Technical Consultant (TC), the laboratory failed to calibrate and/or replace the expired thermometer in the east laboratory that monitors the room temperature and humidity for over 2 (expired 1/15 /2021) of 2 years in use. Findings include: 1. During a tour of the laboratory on 2/14 /2023 at 9:08 am, the surveyor observed a Thomas Scientific thermometer in use for the room temperature and humidity with an expiration date of 1/15/2021. 2. An interview on 2/14/2023 at 9:18 am, the TC confirmed the thermometer in the east laboratory had expired and was not calibrated and/or replaced.

D6018

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)(iii)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;

This STANDARD is not met as evidenced by:
. Based on record review and interview with the Technical Consultant (TC), the Laboratory Director failed to ensure proficiency testing reports were reviewed by the testing personnel (TP) for 4 (event 3 in 2021 and event 1 - 3 in 2022) of 4 testing events reviewed. Findings include: 1. A review of the laboratory's final Medical Laboratory Evaluation (MLE) proficiency testing documents revealed a lack of review of results by the testing personnel listed on the attestation statement sheet for the following testing events: 2021 a. MLE - 3 no review by the TP 2022 a. MLE-1 no review by the TP b. MLE-2 no review by the TP c. MLE-3 no review by the TP 2. An interview on 2/14/2023 at 10:56 am, the TC confirmed the events listed above were not reviewed by the TP listed on the attestation statement sheet for each of the events.