

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0367952	(X3) Date Survey Completed 09/25/2024
Name of Provider or Supplier Brentwood Pediatrics	Street Address, City, State 33215 W 7 Mile Road, Livonia, 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
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 record review and interview with Testing Personnel #1, the laboratory failed to retain its Beckman Coulter AcT Diff hematology quality control and function check documentation at least two years for two (September and October 2022) of 12 months reviewed. Findings include: 1. A review of the laboratory's Beckman Coulter AcT Diff hematology quality control and background count records revealed a lack of documentation between 9/25/22 and 10/31/22. 2. An interview on 9/25/24 at 1:58 pm with Testing Personnel #1 confirmed the laboratory failed to retain documentation of its Beckman Coulter AcT Diff hematology quality control and function checks for at least two years.</p>
D5431	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with Testing Personnel #1 (TP1), the laboratory failed to perform and document background checks for the Beckman Coulter AcT</p>

Diff analyzer for February 1, 2023 to February 27, 2023. Findings include: 1. A review of the laboratory's Beckman Coulter AcT Diff hematology background count records revealed a lack of performance of background counts from 2/1/23 to 2/27/23. A total of 129 patients received testing on dates without background counts performed. 2. An interview on 9/25/2024 at 3:00 pm with TP1 confirmed that background checks were not performed and documented in the timeframes listed above.

D5439

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

Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:

Based on record review and interview with Testing Personnel #1 (TP1), laboratory failed to conduct 6-month Calibration on the Beckman Coulter AcT Diff Analyzer for 2 (March 2023 and June 2024) of 4 events required for 2023 and 2024 Findings include: 1. Record review of the laboratory's Beckman Coulter's ACT Diff Analyzer calibration documentation revealed that the 6-month calibration verification had not been performed and documented at least every six months due March 2023 and June 2024. 2. An interview on 9/25/2024 at 3:00 pm with TP1 confirmed that calibration was not performed and documented in the timeframes listed above.

D5445

CONTROL PROCEDURES
CFR(s): 493.1256(d)(1)(2)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
 Based on record review and interview with Testing Personne l (TP1)1, the laboratory failed to perform control procedures for the Beckman Coulter AcT Diff Analyzer for February 1, 2023 to February 27, 2023. Findings include: 1. A review of the laboratory's Beckman Coulter AcT Diff hematology quality control records revealed a lack of performance of control procedures from 2/1/23 to 2/27/23. A total of 129 patients received testing on dates without controls performed. 2. An interview on 9/25 /2024 at 3:00 pm with TP1 confirmed that quality control was not performed in the timeframes listed above.

D6000

MODERATE COMPLEXITY LABORATORY DIRECTOR
 CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:
 . Based on observation, record review, and interview, the Laboratory Director failed to ensure 6-month Calibrations on the Beckman Coulter AcT Diff Analyzer were performed (Refer to D6020A), failed to ensure control procedures for the Beckman Coulter AcT Diff Analyzer were performed (Refer toD6020B), failed to ensure quality assessment programs established were capable of identifying failures in quality as they occurred (Refer to D6022), and failed to ensure that background checks for the Beckman Coulter AcT Diff analyzer were performed and documented. (Refer D6023).

D6020

LABORATORY DIRECTOR RESPONSIBILITIES
 CFR(s): 493.1407(e)(5)

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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:
 . A Based on record review and interview with Testing Personnel 1 (TP1), laboratory director failed to ensure 6-month Calibrations on the Beckman Coulter AcT Diff Analyzer were performed. (Refer to D5439) B. Based on record review and interview with Testing Personnel l (TP1), the laboratory director failed to ensure control procedures for the Beckman Coulter AcT Diff Analyzer were performed. (Refer to D5445)

D6022

LABORATORY DIRECTOR RESPONSIBILITIES
 CFR(s): 493.1407(e)(5)

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)(5) Ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:

. Based on record review and interview with Testing Personnel #1, the Laboratory Director failed to ensure quality assessment programs established were capable of identifying failures in quality as they occurred for one (February 2023) of 12 months of quality control and function check records reviewed. Findings include: 1. A review of the laboratory's Beckman Coulter AcT Diff hematology quality control and background count records revealed a lack of performance of background counts and control procedures from 2/1/23 to 2/27/23. A total of 129 patients received testing on dates without background counts or controls performed. 2. A review of the laboratory's quality assessment records between September 2022 and September 2024 revealed a lack of documentation showing the errors of not performing background counts or controls were identified and no corrective action documentation was present. 3. An interview on 9/25/24 at 3:00 pm with Testing Personnel #1 confirmed documentation of background counts or controls for patient testing dates in February 2023 were not available. No corrective action for patients was available.

D6023

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(6)

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)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system;

This STANDARD is not met as evidenced by:

. Based on record review and interview with Testing Personnel #1 (TP1); the Laboratory Director failed to ensure that background checks for the Beckman Coulter AcT Diff analyzer were performed and documented. (Refer D5431)