

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0367952	(X3) Date Survey Completed 12/28/2022
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
D5400	<p>ANALYTIC SYSTEMS CFR(s): 493.1250</p> <p>Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.</p> <p>This CONDITION is not met as evidenced by: . Based on record review and interview with Testing Personnel (TP) #1, the laboratory failed to meet applicable analytic system requirements and correct identified problems. Findings include: 1. The laboratory failed to perform quality control testing each day of patient testing for the hematology complete blood count test. Refer to D5445. 2. The laboratory failed to perform and document the function checks as required for the room temperature in the laboratory. Refer to D5431.</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 lack of documentation and interview with Testing Personnel (TP) #1, the laboratory failed to perform and document the function checks as required for the</p>

	<p>room temperature in the laboratory for 20 (May 2021 through December 28, 2022) of 20 months of operation of the Beckman Coulter AcT diff hematology analyzer. Findings include: 1. A record review on 12/28/2022 at 11:34 am revealed a lack of documentation of the room temperature for 20 (May 2021 through December 28, 2022) of 20 months of operation of the Beckman Coulter AcT diff hematology analyzer. 2. When queried on 12/28/2022 at 11:34 am, TP#1 was not able to provide the surveyor the documentation to show the room temperature had been performed and documented. 3. An interview on 12/28/2022 at 11:34 am, TP#1 confirmed the laboratory failed to perform and document the room temperature function checks for the proper operation of the Beckman Coulter AcT diff hematology analyzer.</p>
<p>D5445</p>	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with Testing Personnel (TP) #1, the laboratory failed to perform quality control testing each day of patient testing for the hematology complete blood count test for 2 days (8/30/2022 and 8/31/2022) of 20 months of testing reviewed. Findings include: 1. A record review of the laboratory's quality control documentation for the hematology complete blood count test using the Beckman Coulter AcT diff analyzer revealed a lack of documentation for testing performed on 8/30/2022 and 8/31/2022. 2. A record review for 2 days of 20 months of testing revealed the following: a. 8/30/2022 - 8 patients tested b. 8/31/2022 - 4 patients tested 3. An interview on 12/28/2022 at 9:45 am, TP#1 confirmed the laboratory did not have documentation of quality control performed on the dates listed above when patient testing was reported.</p>
<p>D6033</p>	<p>TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409</p> <p>The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.</p> <p>This CONDITION is not met as evidenced by: . Based on record review and interview with Testing Personnel (TP) #1, the laboratory failed to ensure the testing personnel performing the duties of a Technical Consultant, had met the qualification requirements at 493.1411. Findings include: 1. The laboratory failed to ensure personnel performing the Technical Consultant duty of performing testing personnel competency assessments was qualified. Refer to D6035.</p>
<p>D6035</p>	<p>TECHNICAL CONSULTANT QUALIFICATIONS</p>

CFR(s): 493.1411

(a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service.

This STANDARD is not met as evidenced by:

. Based on record review and interview with the Testing Personnel (TP) #1, the laboratory failed to ensure personnel performing the Technical Consultant duty of testing personnel competency assessments was qualified for 2 (TP#1 and TP#2) of 2 personnel performing competency assessments. Findings include: 1. A review of the laboratory's personnel competency records revealed for 2 (TP#1 and TP#2) of 2 personnel performing competency assessments were not qualified as a Technical Consultant as follows: a. TP#1 tested by TP#2 b. TP#2 tested by TP#1 c. TP#3 tested by TP#1 d. TP#4 tested by TP#1 2. The surveyor requested the qualifications of TP#1 and TP#2 to serve as the Technical Consultant on 12/28/2022 at 9:45 am and the documentation was not made available. 3. An interview on 12/28/2022 at 9:45 am, TP#1 confirmed that TP#1 and TP#2 did not have the qualifications to perform the duties of a technical consultant.