

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0367952	(X3) Date Survey Completed 05/25/2021
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
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: . Based on record review and interview with the Laboratory Director (LD) and Testing Personnel (TP) #2, the laboratory failed to enroll in a proficiency testing program for the mycology wet mount microscopic examination testing for 9 (8/11/2020 to 5/25/2021) of 9 months. Findings include: 1. On 5/25/2021 at 11:07 am during a tour of the laboratory the surveyor identified a AmScope microscope on the countertop. 2. On 5/25/2021 at 11:43 am the surveyor requested a log for the wet mount examination testing, TP2 was unable to provide the documentation so a billing report was generated. 3. A record review of the billing report revealed for 9 (8/11/2020 to 5/25/2021) of 9 months of testing 18 patients had wet mount testing performed. 4. A record review of the proficiency testing reports revealed a lack of documentation for the mycology wet mount testing. 5. An interview on 5/25/2021 at 11:43 am, the LD and TP2 confirmed the laboratory was not enrolled in a proficiency testing program and did not perform twice a year verification of accuracy for the wet mount examination.</p>
D5431	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2)</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.

This STANDARD is not met as evidenced by:

. Based on lack of documentation and interview with Testing Personnel (TP) #2, the laboratory failed to perform and document the function checks as required by the manufacturers for the room temperature for 2 (May 2019 to May 2021) of 2 years of operation for the hematology Beckman Coulter AcT diff instrument. Findings include: 1. A record review revealed lack of documentation of the room temperature for the proper operation of the Beckman Coulter AcT diff instrument for 2 (May 2019 to May 2021) of 2 years. 2. An interview on 5/25/2021 at 1:43 pm, TP2 was unable to provide the surveyor the documentation requested.

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

. Based on record review and interview with Testing Personnel (TP) #2, the Technical Consultant (TC) failed to assure personnel performing wet mount examinations maintained their competency for 3 (TP1, TP7, and TP8) of 3 testing personnel performing the microscopic examination. Findings include: 1. A record review of the competency assessments revealed a lack of documentation for 3 (TP1, TP7, and TP8) of 3 personnel performing the wet mount preparations. 2. When queried on 5/25/2021 at 11:43 am, TP2 was unable to provide the surveyor documentation to show the testing personnel competency assessments had been performed and documented for the 9 months of performing wet mounts examinations. 3. An interview on 5/25/2021 at 11:43 am, TP2 confirmed lack of documentation for the competency assessments for TP1, TP7, and TP8.

D6063

LABORATORY TESTING PERSONNEL

CFR(s): 493.1421

The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.

This CONDITION is not met as evidenced by:

. Based on record review and interview with Testing Personnel #2 (TP2), the laboratory failed to provide the educational requirements for 2 (TP7 and TP8) of 8 testing personnel performing moderately complex testing. Refer to D6065

D6065

TESTING PERSONNEL QUALIFICATIONS

CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:

. Based on record review and interview with Testing Personnel (TP) #2, the laboratory failed to ensure that all testing personnel met the educational requirements at 493.1423 for 2 (TP7 and TP8) of 8 testing personnel as listed on the CMS-209 performing moderately complex mycology testing. Findings include: 1. On 5/25/2021 at 11:43 am, record review for 2 of 9 testing personnel credentials revealed the educational requirements for performing moderately complex mycology testing was not met. 2. During the interview on 5/25/2021 at 11:43 am, TP2 as listed on the CMS-209 confirmed the educational requirements were not met. 3. On 5/25/2021 at 11:43 am, the laboratory was given 7 additional days to supply the necessary educational documents. The documents were not received.