

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0367952	(X3) Date Survey Completed 04/01/2019
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
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with testing personnel #1 and #2 (TP1 and TP2), the laboratory failed to document the testing of the proficiency testing (TP) samples on the patient log sheet for the hematology complete blood cell count (CBC) for six (1st-3rd events 2017 and 2018) of six events reviewed. Findings include: 1. Record review of the American Proficiency Institute (API) final proficiency reports and the patient specimen log revealed the laboratory did not record the PT samples on the patient log sheet like routine patient samples for six of six testing events in 2017 and 2018. 2. During the interview on April 1, 2019 at 10:44 AM, TP1 and TP2 acknowledged the PT samples were not logged on the patient specimen log.</p>
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable,</p>

consultant competency.

This STANDARD is not met as evidenced by:

. Based on record review and interview with testing personnel #1 and #2 (TP1 and TP2), the laboratory failed to ensure a written policy was established that included the competency requirements from subpart M for the hematology complete blood cell count (CBC) for five (TP1 - TP5) of five TP reviewed. Findings include: 1. Record review of the TP competency assessments revealed the laboratory did not establish and implement an assessment that contained the following six minimum regulatory requirements as follows: a. Direct observations of routine patient test performance, patient preparation, specimen handling, processing, and testing. b. Monitoring the recording and reporting of patient test results. c. Review of test results, worksheets, quality control records, proficiency testing results, and preventive maintenance. d. Direct observation of performance of instrument maintenance and function checks. e. Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and f. Assessment of problem solving skills. 2. Record review of the TP competency assessments revealed the laboratory did not perform and document competency assessments with the six requirements for five of five testing personnel from April 2017 to April 2019. 3. During the interview on April 1, 2019 at 10:15 AM, TP1 and TP2 acknowledged the competency assessments were not up to regulatory specifications. .

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 testing personnel #1 and #2 (TP1 and TP2), the laboratory director failed to ensure the final American Proficiency Institute (API) proficiency testing (PT) reports were reviewed by the appropriate TP for six (1st - 3rd events 2017 and 2018) of six events reviewed. Findings include: 1. Record review of the final API reports revealed the appropriate TP did not review the 1st - 3rd events of 2017 and 2018 to evaluate their performance and to identify any problems that require corrective action. 2. During the interview on April 1, 2019 at 11:05 AM, TP1 and TP2 acknowledged the TP did not review the final API proficiency reports. ***Repeat Deficiency from August 10, 2016 survey***