

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D1086213	(X3) Date Survey Completed 09/09/2019
Name of Provider or Supplier Birmingham Pediatrics Wellness Center	Street Address, City, State 6785 Telegraph Road Suite 350, Bloomfield Hills, 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
D6018	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii)</p> <p>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;</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with the Office Manager and Laboratory Director (LD), the laboratory director failed to ensure all proficiency testing reports were reviewed by the appropriate staff to evaluate the laboratory's performance for 2 (September 2017 to September of 2019) of 2 years. Findings include: 1. A record review of the College of American Proficiency Testing records revealed a lack of documentation of a review by appropriate staff for the following testing events: a. 2019 i. FH2-A ii. FH2-B b. 2018 i. FH2-A ii. FH2-B iii. FH2-C c. 2017 i. FH2-C 2. An interview on 9/9/19 at 9:26 am with the Office Manager and the LD confirmed no documentation of a review by appropriate staff was conducted for the above proficiency testing events. **This is a repeat deficiency from the 4/3/17 survey**</p>
D6019	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv)</p> <p>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</p>

and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory.

This STANDARD is not met as evidenced by:

. Based on record review and interview with the Office Manager, the laboratory director failed to ensure an approved corrective action plan was followed when any proficiency testing results are found to be unacceptable or unsatisfactory for 2 (the second event of 2018 and the first event of 2019) of 6 events reviewed. Findings include: 1. A record review of the College of American Pathologists Proficiency Testing reports revealed the following events had unacceptable scores: a. 2018 FH2-B i. Red Blood Cell Count (RBC) score was 80%. ii. Hematocrit score was 80%. iii. Hemoglobin score was 80%. b. 2019 FH2-A i. RBC score was 80%. 2. A record review of the proficiency testing data exposed a lack of corrective action for the second event of 2018 and the first event of 2019. When requested on 9/9/19 at 9:26 am, the laboratory could not provide corrective action for the unacceptable scores. 3. An interview on 9/9/19 at 9:26 am with the Office Manager confirmed corrective action was not completed for the above proficiency testing events with unacceptable scores.

D6021

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 quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

. Based on record review and interview with the Office Manager, the laboratory director failed to ensure quality assessment programs are established and maintained to assure the quality of laboratory services for 2 (September 2017 to September 2019) of 2 years. Findings include: 1. A record review of the laboratory's established procedure manual revealed a lack of a quality assessment program policy. 2. On 9/9/19 at 9:06 am, the surveyor requested an established quality assessment program policy. 3. An interview on 9/9/19 at approximately 11:00 am with the Office Manager confirmed a quality assessment policy had not been available.