

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  23D1086213	<b>(X3) Date Survey Completed</b>  10/12/2021
<b>Name of Provider or Supplier</b>  Birmingham Pediatrics Wellness Center	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5801</b>	<p>TEST REPORT CFR(s): 493.1291(a)</p> <p>The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with the Laboratory Director (LD) and the Laboratory Manager (LM), the laboratory failed to ensure test results were accurately entered into the laboratory information system (LIS) from the patients printed report from the Beckman Coulter AcT diff hematology analyzer for 1 (#2) of 13 patient test reports reviewed. Findings include: 1. A record review of the manually transcribed results into the LIS revealed for 1 (#2) of 13 patient test reports reviewed, the hematocrit (HCT) result was transcribed into the LIS system as 39.0 and the actual result from the Beckman Coulter AcT diff hematology analyzer print was 39.9. . 2. An interview on 10/12/2021 at 12:25 pm, the LD and LM confirmed patient #2 final test report had a incorrect result reported out for the HCT.</p>
<b>D6033</b>	<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</p>

accordance with 493.1413 of this subpart.

This CONDITION is not met as evidenced by:

. Based on record review and interview with the Laboratory Director and Laboratory Manager, the laboratory failed to ensure Testing Personnel #5 performing the duties of a Technical Consultant (TC), met the qualification requirements at 493.1411. Findings include: 1. The laboratory failed to ensure the personnel performing the TC duty of performing testing personnel competency assessments was qualified. Refer to D6035.

**D6035**

**TECHNICAL CONSULTANT QUALIFICATIONS**  
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 a record review and interview with the Laboratory Director (LD) and the Laboratory Manager (LM), the laboratory failed to ensure Testing Personnel (TP) #5, acting as the Technical Consultant (TC), was qualified to perform the TC duty of performing testing personnel competencies for 4 (TP#1 - TP#4) of 5 testing personnel. Findings include: 1. A review of the laboratory's personnel competency records

revealed TP #5 had performed competency assessments for TP #1 - #4 on the following dates: a. TP#1 - 12/11/2020 and 10/08/2021 b. TP#2 - 12/23/2019, 2020 laid off during Covid, and 10/08/2021 c. TP#3 - 03/02/2020 and 09/30/2021 d. TP#4 - 08/11/2021 and 10/11/2021 2. An interview on 10/12/2021 at 10:03 am, the LD and LM confirmed that TP#5 did not meet the qualification requirements to be Technical Consultants.