

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0371828	(X3) Date Survey Completed 08/16/2021
Name of Provider or Supplier Trinity Health Iha Medical Group Pediatrics -	Street Address, City, State 28300 Orchard Lake Road, Suite 100, Farmington 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
D6033	<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 #1, the laboratory failed to ensure the Testing Personnel #1, performing the duties of a Technical Consultant, met the qualification requirements at 493.1411. Findings include: 1. The laboratory failed to ensure the personnel performing the Technical Consultant duty of performing testing personnel competency assessments was qualified. Refer to D6035.</p>
D6035	<p>TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411</p> <p>(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</p>

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 Testing Personnel #1 (TP1), the laboratory failed to ensure personnel performing the Technical Consultant duty of performing testing personnel competency assessments was qualified for 1 (Testing Personnel #1) of 2 personnel performing competency assessments. Findings include:

1. A review of the laboratory's personnel competency records revealed TP1 had performed competency assessments in 2019, 2020, and 2021 for the following testing personnel: a. Testing Personnel #2 b. Testing Personnel #3
2. A review of the laboratory's "Personnel Training and Qualifications" policy revealed a section stating, "Personnel must be evaluated by the technical consultant at least semiannually during the first year of employment. Thereafter, testing personnel are evaluated yearly."
3. An interview with TP1 on 8/16/21 at 9:38 am confirmed TP1 had been performing the competency assessments for the testing personnel listed above and was not qualified to be the laboratory's Technical Consultant.