

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0374918	(X3) Date Survey Completed 05/25/2022
Name of Provider or Supplier Children's Medical Group Of Saginaw Bay Pllc	Street Address, City, State 248 Washington Avenue Ste A, Bay City, 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
D5477	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with the Laboratory Director, the laboratory failed to perform media sterility checks for its throat culture testing for 2 (May 2020 to May 2022) of 2 years reviewed. Findings include: 1. A review of the laboratory's "Quality Control Culture Media" and "Throat Cultures Quality Control Form" documentation from May 2020 to May 2022 revealed a lack of documentation of media sterility checks performed for each new lot and shipment of Hardy Diagnostics Selective Strep Agar used for throat cultures. 2. A review of the laboratory's "Throat Culture Protocol" revealed a lack of a protocol to perform media sterility checks on new lots and shipments. 3. An interview on 5/25/22 at 2:25 pm with the Laboratory Director confirmed the laboratory had not performed media sterility checks for each new lot and shipment of its media used in throat culture testing.</p>
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>

This CONDITION is not met as evidenced by:

. Based on record review and interview with the Laboratory Director, the laboratory failed to ensure Testing Personnel #2, performing the duties of a Technical Consultant had met the qualification requirements at 493.1411. Findings include: 1. The laboratory failed to ensure personnel performing the Technical Consultant duty of performing 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 record review and interview with the Laboratory Director, the laboratory failed to ensure personnel performing the Technical Consultant duty of performing personnel competency assessments was qualified for 1 (Testing Personnel #2) of 2 personnel performing competency assessments. Findings include: 1. A review of the laboratory's personnel competency records revealed Testing Personnel #2 had performed competency assessment for the Laboratory Director, serving as the Clinical Consultant and the Technical Consultant on 10/25/21. 2. A review of the

qualifications for Testing Personnel #2 revealed a lack of documentation required to meet the educational requirements of a Technical Consultant. 3. An interview on 5/25/22 at 1:28 pm with Laboratory Director revealed Testing Personnel #2 was not qualified to perform the duties of a Technical Consultant.