

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0362833	(X3) Date Survey Completed 01/23/2025
Name of Provider or Supplier Bloom Pediatrics	Street Address, City, State 2055 E 14 Mile Road, Birmingham, 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 COMPLEXITY 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 the technical consultant, the laboratory failed to have a qualified person perform the technical consultant duty of testing personnel competency assessment performance (refer to D6035), failed to perform and document direct observations of test performance, specimen handling, processing, and testing (refer to D6047), and failed to perform and document assessment of problem-solving skills (refer to D6052).</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 (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 1 year of laboratory training or experience, or both, in nonwaived 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</p>

oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i)(A) Hold an earned doctoral or master's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(3)(i)(B) Meet either requirements in 493.1405(b)(3)(i)(B) or (b)(4)(i)(B) or (C); AND (b)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i)(A) Have earned a bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(4)(i)(B) Meet 493.1405(b)(5)(i)(B); and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(5)(i) Have earned an associate degree in medical laboratory technology, medical laboratory science, or clinical laboratory science; and (b)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. (b)(6) For blood gas analysis, the individual must- (b)(6)(i) Be qualified under paragraph (b)(1), (2), (3) or (4) of this section; or (b)(6)(ii)(A) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; and (b)(6)(ii)(B) Have at least 2 years of laboratory training or experience, or both, in blood gas analysis; or (b)(7) Notwithstanding any other provision of this section, an individual is considered qualified as a technical consultant under this section if they were qualified and serving as a technical consultant for moderate complexity testing in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024.

This STANDARD is not met as evidenced by:
 . Based on record review and interview with the technical consultant, the laboratory failed to have a qualified person perform the technical consultant duty of testing personnel competency assessment performance for 57 of 57 total testing personnel listed on Form CMS-209. Findings include: 1. A review of the laboratory's testing personnel competency assessments performed in 2024 for 57 testing personnel revealed the assessments were signed by a person not listed on Form CMS-209 as a technical consultant. 2. An interview on 1/23/25 at 9:53 am with the technical consultant confirmed the person who signed the competency assessments was not qualified as a technical consultant.

D6047

TECHNICAL CONSULTANT RESPONSIBILITIES
 CFR(s): 493.1413(b)(8)(i)

(b)(8)(i) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing;

This STANDARD is not met as evidenced by:
 . Based on record review and interview with the technical consultant, the technical consultant failed to perform and document direct observations of test performance, specimen handling, processing, and testing for 10 (March 2024 to January 2025) of 10 months reviewed. Findings include: 1. A review of the laboratory's competency assessment records revealed the document used to aid in performing and documenting testing personnel competency assessments was missing direct observations of test

	<p>performance, specimen handling, processing, and testing. 2. An interview on 1/23/25 with at 1:00 pm the technical consultant confirmed the competency assessment documentation used to assess testing personnel competency did not include documentation of direct observations of test performance, specimen handling, processing, and testing.</p>
<p>D6052</p>	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(vi)</p> <p>(b)(8)(vi) Assessment of problem-solving skills; and</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with the technical consultant, the technical consultant failed to perform and document assessment of problem-solving skills for 10 (March 2024 to January 2025) of 10 months reviewed. Findings include: 1. A review of the laboratory's competency assessment records revealed the document used to aid in performing and documenting testing personnel competency assessments was missing assessment of problem-solving skills. 2. An interview on 1/23/25 at 1:00 pm with the technical consultant confirmed the competency assessment documentation used to assess testing personnel competency did not include documentation of assessment of problem-solving skills.</p>
<p>D6063</p>	<p>LABORATORY TESTING PERSONNEL CFR(s): 493.1421</p> <p>The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.</p> <p>This CONDITION is not met as evidenced by: . Based on record review and a lack of documentation, the laboratory failed to ensure its moderate complexity testing personnel were qualified to perform Complete Blood Count (CBC) testing using the Beckman Coulter DxH 500 analyzer. Refer to D6035.</p>
<p>D6065</p>	<p>TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i)</p> <p>(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; or (b)(2) Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology, or nursing from an accredited institution; or (b)(3) Meet the requirements in 493.1405(b)(3)(i)(B), (b)(4)(i)(B), (b)(4)(i)(C) or (b)(5)(i)(B); or (b)(4) Have earned an associate degree in a chemical, biological, clinical or medical laboratory science, or medical laboratory technology or nursing from an accredited institution; or (b)(5) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least a duration of 50 weeks and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(6)(i) Have earned a high school diploma or equivalent; and</p>

This STANDARD is not met as evidenced by:

. Based on a lack of documentation and interview with the technical consultant, the laboratory failed to ensure testing personnel performing Complete Blood Count (CBC) testing using the Beckman Coulter DxH 500 analyzer were qualified for 9 of 57 total testing personnel listed on Form CMS-209. Findings include: 1. A review of the laboratory's testing personnel qualification records revealed the following personnel lacked documentation of meeting the educational requirements at 493.1423: a. Testing Personnel #3 had a bachelor's degree that did not specify the major of study. b. Testing Personnel #11 had a bachelor's degree that did not specify the major of study. c. Testing Personnel #14 had a foreign degree without appropriate equivalency documentation. d. Testing Personnel #15 had an associate degree that did not specify the major of study. e. Testing Personnel #22 had a foreign degree without appropriate equivalency documentation. f. Testing Personnel #24 had a "Cum Laude" certificate for grade point average, not an earned diploma or equivalent. g. Testing Personnel #29 had no education documentation present. h. Testing Personnel #48 had a bachelor's degree in interdisciplinary healthcare services. i. Testing Personnel #57 had a bachelor's degree of Integrative Studies. 2. The surveyor requested additional information for the testing personnel listed above on 1/23/25 at 12:00 pm and it was not made available. 3. The laboratory was provided with an additional seven days after the survey's conclusion to provide additional information for the testing personnel listed above and it was not received.