

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D2254809	(X3) Date Survey Completed 05/05/2025
Name of Provider or Supplier Bioprecision Laboratories, Inc	Street Address, City, State 23133 Orchard Lake Road Suite 203, Farmington, 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
D0000	A validation survey was performed on May 5, 2025 by the State of Michigan Licensing and Regulatory Affairs Department. The laboratory was found to be out of compliance with CLIA regulations (42 CFR Part 493, effective April 24, 2003) for the following condition-level deficiencies: 493.1409 Condition: Laboratories performing moderate complexity technical consultant.
D3011	<p>FACILITIES CFR(s): 493.1101(d)</p> <p>Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.</p> <p>This STANDARD is not met as evidenced by: . Based on observation and interviews with the laboratory director and technical consultant #2, the laboratory failed to have an operating eye wash station for 22 (July 2023 to May 2025) of 24 months reviewed. Findings include: 1. The surveyor observed the laboratory's eye wash station during a tour of the laboratory on 5/5/25 at 8:55 am. 2. An interview on 5/5/25 at 9:12 am with the laboratory director revealed the laboratory moved to its current address in July 2023. 3. An interview on 5/5/25 at 10:01 am with the laboratory director and technical consultant #2 revealed the eye wash station was inoperable.</p>
D5415	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage</p>

requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:
. Based on observation and interview with the laboratory director, the laboratory failed to label reagent containers to include the expiration dates for four reagents observed. Findings include: 1. The surveyor observed four reagents used in urine toxicology testing on 5/5/25 at 8:55 am that lacked expiration date information: a. Plastic jug with a red cap connected to the P500 Diatron instrument labeled "2mL of Cuvette Cleaner w/ each Liter of DI water." b. Plastic jug with a blue cap connected to the P500 Diatron instrument labeled "2mL of Sol. 3 w/ Each Liter of DI Water." c. Green-capped 50 mL conical tube labeled "70% alcohol." d. Green-capped 50 mL conical tube labeled "Bleach." 2. An interview on 5/5/25 at 9:05 am with the laboratory director confirmed the reagents listed above did not include the expiration dates.

D6033

TECHNICAL CONSULTANT-MODERATE COMPLEXITY
CFR(s): 493.1409

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.

This CONDITION is not met as evidenced by:
. Based on record review and a lack of documentation, the laboratory failed to have qualified technical consultants. 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 (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 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 a lack of documentation, the laboratory failed to have qualified technical consultants for two (technical consultants #1 and #2) of two staff performing technical consultant duties. Findings include: 1. A review of the laboratory's personnel records revealed a lack of documentation showing the following personnel met technical consultant qualification requirements: a. Laboratory director, technical consultant #1, performing the technical consultant duty of administering testing personnel competency assessments had a Doctor of Philosophy in Molecular Biology and lacked documentation of at least one-year documented training or experience in nonwaived toxicology testing. b. Technical consultant #2 had a Bachelor of Science in Medical Laboratory Technology and lacked documentation of at least two years of documented training or experience in nonwaived toxicology testing. 2. The laboratory was given seven days to provide any additional supporting documentation, and it was not received.