

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0363983	(X3) Date Survey Completed 05/08/2025
Name of Provider or Supplier Bay Area Family Physicians	Street Address, City, State 34301 23 Mile Road Suite 100, New Baltimore, 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 8, 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 deficiency: 493.1409 Condition: Laboratories performing moderate complexity technical consultant.
D5801	<p>TEST REPORT CFR(s): 493.1291(a)</p> <p>(a) 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 technical consultant #2, the laboratory failed to accurately transcribe test results for one (Patient #10) of 11 patient test reports reviewed. Findings include: 1. A review of the laboratory's "Direct Wet Preparation/KOH Procedure" revealed a section titled "Reporting of Findings" stating, "Report all organisms, cells, bacteria, and sperm observed. Quantitate amounts as follows: a. Cells: average number per high power field. b. Bacteria, crystals: few, 1+, 2+, 3+, or 4+. c. Trichomonas, yeast, and sperm: rare, few, many." 2. A review of Patient #10's test report dated 3/13/25 revealed the following results: a. Hyphae: None b. KOH: Few c. Clue Cells/hpf: None d. Bacteria: 1+ e. Trichomonas: None f. Yeast: Rare 3. The surveyor asked technical consultant #2 what the result in the "KOH" field correlated to on 5/8/25 at 12:15 pm. Technical consultant #2 indicated it was where</p>

the provider documented the yeast result and confirmed the discrepancy between the "rare" and "few" designations.

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 lack of documentation, the laboratory failed to have a qualified technical consultant. Refer 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 lack of documentation, the laboratory failed to have a qualified technical consultant for one (technical consultant #3) of three technical consultants listed on Form CMS-209. Findings include: 1. A review of technical consultant #3's personnel records revealed documentation of at least two years of hematology testing experience and a Bachelor of Science degree yet lacked the discipline information for the degree. 2. The surveyor requested additional documentation to support the degree was either in a chemical, biological, clinical or medical laboratory science, or medical technology on 5/8/25 at 10:32 am. 3. The laboratory was given seven days to provide any additional qualification documentation, and it was not received.