

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D1107008	(X3) Date Survey Completed 08/26/2026
Name of Provider or Supplier Brent M Boyce Md Pc	Street Address, City, State 4497 Sheffield Place, 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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: . Based on record review and interview with testing personnel #2, the laboratory failed to establish a competency assessment policy for three (May 2026 to August 2026) of three months since the laboratory initiated patient testing. Findings include: 1. A review of the laboratory's policies and procedures revealed a lack of competency assessment policy. 2. The surveyor requested the competency assessment policy on 8/26/26 at 10:57 am and it was not made available. 3. An interview on 8/26/26 at 11:12 am with testing personnel #2 confirmed a competency assessment policy was not available.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) (b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (b)(2)(i) Accuracy. (b)(2)(ii) Precision. (b)(2)(iii) Analytical sensitivity. (b)(2)(iv) Analytical specificity to include interfering substances. (b)(2)(v) Reportable range of test results for the test system. (b)(2)(vi) Reference intervals (normal values). (b)(2)(vii) Any other performance characteristic required for test performance.

This STANDARD is not met as evidenced by:

. Based on record review and interview with testing personnel #2, the laboratory failed to establish performance specifications for its frozen section histopathology testing for three (May 2026 to August 2026) of three months since it started patient testing.

Findings include: 1. A review of the laboratory's records revealed a lack of performance specifications for its frozen section histopathology testing. 2. An interview on 8/26/26 at 10:20 am with testing personnel #2 confirmed the laboratory had not established performance specifications prior to testing patients using frozen section histopathology. 3. A review of the laboratory's patient testing logs revealed a total of 160 patients received testing between 5/6/26 and 8/19/26.