

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0373059	(X3) Date Survey Completed 01/08/2026
Name of Provider or Supplier Harbor Beach Community Hospital	Street Address, City, State 210 S 1st Street, Harbor Beach, 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
D5203	<p>SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232</p> <p>The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results.</p> <p>This STANDARD is not met as evidenced by: . Based on observation, record review, and interview with the Technical Supervisor (TS), the laboratory failed to label 3 of 3 patient specimen tubes with collection times per laboratory policy. Findings include: 1. During a tour of the laboratory on January 7, 2026, at 10:30 am, the surveyor observed 3 specimen collection tubes processed for patient testing that did not include the collection time on the label. 2. Review of the laboratory policy titled "Specimen Labeling," Policy #1900.0039, Section I, "Procedure" states: "Anybody collecting specimens for laboratory analysis is responsible for: A. Putting the patient information on the sample, (if no patient labels are available, patient's name, PID #, and ordering physician, must be hand written on the specimen). B. Collection date C. Collection time D. Collector's initials E. Specimen source" 3. An interview with the TS on January 7, 2026, at 10:45 am, confirmed that the collection tubes did not include the specimen collection time required by the laboratory policy.</p>
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>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.</p>

This STANDARD is not met as evidenced by:
. Based on record review and interview with the Technical Supervisor (TS), the laboratory failed to ensure competency assessment for the TS was performed in accordance with laboratory policy, for 1(2025) of 4 years reviewed. Findings include: 1. Record review of competency assessment (CA) documentation revealed the CA for the current TS was performed by Testing Personnel (TP1), who previously served as the TS and transitioned to Testing Personnel in 2024. 2. Record review of Laboratory Policy 1900.0063a, titled "Competency Assessment of non-testing personnel," Procedure I revealed: "The laboratory medical director will perform, document and sign the annual competency evaluation for the lab's technical consultant, technical supervisor, and the general supervisor..." 3. Interview with the TS on January 8, 2026, at 11:30 am confirmed that the 2025 competency assessment for the current TS was performed by the former TS while functioning as Testing Personnel, and not by the Laboratory Director.

D5415

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(c)

(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 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 Technical Supervisor (TS), the laboratory failed to label two secondary containers with preparation and expiration dates used for patient testing. Findings include: 1. During a tour of the laboratory on January 7, 2026, at 11:00 am, the surveyor observed two secondary reagent containers, one labeled W1 2% Wash and one labeled DI Water, without preparation or expiration dates on the containers. 2. On January 7, 2026, at 11:10 am, an interview with the TS confirmed that the containers were not labeled with preparation or expiration dates.