

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0368619	(X3) Date Survey Completed 01/27/2026
Name of Provider or Supplier Corewell Health Taylor Hospital Laboratory	Street Address, City, State 10000 Telegraph Road, Taylor, 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 January 26, 2026 to January 27, 2026 by the Michigan Department of Licensing and Regulatory Affairs. The laboratory was determined to be out of compliance with CLIA regulations (42 CFR Part 493, Laboratory Requirements) for the following Condition: 493.1219 Condition: Histopathology
D5028	<p>HISTOPATHOLOGY CFR(s): 493.1219</p> <p>If the laboratory provides services in the subspecialty of Histopathology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1273, and 493.1281 through 493.1299.</p> <p>This CONDITION is not met as evidenced by: . Based on record review and interviews, the laboratory failed to establish policies and procedures to assess and document competency for all laboratory personnel (refer to D5209) and the laboratory failed to verify accuracy of its gross specimen and microscopic tissue examination testing at least twice annually (refer to D5217).</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> <p>This STANDARD is not met as evidenced by: . Based on record review and interviews with the general supervisor (GS) and laboratory director (LD), the laboratory failed to establish policies and procedures to</p>

assess competency for all laboratory personnel for two (2024 and 2025) of two years reviewed. Findings include: 1. A review of the laboratory's Form CMS-209 revealed personnel serving in the following roles: a. Laboratory Director (LD) also listed as Clinical Consultant (CC1) and Testing Personnel (TP24). b. Technical Supervisor (TS1) also listed as Testing Personnel (TP25). c. Technical Consultants (TC1, TC2, TC3). d. General Supervisor (GS1). 2. A review of the laboratory's policy titled "Laboratory Education - Employee Competency Assessment" revealed on page 1, Section I, "Purpose and Objective," the policy states: "The purpose of this procedure is to define the process for competency assessment of non-physician laboratory personnel during the term of their employment." Further review of the policy revealed it did not address competency assessment for individuals serving as clinical consultant, technical supervisor, technical consultant, general supervisor or physician testing personnel. 3. A review of personnel records revealed the following: a. CC1: No documentation indicating that a competency assessment was performed in 2024 or 2025 for either of the individual's assigned roles-Clinical Consultant or Testing Personnel (TP24). b. TS1: No documentation indicating that a competency assessment was performed in 2024 or 2025 for either of the individual's assigned roles-Technical Supervisor or Testing Personnel (TP25). c. TC1: No documentation indicating a competency assessment was performed in 2024. d. TC2: No documentation indicating a competency assessment was performed in 2024. e. TC3: No documentation indicating a competency assessment was performed in 2024. f. GS1: No documentation indicating a competency assessment was performed in 2024. 4. On 1/26/2026 at 11:33 am, a request was made to the GS for additional competency assessment documentation and all competency assessment policies. No additional competency assessment documentation or competency assessment policies were provided prior to survey exit. 5. On 1/26/2026 at approximately 2:00 pm, an interview was conducted with the LD, and it was determined that CC1 and TS1 were confirmed as physician testing personnel (TP24 and TP25) performing high complexity testing for tissue specimen grossing and microscopic tissue examination. The LD indicated that his understanding was that physicians were exempt from competency assessments based on their education and credentials. 6. An interview conducted on 1/27/2026 at 3:30 pm with the GS and LD confirmed that annual competency assessment documentation was missing for personnel listed above.

D5217

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
 CFR(s): 493.1236(c)(1)

At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.

This STANDARD is not met as evidenced by:
 . Based on record review and interview with the general supervisor and laboratory director, the laboratory failed to verify accuracy of its gross specimen and microscopic tissue examination testing at least twice annually for two (2024 and 2025) of two years reviewed. Findings include: 1. A review of the laboratory's records revealed a lack of documentation for twice annual verification of accuracy for tissue specimen grossing and microscopic tissue examination performed in 2024 and 2025. 2. On 1/26/2026 at 11:33 am, a request was made to the general supervisor for twice annual verification of accuracy testing for tissue specimen grossing and microscopic tissue examination performed in 2024 and 2025. 3. On 01/26/2026 at approximately 2:00 pm, an interview with the general supervisor and the laboratory director confirmed that the twice annual verification of accuracy was not performed for 2024 and 2025.

D5417

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

(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:

. Based on observation and interview with testing personnel #6, the laboratory failed to ensure its Anti-M reagent had not exceeded expiration dates for one of two bottles available in the laboratory. Findings include: 1. The surveyor observed one bottle of lot 99304 Anti-M Murine Monoclonal Gamma-clone reagent with the expiration date of 1/23/26 in the reagent tray on 1/26/26 at 3:06 pm. A second bottle was in a plastic bag on another shelf in the refrigerator. 2. An interview on 1/26/26 at 3:30 pm with testing personnel #6 confirmed the Anti-M bottle had exceeded its expiration date.

D5775

COMPARISON OF TEST RESULTS
CFR(s): 493.1281(a)(c)

(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites.

This STANDARD is not met as evidenced by:

. Based on record review and interview with testing personnel #6, the laboratory failed to evaluate and define the relationship between its Ortho Vision, manual gel method, and tube method blood bank testing for one (December 2025) of four events reviewed. Findings include: 1. A review of the laboratory's "[Health System Name]- Correlation of Results Between Instrument and Methods" policy revealed the following testing performed using Ortho Vision, manual gel method, and tube method: a. ABO/Rh b. Antibody Screen c. Neonatal Direct Antiglobulin Test (DAT) d. Antigen Typing e. Antibody Identification Panel f. Anti-Human Globulin (AHG) crossmatch 2. A review of the laboratory's "Correlation of Results Between Instruments and Methods" logs revealed correlations were completed on the following dates: a. 7/22/25 b. 12/26/24 c. 6/18/24 3. An interview on 1/27/26 at 11:18 am with testing personnel #6 confirmed the second event for 2025 had not been completed.

D6053

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(9)

(b)(9) Evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

. Based on record review and interview with the general supervisor (GS), the laboratory failed to conduct a semiannual competency assessment for 1 (TP16) of 4 newly hired testing personnel (TP) performing moderately complexity testing. Findings include: 1. A review of the laboratory's Form CMS-209 and personnel

records revealed that TP16 performed moderate and high complexity testing. 2. A review of personnel competency assessment documentation revealed TP16 had one competency assessment documented and was hired in January 2025. 3. A review of the laboratory's policy titled "Laboratory Education - Employee Competency Assessment" revealed on page 3, Section VII, "Manager (or Designee) Responsibilities," paragraph B, the following: a. Item 1 states: "New Testing Personnel: Once training is complete, competency must be assessed at least semi-annually ..." b. Paragraph a, Notes, section i states: "Semi-annual competency assessments must be completed within seven (7) months." 4. On 1/26/2026 at 11:33 am, an interview with the GS confirmed that only one competency assessment had been conducted in 2025 for TP16.

D6127

TECHNICAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1451(b)(9)

(b)(9) Evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:
. Based on record review and interview with the general supervisor (GS), the laboratory failed to conduct a semiannual competency assessment for 1 (TP16) of 4 newly hired testing personnel (TP) performing high complexity testing. Findings include: 1. A review of the laboratory's Form CMS-209 and personnel records revealed that TP16 performed moderate and high complexity testing. 2. A review of personnel competency assessment documentation revealed TP16 had one competency assessment documented and was hired in January 2025. 3. A review of the laboratory's policy titled "Laboratory Education - Employee Competency Assessment" revealed on page 3, Section VII, "Manager (or Designee) Responsibilities," paragraph B, the following: a. Item 1 states: "New Testing Personnel: Once training is complete, competency must be assessed at least semi-annually ..." b. Paragraph a, Notes, section i states: "Semi-annual competency assessments must be completed within seven (7) months." 4. On 1/26/2026 at 11:33 am, an interview with the GS confirmed that only one competency assessment had been conducted in 2025 for TP16.