

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  23D1105840	<b>(X3) Date Survey Completed</b>  03/10/2025
<b>Name of Provider or Supplier</b>  Premier Diagnostics	<b>Street Address, City, State</b>  1349 S Rochester Road Suite 210, Rochester Hills, MI	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D3009</b>	<p>FACILITIES CFR(s): 493.1101(c)</p> <p>The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements.</p> <p>This STANDARD is not met as evidenced by:</p> <p>. A. Based on observation, record review, and interview with the Laboratory Supervisor (LS), the laboratory failed to operate as a separate and distinct laboratory to comply with 493.55 for two (January 2023 to January 2025) of two years reviewed. Findings include: 1. On March 10, 2025, at 9:45 am, a tour of the laboratory's testing area was performed. The surveyor observed the laboratory testing area was equipped with instruments and supplies for processing histopathology patient slides to include: a. Tissue Tek   VIP Tissue Processor b. Tissue Tek   Tissue Processor c. Tissue Tek   SCA Automated Coverslipper d. Lecia   Tissue Autostainer e. Lecia Microtome f. Tissue Tek TEC   Tissue Embedder h. Paraffin Wax Bath i. Microscope g. Refrigerator 2. A review of the laboratory's (Laboratory A, Premier Diagnostics) procedure manual revealed a lack of policies pertaining to specimen processing as well as the use and maintenance of the equipment listed above. 3. An interview with LS on 03/10/2025 at 3:00 pm revealed that specimen processing was performed by another CLIA certified laboratory (Laboratory C) operating in the same physical location as Laboratory A. Furthermore, LS stated procedures for specimen processing were outlined in Laboratory C's procedure manual. LS further stated patient slides processed at Laboratory C were forwarded to this laboratory (Laboratory A) for review and confirmed that the tour conducted earlier at 9:45 am was of the testing area belonging to Laboratory C. 4. A review of Laboratory C's address in Aspen Web revealed its operating address as 1349 S. Rochester Road, Suite 210, Rochester Hills, MI 48307 and its hours of laboratory testing as Monday through Friday from 10:00 am to 6:00 pm. 5. A review of the CMS 116 completed by Laboratory A, signed and</p>

dated 03/02/2025 by the laboratory director revealed its operating address as 1349 S. Rochester Road, Suite 210, Rochester Hills, MI 48307 and its hours of laboratory testing as Monday through Friday from 10:00 am to 7:00 pm. B. Based record review and interview with the Laboratory Supervisor (LS), the laboratory failed operate as a separate and distinct laboratory to comply with 493.55 for two (January 2023 to January 2025) of two years reviewed. Findings include: 1. A record review of Laboratory A's microscope maintenance logs revealed that there was single set of data recorded. The log listed dates temperatures were recorded, however, there was no distinction pertaining to which laboratory documented the temperatures. 2. An interview with the LS on 03/10/2025 at 3:00 pm revealed that Laboratory A and Laboratory B, two separately certified CLIA laboratories with the same physical location and testing personnel, shared maintenance data records. LS further stated Laboratory A's days of operation and Laboratory B's days of operation did not overlap. 3. A review of Laboratory B's address in Aspen Web revealed its operating address as 1349 S. Rochester Road, Suite 210, Rochester Hills, MI 48307 and its hours of laboratory testing as Monday, Tuesday, Thursday from 10:00 am to 6:30 pm. 4. A review of the CMS 116 completed by Laboratory A, signed and dated 03/02/2025 by the laboratory director revealed its operating address as 1349 S. Rochester Road, Suite 210, Rochester Hills, MI 48307 and its hours of laboratory testing as Monday through Friday from 10:00 am to 7:00 pm. 5. Further record review of the microscope maintenance logs revealed temperatures were not separate and distinctly documented on the following dates patient testing occurred: a. 01/08/2023 b. 04/14/2023 c. 11/06/2023 d. 03/04/2024 e. 07/01/2024 f. 12/30/2024 g. 01/25/2025 h. 04/04/2023 i. 05/01/2023 j. 11/12/2024 k. 01/16/2024 l. 01/07/2024 6. An interview on 03/10/2025 at 3:00 pm with the LS confirmed that temperatures were not documented separately and distinctly for Laboratory A.

**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 the Laboratory Supervisor (LS), the laboratory failed to establish competency assessment policies for testing personnel for 2 (January 2023 to January 2025) of 2 years reviewed. Findings include: 1. A review of the laboratory's policies and procedures revealed a lack of a personnel competency assessment policy. 2. An interview 03/10/2025 at 11:56 am with the LS confirmed that the policies for personnel competency assessment had not been established for the laboratory.