

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  52D0393406	<b>(X3) Date Survey Completed</b>  07/10/2025
<b>Name of Provider or Supplier</b>  Uw Health-Union Corners Lab	<b>Street Address, City, State</b>  2402 Winnebago St, Madison, WI	
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>D5441</b>	<p><b>CONTROL PROCEDURES</b> CFR(s): 493.1256(a)(b)(c)(g)</p> <p>(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance.</p> <p>This STANDARD is not met as evidenced by: Based on review of individualized quality control plans (IQCPs) and interview with Technical Consultant (Staff C), three of three IQCPs did not specify the type of external quality control (QC) materials being used for respiratory virus, serum pregnancy, and troponin-I testing performed in the laboratory. Findings include: 1. Review of the three IQCPs revealed that the IQCPs did not include specific information about the type of testing control materials being used for external QC such as manufacturer, type, how many, and which level(s). 1a. "SAT. Genexpert IQCP Union Corners" (Effective date: 07/01/2025) stated "Analyze two levels of QC", but did not specify manufacturer, type, and which level(s). 1b. "SAT. Serum Preg IQCP Union Corners" (Effective date: 07/07/2025) stated "Analyze three levels of QC", but did not specify manufacturer, type, and which level(s). 1c. "Union Corners Stratus IQCP" (Effective date: 05/01/2025) stated "Two levels of QC are run for Troponin Testing purchased from Bio-Rad", but did not specify the type and which levels. 2. Interview with Staff C on July 10, 2025, at 2:15 PM confirmed that</p>

the IQCPs did not include specific information about the type of external QC materials being used for respiratory virus, serum pregnancy, and troponin-I testing performed in the laboratory.

**D6004**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(a)(b)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reappoints performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:

Based on surveyor review of laboratory records and communication sent from this laboratory to the state agency and interview with the Director, Laboratory Services (Staff D), the Laboratory Director did not ensure compliance with the regulation at 493.51(b), 'Notification Requirements for Laboratories Issued a Certificate of Compliance', when the laboratory added non-waived testing in one of one new subspecialty and did not notify the Department of Health and Human Services (HHS) within six months of the addition of the virology sub-specialty. Findings include: 1. Review of an email communication sent by the laboratory to the state agency on May 27, 2025, showed the laboratory requested addition of the virology subspecialty effective June 15, 2025. 2. Review of laboratory records, including verification studies of virology testing on the Cepheid GeneXpert 16 module test system, showed the laboratory began patient virology testing on March 25, 2024. 3. Interview with Staff D on July 10, 2025, at 11:30 AM confirmed the laboratory director did not ensure compliance with the regulation at 493.51(b) and confirmed the laboratory did not notify HHS within six months of performing testing in the virology subspecialty, a subspecialty that was not on the laboratory's CLIA certificate prior to June 15, 2025.

**D6054**

**TECHNICAL CONSULTANT RESPONSIBILITIES**

CFR(s): 493.1413(b)(9)

(b)(9) Thereafter, evaluations must be performed at least annually

This STANDARD is not met as evidenced by:

Based on record review and interview with a Technical Consultant (Staff A), Staff A did not perform annual competency assessment evaluation for one (Staff B) of two testing personnel performing provider performed microscopy (PPM) procedures at this location for one out of two years reviewed. Findings include: 1. Review of annual competency assessment records revealed Staff A completed a competency assessment in 2025 at this location for Staff B. Records were not available to show Staff A had completed a competency assessment for Staff B at this location in 2024. 2. Interview with Staff A on July 10, 2025, at 8:15 AM confirmed that Staff B did not have an annual competency assessment done at this location in 2024. 3. An email communication on July 10, 2025, at 11:09 AM from Staff A revealed that Staff B

performed and resulted five PPM tests in 2024 at this location, indicating the need for performance of the competency assessment at this location in 2024.