

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D2005390	(X3) Date Survey Completed 04/29/2025
Name of Provider or Supplier Madison Womens Health Llp	Street Address, City, State 5801 Research Park Blvd Ste 400, Madison, WI	
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
D5024	<p>HEMATOLOGY CFR(s): 493.1215</p> <p>If the laboratory provides services in the specialty of Hematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1269, and 493.1281 through 493.1299.</p> <p>This CONDITION is not met as evidenced by: Based on surveyor observation in the laboratory, review of laboratory records and procedures, and interview with the Technical Consultant, the laboratory did not meet the requirements specified in 493.1230 through 493.1256 for Fern Tests, a moderate complexity hematology microscopic procedure, performed by a physician. Findings include: 1. The laboratory did not perform competence evaluations for a physician performing Fern Tests, a hematology procedure. See D5209. 2. The laboratory did not verify the accuracy of the Fern Test procedure twice annually in 2023 and 2024. See D5217. 3. The laboratory did not develop a written procedure for Fern Test performance. See D5401.</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 surveyor observation, review of laboratory records, and interview with the Technical Consultant, the laboratory did not follow their competence evaluation procedure for one of one hematology procedure and did not evaluate competence of a</p>

	<p>physician performing fern tests. Findings include: 1. Observation of slides on the laboratory counter on April 29, 2025, at 11:00 AM revealed two slides. One slide was labeled "Fern+", the second slide labeled "Fern". 2. Review of laboratory competence evaluation records showed no evidence of evaluation of physician competence in performing fern tests. 3. Interview with the Technical Consultant on April 29, 2025, at 11:05 AM confirmed a physician (Staff A) performed occasional patient fern tests and confirmed the laboratory had not evaluated the competence of the physician in performing the test.</p>
<p>D5217</p>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of proficiency testing (PT) and other laboratory records and interview with the Technical Consultant, the laboratory did not verify the accuracy of fern tests, one of one hematology test performed in the laboratory, twice annually in 2023 and 2024. Findings include: 1. Review of PT records from 2023 and 2024 showed no evidence the laboratory participated in PT for fern testing. 2. Review of other laboratory quality assurance records showed no evidence of twice annual verification of the accuracy of physician performed Fern Testing. 3. Interview with the Technical Consultant on April 29, 2025, at 11:05 AM confirmed the laboratory had not performed PT for fern testing and had not developed an alternative method for verifying the accuracy of the fern test procedure twice annually.</p>
<p>D5401</p>	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of laboratory procedures and interview with the Technical Consultant, the laboratory did not have a written procedure for Fern Tests, one of one hematology test performed in the laboratory. Findings include: 1. Review of laboratory procedures showed no evidence of a Fern Test procedure. 2. Interview with the Technical Consultant on April 29, 2025, at 11:05 AM confirmed the laboratory had not developed a Fern Test procedure and confirmed a physician performed occasional Fern Tests in the laboratory.</p>
<p>D6004</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b)</p> <p>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</p>

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 reapportions 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 review of the Centers for Medicare and Medicaid Services (CMS) Application for Certification (Form CMS-116) and the Food and Drug Administration (FDA) CLIA Search Database and interview with the Technical Consultant, the Laboratory Director did not ensure compliance with 493.51(b), Notification Requirements for Laboratories Issued a Certificate of Compliance, when the laboratory started fern testing, a hematology test, and did not notify the Department of Health and Human Services (HHS) of the addition of the hematology specialty. Findings include: 1. Review of the Form CMS-116 submitted for this survey and signed by the laboratory director on April 29, 2025, showed the laboratory was not performing testing in the hematology specialty and did not include Fern Tests in the provided list of non-waived tests. 2. Review of the FDA CLIA Search Database showed the FDA classified Fern testing as a moderate complex test in the hematology specialty. 3. Interview with the Technical Consultant on April 29, 2025, at 11:05 AM confirmed a provider performed fern tests in the laboratory and confirmed the laboratory did not inform HHS of the addition of the hematology specialty to the CLIA certificate.