

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D2199019	(X3) Date Survey Completed 11/04/2025
Name of Provider or Supplier Mens Health Chicago, Llc	Street Address, City, State 1325 Remington Rd Ste T, Schaumburg, IL	
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
D5291	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records, lack of documentation, and interviews with testing personnel (TP) #1; the laboratory failed to follow written policies and procedures for an ongoing mechanism to monitor, assess, and correct problems identified in the general laboratory system for two of two years reviewed in the subspecialty of endocrinology. Findings include: 1. Review of laboratory policies and procedures revealed the policy titled "Quality Assurance Manual", which stated, under "8. Quality Assessment Monitoring", "The laboratory will have a mechanism for documenting Quality Assessment issues. At least annually, one activity for each of the following processes will periodically be reviewed: general, pre-analytic, analytic and post-analytic will be investigated. The assigned person(s) will collect data and follow-up with a written summary and/or corrective action for each activity. See the Monitoring Quality Assessment form." 2. Review of laboratory records, including "Monitoring Quality Assessment" forms, revealed a lack of documentation of annual quality assurance reviews performed in the laboratory for the previous two years. 3. Interview with TP #1 on 11/04/2025, at 12:12 pm, confirmed the laboratory failed to follow written policies and procedures for an ongoing mechanism to monitor, assess, and correct problems identified in the general laboratory system for two of two years reviewed in the subspecialty of endocrinology.</p>