

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D2208265	(X3) Date Survey Completed 04/08/2025
Name of Provider or Supplier Huntsville Mens Clinic	Street Address, City, State 250 Chateau Drive Sw, Suite 150, Huntsville, AL	
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
D6033	<p>TECHNICAL CONSULTANT-MODERATE COMPLEXITY CFR(s): 493.1409</p> <p>The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on a review of laboratory records and an interview with the current Laboratory Manager, the laboratory failed to fill the position of Technical Consultant after the previous Technical Consultant was terminated. This was noted from January 2023 to the date of the current survey on 4/8/2025. The findings include: 1. Refer to D6036.</p>
D6036	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413</p> <p>The technical consultant is responsible for the technical and scientific oversight of the laboratory. The technical consultant is not required to be onsite at all times testing is performed; however, he or she must be available to the laboratory on an as needed basis to provide consultation, as specified in paragraph (a) of this section.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the CMS 209 form (Laboratory Personnel Report) and an interview with the Laboratory Manager, the laboratory failed to fill the position of Technical Consultant after the previous Technical Consultant was terminated. This was noted from January 2023 to the date of the current survey on 4/8/2025. The findings include: 1. A review of the 209 Laboratory Personnel Report revealed the Laboratory Director was also listed as the Technical Consultant, however, the Laboratory Director does not have at least one year of laboratory training or</p>

experience in the designated specialty area of service for which the Technical Consultant is responsible. 2. During an interview on 4/11/2025 at 11:02 AM, the Laboratory Manager confirmed the Laboratory Director does not have the one year experience.