

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2161122	(X3) Date Survey Completed 09/19/2024
Name of Provider or Supplier Houston Male Health Clinic Pllc	Street Address, City, State 6625 Spring Stuebner Rd #205, Spring, TX	
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
D0000	An announced survey of the laboratory was conducted on 09/19/2024. The laboratory was found in compliance with applicable CLIA regulations (42 CFR Part 493, Requirements for Laboratories) for the specialties/subspecialties for which it was surveyed. STANDARD LEVEL DEFICIENCIES were cited.
D5407	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory's policies/procedures and staff interview, the laboratory failed to ensure policies and procedures were approved by the current laboratory director for three of five policies reviewed. Findings included: 1. Review of laboratory's policies/procedures revealed the following 3 of 5 reviewed procedures did not have documented approval of the current laboratory director: "Individualized Quality Control Plan (IQCP) Annual Review" policy "Digital Thermometer Device Verification" policy "Centrifuge" policy 2. In an interview on 09/19/2024 at 1050 hours in the breakroom, the laboratory's Technical Consultant number 1 (as indicated on submitted Form CMS 209) confirmed the findings.</p>
D6046	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)</p> <p>(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.</p>

This STANDARD is not met as evidenced by:

Based on review of laboratory's submitted Form CMS 209 (Laboratory Personnel Report), personnel competency assessments for 2023 and 2024, and staff interview, the laboratory's technical consultants (TCs) failed to evaluate four of eight competency assessments performed on five testing personnel (TP) in 2023 and 2024. Findings included: 1. Review of laboratory's submitted Form CMS 209 revealed the laboratory had two TCs. TC number 1 was also TP number 1. 2. Review of personnel competency assessments for 2023 and 2024 revealed the following 4 of 8 reviewed competencies were performed by other testing personnel, not one of the two technical consultants: 2023 Annual competency for TP1 Competency assessed: 07/25/2023 Evaluator: TP2 2024 Annual competency for TP1 Competency assessed: 07/20/2024 Evaluator: TP2 2024 Annual competency for TP2 Competency assessed: 01/30/2024 Evaluator: TP4 Semiannual competency for TP3 Competency assessed: 08/04/2024 Evaluator: TP2 3. In an interview on 09/19/2024 at 1050 hours in the breakroom, the laboratory's Technical Consultant number 1 (as indicated on submitted Form CMS 209) confirmed the findings.