

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D0660126	<b>(X3) Date Survey Completed</b>  07/22/2019
<b>Name of Provider or Supplier</b>  Lab For Male Repro Research Testing	<b>Street Address, City, State</b>  One Baylor Plaza,N730 Ms380, Houston, TX	
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>D0000</b>	<p>Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility representative(s) were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.</p>
<b>D6102</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1445(e)(12)</p> <p>The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.</p> <p>This STANDARD is not met as evidenced by: I. Based on the laboratory's submitted CMS 209 form, personnel records and staff interview, it was revealed the laboratory director failed to ensure 1 of 3 testing personnel had documentation of training to perform high complexity testing. Findings include: 1. A review of the laboratory's submitted CMS 209 form (signed by the laboratory director on 7/21/19) revealed the laboratory identified 3 testing personnel. 2. A review of testing person # 3's (as indicated on the CMS 209 form) personnel records revealed no documentation of training to perform high complexity testing on</p>

the Urovysion analyzer. 3. The laboratory was asked to provide documentation of training. No documentation was provided. 4. An interview with the general supervisor (as indicated on the CMS 209 form) on 7/22/19 at 10:30 in the conference room confirmed the above findings.