

<p>Statement of Deficiencies</p>	<p>(X1) Provider/Supplier/CLIA Identification Number 45D0494937</p>	<p>(X3) Date Survey Completed 02/03/2023</p>
<p>Name of Provider or Supplier Care For Women</p>	<p>Street Address, City, State 350 Kingwood Medical Drive, Suite #350, Kingwood, TX</p>	
<p>For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.</p>		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
<p>D0000</p>	<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 in compliance with applicable CLIA Conditions, 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 CMS Southern Operations Branch-Dallas for referral to the Office of 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>
<p>D2009</p>	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory's American Proficiency Institute (API) proficiency testing (PT) documents for 2021 and 2022 and staff interview it was determined the laboratory failed to ensure testing personnel and laboratory director signed attestation documents for 1 of 6 events reviewed. Findings included: 1. Review of laboratory's API Attestation Statements revealed: "SIGNATURES REQUIRED - For all PT results, an attestation statement must be signed by testing personnel and the laboratory director..." 2. Review of laboratory's API PT documents for 2021 and 2022 revealed the following 1 of 6 reviewed event's attestation statements did not have testing personnel and laboratory director's signatures: Attestation Statement: API 2022</p>

Microbiology - 1st (first) Event 3. In an interview on 02/03/2023 at 1030 hours in the office, the Laboratory Director, after review of the data, confirmed the findings.