

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0934825	(X3) Date Survey Completed 10/15/2026
Name of Provider or Supplier Renaissance Women's Healthcare, Pa	Street Address, City, State 5115 S Mccoll Road, Edinburg, 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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) (b)(1) 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. This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing policy, review of the laboratory's American Proficiency Institute's (API) proficiency testing records from 2025 and 2026, and staff interview, the laboratory failed to ensure testing personnel signed the attestation statements for 6 of 6 proficiency testing events. The findings included: 1. The laboratory's policy titled "Proficiency Testing" (approved on 09/01 /2024) stated: "The attestation statement shall be signed and dated by testing personnel and the Lab Director at the time of testing." 2. A review of the laboratory's American Proficiency Institute's proficiency testing records from 2025 (Microbiology Events 1, 2 and 3) and 2026 (Microbiology Events 1, 2, and 3) determined the attestation statements provided the following instructions: "SIGNATURES REQUIRED - For all PT results an attestation statement must be signed by the testing personnel and the laboratory director..." 3. Further review of the proficiency testing records determined testing personnel names were printed in the same handwriting on 6 of 6 attestation statements. There were no testing personnel signatures on the statements. The events without signatures were: 2025 Microbiology event 1 2025 Microbiology event 2 2025 Microbiology event 3 2026 Microbiology event 1 2026 Microbiology event 2 2026 Microbiology event 3 4. The technical consultant confirmed the findings after his review of the records on 10/15/2026 at 900 hours in the break room.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2)

(b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's quality assurance records from April 2026 to August 2026, and staff interview, the laboratory failed to have documentation of the remediation of patients when quality control testing was not performed in accordance with the laboratory's Individual Quality Control Plan. The findings included: 1. The laboratory's quality assurance records from April 2026 to August 2026 identified the following lots of testing kits for which the laboratory failed to have documentation of performing quality control testing following its Individualized Quality Control Plan prior to placing them into use. They were: a) CT/GC Lot: 45905 Lot: 46302 b) MPV Lot: 7504 Lot: 7605 2. No patient remediation was performed on patient tested using the identified reagent lots. 3. The technical consultant confirmed the findings in an interview conducted on 10/15/2026 at 0930 hours in the break room.