

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2113679	(X3) Date Survey Completed 12/05/2024
Name of Provider or Supplier Advanced Reproductive And Urologic Procedures	Street Address, City, State 7200 Cambridge Room B10,609, Houston, 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	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility was found to be in compliance with applicable Conditions in the CLIA program, and recertification is recommended.
D5415	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.</p> <p>This STANDARD is not met as evidenced by: Based on the surveyor's direct observation, the manufacturer's package inserts, and confirmed in an interview, the laboratory failed to document opened dates and revised expiration dates on thawed opened QC vials for 2 of 3 lot numbers in use for Beckman Coulter Unicel DxI 600 Chemistry analyzers. The findings were: 1. Review of the manufacturer's package insert titled Liquichek Immunoassay Plus Control Level 1, 2 and 3 (English. 2023-05. 4203-00) under STORAGE and STABILITY revealed, "Once thawed, opened, and stored tightly capped at 2 to 8C, this product will be stable as follows: -All Analytes: 14 days Except -Estradiol: 5 days" 2. Review of the manufacturer's package insert titled Access Hybritech p2PSA QC (Instructions For Use B09089 H AUGUST 2024) under PRODUCT INFORMATION revealed "Vial is stable at 2 to 10C for 60 days after initial use." 3. Surveyor's direct observation on 12/04/2024 at 3:45 pm in the laboratory revealed no opened dates and revised expiration dates documented on the thawed opened QC for 2 of 3 lot numbers in use. BioRad Liquichek Immunoassay Plus Control Level 1 Lot#: 85351 Original Exp. 2025-02-28 Level 2 Lot#: 85352 Original Exp. 2025-02-28 Level 3 Lot#: 85353 Original Exp. 2025-02-28 Access Hybritech p2PSA QC Lot: 439759 Original Exp.</p>

2025-01-31 for all level 1, 2, and 3 4. An interview at 3:50 pm on 12/04/2024 in the laboratory, the Laboratory Director (as indicated on the CMS 209 form) confirmed the above findings. Key: QC=Quality Control C=Celsius CMS=Center for Medicare and Medicaid Services