

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2250813	(X3) Date Survey Completed 03/31/2026
Name of Provider or Supplier Westwater Diagnostics Pllc	Street Address, City, State 407 E 25th St, 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	An announced survey of the laboratory was conducted on 03/31/2026. The laboratory was found in substantial 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.
D3013	<p>FACILITIES CFR(s): 493.1101(e)</p> <p>Records and, as applicable, slides, blocks, and tissues must be maintained and stored under conditions that ensure proper preservation.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor's observations, review of laboratory's policies/procedures, temperature/humidity logs and staff interview, the laboratory failed to define and monitor temperature/humidity conditions to ensure slides were maintained under proper preservation conditions for one of one room where previous histology/cytology cases' specimen slides and blocks were stored. Findings included: 1. Surveyor's observations on 03/31/2026 at 1000 hours revealed slides and blocks from previous histology and cytology cases were stored in the office. There was no mechanism observed to monitor storage conditions in the room. 2. Review of laboratory's policies /procedures revealed there were no protocols in place defining monitoring storage conditions of previous case slides and blocks to ensure preservation. 3. Review of laboratory's temperature/humidity logs revealed there was no documentation of monitoring temperature or humidity in the slide/block storage area available for review. 4. In an interview on 03/31/2026 at 1030 hours in the office, Technical Supervisor number two (as indicated on submitted form CMS 209) confirmed the findings.</p>
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p>

(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:

Based on surveyor's observations and staff interview, the laboratory failed to ensure reagents were not used beyond expiration date for seven of seven tissue marking dyes used in laboratory's histology procedures. Findings included: 1. Surveyor's observations on 03/31/2026 at 1000 hours in the laboratory revealed the following expired in-use Tissue Marking Dyes for laboratory's histology procedures sitting on the countertop in the specimen processing area: Vector Surgical REF (Reference): VIVSY Lot: VYS.1024 Expiration date: 2025-08-03 Vector Surgical REF: VIVSB Lot: VBS.1024 Expiration date: 2025-08-01 Vector Surgical REF: VIVSG Lot: VGS.1024 Expiration date: 2025-08-07 Vector Surgical REF: VIVSU Lot: VUS.0924 Expiration date: 2025-07-26 Vector Surgical REF: VIVSV Lot: VVS.1024 Expiration date: 2025-08-02 Vector Surgical REF: VIVSR Lot: VRS.0924 Expiration date: 2025-07-22 Vector Surgical REF: VIVSO Lot: VOS.0924 Expiration date: 2025-07-27 2. In an interview on 03/31/2026 at 1000 hours in the laboratory, Technical Supervisor number two (as indicated on submitted form CMS 209) confirmed the findings.

D5433

MAINTENANCE AND FUNCTION CHECKS

CFR(s): 493.1254(b)(1)

(b)(1)(i) Establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (b)(1)(ii) Perform and document the maintenance activities specified in paragraph b(1)(i) of this section.

This STANDARD is not met as evidenced by:

Based on review of laboratory's policies/procedures, surveyor's observations, patient test logs and staff interview, the laboratory failed to follow its own policy and document yearly equipment maintenance for four of four instruments used in laboratory's cytology/histology procedures. Findings included: 1. Review of laboratory's policy "LG-0008 - Quality Management" (Revision 2, effective 05/05/2023) revealed: "QC - Equipment ... Equipment/instrumentation: the laboratory must maintain records of ... maintenance... ...equipment must be formally tested at least yearly ..." And, " ... Centrifuge calibration should be performed and documented yearly ..." And, "Microscopes must be thoroughly cleaned, inspected, and lubricated at least yearly." 2. Surveyor's observations on 03/31/2026 at 0940 hours in the laboratory revealed the following equipment was missing yearly maintenance as evidenced by service dates documented on the instruments' labels: Device: Tabletop Centrifuge Service Date: 04/30/2024 Next Service: 04/30/2025 Device: Microwave Service Date: 03/31/2024 Next Service: 03/31/2025 Device: Heating Device Serial No (number) C&AR.120015 Service Date: 01/2022 Next Service: 01/2023 3. Surveyor's observations on 03/31/2026 at 1040 hours in the office revealed an Olympus microscope was also missing yearly maintenance as evidenced by service /maintenance dates documented on the instrument's label: Device: BX45 Microscope Service Date: 03/01/2025 Next Service: 03/01/2026 4. In interviews on 03/31/2026 at

0940 hours in the laboratory and 1040 hours in the office, Technical Supervisor number two (as indicated on submitted form CMS 209) confirmed the findings. Key: CMS - Centers for Medicare and Medicaid Services