Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 10D2325340	**(X3) Date Survey Completed** 10/13/2025
Name of Provider or Supplier Amc Hlwd Llc	**Street Address, City, State** 2514 Hollywood Blvd Suite 105, Hollywood, FL	

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 CLIA initial survey was conducted at AMC HLWD LLC on October 13, 2025. The laboratory was surveyed under 42 CFR Part 493 CLIA requirements. Standard deficiencies cited are as follows:
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) (c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observation, review of package insert and staff interview, the laboratory failed to properly label Nova-One Diagnostics Quality Control (QC) vials on 10/13 /2025 with open date and new expiration date. Findings included: -During the laboratory tour on 10/13/2025 at 10:15 AM, the surveyor observed that the laboratory was using NOVA-ONE Diagnostics QC in the FREND IMMUNOASSAY analyzer. The laboratory had Control level 1 with Lot number 6361A25001 and control level 2 with Lot number 6362A25001 for Testosterone and PSA (Prostate Specific Antigen), the vials had no open date and new expiration date. -Review of the Nova-One Diagnostics Control user instructions revealed that opened controls had an expiration date of 30 days after first use, the laboratory could not provide documentation when the laboratory opened the vials in use. -During an interview on 10/13/2025 at 11:40 AM the Testing Personnel #1 confirmed that the QC vials were not labeled with the expiration date.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g)

	(d) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493. 1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (d)(3) At least once each day patient specimens are assayed or examined perform the following for: This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to have a complete Individualized Quality Control Plan (IQCP) and failed to run 2 levels of controls each day of patient testing from 07/29/2025 to 10/09/2025 for Testosterone and Prostate Specific Antigen (PSA). Findings Include: -Review of the Manufacturer' Instructions (MI) for FREND System by NanoEntrek revealed that on page 8 of the Testosterone and PSA, leaflet it stated: "External quality control testing. Each laboratory operates under a different set of regulations. Every laboratory must follow the standardized procedures acceptable to the regulatory agencies to whom the laboratory is responsible." -The laboratory did a risk assessment on 06/06/2025 and ran two controls from 06/06/2025 to 07/25/2025. The laboratory started patient testing on 07 /07/2025. -The laboratory failed to do a Quality Control Plan and a Quality Assessment Plan signed and approved by the Laboratory Director. -The laboratory tested 76 patients in the following days without having at least two levels of QC and without having an approved IQCP for Testosterone and PSA: 07/29/2025 (3 patients), 07/30/2025 (3 patients, 07/31/2025 (1 patient), 08/01/2025 (3 patients), 08/07/2025 (1 patient), 08/08/2025 (1 patient), 08/12/2025 (1 patient), 08/14/2025 (1 patient), 08/15 /2025 (3 patients), 08/18/2025 (3 patients), 08/20/2025 (1 patient), 08/21/2025 (8 patients) 08/22/2025 (2 patients), 08/25/2025 (1 patient), 08/26/2025 (2 patient), 08/28 /2025 (2 patients), 08/29/2025 (1 patient), 09/08/2025 (3 patients), 09/11/2025 (2 patients), 09/15/2025 (3 patients), 09/17/2025 (1 patient), 09/18/2025 (3 patients), 09 /24/2025 (1 patient), 09/25/2025 (1 patient), 09/26/2025 (1 patient), 09/29/2025 (6 patients), 09/30/025 (1 patient), 10/01/2025 (3 patients, 10/02/2025 (2 patients, 10/03 /2025 (2 patients), 10/07/2025 (4 patients), 10/08/2025 (1 patient), 10/09/2025 (5 patients) During an interview on 10/13/2025 at 11:40 AM, Testing Personnel #1 confirmed that the laboratory did not run controls on the same testing date of the samples of reference.