Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0903784	06/27/2025
Name of Provider or Supplier	**Street Address, City, State**	
Advanced Diagnostic Imaging Pc	3939 Central Pike 1st Floor, Hermitage, TN	

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
D2010	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2) (b)(2) The laboratory must test samples the same number of times that it routinely tests patient samples. This STANDARD is not met as evidenced by: Based on review of the laboratory's American Association of Bioanalysts/Medical Laboratory Evaluation(AAB/MLE) proficiency testing (PT) records, lack of procedure, and interview with the laboratory supervisor, the laboratory failed to test PT samples the same number of times it routinely tests patient samples for five of five events reviewed from 2024 and 2025. The findings include: 1. Review of the laboratory's proficiency testing records for Nonchemistry revealed the laboratory performed PT samples twice for five of five Nonchemistry events in 2024 and 2025 as follows: 2024 event M1- performed two times for all five samples 2024 event M2- performed two times for all five samples 2024 event M3- performed two times for all five samples 2025 event M1- performed two times for all five samples 2025 event M2- performed two times for all five samples 2. Review of the laboratory procedure manual revealed no requirement to re-test every patient CBC sample. 3. During an interview with the laboratory supervisor on 06/25/2025 at 11:45 am, the laboratory supervisor confirmed the laboratory failed to test proficiency testing samples the same number of times it routinely tests patient samples for five of five PT events reviewed from 2024 and 2025. .
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 of the laboratory, review of the manufacturer control package insert, and interview with the laboratory supervisor, the laboratory failed to label three of three control vials used for performing quality control on the Complete Blood Count (CBC) hematology analyzer with an open date and a corrected expiration date on the date of the survey 06/25/2025. The findings include: 1. Observation of the laboratory on 06/25/2025, at 08:40 a.m., revealed the Sysmex XP-300 CBC analyzer (serial number A6258) used for patient testing. Also observed were three levels: Level 1- Low Abnormal [lot 51050710], Level 2- Normal [lot 51050711], and Level 3- High Abnormal [lot 51050712] of Eightcheck-3WP X-TRA Controls that were not labeled with an open date and corrected expiration date. 2. A review of the manufacturer's control package insert revealed the following: "Opened and recapped vials and vials whose caps have been pierced will retain stability for 14 days if stored at 2-8 [degrees Celsius] after being recapped." 3. An interview with the laboratory supervisor on 06/25 /2025, at 8:45 a.m., confirmed the above survey findings.