Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0903784	04/10/2023
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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on review of the laboratory quality control (QC) records and interview with the laboratory supervisor, the laboratory failed to retain the complete blood count (CBC) QC manufacturer assay sheets in 2021, 2022, and 2023. The findings include: 1) Review of the laboratory quality control records for CBC testing revealed the following: - Lot numbers 1306, 2193, and 3080 of EightCheck 3WP Xtra were in-use in 2021, 2022, and 2023. - Manufacturer's assay sheets for lot numbers 1306 and 2193 could not be provided at the time of the survey. 2) Interview with the laboratory supervisor on April 10, 2023 at 1:30 pm confirmed the laboratory failed to retain the manufacturer assay sheets for historical CBC control lots in 2021, 2022, and 2023 including lot number 1306 and 2193.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6)

	The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on a review of the laboratory's procedure manual and interview with the laboratory supervisor, the laboratory manual failed to include reference intervals (normal values) for Complete Blood Count (CBC) testing. The findings include: 1. A review of the laboratory's procedure manual revealed no reference intervals listed for CBC testing. 2. An interview on April 10, 2023 at 1:30 pm with the laboratory supervisor, confirmed there were no reference intervals included in the procedure manual for CBC testing.