Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2036810	11/05/2025
Name of Provider or Supplier	**Street Address, City, State**	
Advanced Medical Sports And Spine	2002 Orange Road - Suite 201, Culpeper, VA	

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 recertification survey was conducted at Advanced Medical Sports and Spine on November 5, 2025 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. The specific deficiency cited is as follows:
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies and procedures, Toxicology Quality Control (QC) records, patient records, lack of documentation and an interview, the laboratory failed to follow their established quality control policy to re-run QC material and document corrective actions for "unacceptable" Toxicology QC for one (1) of twenty-five (25) patient testing days reviewed from September 2023 until the date of the survey on November 5, 2025. The findings include: 1. Review of the laboratory's policies and procedures revealed a policy, "Quality Control Policy and Guidelines", with the following statements, "Daily QC Guidelines-1. Medica EasyRA-run two levels of controls for each assay each day of patient testing...7. If all controls are in, you may now run and report patient results. 8. If one or more controls are still out after repeating testing, open or make a new set of controls materials and re-run...

	11. DO NOT report patient results until the problem is corrected and the controls are within range. 12. Document corrective actions on the Corrective Action Log Sheets." 2. Review of the laboratory QC records for the Medica EasyRA Chemistry Analyzer from September 2023 until November 5, 2025 revealed 1 day, 03/16/2024, when the BioRad Liquichek Qualitative Urine Toxicology Negative Control resulted as Positive for Amphetamine, Cocaine, Opiate, and Oxycodone. Further review revealed a lack of documentation of repeat analysis or corrective actions taken for the above listed negative control and analytes. The surveyor noted a repeat analysis of the Urine Toxicology Positive Control on 03/16/2024 with acceptable positive results for the above listed analytes. The surveyor requested to review documentation of the BioRad Negative QC repeat analysis and corrective actions taken for the above listed out of range QC. The laboratory provided no documentation for review. In an interview with Laboratory Director/Testing Personnel (LD/TP) on November 5, 2025 at 11:30 AM, the LD/TP stated, "I must have repeated the Positive QC instead of the Negative QC." 3. Review of the laboratory's patient records for 03/16/2024 revealed sixty (60) patient urine toxicology specimens were tested and resulted for Amphetamine, Cocaine, Opiate, and Oxycodone. 4. In an exit interview with the LD/TP on November 5, 2025 at 12:00 PM, the above findings were confirmed.