

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D2036810	(X3) Date Survey Completed 07/18/2023
Name of Provider or Supplier Advanced Medical Sports And Spine	Street Address, City, State 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 July 18, 2023 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 deficiencies cited are as follows:
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory's quality control (QC) records, lack of documentation, and interview, the laboratory failed to retain the manufacturer's package inserts for two (2) of four (4) toxicology QC lot numbers utilized for evaluating the precision/accuracy of the Medica Easy RA analyzer in the twenty-two months reviewed (October 2021 to July 18, 2023). The findings include: 1. Review of the laboratory's Medica Easy RA analyzer's QC records revealed the following 4 Diagnostic Products International (dP) H-TROL QC lot numbers (#) placed in use to evaluate precision/accuracy for toxicology patient testing from October 2021 through the date of the survey on July 18, 2023: #1127 #1128 #1812 #1813 2. The surveyor requested to review the H-TROL QC package inserts for the 4 lot numbers listed above. The laboratory provided package inserts for QC lot numbers 1812 and 1813. The package inserts for lot numbers 1127 and 1128 were not available for review. 3. In an exit interview with the laboratory director on July 18, 2023, at approximately 11:30 AM, the above listed findings were confirmed.</p>
D5415	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p>

Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:

Based on tour of the laboratory, review of the manufacturer's package insert and interviews, the laboratory failed to label two (2) of 2 Diagnostic Product International H-trol Custom Liquid Control vials with date placed in service and revised expiration date according to the manufacturer's package insert on the date of the survey on July 18, 2023. The findings include: 1. A tour of the laboratory area on July 18, 2023 at approximately 9:00 AM revealed 2 H-trol Liquid Control vials (levels 1 & 2) on the shelf of the laboratory refrigerator and one vial of H-trol Liquid Control Level 1 QC in the freezer. The lot numbers and expiration dates for the toxicology QC vials were: H-trol level 1 lot number (#) 1812, expiration date 2/28/2025; and H-trol level 2 lot # 1813, expiration date 2/28/2025. The surveyor noted the 2 vials stored in the refrigerator lacked documentation of date placed in service and revised expiration date. There were no other QC vials found in the refrigerator. The surveyor inquired with the laboratory director (LD) where the QC vials were kept if they were in use. The LD stated the QC vials in use were kept in the refrigerator and the unopened vials were kept in the freezer. 2. Review of the Diagnostic Product International H-trol Custom Liquid Control package insert revealed the following statement, "Storage & Stability - Unopened: A. The controls are stable until the expiration date when stored at -20 to -80 C and protected from light. B. The controls are stable until the expiration date when stored at 2-8 C, however, no stability claims can be made for Oxazepam as it may deteriorate over time when stored refrigerated. After opening: A. The controls are stable for six months or until the expiration date, whichever comes first, when stored at -20 to -80 C (Controls can be aliquoted and frozen.) B. The controls are stable for 31 days or until the expiration date, whichever comes first, when stored tightly capped at 2-8 C. Thaw controls as needed; allow to come to room temperature followed by gentle swirling before use." 3. In an exit interview with the laboratory director on July 18, 2023, at approximately 11:30 AM, the above listed findings were confirmed.