

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D2036810	(X3) Date Survey Completed 09/22/2021
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 September 22, 2021 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows:
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on review of procedures, tour, and an interview, the laboratory failed to ensure that twenty-eight (28) of 28 frozen urine specimens were stored at -20 degrees Celsius (C) per their approved procedure on the date of the inspection, September 22, 2021. Findings include: 1. Review of the laboratory's policy manual revealed a Urine Drug Screen Testing Procedure that stated under Sample Stability and Storage: "If the sample cannot be run immediately, store up to 7 days at 2-8 C, for longer storage the urines are stable at -20 C up to 12 months". 2. During a tour of the laboratory, the inspector noted the freezer temperature recorded as -15 degree C (the FisherBrand Traceable digital thermometer reading displayed a daily minimum reading as captured at -18 C and maximum had been 1 C). A review of the freezer contents revealed 28 patient urine samples stored for future batch testing. The inspector inquired of the storage temperature -20 C requirement. The lab director (LD) stated at approximately 11:55 AM: "Since test volumes have decreased due to the pandemic, I am batching runs which requires freezing patient samples. I can get a freezer that maintains -20 or colder since this unit does not". 3. An interview with the LD on 9/22/21 at approximately 12:30 PM, the above findings were confirmed.</p>

D5411

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT

CFR(s): 493.1252(a)

Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.

This STANDARD is not met as evidenced by:

Based on a tour, review of manufacturer's package insert instructions, and an interview, the laboratory failed to follow manufacturer's enzyme immunoassay reagent storage requirements for 10 of 10 urine drug test kits and 2 of 2 analyzer cleaner kits on the date of the inspection, September 22, 2021. Findings include: 1. During a tour of the laboratory, the inspector noted the refrigerator temperature recorded by the FisherBrand Traceable thermometer as 1 degree C with the following lot numbered (#) reagents and analyzer cleaner kits stored in the refrigerator: LIN-ZHI enzyme immunoassay reagents: 2 boxes Oxycodone (# 2003060, # 2106108), Amphetamines (# 2108085), 2 boxes Opiate (# 2008045, # 2107059), 2 boxes Cocaine Metabolite (each # 2104060), 2 boxes Benzodiazepine (#2005014, # 2108059), Methadone (# 2107024); EasyRa Cleaner Kits: 2 boxes (each # 21225). 2. Review of the outer package of the urine drug screen reagents and cleaner kits outlined above revealed storage temperature instructions: LIN-ZHI : "Store at 2-8 C" EasyRa Cleaner: "Store at 4-25 C" 3. The inspector inquired of the lab director (LD) at approximately 11:55 AM, to describe the policy regarding the storage of the twelve chemistry reagents/kits outlined above. The LD stated: "They should be stored per the package instructions. I can turn the temperature control valve up to get it into range". 4. An interview with the LD on 9/22/21 at approximately 12:30 PM, the above findings were confirmed.

D5785

CORRECTIVE ACTIONS

CFR(s): 493.1282(b)(3)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met.

This STANDARD is not met as evidenced by:

Based on a review of procedures, manufacturer's guidelines, daily temperature logs, lack of documentation, client test logs, and an interview, the laboratory failed to document corrective action on dates that the refrigerator/freezer temperatures were outside of acceptable limits for one hundred seventy-two (172) of two hundred seventy-six (276) days while reporting two thousand six hundred forty-three (2,643) client urine drug screens during the review timeframe of June 2019 to September 22, 2021. Findings include: 1. Review of the laboratory's procedure manual revealed urine drug screen patient sample storage requirements as: "Sample Stability and Storage: if the sample cannot be run immediately, store up to 7 days at 2-8 C, for longer storage the urines are stable at -20 C up to 12 months". 2. Review of the laboratory's urine drug screen LIN-ZHI manufacturer's reagent guidelines revealed printed outer package storage temperature instructions: "Store at 2-8 C". 3. Review of the daily temperature logs from June 2019 to the date of the survey on 09/22/21 revealed no corrective action documented when: a. the reagent refrigerator temperature was colder

than acceptable (less than 2 degrees Celsius) on the following dates: 6/14/19, 6/20/19, 6/24-6/25/19, 7/10-7/11/19, 7/16/19, 7/18/19, 7/23/19, 7/25/19, 7/28/19, 9/3-9/4/19, 9/12/19, 9/20/19, 10/6/19, and 12/6/19, 3/13/20, 3/21/20; b. the sample storage freezer did not meet protocol criteria (warmer than -20 Celsius) on the following dates: 6/3-6/7/19, 6/12/19, 6/14/19, 6/19/19, 6/21/19, 6/24-6/26/19, 6/28/19, 7/3/19, 7/10-7/12/19, 7/16-7/19/19, 7/23-7/26/19, 7/28/19, 7/30/19, 8/1-8/2/19, 8/8-8/9/19, 8/13-8/14/19, 8/16/19, 8/19/19, 8/21-8/23/19, 8/29-8/30/19, 9/3-9/4/19, 9/6/19, 9/10-9/13/19, 9/17-9/18/19, 9/20/19, 9/27/19, 10/2/19, 10/4/19, 10/8/19, 10/10/19, 10/16-10/18/19, 10/22/19, 10/25/19, 11/8/19, 11/22/19, 11/25-11/27/19, 12/6/19, 12/12/19, 12/20/19, 1/3/20, 1/8/20, 1/10/20, 1/15-1/17/20, 1/21/20, 1/24/20, 1/29-1/31/20, 2/7/20, 2/11-2/14/20, 2/17-2/18/20, 2/21/20, 2/24-2/26/20, 2/28/20, 3/6/20, 3/10-3/13/20, 3/20-3/21/20, 3/27-3/28/20, 5/13-5/14/20, 6/3/20, 6/19/20, 6/26/20, 7/1-7/2/20, 7/11/20, 7/13/20, 7/16/20, 7/28-7/29/20, 8/6/20, 8/11/20, 8/13/20, 8/25-8/27/20, 9/10/20, 9/12/20, 9/24-9/25/20, 10/8/20, 10/22/20, 11/11/20, 11/25/20, 12/10/20, 12/17/20, 1/7/21, 1/21/21, 2/4/21, 2/18/21, 3/4/21, 3/8/21, 3/23/21, 4/6/21, 4/15/21, 4/19/21, 4/29/21, 5/3/21, 5/13/21, 5/27/21, 6/3/21, 6/17/21, 7/1/21, 7/19-7/20/21, 8/2/21, 8/5/21, 8/30/21, 9/1/21, 9/20-9/21/21. The inspector requested to review corrective action for the dates outlined above. No record of corrective action for the above 172 temperatures recorded outside of the criteria for proper storage were available for review. 4. Review of test log records revealed 2,643 client urine drug screens were resulted during the twenty-seven months review timeframe (June 2019 to 09/22/21). 5. An interview with the lab director on 9/22/21 at approximately 12:30 PM confirmed the above findings.