

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  05D1058036	<b>(X3) Date Survey Completed</b>  04/07/2021
<b>Name of Provider or Supplier</b>  Lags Spine & Sportscare Medical Center Inc	<b>Street Address, City, State</b>  801 E Chapel St, Ste 6, Santa Maria, CA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5401</b>	<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 observation of the Agilent Triple Quad 6460 LC/MS analyzer, review of the proficiency testing report DMPM- B 2020 CAP (Drug Monitoring for Pain Management, College of American Pathologists) and laboratory records including testing contrived (spiked) specimens, the lack of a laboratory document, and interview with the Testing Person, it was determined the laboratory failed to have a written policy and procedure for verifying the accuracy of testing for all drugs using the LC /MS methodology. Findings included: a. Records for 2019 documented two events of split sample testing/correlation with a qualified laboratory as the means to satisfy the requirement to verify the accuracy of testing at least twice annually. However, results for LAGS Spine &amp; Sportscare Medical Center Inc. were Negative for all 48 drugs. Date ----- 5/08/19, one sample 6/03/19, one sample b. Records for 2020 documented the laboratory's practice of multiple means to satisfy the requirement to at least twice annually verify the accuracy of testing for each drug by LC/MS: 1) Split sample testing/correlations were performed with a qualified laboratory. One event was comprised of randomly selected patients samples, as was done in 2019. A second event was comprised of contrived specimen, prepared by spiking remnant urine specimen with specified quantities of each drug. 2) The laboratory also chose to enroll in the CAP - DMPM proficiency testing program. c. The laboratory was unable to provide for review written procedure for the aforementioned activities; and this was affirmed by the Testing Person (4/07/21). And thus it was determined the laboratory failed to have a written policy and procedure for</p>

at least twice annually verifying the accuracy of LC/MS testing for all drugs by performing split sample correlation testing, creating contrived specimen, and monitoring the drugs present in the CAP samples. d. The laboratory estimated the annual volume of 300,000 tests in Toxicology screening and confirmation.

**D5417**

**TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT**  
CFR(s): 493.1252(d)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:

Based on observation of expired control and calibrator materials for the Beckman AU480 analyzer, review of QC records and patients test records, and interview with laboratory personnel, it was determined that the laboratory used Control and Calibrator materials past their expiration dates. Findings included: a. Opened bottles of Tramadol Low Control (Immunoanalysis, lot # E39084) and High Control (Immunoanalysis, lot #E39085) had expired in February 2021. b. QC records documented the expired Tramadol controls were used in March - April 2021. c. Opened bottles of Calibrators used to establish assay cut-offs were expired, as follows: Calibrator Lot # Expired

----- Tramadol 2 .....E39041  
..... January 2021 Specialty 2 .....11275159- N2 .....2/27/21 (Buprenorphine)  
6AM/Ecstasy....9R548UL- N2 .....4/02/21 d. Laboratory personnel affirmed (4/07/21)  
the materials were expired and still in routine use. e. The reliability and quality of  
toxicology screening results for Tramadol, Buprenorphine, and 6AM/Ecstasy could  
not be assured when expired controls and calibrators were used. The monthly volume  
of patients specimen screened in 2021 were as follows: Month Number of patients  
----- February ..... 2,213  
March ..... 2,925 April (to 4/06/21) .... 550 .

**D5891**

**POSTANALYTIC SYSTEMS QUALITY ASSESSMENT**  
CFR(s): 493.1299(a)

The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291.

This STANDARD is not met as evidenced by:

Based on review of test requisitions and laboratory pathology reports for Epidermal Nerve Fiber Density (ENFD) on skin biopsies and interview with laboratory personnel, it was determined the laboratory failed to establish and follow policies and procedures for an ongoing self-audit to monitor, assess, and correct problems postanalytically. Findings included: a. Histopathology test requisitions from 2019 - 2021 documented Clinical Information, Clinic/Facility locations as follows:  
Accession # Clinic/facility ----- SM19-  
03220 Bakersfield SM20-05390 Fresno 1 SM20-05689 Visalia SM20-05978 Fresno 1  
SM20-06777 Fresno 2 SM21-06987 Oxnard b. Laboratory personnel affirmed (4/07  
/21) specimen were submitted from the various LAGS Medical Centers in Santa  
Barbara, Santa Maria, Madera, Modesto, Oxnard, Bakersfield, Fresno (2 locations),

Grover Beach, Templeton, Thousand Oaks, and Lompoc. c. For 6 out of 6 laboratory ENFD reports from 2019 - 2021, the address/location of the "Ordering Physician Information" failed to match the Clinical Information, Clinic/Facility on the test requisition records. d. The laboratory released approximately 2,500 ENDF pathology reports annually with inaccurate clinic locations.