

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2020310	(X3) Date Survey Completed 07/26/2018
Name of Provider or Supplier Infiniti Labs Inc	Street Address, City, State 6015 Benjamin Rd Ste 315, Tampa, FL	
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
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 observation, record review, and staff interview the laboratory failed to follow their written Reagent and Supplies Policy for verification of reagents and rotation of reagents for toxicology testing for 2 of 2 years (2016-2018) reviewed. Findings included: 1. A review of the procedure titled "Reagent and Supplies" in the LCMS (Liquid Chromatography - Mass Spectrophotometry) laboratory's procedure manual revealed that performance of all new lot numbers of reagents will be checked prior to patient testing and that there would be a rotation of stock with the earliest expiration or latest received date placed in the front and newest or latest expiration placed in the back. 2. A tour of the LCMS laboratory on 07/25/18 at 10:30 AM, showed that the methanol flammable cabin had 2 lots of methanol (#58059 and #58033) in use. 3. During an interview on 07/25/18 at 11:30 AM, the LCMS Technical Supervisor stated that the laboratory did not verify new lots of methanol or acetonitrile. 4. During an interview on 07/26/18 at 3:30 PM, the LCMS Laboratory Manager stated that the laboratory did not know the number on the upper left of the label on the reagents was a lot number and that the laboratory was not ensuring reagents were being rotated as per the laboratory's policy.</p>
D5415	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other</p>

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 observation and interview with the Liquid chromatography-mass spectrometry (LCMS) Technical supervisor, the laboratory failed to label clear glass bottles with preparation and expiration dates on the top of two out of five LCMS instruments. Findings Included: 1. Tour of the LCMS laboratory on 07/25/18 at 10:30 AM it was noticed that there were clear glass bottles that did not have preparation dates and expiration dates on top of each of the two out five machines. 2. During an interview on 07/25/18 at 11:00 AM the LCMS Technical Supervisor confirmed that the clear glass bottles did not have preparation and expiration dates.