

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2076634	(X3) Date Survey Completed 11/02/2018
Name of Provider or Supplier Jemin N Gajipara Md Pa	Street Address, City, State 8210 Walnut Hill Ln, #905, Dallas, TX	
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
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 record review and interview with the Testing Person the laboratory failed to maintain maintenance records and temperature logs for 4 months (March 18- June 18) out of 2 years reviewed (October 16-October 18). Findings Included: Review of maintenance records on the toxicology screening analyzer revealed no documentation of daily maintenance on April 2, 5, 16, 18, 19 and May 3, 15 in 2018. No pH's documentation was provided for May 18. Documentation of refrigerator temperatures were missing from March 18- June 18. Freezer temperatures were missing in April and May 18. Room temperature, humidity, and incubator temperatures were missing for April and May 18. During an interview on 11/02/18 at 5:00 PM the Testing Person revealed that she started working in June 18 and could not locate the missing records.</p>
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of AAB (American Association of Bioanalysts) proficiency testing and interview with the Laboratory Director the laboratory failed to verify the accuracy of the toxicology screening for 2 out of 2 years (2016-2018) reviewed. Findings</p>

Included: Review of AAB proficiency testing revealed that the laboratory was using the quantitative proficiency testing. Review of patient test reports revealed that the laboratory was reporting semi qualitative values. During an interview on 11/02/18 at 12:35 PM the Laboratory Director confirmed that the proficiency testing performed did not cover the testing performed to determine accuracy.

D5415

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

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 observations, record review and interview with the Testing Person the laboratory failed to label the mobile phase A and B bottles with the lot numbers used to make the solutions since starting Toxicology confirmation testing 02/18. Findings Included: During a tour of the laboratory on 11/02/18 at 9:30 AM it was observed 2 glass bottles labeled "A" and "B". Review of policy and procedures (last reviewed by the Laboratory Director on 11/01/18) revealed that "Reagents, solutions, standards, and controls will be labeled as to content, date of preparation and expiration date." During an interview on 11/02/18 at 9:40 AM the Testing Person confirmed that it was Mobile Phase A and Mobile Phase B in the bottles and showed a log sheet of the date made and put in use. This deficiency was corrected on-site.