

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 45D2044559	<b>(X3) Date Survey Completed</b> 01/24/2018
<b>Name of Provider or Supplier</b> Genotox Laboratories, Ltd (Gll)	<b>Street Address, City, State</b> 2170 Woodward Street Suite 100, Austin, TX	
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>D0000</b>	Intake: TX00278067 As a result of an unannounced on-site complaint investigation, the laboratory is not in compliance with all of the Conditions of Participation required for certification in the CLIA program at 42 CFR part 493. The following Conditions were not met: D5300 - 42 C.F.R. 493.1240 Condition: Preanalytic systems; D6076 - 42 C.F.R. 493.1441 Condition: Laboratories performing high complexity testing; laboratory director; The complaint was substantiated.
<b>D5300</b>	<p><b>PREANALYTIC SYSTEMS</b> CFR(s): 493.1240</p> <p>Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the preanalytic systems and correct identified problems as specified in 493.1249 for each specialty and subspecialty of testing performed.</p> <p>This CONDITION is not met as evidenced by: Based on review of laboratory policies for specimen acceptability and rejection, surveyor observations, patient test records, and interview with facility personnel, the laboratory failed to reject 8 of 83 specimens submitted to the laboratory that met the laboratory's established rejection criteria on January 23, 2018 and January 24, 2018. Refer to D5311.</p>
<b>D5311</b>	<p><b>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL</b> CFR(s): 493.1242(a)</p> <p>The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when</p>

appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.

This STANDARD is not met as evidenced by:

Based on review of laboratory policies for specimen acceptability and rejection, surveyor observations, patient test records, and interview with facility personnel, the laboratory failed to reject 8 of 83 specimens submitted to the laboratory that met the laboratory's established rejection criteria on January 23, 2018 and January 24, 2018. The findings included: 1. Review of the laboratory's policy update communication to the laboratory's clients "Shipping Specimens in Point of Care Testing Cups (POCT)", dated November 1, 2017, states the following: "Consistent with our ongoing quality improvement efforts we recently completed sample stability and transportation studies evaluating the degradation of samples supplied in the various containers currently used by our clients for shipping samples to the lab. The key finding from these studies is that transportation of urine drug test specimens in point of care testing cups is associated with significant degradation in sample integrity. The degradation is substantial and affects a high number of the drugs and metabolites commonly included in testing for medication and sobriety monitoring. As a result: Effective November 14, 2017, Genotox Laboratories will no longer accept specimens in Point of Care Testing Cups (POCT)." 2. On 1/23/2017 at 14:10 hours in the accessioning area, the surveyor observed the following 2 of 6 specimens received in blue lid Pre-Screen Plus 13 panel point of care specimen containers: Specimen 1801233000 - collected 1/22/2018 and received in the laboratory at 11:10 hours on 1/23/2018 Specimen 1801233001 - collected 1/22/2018 and received in the laboratory at 11:12 hours on 1/23/2018 On 1/23/2017 at 16:41 hours in the accessioning area, the surveyor observed the following 3 of 5 specimens received in blue lid Pre-Screen Plus 13 panel point of care specimen containers: Specimen: 1801233531 - collected 1/22/2018 and received in the laboratory at 11:18 hours on 1/23/2018 Specimen 1801233537 - collected 1/22/2018 and received in the laboratory at 11:24 hours on 1/23/2018 Specimen 1801233540 - collected 1/22/2018 and received in the laboratory at 11:27 hours on 1/23/2018 On 1/24/2018 at 14:00 hours in the accessioning area, the surveyor observed the following 3 of 72 specimens stored in the accessioning area refrigerators in blue lid Pre-Screen Plus 13 panel point of care specimen containers: Specimen: 1801220029 - collected 1/18/2018 and received in the laboratory at 12:40 hours on 1/22/2018 Specimen: 1801220032 - collected 1/19/2018 and received in the laboratory at 12:41 hours on 1/22/2018 Specimen: 1801220034 -collected 1/19/2018 and received in the laboratory at 12:43 hours on 1/22/2018 In summary, the surveyor observed 8 of 83 specimens received in to the laboratory in the Pre-Screen Plus blue lid point of care specimen containers. 3. Based on review of patient test records, the following patient reports: 1801233000, 1801233001, 1801233531, 1801233537, 1801233540, included the following statement: "This specimen does not meet stability requirements. Confirmation results may not be quantitatively accurate due to degradation." Based on review of patient test records, the following patient reports: 1801220029, 1801220032, 1801220034 included the following statement: "This specimen does not meet stability requirements. Confirmation results may not be quantitatively accurate due to degradation. Due to no buccal swab previously on file, unable to perform ToxProtect TM." 4. In an interview at 16:41 hours on 1/23/2018 in the accessioning area, the Technical Supervisor 3 (as listed on the CMS-209 laboratory personnel report) stated the laboratory had been making an exception for one client but was otherwise not accepting specimens submitted in point of care cups.

**D6076**

**LABORATORY DIRECTOR**

CFR(s): 493.1441

The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.

This **CONDITION** is not met as evidenced by:

Based on review of laboratory policies for specimen acceptability and rejection, surveyor observations, patient test records, and interview with facility personnel, the laboratory director failed to provide overall management and direction of the laboratory services by failing to ensure that laboratory personnel followed specimen rejection policy for specimens submitted to the laboratory that were not suitable for testing. Refer to D6087.

**D6087**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(3)(iii)

The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results.

This **STANDARD** is not met as evidenced by:

Based on review of laboratory policies for specimen acceptability and rejection, surveyor observations, patient test records, and interview with facility personnel, the laboratory director failed to ensure that laboratory personnel followed specimen rejection policy for specimens submitted to the laboratory that were not suitable for testing. Refer to D5311.