Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2111111	08/06/2020
Name of Provider or Supplier	**Street Address, City, State**	
Md Toxicology Group	11827 Starcrest Drive, San Antonio, 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
D0000	Intakes TX00354425 TX00349249 The laboratory was found to be out of compliance based on the following CONDITION LEVEL DEFICIENCY: D5300 - 42 C.F.R. 493.1240 Condition: Pre-Analytic Systems Noted deficiencies and plans of correction were discussed with the laboratory representative at the exit conference. The facility representative was given an opportunity to provide evidence of compliance with noted deficiencies and no such evidence was provided prior to survey exit. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider /supplier, the State Survey Agency (SA) should be notified immediately.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) 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. This STANDARD is not met as evidenced by: Based on review of the laboratory's records, and staff interview, it was revealed the laboratory failed to retain instrument testing records for all toxicology specimens tested by LCMS. The findings were: 1. A review of the facility's records revealed the laboratory's LCMS (liquid chromatography/mass spectometry) instruments were repossessed on 03/10/2020. 2. The laboratory was asked to provide evidence of retaining the instrument testing records for all samples tested on the LCMS. No documentation was provided. 3. The laboratory reported testing: January - December 2019: 9931 samples January - March 10, 2020: 1050 samples 4. An interview with the manager on 07/30/2020 at 1100 hours in the laboratory revealed the facility did not

	retain or have access to the instrument data for all samples tested on the LCMS instruments. This confirmed the findings.
D5300	PREANALYTIC SYSTEMS CFR(s): 493.1240 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. This CONDITION is not met as evidenced by: Based on review of the laboratory's records, review of patient test records and staff interview, it was revealed the laboratory failed to identify and correct issues in pre-analytic systems. The findings were: 1. The laboratory failed to ensure samples which did not meet the laboratory's instructions for labeling with two identifiers were rejected (refer to D5305). 2. The laboratory failed to ensure toxicology oral fluids were tested within the laboratory's defined acceptable time (refer to D5311). 3. The laboratory failed to ensure specimen collection instructions provided to clients reflected how the laboratory stated samples should be received (refer to D5317).
D5305	TEST REQUEST CFR(s): 493.1241(c) The laboratory must ensure the test requisition solicits the following information: (1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (2) The patient's name or unique patient identifier. (3) The sex and age or date of birth of the patient. (4) The test(s) to be performed. (5) The source of the specimen, when appropriate. (6) The date and, if appropriate, time of specimen collection. (7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable. This STANDARD is not met as evidenced by: Based on surveyor observation, review of laboratory procedures, review of patient test records, and staff interview, it was revealed the laboratory failed to follow its policy for two patient identifiers. The findings were: 1. A review of the laboratory's policy titled "Urine/Oral/Viral Transport Media SAmple Collection Procedure" (Updated: July 31, 2018 Rev. 04) under the section titled "Specimen Labeling Guidelines" revealed: 'Specimen container must have two patient identifiers. All specimens are to be lableled at time of collection with: - patient's full name - Patient's DOB - Collection date/time (24hr) - Collector's name or initials' 2. Further review of the policy under the section titled "Sample rejection criteria" revealed: 'Any sample received in lab without an MD Toxicology requisition form Specimen without a name

	on the cup (patient identifiers)..." 3. Surveyor observation of patient samples stored in the facility's refrigerator on 07/20/2020 at 15:15 hours identified the follow two specimen containers which were received with only the patient's name on the urine container, however, the samples were accessioned by the laboratory and sent out to a reference laboratory for testing. They were: MD Toxicology Accession numbers: 78363 77789 4. A review of patient test reports revealed both samples were reported out to the ordering physician. 5. An interview with the manager on 07/31/2020 at 1100 hours in the conference room - after his review of the records - confirmed the findings.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) 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 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 the laboratory's policies, review of laboratory's sample stability studies, review of patient test records, and staff interview, it was revealed the laboratory failed to ensure toxicology oral samples were tested within the required time frame. The findings were: 1. A review of the laboratory's policy titled "Urine/Oral /Viral Transport Media Sample Collection Procedure (Updated: July 31, 2018 Rev. 04) under the section titled "Transport" revealed: "Samples must be received at this facility within 7 days from the date of collection; stored and shipped at a temperature of 2 to 8C. Oral fluid received with (sic) 5 days." 2. A review of the laboratory's oral fluid stability studies revealed samples were determined to be stable for 5 days after collection. 3. A review of patient test records from February 2020 revealed 3 of 47 samples were tested when the time from collection to receipt by the laboratory exceeded 5 days. They were: a) specimen: 77189 collected: 2/11/2020 received: 2/17 /2020 elapsed time: 6 days b) specimen: 77187 collected: 2/11/2020 received: 2/17 /2020 elapsed time: 6 days c) specimen: 77117 collected: 2/6/2020 received: 2/12 /2020 elapsed time: 6 days 4. The laboratory was asked to provide documentation of rejecting the samples for exceeding the required stability, or of performing additional studies to show samples were stable for longer than the defined 5 days. No documentation was provided. 5. An interview with the manager on 08/06/2020 at 1400 hours in the conference room - after his review of the records- confirmed the findings.
D5317	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(d) If the laboratory accepts a referral specimen, written instructions must be available to the laboratory's clients and must include, as appropriate, the information specified in paragraphs (a)(1) through (a)(7) of this section. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, review of the laboratory's specimen

	handling instructions provided to clients and staff interview, it was revealed the laboratory failed to provide instructions which matched the laboratory's policy. The findings were: 1. A review of the laboratory's policy titled "Urine/Oral/Viral Transport Media Sample Collection Procedure" (Updated: July 31, 2018 Rev. 04) under the section titled Storage" revealed: "Adhering to proper storage and transportation guidelines diminishes discrepancies and increases the reliability of the results reported. Testing fresh urine specimens is ideal. If patients' samples cannot be tested the same date they are collected, they must be stored at a temperature of 2C to 8C." 2 Further review of the policy under the section titled "Transport" revealed: "Samples must be received at this facility within 7 days from the date of collection; stored and shipped at a temperature of 2C to 8C." 3. A review of the laboratory's specimen handling instructions provided to clients titled "How to Collect Patient Samples Properly" does not instruct clients to storage the samples at 2C to 8C. 4. A review of the laboratory's shipping instructions provided to clients titled "Packaging Sample for Shipment" does not instruct clients to ship the samples at 2C to 8C. 5. An interview with the owner on 08/06/2020 at 1315 hours revealed that all samples were to be stored by the clients and shipped to the laboratory at 2C to 8C. He stated he didn't know why the instructions to clients did not have that information included. This confirmed the findings.
D5817	TEST REPORT CFR(s): 493.1291(i) If a laboratory refers patient specimens for testing-- (i)(1) The referring laboratory must not revise results or information directly related to the interpretation of results provided by the testing laboratory; (i)(2) The referring laboratory may permit each testing laboratory to send the test result directly to the authorized person who initially requested the test. The referring laboratory must retain or be able to produce an exact duplicate of each testing laboratory's report; and (i)(3) The authorized person who orders a test must be notified by the referring laboratory of the name and address of each laboratory location where the test was performed. This STANDARD is not met as evidenced by: Based on review of facility records, review of patient test reports and staff interview, it was revealed the laboratory failed to identify the testing laboratory's name and address on patient reports for samples which were referred out for testing. The findings were: 1. A review of the facility's records revealed the laboratory's LCMS (liquid chromatography/mass spectometry) instruments were repossessed on 03/10 /2020. As a result, the facility started referring all toxicology samples out for testing to multiple laboratories. 2. A review of the facilitity's records also revealed the laboratory started referring gastrointestinal to another laboratory in March 2020. 3. A sampling of patient test reports from May 2020, June 2020 and July 2020 revealed the laboratory failed to identify the testing laboratory on 47 of 47 toxicology patient reports. They were: a) May 2020 Date ID number 5/5 77967 5/7 77992 5/7 78031 5 /11 78046 5/11 78054 5/14 78100 5/14 78142 5/27 78314 5/29 78372 b) June 2020 Date ID number 6/10 78019 6/10 78017 6/10 78010 6/10 78007 6/10 78071 6/11 78077 6/11 78079 c) July 2020 Date ID number 7/7 79129 7/7 79126 7/7 79130 7/8 79174 7/8 79173 7/8 79171 7/9 79147 7/9 79189 7/9 79193 7/9 79196 7/9 79200 7/10 79222 7/10 79233 7/10 79236 7/13 79268 7/13 79262 7/13 79264 7/13 79269 7/15 79227 7/16 79279 7/16 79287 7/16 79293 7/16 79298 7/16 79301 7/16 79303 7/16 79306 7/16 79320 7/16 79298 7/20 79347 7/20 79350 7/20 79353 4. A sampling of gastrointestinal samples from May 2020 revealed 6 of 6 patient reports failed to

	identify the testing laboratory. They were: Date ID number 5/26 78172 5/26 78173 5 /26 78246 5/29 78320 5/29 78321 5/29 78322 5. An interview with the manager on 08 /06/2020 at 1400 hours in the conference room revealed the laboratory did not provide the testing facility's name and address on patient reports for samples which were sent out for testing. This confirmed the findings.