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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 23D2113834 | (X3) Date Survey Completed 03/07/2019 |
| Name of Provider or Supplier Tox Testing Inc | Street Address, City, State 16100 19 Mile Road Suite 200, Clinton Township, MI | |
| 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 |
|---------------------------|--|
| D5309 | <p>TEST REQUEST CFR(s): 493.1241(e)</p> <p>If the laboratory transcribes or enters test requisition or authorization information into a record system or a laboratory information system, the laboratory must ensure the information is transcribed or entered accurately.</p> <p>This STANDARD is not met as evidenced by: . Based on physician standing order review, record review, and interview with the technical supervisor (TS) and general supervisor (GS), the laboratory failed to order tests correctly for five (#9, #11 - #14) of five patients reviewed. Findings include: Patient #9 1. Review of the physician standing order and the test requisition for patient #9 revealed the following drug results for the "10 Panel (DRUG SCREENS WITH REFLEX TO CONFIRMATION)" were not run: a. Marijuana metabolite (THC). 2. Review of the confirmation test report for patient #9 revealed the following: a. No results for Barbiturates and Marijuana. b. Results for Cyclobenzaprine and Gabapentin. Patient #11 and #12 1. Review of the physician standing order and the test requisition for patient #11 and #12 revealed the following drug results for the "10 Panel (DRUG SCREENS WITH REFLEX TO CONFIRMATION)" were not ordered that were run: a. Run not ordered - Heroin Meta 6AM and Alcohol. 2. Review of the confirmation test report for patient #11 and #12 revealed the following: a. No results for Barbiturates and Marijuana. b. Results for MDMA, MDEA, MDA, 6-Monoacetylmorphine, Cyclobenzaprine, and Gabapentin. Patient #13 1. Review of the confirmation test report for patient #13 revealed the following: a. No results for Barbiturates and Marijuana. b. Results for Cyclobenzaprine and Gabapentin. Patient #14 1. Review of the physician standing order and the test requisition for patient #14 revealed the following drug results for the "10 Panel (DRUG SCREENS WITH REFLEX TO CONFIRMATION)" were not ordered that were run: a. Run not ordered - Heroin Meta 6AM, Alcohol, and Ecstasy. 2. Review of the confirmation test report</p> |

for patient #14 revealed the following: a. No results for Barbiturates and Marijuana. b. Results for MDMA, MDEA, MDA, 6-Monoacetylmorphine, Cyclobenzaprine, and Gabapentin. 3. During interview on March 7, 2019 at approximately 4:00 PM, the TS and GS acknowledged there were discrepancies between the test requisition and test report.

D5431

MAINTENANCE AND FUNCTION CHECKS

CFR(s): 493.1254(a)(2)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted.

This STANDARD is not met as evidenced by:

. Based on lack of records and interview with the technical supervisor (TS) and general supervisor (GS), the laboratory failed to document for six (#3 - #8) of eight patient charts audited the daily background count for the Horiba ABX Micros 60 hematology instrument as defined by the manufacturer. Findings include: 1. Record review of the daily background counts revealed there was no documentation to show the instrument had been started up at the beginning of the work day for six patient results audited as follows: a. September 26, 2017 b. December 7, 2017 c. February 4, 2018 d. May 25, 2018 e. July 30, 2018 f. November 2, 2018 2. On March 7, 2019 at approximately 3:30 PM when queried, the GS was unable to provide the documentation requested. 3. During the interview on March 7, 2019 at approximately 3:30 PM, the TS and GS confirmed an acceptable background count was not documented before patient testing.

D5445

CONTROL PROCEDURES

CFR(s): 493.1256(d)(1)(2)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

. Based on procedure review, lack of quality control records, and interview with the technical supervisor (TS) and general supervisor (GS), the laboratory failed to perform quality control as required for the hematology complete blood cell count (CBC) for seven (#2 - #8) of eight patient results audited. Findings include: 1. Procedure review for the "Quality Control" stated "2 of 3 controls must be within 2 SD" of the mean to be acceptable. 2. Record review for the daily hematology controls revealed the laboratory did not have any documentation to show the controls had been run each day of patient testing prior to reporting patient results as follows: a. June 21, 2017 b. September 26, 2017 c. December 7, 2017 e. February 4, 2018 f. May 25, 2018 g. July 30, 2018 h. November 2, 2018 3. During the interview on March 7, 2019 at

approximately 3:30 PM, the TS and GS confirmed there was no documentation to show quality control material was tested prior to reporting out patient test results.

D6018

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(4)(iii)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;

This STANDARD is not met as evidenced by:

. Based on record review and interview with the technical supervisor (TS) and the general supervisor (GS), the laboratory failed to ensure the American Proficiency Institute proficiency testing results were reviewed for six (1st-3rd events in 2017 and 2018) of six events by the testing personnel. Findings include: 1. Record review of the proficiency testing reports revealed the there was no documentation to show the testing personnel had reviewed the final graded proficiency testing results as follows: a. 2017 1. 1st - 3rd event for hematology 2. 1st and 2nd events for miscellaneous chemistry 3. 1st and 3rd events for chemistry b. 2018 1. 1st - 3rd events for hematology 2. 3rd event for chemistry 2. During the interview on March 7, 2019 at 10:00 AM, the TS and GS acknowledged the testing personnel did not review the final graded proficiency testing reports.