Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D2099148	09/19/2018
Name of Provider or Supplier	**Street Address, City, State**	
American Medical Center Laboratory	20820 Greenfield Road 2nd Floor, Oak Park, 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
D5022	TOXICOLOGY CFR(s): 493.1213 If the laboratory provides services in the subspecialty of Toxicology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: . Based on record review and interview, the laboratory failed to meet the requirements for the specialty in Toxicology as specified in 493.1230 through 493.1256, and 493.1281 through 493.1299. Findings include: 1. The laboratory failed to verify the accuracy of the urine toxicology specific gravity testing. Refer to D5217. 2. The laboratory failed to have a written and/or electronic request for patient testing. Refer to D5301. 3. The laboratory failed to enter test requisitions accurately. Refer to D5309. 4. The laboratory failed to perform and document refrigerator/freezer and humidity thermometer calibrations, timer checks, and centrifuge rotations per minute (RPM) checks. Refer to D5429. 5. The laboratory failed to perform the routine chemistry and toxicology daily quality control. Refer to D5445. 6. The laboratory failed to follow written policies and procedures for an ongoing mechanism to monitor, assess, and correct problems in the laboratory analytic systems. Refer to D5791. 7. The laboratory failed to identify the name and address of the facility performing the primary and secondary toxicology testing. Refer to D5805.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) 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.

	This STANDARD is not met as evidenced by: . Based on record review and interview, the laboratory failed to verify the accuracy at least twice annually for the urine toxicology specific gravity testing on the BS-480 Mindray chemistry analyzer for one (2018) of two years of testing. Findings include: 1. On September 19, 2019 at 11:54 AM, verification of accuracy record review for the urine toxicology specific gravity testing revealed there was no documentation to show the testing was completed at least twice annually in 2018. 2. During the interview on September 19, 2018 at 11:54 AM, the laboratory director as listed on the CMS-209 confirmed the testing was not completed.
D5301	TEST REQUEST CFR(s): 493.1241(a) The laboratory must have a written or electronic request for patient testing from an authorized person. This STANDARD is not met as evidenced by: . Based on record review and interview, the laboratory failed to have a written and/or electronic request for patient testing from an authorized person for the toxicology "Comprehensive Drug Analysis" testing for one (#1) of eight patient charts audited. Findings include: 1. On September 19, 2018 at approximately 2:30 PM, record review revealed for one (#1) of eight patient charts audited, the laboratory did not have a written and/or electronic request for the toxicology testing. 2. During the interview on September 19, 2018 at approximately 4:00 PM, the office staff personnel confirmed the laboratory did not have a written and/or electronic request for the laboratory testing performed.
D5309	TEST REQUEST CFR(s): 493.1241(e) 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. This STANDARD is not met as evidenced by: . Based on record review and interview, the laboratory failed to order tests correctly for seven (#2-#8) of eight patient requisitions audited. Findings include: 1. On September 19, 2018 at approximately 4:00 PM, record review for seven (#2 #8) of nine patient test requisitions and final reports from June 5, 2018 to September 10, 2018 revealed the following discrepancies: Patient #2 a. The electronic requisition revealed an order for a urine "Comprehensive Drug Analysis" panel. b. The electronic order submitted by the physician on March 3, 2018 included the following tests that were not on the final report: Zaleplon and THC-OH. Patient #3 a. The electronic requisition revealed an order for a urine "Comprehensive Drug Analysis" panel. b. The electronic order submitted by the physician on May 30, 2018 included the following tests that were not on the final report: Zaleplon and THC-OH. Patient #4 a. The electronic requisition revealed an order for a urine "Comprehensive Drug Analysis" panel. b. The electronic order submitted by the physician on July 11, 2018 included the following tests that were not on the final report: Zaleplon and THC-OH. Patient #5 a. The electronic requisition revealed an order for a urine "Primary Testing Only". b. The electronic order submitted by the physician on July 19, 2018 did not

	include a "Comprehensive Drug Analysis" panel that included the following tests that were not ordered: Amphetamine, Methamphetamine, Amobarbital Pentobarbital, Butabarbital, Butalbital, Phenobarbital, Alprazolam, Clonazepam, 7-Amino Clonazepam, Flunitrazepam, Flurazepam, Hydroxyalprazolam, Lorazepam, Midazolam, Nordiazepam, Oxazepam, Temazepam, Codeine, Norhydrocodone, Hydrocodone, Hydromorphone, Morphine, MDA, MDEA, MDMA, Meperidine, Naloxone, Naltrexone, Zolpidem, Zaleplon, Cyclobenzaprine, Carissoprodol, Meprobamate, Sertaline, Amitriptyline, Desipramine, Doxepin, Imipramine, Nortriptyline, Buprenorphine, Norbuprenorphine, THC-OH, THC-COOH, Benzoylecgonine, Fentanyl, Norfentanyl, Gabapentin, 6-MAM, Ketamine, Norketamine, EDDP, Methadone, PCP, Methylphenidate, Ritilinic Acid, Pregabaline, Oxycodone, Noroxycodone Oxymorphone, Propoxyphone, Tramadol, D-Desmethyltramadol and Cotinine. Patient #6 a. The electronic requisition revealed an order for a urine "Comprehensive Drug Analysis" panel. b. The electronic order submitted by the physician on August 1, 2018 included the following tests that were not on the final report: Zaleplon and THC-OH. Patient #7 a. The electronic requisition revealed an order for a "Oral" panel for oral fluid specimen. b. The electronic order submitted by the physician on August 1, 2018 included the following tests that were not on the final report: Clonazepam, 7-Amino Clonazepam, Norhydrocodone, Zaleplon, THC-OH, Norfentanyl, Norketamine, EDDP, Noroxymorphone, and D-Desmethyltramadol. Patient #8 a. The electronic requisition revealed an order for a "Oral" panel for oral fluid specimen. b. The electronic order submitted by the physician on August 15, 2018 included the following tests that were not on the final report: Clonazepam, 7-Amino Clonazepam, Norhydrocodone, Zaleplon, THC-OH, Norfentanyl, Norketamine, EDDP, Noroxymorphone, and D-Desmethyltramadol. 2. During the interview on September 19, 2018 at approximately 4:00 PM, the laboratory director as listed on the CMS-209 was informed that discrepancies were noted on the final reports.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: . Based on observation, lack of records, and interview, the laboratory failed to perform and document refrigerator/freezer and humidity thermometer calibrations, timer checks, and centrifuge rotations per minute (RPM) checks for two (September 2016 - September 2018) of two years. Findings include: 1. During a tour of the laboratory on September 19, 2018 at 8:50 AM, the surveyor observed "Fisher Scientific" thermometers in the Whirlpool refrigerator and freezer with a calibration due date of 11/14/14 and a "Control Company" hygrometer/room temperature thermometer on the desk next to the AbSciex Triple Quad 4500MD LC/MS analyzer with no calibration due date or put into use date. 2. On September 19, 2018 at approximately 10:04 AM, the laboratory did not have available to the surveyor records to show the thermometers had been calibrated, timer and centrifuge checks performed and documented for two (September 2016 - September 2018) of two years of operation. 3. On September 19, 2018 at approximately 10:04 AM, the laboratory director as listed on the CMS-209 confirmed the thermometer calibrations, timer and centrifuge checks had not been performed and documented.

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 record review and interview, the laboratory failed to perform the routine chemistry and toxicology quality control each day of patient testing for two (June 5 and June 15, 2018) of nine days of patient testing audited on the day of the survey. Findings include: 1. On September 19, 2018 at approximately 2:28 PM, record review for two (June 5 and 15, 2018) of nine days of patient testing audited, there was no documentation of two levels of quality control performed and documented prior to testing patient samples as follows: a. June 5, 2018 - 60 patients tested b. June 15, 2018 - 89 patients tested 2. During the interview on September 19, 2018 at approximately 2: 28 PM, testing personnel #1 as listed on the CMS-209 confirmed quality control was not performed and documented prior to testing patient samples.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: . Based on record review and interview, the laboratory failed to follow written policies and procedures for an ongoing mechanism to monitor, assess, and correct problems as specified in 493.1251 through 493.1283 in the analytic laboratory systems for seven (March -September 2018) of 12 months reviewed. Findings include: 1. On September 19, 2018 at 12:42 PM, record review of the monthly quality assurance forms revealed the laboratory did not have documentation to show the analytic systems were being monitored for seven (March - September 2018) of 12 months reviewed. 2. During the interview on September 19, 2018 at 12:42 PM, the laboratory director as listed on the CMS-209 confirmed there was no quality assurance documentation in 2018.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units

	of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: . Based on record review and interview, the laboratory failed to identify the name and address of the facility performing the secondary toxicology testing for eight (#1 - #8) of eight patient charts audited. Findings include: 1. On September 19, 2018 at approximately 3:30 PM, record review of the final patient results for eight (#1 - #8) of eight charts audited revealed the name and address of the testing facility was not included on the final report. 2. During the interview on September 19, 2018 at approximately 3:30 PM the laboratory director as listed on the CMS-209 confirmed the final reports did not include the name and address of the testing facility.