

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D2099148	(X3) Date Survey Completed 11/23/2020
Name of Provider or Supplier American Medical Center Laboratory	Street Address, City, State 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	<p>TOXICOLOGY CFR(s): 493.1213</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: . Based on the number and severity of the deficiencies cited herein, the Condition: Toxicology was not met. Findings include: 1. The laboratory failed to verify the accuracy of toxicology analytes at least twice annually. Refer to D5217. 2. The laboratory failed to ensure reagents used in toxicology testing did not exceed their expiration date. Refer to D5417.</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 record review and interview with the Laboratory Director (LD), the laboratory failed to verify the accuracy of toxicology analytes at least twice annually for 2 (November 2018 to November 2020) of 2 years reviewed. Findings include: 1. A review of the laboratory's test menu revealed it tests urine and oral specimens for the following analytes: a. 6-MAM b. 7-amino clonazepam c. Alpha-hydroxyalprazolam d. Alprazolam e. Amitriptyline f. Amphetamine g. Benzoylcegonine h. Buprenorphine i. Carisoprodol j. Cotinine k. Codeine l. Cyclobensaprine m. Desipramine n. Desmethyl-tapentadol o. Doxepin p. 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP)</p>

q. Fentanyl r. Flunitrazepam s. Flurazepam t. Gabapentin u. Hydrocodone v. Hydromorphone w. Imipramine x. Ketamine y. Lorazepam z. 3,4-Methylenedioxyamphetamine (MDA) aa. 3,4-Methylenedioxy-N-ethylamphetamine Drug (MDEA) bb. 3,4-Methylenedioxymethamphetamine (MDMA) cc. Mepiperidine dd. Meprobamate ee. Methadone ff. Methamphetamine gg. Methylphenidate hh. Midazolam ii. Morphine jj. Naloxone kk. Naltrexone ll. Norbuprenorphine mm. Nordiazepam nn. Norfentanyl oo. Norhydrocodone pp. Norketamine qq. Noroxymorphone rr. Nortriptyline ss. Oxazepam tt. Oxycodone uu. Oxymorphone vv. Phenylcyclohexyl piperidine (PCP) ww. Pregabalin xx. Propoxephene yy. Ritalinic Acid zz. Sertraline aaa. Tapentadol bbb. Temazepam ccc. Tramadol ddd. Zolpidem eee. Tetrahydrocannabinol (THC) fff. Amobarbital Pentobarbital ggg. Butobarbital hhh. Butalbital

2. A review of the laboratory's "Comparison Test" data revealed a lack of documentation for twice annual verification of accuracy testing for the following analytes not covered by the College of American Pathologists' proficiency testing events in 2019 and 2020: a. Amitriptyline b. Cotinine c. Desipramine d. Doxepin e. Imipramine f. Ketamine g. Methylphenidate h. Midazolam i. Naloxone j. Naltrexone k. Norketamine l. Nortriptyline m. Nortriptyline n. Zolpidem o. Amobarbital Pentobarbital p. Butobarbital

3. A review of the laboratory's College of American Pathologists' proficiency testing records revealed a lack of enrollment for 2019, resulting in the lack of twice annual verification of accuracy for the following analytes in 2019 not covered under the laboratory's "Comparison Test" data: a. Carisoprodol b. Meprobamate c. Norhydrocodone d. Noroxymorphone e. Propoxephene f. Temazepam g. Butalbital

4. An interview on 11/23/20 at 10:30 am with the LD confirmed the laboratory did not verify the accuracy of all of its toxicology analytes at least twice annually. ***This is a repeated deficiency from the 9/19/18 recertification survey***

D5417

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

Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:
. Based on observation, record review, and interview with Testing Personnel #1 (TP1), the laboratory failed to ensure reagents used in toxicology testing did not exceed their expiration date for 312 patients tested since the expiration date elapsed. Findings include: 1. The surveyor observed a bottle of Methanol with the expiration date of 7/22 /2020. 2. An interview with TP1 on 11/23/20 at 9:14 am revealed the laboratory had not received a new lot of Methanol since they started working at the facility in June 2019 and the contents of the expired bottle were used in reagent preparation. 3. A review of the laboratory's "Drugs in Urine 4500 LCMSMS" procedure revealed Methanol is used in preparing the Mobile Phase B reagent used in toxicology testing. 4. A review of the laboratory's "Test Reagents" procedure revealed a section stating, "No material will routinely be used that is out-of-date." 5. An interview with TP1 on 11/23/20 at 12:17 am revealed 312 patients had been tested since the Methanol had expired.

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 record review and interview, the laboratory director failed to provide overall management and direction. Findings include: 1. The Laboratory Director failed to ensure quality assessment programs were maintained. Refer to D6094. 2. The Laboratory Director failed to ensure testing personnel were trained to perform toxicology testing prior to reporting patient test results. Refer to D6101. 3. The Laboratory Director failed to ensure testing personnel were competent to perform toxicology testing. Refer to D6103.

D6094

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:

. Based on record review and interview with the Laboratory Director (LD), the Laboratory Director failed to ensure quality assessment programs were maintained for 2 (November 2018 to November 2020) of 2 years. Findings include: 1. A review of the laboratory's "Laboratory Quality Assessment Plan" procedure revealed a section stating, "The Comprehensive Quality Assessment Program (QA) is structured to monitor and evaluate the ongoing and overall quality of all aspects of the testing process (Pre-analytic, Analytic, and Post-analytic)." 2. A review of the laboratory's records revealed a table of contents stating, "6. Quality Assessment Documentation Folder Quality Assurance Goal. 6.1 Monthly Meeting". Documentation of quality assessments was not available. 3. The surveyor requested the laboratory's quality assessment documentation from November 2018 to November 2020 on 11/23/20 at 9:57 am and it was not made available. 4. An interview on 11/23/20 at 9:57 am with the LD revealed the laboratory has not performed ongoing quality assessments for its high complexity toxicology testing.

D6101

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(11)

The laboratory director must employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart.

This STANDARD is not met as evidenced by:

. Based on observation, record review, and interviews, the Laboratory Director failed to ensure testing personnel were trained to perform toxicology testing prior to reporting patient test results for 2 (Testing Personnel #1 and Office Personnel #1) of 2 personnel employed by the laboratory. Findings include: 1. An interview with the Laboratory Director (LD) on 11/23/20 at 9:23 am revealed Testing Personnel #1 started employment with the laboratory on 6/3/2019. 2. An interview with Office

	<p>Personnel #1 on 11/23/20 at 11:42 am revealed he has been performing toxicology testing. 3. A review of the laboratory's personnel records revealed a lack of documentation of training in toxicology testing for Testing Personnel #1 and Office Personnel #1. 4. An interview on 11/23/20 at 12:17 pm with the LD confirmed testing personnel did not have documented training or competency assessments.</p>
<p>D6103</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13)</p> <p>The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills.</p> <p>This STANDARD is not met as evidenced by: . Based on observation, record review, and interviews, the Laboratory Director failed to ensure testing personnel were competent to perform toxicology testing for 2 (Testing Personnel #1 and Office Personnel #1) of 2 personnel employed by the laboratory. Findings include: 1. An interview with the Laboratory Director (LD) on 11/23/20 at 9:23 am revealed Testing Personnel #1 started employment with the laboratory on 6/3/2019. 2. An interview with Office Personnel #1 on 11/23/20 at 11:42 am revealed he has been performing toxicology testing. 3. A review of the laboratory's "Testing Personnel- Performance Evaluation Competency Assessment" procedure revealed a section stating, "The required competencies for this position are as per the attached initial and periodic competency review." 4. A review of the laboratory's "Overall Competency Testing Program Assessment" procedure revealed a section stating, "To ensure that individuals responsible for laboratory testing maintain competency in order to perform test procedures and analysis accurately, proficiently, and according to the specified policy and procedure." 5. A review of the laboratory's personnel records revealed a lack of competency assessment documentation for Testing Personnel #1 and Office Personnel #1. 5. An interview on 11/23/20 at 12:17 pm with the LD confirmed testing personnel did not have documented competency assessments.</p>
<p>D6134</p>	<p>CLINICAL CONSULTANT CFR(s): 493.1453</p> <p>The laboratory must have a clinical consultant who meets the requirements of 493.1455 of this subpart and provides clinical consultation in accordance with 493.1457 of this subpart.</p> <p>This CONDITION is not met as evidenced by: . Based on record review and interview with the Laboratory Director, the laboratory failed to ensure the Clinical Consultant met the qualification requirements at 493.1457 of this part. Findings include: 1. The laboratory failed to employ a qualified Clinical Consultant. Refer to D6135.</p>
<p>D6135</p>	<p>CLINICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1455</p>

The clinical consultant must be qualified to consult with and render opinions to the laboratory's clients concerning the diagnosis, treatment and management of patient care. The clinical consultant must-- (a) Be qualified as a laboratory director under 493.1443(b)(1), (2), or (3)(i) or, for the subspecialty of oral pathology, 493.1443(b)(6); or (b) Be a doctor of medicine, doctor of osteopathy, doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located.

This STANDARD is not met as evidenced by:

. Based on record review and interview with the Laboratory Director, the laboratory failed to employ a qualified Clinical Consultant for 2 (November 2018 to November 2020) of 2 years. Findings include: 1. A review of the CMS-209 form revealed the Laboratory Director was also listed as the Clinical Consultant. 2. A review of the Laboratory Director's qualifications revealed the following: a. He did not qualify as a laboratory director under 493.1443(b)(1), (2), or (3)(i). b. He is not a doctor of medicine, doctor of osteopathy, doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located. 3. An interview on 11/24/20 at 11:50 am with the Laboratory Director confirmed he did not meet the qualifications to serve as the Clinical Consultant.

D6168

TESTING PERSONNEL

CFR(s): 493.1487

The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493.1495 of this subpart for the volume and complexity of testing performed.

This CONDITION is not met as evidenced by:

. Based on document review and interviews, the laboratory failed to ensure personnel performing high complexity toxicology testing met the qualification requirements at 42 CFR 493.1489 for 1 (Office Personnel #1) of 2 testing personnel. Findings include: 1. The laboratory failed to ensure testing personnel was qualified to perform high complexity toxicology testing. See D6171.

D6171

TESTING PERSONNEL QUALIFICATIONS

CFR(s): 493.1489(b)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or

medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations.

This STANDARD is not met as evidenced by:

. Based on record review and interviews, the laboratory failed to ensure testing personnel was qualified to perform high complexity toxicology testing for 1 (Office Personnel #1) of 2 testing personnel. Findings include: 1. An interview on 11/23/20 at 11:42 am with Office Personnel #1 revealed he has been performing toxicology testing at the laboratory. 2. A review of the laboratory's personnel records revealed a lack of qualification documentation for Office Personnel #1. 3. An interview on 11/23/20 at 12:17 pm with the Laboratory Director revealed Office Personnel #1 was not qualified to be performing high complexity testing.