

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 14D1044662	<b>(X3) Date Survey Completed</b> 01/27/2022
<b>Name of Provider or Supplier</b> Medical Assay Laboratory I	<b>Street Address, City, State</b> 8205 S Cass Ave, Ste 108, Darien, IL	
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>D5002</b>	<p>BACTERIOLOGY CFR(s): 493.1201</p> <p>If the laboratory provides services in the subspecialty of Bacteriology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1261, and 493.1281 through 493.1299.</p> <p>This CONDITION is not met as evidenced by: Based on direct observation, record review, and interview, the laboratory failed to perform antimicrobial control drug sensitivity procedures each day of testing (D5507) to ensure sensitivity results are accurate and reliable, affecting 948 patient results.</p>
<b>D5507</b>	<p>BACTERIOLOGY CFR(s): 493.1261(b)(c)</p> <p>(b) For antimicrobial susceptibility tests, the laboratory must check each batch of media and each lot number and shipment of antimicrobial agent(s) before, or concurrent with, initial use, using approved control organisms. (b)(1) Each day tests are performed, the laboratory must use the appropriate control organism(s) to check the procedure. (b)(2) The laboratory's zone sizes or minimum inhibitory concentration for control organisms must be within established limits before reporting patient results. (c) The laboratory must document all control procedures performed, as specified in this section.</p> <p>This STANDARD is not met as evidenced by: Based on direct observation, record review, and interview, the laboratory failed to check and document the laboratory's zone sizes for control organisms within the manufacturer's established limits each day tests are performed before reporting patient results, affecting 948 patient results. Findings include: 1. The Mueller Hinton Plate</p>

and Sensitivity Disks Quality Control (QC) worksheets from the months of October 2019, February, June and November of 2020, March, August and December of 2021, the Antimicrobial Susceptibility test Discs package insert, the laboratory's test volume worksheet, the Kirby Bauer Procedure for Susceptibility Testing procedures, and selected patient results were reviewed. 2. On January 27, 2022 at 12:30 PM during a tour of the Microbiology laboratory, the surveyor observed that the laboratory performed antimicrobial sensitivity testing using the Kirby Bauer method. The surveyor then requested to see the 0.5 McFarland turbidity standard used as a reference to adjust the turbidity of bacterial suspensions so that the number of bacteria will be within the manufacturer's standardized range for microbial testing. The general supervisor (GS)-AS stated the laboratory did not use or have the 0.5 McFarland standard. 3. Review of the procedures manual and package insert revealed the following: \*Both required the use of the 0.5 McFarland BaSO4 Turbidity Standard and \*Step #3 in the procedure manual instructed the testing personnel to "Adjust the turbidity of the active growing broth culture with sterile saline or broth to obtain a turbidity visually comparable to a 0.5 McFarland turbidity standard." \*The laboratory failed to utilize the McFarland standard as indicated in the manufacturer's and laboratory procedure for 35 out of 35 weekly sensitivities performed during the months selected for review. 4. The test volume worksheet completed by the laboratory documented that 948 sensitivity tests were performed and reported during the year of 2021. 5. The QC worksheets and seven selected patients' final reports revealed the laboratory failed to perform antimicrobial sensitivity QC procedures for six of seven days sensitivities were reported. 6. Further review of the QC worksheets showed the laboratory performed QC procedures once per week. 7. The QC worksheets and package insert revealed the following: \*The laboratory used multiple versions of the QC worksheet to document the pathogenic control organisms' drug susceptibility zones, one QC worksheet was marked "Doctor's Clinical Laboratory", received via email on 03/02/2022. \*The QC worksheet provided by GS-AS on the day of survey showed that four of 14 drug concentrations on the worksheets failed to reflect the concentrations stated in the package insert. QC Worksheet microgram(mcg) Manufacturer Ampicillin (AMP) (30 milligram) AMP (10 mcg) Cephalothin (CEP) (10 milligram) CEP (30 mcg) Nitrofurantoin (NTF) (399 mcg) NTF (300 mcg) Trimethoprim/ SXT (1.25/23.75 mcg) Sulfamethoxazole(SXT) (25 mcg) \*The control organisms on the worksheet were listed under the wrong control identification number. QC Worksheet Manufacturer S.Aureus (ATCC 25922) and E.Coli (ATCC 25923) S. Aureus (ATCC 25923) and E.Coli (ATCC 25922) \*6 out of 14 drugs' acceptable zone ranges on the worksheet failed to reflect the acceptable zone ranges defined in the package insert for the same drugs. QC Worksheet (Acceptable Zones) Manufacturer S.Aureus (25922) & E.Coli (25923) S.Aureus (25923) & E.Coli (25922) AMP (30 milligram) 27-35 16-22 AMP 10mcg 27-35 16-22 CEP (10 milligram) 29-37 17-22 CEP 30mcg 29-37 15-21 NTF (399mcg) 18-22 20-24 NTF 300mcg 18-22 20-25 Tetracycline 19-28 18-25 Tetracycline 24-30 18-25 Vancomycin 15-19 NR Vancomycin 17-21 NR SXT (25mcg) 24-32 24-32 SXT 1.25/23.75 24-32 23-29 Amox/Clav. 28-36 19-25 Amox/Clav 28-36 18-24 \*The laboratory failed to utilize the correct zones as indicated in the manufacturer's procedure for 35 out of 35 weekly sensitivities performed during the months selected for review. 8. On a Recertification survey conducted on 01/27/2022 at 3:00 PM, the LD and GS confirmed the above findings.

**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 direct observation, record review, and interview, the laboratory failed to have a director who meets the qualification requirements for high complexity testing (D6078) and provide overall management to ensure test procedures are followed (D6087) and to employ individuals with the appropriate education and experience (D6101) for testing performed in the specialty of Microbiology.

**D6078**

**LABORATORY DIRECTOR QUALIFICATIONS**

CFR(s): 493.1443

The laboratory director must be qualified to manage and direct the laboratory personnel and performance of high complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R. (a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory director must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2) Be a doctor of medicine, a doctor of osteopathy or doctor of podiatric medicine licensed to practice medicine, osteopathy or podiatry in the State in which the laboratory is located; and (b)(2)(i) Have at least one year of laboratory training during medical residency (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or (b)(2)(ii) Have at least 2 years of experience directing or supervising high complexity testing; or (b)(3) Hold an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution and-- (b)(3)(i) Be certified and continue to be certified by a board approved by HHS; or (b)(3)(ii) Before February 24, 2003, must have served or be serving as director of a laboratory performing high complexity testing and must have at least-- (b)(3)(ii)(A) Two years of laboratory training or experience, or both; and (b)(3)(ii)(B) Two years of laboratory experience directing or supervising high complexity testing. (b)(4) Be serving as a laboratory director and must have previously qualified or could have qualified as a laboratory director under regulations at 42 CFR 493.1415, published March 14, 1990 at 55 FR 9538, on or before February 28, 1992; or (b)(5) On or before February 28, 1992, be qualified under State law to direct a laboratory in the State in which the laboratory is located; or (b)(6) For the subspecialty of oral pathology, be certified by the American Board of Oral Pathology, American Board of Pathology, the American Osteopathic Board of Pathology, or possess qualifications that are equivalent to those required for certification.

This STANDARD is not met as evidenced by:

Based on direct observation, record review, and interview, the laboratory failed to employ a qualified director who meets the education and experience to provides overall management and direction for the Microbiology and Virology testing performed in the laboratory. Findings: 1. The Laboratory Personnel Report (CMS 209), procedures manuals, and personnel files were reviewed. 2. During a tour of the

laboratory on January 27, 2022 at 11:55 AM, the surveyor observed the following high complexity tests and test systems being performed: \*ATILA SARS-CoV-2 Polymerase Chain Reaction (PCR) assay and the \*Microbial isolation, identification, and sensitivity procedures for pathogenic organisms. 3. Review of the educational credential documentation of Staff-CC listed as the laboratory director (LD) revealed they possessed a Masters of Science and a Doctrine of Philosophy. Staff-CC failed to meet the required criteria listed under 493.1443(b) (b)(3) Hold an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution and- (b)(3)(i) Be certified and continue to be certified by a board approved by HHS; which are ABB - American Board of Bioanalysis, ABB - Public Health Microbiology certification, ABCC - American Board of Clinical Chemistry, ABCC 24 month-Commission on Accreditation in Clinical Chemistry (COMACC) accredited program, ABFT - American Board of Forensic Toxicology (limited to individuals with a doctoral degree)\*, ABHI - American Board of Histocompatibility and Immunogenetics, ABMGG - American Board of Medical Genetics and Genomics (formerly ABMG - American Board of Medical Genetics), ABMLI - American Board of Medical Laboratory Immunology, ABMM - American Board of Medical Microbiology, NRCC - National Registry for Certified Chemists (limited to individuals with a doctoral degree)\*, 4. Further review of the employee records showed the curriculum vitae (CV) of Staff-CC failed to provide any documentation of previous supervisory experience in a high complexity CLIA certified laboratory. 5. On a Recertification survey conducted on 01/27/2022 at 3:00 PM, the LD confirmed the above findings.

**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 record review and interview, the laboratory director (LD) failed to ensure laboratory personnel conducting Microbiology testing performed antimicrobial sensitivity methods as required for accurate and reliable results, affecting 948 patients test results. Findings include: 1. The Mueller Hinton Plate and Sensitivity Disks Quality Control (QC)worksheets, the Antimicrobial Susceptibility test Discs package insert, the laboratory's test volume worksheet and the Kirby Bauer Procedure for Susceptibility Testing procedures were reviewed. See D5002 and D5507. 2. The LD failed to ensure the Microbiology technical supervisor (TS) and general supervisor (GS) performed their responsibilities to provide accurate and reliable antimicrobial drug sensitivity testing. See D5002 and D5507. 3. The LD failed to ensure the laboratory had mcfarland standard as required for sensitivity testing. See D5507. 4. The LD failed to ensure TS, GS, and testing personnel followed the Kirby Bauer procedure and performed control procedures each day of patient testing. See D5002 and D5507. 5. The LD failed to ensure the documentation of control procedures included an ongoing process to review and adjust drug discs information as defined by the package inserts for pathogenic drug sensitivity testing. See D5507. 6. On a Recertification survey conducted on 01/27/2022 at 3:00 PM, the LD and GS confirmed the above findings.

**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 record review, the Laboratory Personnel Report (CMS 209), and interview, the laboratory director (LD) failed to employ laboratory personnel with the appropriate education and experience to provide consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities for highly complex testing. Findings: 1. The LD failed to employ qualified personnel to perform the responsibilities of a testing personnel (TP). See D6063, D6065 and D6168, D6171. 2. The LD failed to ensure technical supervisor and general supervisor performed their required responsibilities. See D6087.

**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 record review, CMS-209 (Laboratory Personnel Report), and interview; the laboratory failed to have individuals who meet the qualification requirements for performing high complexity of testing (D6171) for one out of ten testing personnel (TP).

**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, lack of documentation, and interview, the laboratory failed to ensure laboratory personnel meet the education criteria to perform highly complex testing in the laboratory for one out of ten testing personnel (TP). Findings: 1. The employee files and the Laboratory Personnel Report (CMS-209) were reviewed. 2. The CMS 209 listed Staff-VS as TP in the laboratory. 3. The employee files revealed Staff-VS education credentials were from Antigua and had not been evaluated for United States education equivalency. 4. Further review showed that Staff-VS had received training, competency, and was conducting tests in the specialty of Microbiology. 5. On a Recertification survey conducted on 01/27/2022 at 3:00 PM, the laboratory director confirmed the above findings.