Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D1044662	05/07/2019
Name of Provider or Supplier	**Street Address, City, State**	
Medical Assay Laboratory I	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.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D2006	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b) The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records, laboratory testing logs and interview with the laboratory director; the laboratory failed to examine PT samples in the same manner as it tested patients' specimens. Findings include: 1. PT records were reviewed from the 2nd Quarter of 2017 through the 1st Quarter of 2019. 2. Review of laboratory testing logs revealed all syphilis serology and general immunology testing were documented on individual laboratory log sheets. A separate testing log sheet was completed for each individual analyte tested in syphilis and immunology. 3. Testing logs for PT revealed that results for analytes for both syphilis serology and general immunology (ANA) were documented on the same laboratory log sheets. No patients' tests were documented on the PT testing logs. 4. At 10:30 AM on Mary 7, 2019, the laboratory director confirmed the surveyor's findings.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable,

	consultant competency. This STANDARD is not met as evidenced by: Based on review of Laboratory Personnel Report (CMS 209), policies and procedures manuals, personnel records and interview with the laboratory director; the laboratory failed to establish and follow written policies and procedures to assess consultant competency. Findings include: 1. Review of the CMS 209 submitted to the surveyor on May 7, 2019 revealed that there were persons listed for the following positions in the laboratory: Laboratory Director, Clinical Consultant, Technical Supervisor /Consultant, General Supervisor, High Complexity Testing Personnel, and Moderate Complexity Testing Personnel. 2. Review of the laboratory's policies and procedures manual revealed that there were no individuals who were assigned to the positions of Technical Supervisor /Consultant and General Supervisor. 3. Review of personnel records revealed that there were no competency assessments performed on personnel that pertained to the duties and responsibilities of Technical Supervisor/ Consultant or General Supervisor. Records show that all personnel were given identical evaluations that pertained to test performance, only. 4. At 10:30 AM on May 7, 2019, the laboratory director confirmed the surveyor's findings.
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method. This STANDARD is not met as evidenced by: Based on record review and interview with the laboratory director; the laboratory director failed to ensure that verification procedures used were adequate to determine the precision of the method used to test coagulation tests. Findings include: 1. At 9:30 AM on May 7, 2019, during the walk through of the laboratory, the laboratory director revealed that the laboratory purchased a new coagulation analyzer. 2. Review of laboratory records revealed that there was no documentation to show that the laboratory verified the precision of its coagulation analyzer. 3. At 2:30 PM on May 7, 2019, the laboratory director confirmed the surveyor's findings.
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of the procedure's manuals, personnel records and interview with the laboratory director; the laboratory director failed to specify in writing the

	responsibilities and duties of each consultant, supervisor, and which tests everyone is authorized to perform. Finding include: 1. Review of the procedure's manual revealed that there was no documentation, in writing, that described the duties and responsibilities of the following positions: a. Technical Supervisor/Consultant b. General Supervisor c. High Complexity Testing Personnel (specified tests) e. Moderate Complexity Testing Personnel (specified tests) 2. Review of personnel records revealed that the laboratory director did not specified in writing personnel assigned to the following positions: a. Technical Supervisor/Consultant b. General Supervisor 3. At 10:30 AM on May 7, 2019, the laboratory director confirmed the surveyor's findings.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on review of personnel records and interview with the laboratory director; the technical supervisor failed to be responsible for identifying training needs and assuring that everyone performing tests receives regular in-service training and education for its coagulation testing. Findings include: 1. At 9:30 AM on May 7, 2019, the surveyor performed a walk-through of the laboratory. At that time the surveyor asked the laboratory director if there were any new instrumentation or tests added since the last survey in 2017. 2. The laboratory director told the surveyor that a new coagulation analyzer was added in September 2018. 3. Review of personnel records revealed that there was no documentation to show that testing personnel were trained to perform testing on the new coagulation analyzer for 6 of 6 testing personnel. 4. At 10:30 AM on May 7, 2019, the laboratory director confirmed the surveyor's findings.
D6125	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(v) The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. This STANDARD is not met as evidenced by: Based on review Laboratory Personnel Report - CLIA (CMS 209), personnel records, and interview with the laboratory director, the procedures for evaluation of the competency of the staff did not include assessment of test performance through testing previously analyzed specimens, internal blind testing, or external proficiency testing samples. Findings include: 1. There was one new laboratory person list on the CMS 209. 2. Review of personnel records revealed that there was no documentation to show that the new testing personnel tested previously analyzed specimens, internal blind specimens, or external proficiency testing samples when her competency was

	evaluated 3. At 10:30 AM on May 7, 2019, the laboratory director confirmed the surveyor's findings