

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D1044662	(X3) Date Survey Completed 06/06/2025
Name of Provider or Supplier Medical Assay Laboratory I	Street Address, City, State 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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>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.</p> <p>This STANDARD is not met as evidenced by:</p> <p>a) Based on review of laboratory policies and procedures, competency records, the CMS-209 (Laboratory Personnel Report), lack of documentation, and interview with the technical consultant (TC); the laboratory failed to establish and follow written policies and procedures to assess the competency of one of one TC. Findings Include: 1. Review of laboratory policy and procedure titled "Personnel Competency Evaluation" under the section titled "procedure" stated, "1. Each calendar year, each employee will receive the employee competency checklist. The lab director or designee will decide which procedures each employee is responsible." 2. Review of laboratory competency records revealed that one of one TC identified on the CMS-209 failed to have competency evaluations documented in 2023 and 2024. 3. Interview with the TC on 06/05/2025, at 11:30 am, confirmed the laboratory failed to complete competency assessment records in 2023 or 2024 for the TC. b) Based on review of laboratory policies and procedures, competency records, the CMS-209 (Laboratory Personnel Report), lack of documentation, and interview with the technical consultant (TC); the laboratory failed to follow written policies and procedures to assess the competency of one of six testing personnel (TP) in the specialty of hematology. Findings Include: 1. Review of laboratory policy and procedure titled "Personnel Competency Evaluation" under the section titled "procedure" stated, "1. Each calendar year, each employee will receive the employee competency checklist. The lab director or designee will decide which procedures each employee is responsible." 2. Review of laboratory competency records revealed that one of six TP identified on the CMS-209 (TP #1) failed to have competency</p>

evaluations documented for the position in 2023 and 2024. 3. Interview with the TC on 06/05/2025, at 11:30 am, confirmed the laboratory failed to follow written policies and procedures to assess the competency of one of six TP performing coagulation testing in the specialty of hematology.

D5213

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
CFR(s): 493.1236(b)(1)

(b) The laboratory must verify the accuracy of the following: (b)(1) Any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program.

This STANDARD is not met as evidenced by:
Based on review of American Proficiency Institute (API) proficiency testing (PT) records, laboratory records, lack of documentation, and interviews with the technical consultant (TC) and laboratory director (LD); the laboratory failed to ensure accuracy of 10 of 10 analytes not evaluated by the PT provider in the specialties of chemistry and microbiology in 2024 and 2025. Findings include: 1. Review of API comparative evaluation summaries for the PT events of 2024 and 2025 revealed the following ungraded PT samples: PT Event: Analyte: # Ungraded: 2024 Event 1 - Chemistry Total Bilirubin Three 2024 Event 2 - Chemistry Iron One 2024 Event 2 - Microbiology Ciprofloxacin One 2025 Event 1 - Chemistry FT3* Five *FT3 = free triiodothyronine 2. Review of laboratory records found no documented review of the ungraded PT analytes in the specialties of chemistry and microbiology in 2024 and 2025. 3. Interviews with the TC and LD on 06/06/2025, at 12:14 pm, confirmed the laboratory failed to ensure accuracy of 10 of 10 analytes not evaluated by the PT provider in the specialties of chemistry and microbiology in 2024 and 2025.

D5401

PROCEDURE MANUAL
CFR(s): 493.1251(a)

(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

This STANDARD is not met as evidenced by:
Based on direct observation, review of the laboratory's test volume worksheet, laboratory policies and procedures, lack of documentation, and interview with the technical consultant (TC); the laboratory failed to establish a procedure for four of four virology analytes performed on the Atila Powergene 9600 Real-Time Polymerase-Chain Reaction (RT-PCR) analyzer, affecting 7,818 patients from June 2024 through June 2025. Findings include: 1. Upon a tour of the laboratory on 06/05/2025, at 2:22 pm, surveyors observed an Atila Powergene 9600 RT-PCR analyzer (Serial Number: MDA6094552290) used for performing respiratory syncytial virus (RSV), Influenza A, Influenza B, and Covid-19 testing. 2. Review of the laboratory's test volume worksheet revealed 7,818 patients had been tested for RSV, Influenza A & B, and Covid-19 from June 2024 through June 2025. 3. Review of laboratory policies and procedures revealed the laboratory failed to have a procedure in place for virology testing on the Atila Powergene 9600 RT-PCR analyzer. 4. Interview with the TC on 06/06/2025, at 9:35 am, confirmed the laboratory failed to establish a

procedure for four of four virology analytes performed on the Atila Powergene 9600 RT-PCR analyzer, affecting 7,818 patients from June 2024 through June 2025.

D5449

CONTROL PROCEDURES

CFR(s): 493.1256(d)(3)(ii)(g)

(d)(3)(ii) Each qualitative procedure, include a negative and positive control material;

This STANDARD is not met as evidenced by:

Based on review of the manufacturer's package insert, patient test reports, quality control (QC) records, and interview with the laboratory director (LD); the laboratory failed to ensure positive and negative control materials were tested each day of testing for two of two applicable patients reported utilizing the API 20 E identification system in the subspecialty of bacteriology. Findings include: 1. Review of the manufacturer's package insert for the API 20 E identification system revealed, under "Quality Control", "It is the responsibility of the user to perform Quality Control in accordance with any local applicable regulations." 2. Review of two of two applicable patient test reports and the laboratory's quality control records for the API 20 E identification system revealed the laboratory had not performed QC on the date patient testing was performed. Patient: Date of Testing: Date QC Performed: 123936 07/12/2024 05/15/2024 130460 06/05/2025 03/15/2025 3. Interview with the LD on 06/06/2025, at 12:14 pm, confirmed the laboratory failed to ensure positive and negative control materials were tested each day of testing for two of two applicable patients reported utilizing the API 20 E identification system in the subspecialty of bacteriology.

D6107

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(15)

(e)(15) 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 laboratory policies and procedures, CMS-209 (Laboratory Personnel Report), lack of documentation, and interview with the technical consultant (TC); the laboratory director (LD) failed to specify, in writing, the responsibilities and duties for one of one TC listed on the CMS-209. Findings include: 1. Review of the laboratory policies and procedures failed to identify documentation that specified, in writing, the responsibilities and duties for one of one TC listed on the CMS-209. 2. Interview with the TC on 06/05/2025, at 11:30 am, confirmed the LD failed to specify, in writing, the responsibilities and duties for one of one TC listed on the CMS-209.