Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0692370	01/31/2025
Name of Provider or Supplier	**Street Address, City, State**	
International Medical Laboratory	15 Corporate Park, Irvine, CA	

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
D2075	GENERAL IMMUNOLOGY CFR(s): 493.837(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on review of the laboratory's AAB-Medical Laboratory Evaluation (AAB) proficiency testing (PT) records, seven (7) randomly chosen patients sampling, and interview with the laboratory's technical supervisor (TS) and testing personnel (TP); it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for Rheumatoid Factor (RA/RF) on the third event of 2024 (Q3-2024). The findings included: 1. The API proficiency program gave an unsatisfactory score of 60% for RA/RF on the third event of 2024 (Q3-2024). 2. The TS and TP confirmed on January 31, 2025, at approximately 11:25 a.m. that the laboratory received the above proficiency score of 60% for RA/RF for the third event of 2024 described in 1. 3. From three (3) out of seven (7) patients test results reviewed, RA/RF test results have been reported during the time the PT survey was unacceptable for which results cannot be assured. 3. Based on the laboratory's annual testing declaration submitted on the day of the survey January 31, 2025, the laboratory tested and reported approximately 15,300 General Immunology tests including RA/RF by the Roche Cobas 6000 instrument.
D2098	ENDOCRINOLOGY CFR(s): 493.843(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.

	This STANDARD is not met as evidenced by: Based on review of the laboratory's AAB-Medical Laboratory Evaluation (AAB) proficiency testing (PT) records, the Certification and Survey Provider Enhancement Reporting (CASPER) report, and interview with the laboratory technical consultant (TS) on January 31, 2025, at approximately 12:00 p.m., it was determined that the laboratory failed to attain a score of at least 80% of acceptable responses for the HCG analyte for the third event of 2024 (Q3-2024). The findings include: 1. Based on the AAB and CASPER reports the laboratory obtained a score of 40% for the HCG analyte. This score resulted in an unsatisfactory analyte performance for the event. 2. The laboratory's TC affirmedon January 31, 2025 at approximately 12:30 p.m., that the laboratory received a 40% score for the HCG analyte as stated in number 1. 3. The laboratory's testing declaration form signed by the laboratory director on 12/18/2024, stated that the laboratory performed approximately 24,600 Endocrinology samples including HCG, annually.
D3007	FACILITIES CFR(s): 493.1101(b) The laboratory must have appropriate and sufficient equipment, instruments, reagents, materials, and supplies for the type and volume of testing it performs. This STANDARD is not met as evidenced by: Based on the surveyor's observation during the laboratory's tour, review of laboratory policies and procedures, and interviews with the technical supervisor (TS) and testing personnel (TP); it was determined that the laboratory failed to have and use a Biosafety Cabinet (BSC) when processing microbiology samples (sputum, wounds, etc.). Findings include: 1. The surveyor observed during the laboratory's tour no BSC was available in the microbiology laboratory were sputum and other samples are processed. 2. The TS and TP affirmed by interview that the laboratory lacked a designated BSC for the processing of sputum and other microbiologic specimens possibly containing highly pathogenic organisms. 3. Based on the testing volume declaration the laboratory processed and reported approximately 9,5000 microbiology tests annually.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on the surveyor's observation during the laboratory tour and interview with the laboratory technical supervisor (TC) and testing personnel (TP); it was determined that the laboratory failed to have procedures and changes in procedures approved, signed, and dated by the current laboratory director before use. The findings included: 1. On the day of the survey January 31, 2025, at approximately 2:00 p.m. the Individualized Quality Control Program (IQCP) microbiology manual in place in the laboratory had not been approved, signed, and dated by the laboratory director. 2. The TC and TP affirmed on December 31, 2025, that the laboratory failed to update protocols for the current IQCP in place for testing performed in the microbiology laboratory and that the effective date and the laboratory director's signature were

	missing. 4. The laboratory's testing declaration form stated that the laboratory processes approximately 9,500 bacteriology patients' samples annually.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on the surveyor's observation during the laboratory tour and interviews with the laboratory technical supervisor (TS) and testing personnel (TP); it was determined that the laboratory failed to follow the BBL antibiotic dispenser manufacturer's instructions on the use of a desiccant plate or desiccant materials when storing antibiotics in the freezer or refrigerator. The findings included: 1. The laboratory used three (3) BBL Antibiotic Dispensers in the microbiology laboratory to perform antibiotic susceptibility by the manual Kirby Bauer Method for which none of the three (3) antibiotic dispensers had desiccants. 2. The laboratory did not have available any antibiotic desiccant as recommended by BBL antibiotic dispenser manufacturer. 3. The TS and TP affirmed on December 31, 2025, at approximately 1:30 p.m. that no desiccants were available and used when storing BBL antibiotic discs dispensers in the freezer or refrigerator. 4. According to the testing volume declaration at the time of the survey, the laboratory performed 9,500 Bacteriology susceptibility testing by the manual Kirby Bauer method annually.
D5503	BACTERIOLOGY CFR(s): 493.1261(a)(2) (a) The laboratory must check the following for positive and negative reactivity using control organisms: (a)(2) Each week of use for gram stains. This STANDARD is not met as evidenced by: Based on the surveyor's observation during the laboratory tour, review of the laboratory's bacteriology quality control records, and an interview with laboratory's technical supervisor (TS) and testing personnel (TP) on January 31, 2024, at approximately 2:30 p.m.; it was determined that quality control result for gram staining documentation were missing for 2023 and 2024. Findings include: 1. Based on the surveyor's observation there were no in-house prepared or commercial quality control slides for Gram stain available. 2. Based on review of the laboratory documentation for Gram stain quality control in microbiology, there were no records to document controls were examined weekly. 3. The TC and TP affirmed the Gram stain controls were not used or documented for the years 2023 and 2024.

D6082	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1) The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing. This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's policies and procedures, proficiency testing records, quality control documentation, seven (7) randomly selected patients test records, observation during the laboratory tour, and interviews with the laboratory technical supervisor and testing personnel on January 31, 2025; it was determined that the laboratory director is cited herein due to failure to ensure that several aspects of the preanalytic, analytical, and postanalytic phases of the laboratory testing were monitored. See D2075, D2098, D3007, D5407, D5437, and D5503