Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D0170905	05/10/2023
Name of Provider or Supplier	**Street Address, City, State**	
Immco Diagnostics Inc	10 Earhart Drive, Williamsville, NY	

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
D0000	An announced CLIA exempt-state validation survey was conducted at the Immco Diagnostic Inc. from May 9 to May 10 2023, by the CMS New York and Boston CLIA federal surveyors. The laboratory was surveyed under 42 CFR part 493 CLIA regulations. The laboratory was found to not be in compliance with condition-level CLIA requirements. The survey findings are cited as the following:
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on the review of proficiency testing records and interview with the general supervisor (GS), the laboratory failed to have the individual performing test samples and the laboratory director attest to the routine integration of the samples into the patient workload using the laboratory's routine methods from 2021 to 2022. Findings Include: 1. On the day of survey, May 9, 2023 and May 10, 2023, the laboratory could not provide attention statements for the follow PT events: 2022 - S2 - C - NO ATTESTATION. June 2022 - UK NEQAS Myositis Associated Antibodies. Feb 2022 - UK NEQAS Myositis Associated Antibodies. Feb 2022 - UK Paraneoplastic Antibodies. 2022 mag Igm - No Attestation. UK NEQAS Attestation form 2022 not signed by LD. 2. The GS and LD confirmed the findings on May 10, 2022 at 3:30 pm.
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years.

	This STANDARD is not met as evidenced by: Based on lack of records and interview with the general supervisor (GS), the laboratory failed to retain the College of American Pathologist (CAP) and UK NEQAS proficiency testing (PT) records form 2021. Findings Include: 1. On the day of survey, May 9, 2023, the GS was unable to provide PT records for CAP and UK NEQAS for 2021. 2. The GS could not provide the In house PT records for the analytes listed on DX0341 performed in October 2022. 3. On May 9, 2023 around 11: 00 and the GS stated after the CLEP survey she discarded all the 2021 PT records and was unable to find the in house PT records from October 2022.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on a review of the laboratory proficiency testing programs records and an interview with the general supervisor (GS), the laboratory failed to evaluate and document PT results of less than 100% in 2021 and 2022. Findings Include: 1. QAP Number: 045 - Proficiency Testing in the Quality Assurance Policy - 5.0 Procedure - 5.1.5 states, "Remedial action for all proficiency testing must be performed and documented for all results that were not 100% accurate. 5.1.7 The Technologist performing the assay must signed the attestation statement if applicable. Copes of all data regarding the assay must be included even though the actual test results are electronically submitted to the respective agency". 1. On the days of survey, May 9, 2023 to May 10, 2023, the laboratory could not provide correction actions documents for the following PT program events: a. UK NEQAS MAG IgM - Distribution 223 May 2022 - 2 samples (50%). b. UK NEQAS Celiac Disease - Distribution 226 November 2022 - 2 samples (50%). c. College of American Pathologist (CAP) HQBX2-A 2021 Dermatologic Biopsy Module - 3 samples (66%). 3. The Laboratory Director, TS and GS confirmed the findings above during the submission on May 10, 2023 around 2:30 pm.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on the lack of documents during the quality assurance record review, review of policy and procedures, and an interview with the laboratory director, the laboratory failed to follow established policies for addressing specimen identification errors occurring during the accessioning process during the months of February 2022 and March 2023. Finding Include: 1. On May 09, 2023, at approximately 1:30 PM, a review of the laboratory's quality assurance records from the 2023- Quality Assurance (QA) log revealed the following: a. March 2023: i. Name on request and tube differ - 1. ii. Problem/occurrence column had no information documented in the section. iii.

	Action Taken column states " LC called for patient results on Pt#2. This is how discrepancy was found". iv. Date completed column has no information documented in the section. v.The laboratory did not have a CAPA report accompanying this documentation. . 2. On May 10, 2023, at approximately 11:00 am, a review of the laboratory's 2022- Quality Assurance Log revealed the following: a. February 2022 i. Quality Assurance Totals for the month of February 2022 indicate the laboratory received a name on request and tube differ. Documented actions performed by the laboratory included: 1. During the February 2022 incident the laboratory director sent an email apologizing for delayed results. 2. The patient test report displays a note "Pt. name on req. looked like "Loan", not Wan. 2/9/22. 3. The Laboratory included the Immcostripe Myositis Immunoassay test worksheet dated 12/9/2021. 4. The laboratory did not have a CAPA report accompanying this documentation. ii. The QA Log binder included a diagnostic Immunology QAPI Program -2022 Chart which displayed that no CAPAs were open/initiated from January 2022 - December 2022. 3. On May 9, 2023, at approximately 2:00 PM, a review of the laboratory's policy and procedure revealed the laboratory has an established Specimen Collection and Processing Procedure and "Corrective and Preventative Action" (CAPA) Procedure. The procedures included the following: a. Specimen Collection and Processing: i. Subsection 5.5: Unlabeled Specimens. ii. 5.5.2.2 "Under no circumstances must a specimen be tested if not properly labeled. This means: Patient name on the request and tube differ". b.CAPA: i. In response to major/minor non-conformances, the laboratory must document long-term actions taken to prevent the occurrence from recurring. ii. Completed CAPA will be maintained by the QA. 4. During the exit interview, the laboratory director confirmed the laboratory did not follow the established Corrective and Preventative Action Procedure for the incidents when the laboratory processed and resulted samples from incidents when patient requisitions differed from the specimen tube.
D5300	PREANALYTIC SYSTEMS CFR(s): 493.1240 Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the preanalytic systems and correct identified problems as specified in 493. 1249 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on a review of records, laboratory reference manual, final test reports, test requisitions, and interview with the general supervisor (GS), the laboratory failed to monitor and evaluate the overall quality of preanalytic systems. Findings include: 1. The laboratory failed to ensure patient specimen stability for the MBL DSG-1 & DSG-3, the Paraneoplastic Neuronal Profile, and QUANTA Lite sp100 and gp210 patient specimens prior to patient testing. Refer to D5311.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when

appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.

This STANDARD is not met as evidenced by:
Based on a review of records, laboratory reference manual, test requisitions, final patient test reports, and interview with the general supervisor (GS), the laboratory failed to ensure patient specimen stability for one MBL DSG-1 & DSG-3 ELISA patient test, four of four Paraneoplastic Neuronal Profile patient tests, and three of six QUANTA Lite sp100 and gp210 patient tests. Findings include: MBL DSG-1 & DSG-3 ELISA 1. On 05/10/2023 at 11:30 am, the GS stated the laboratory performed the MBL DSG-1 & DSG-3 ELISA test for the detection of autoantibodies to DSG-1 (Desmoglein -1) and DSG-3 (Desmoglein-3). 2. On 05/10/23, a review of the laboratory reference manual for DSG-1 and DSG-3 (pages 42 and 43) stated, "Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is table refrigerated (2-8C) up to five days and frozen (-20C or lower) up to one year". 3. On 05/10/2023, a review of a patient's final test report and test requisition revealed no evidence the specimen was transported to the laboratory frozen (-20C or lower), according to the laboratory reference manual. a. Patient sample# 23-023814 collected on 01/27/2023; received on 02/06/2023 (9 days later); and reported on 02/21/2023. 4. The GS confirmed the findings on 05/10/2023 at 12:45 pm. PARANEOPLASTIC NEURONAL PROFILE 1. On 05/10/2023 at 10:00 am, the GS stated the laboratory performed the Paraneoplastic Neuronal Profile test for the detection of anti-neuronal (paraneoplastic) autoantibodies (anti-Yo, Anti-Hu, anti-Ri, and anti-Tr). 2. On 05/10/23, a review of the laboratory reference manual for Paraneoplastic Neuronal Profile (page 51) stated, "Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is stable refrigerated (2-8C) up to five days and frozen (-20C or lower) up to one year". 3. On 05/10/2023, a review of patient's final test reports and test requisitions revealed no evidence the specimens were transported to the laboratory according to the laboratory reference manual for four of four patients: a. Patient sample# 23-030314 - CSF (Cerebrospinal Fluid) collected on 04/03/2023; received on 04/12/2023 (9 days later); and reported on 04/14/2023. No evidence to show the specimen was transported to the laboratory frozen (-20C or lower). b. Patient sample# 23-030598 030314 - CSF (Cerebrospinal Fluid) collected on 04/06/2023; received on 04/12/2023 (6 days later); and reported on 04/14/2023. No evidence to show the specimen was transported to the laboratory frozen (-20C or lower). c. Patient sample# 23-030393 030314 - CSF (Cerebrospinal Fluid) collected on 04/07/2023; received on 04/12/2023 (5 days later); and reported on 04/14/2023. No evidence to show the specimen was transported to the laboratory refrigerated (2-8C). d. Patient sample# 23-030821 - CSF (Cerebrospinal Fluid) collected on 04/10/2023; received on 04/13/2023 (3 days later); and reported on 04/14/2023. No evidence to show the specimen was transported to the laboratory at ambient temperature. 4. The GS confirmed the findings on 05/10/2023 at 10:35 am. QUANTA LITE sp100 AND gp210 ELISA 1. On 05/10/2023 at 12:05 pm, the GS stated the laboratory performed the QUANTA Lite sp100 ELISA test for the detection of anti-sp100 antibody of the IgG class and the QUANTA Lite gp210 ELISA test for the detection of anti-gp210 antibody of the IgG class. 2. On 05/10/23, a review of the laboratory reference manual (pages 61 and 62) stated: a. QUANTA Lite sp100 ELISA test - "Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is stable refrigerated (2-8C) up to five days and frozen (-20C or lower) up to one year" b. QUANTA Lite gp210 ELISA test- "Sample is stable at ambient temperature during shipment. If sample is stored prior to

	shipment, it is stable refrigerated (2-8C) up to five days and frozen (-20C or lower) up to one year" 3. On 05/10/2023, a review of patient's final test reports and test requisitions on 02/21/2023 and 04/11/2023 revealed no evidence the specimens were transported, according to the laboratory reference manual for three of six patients. a. Patient sample# 23-023906 collected on 02/02/2023; received on 02/08/2023 (6 days later); and reported gp210 IgG test results on 02/21/2023. There was no evidence the specimen was transported frozen (-20C or lower). b. Patient sample# 23-030417 collected on 04/04/2023; received on 04/10/2023 (6 days later); and reported sp100 IgG test results on 04/11/2023. There was no evidence the specimen was transported frozen (-20C or lower). c. Patient sample# 23-030418 collected on 04/04/2023; received on 04/10/2023 (6 days later); and reported sp100 IgG test results on 04/11 /2023. There was no evidence the specimen was transported frozen (-20C or lower). 4. The GS confirmed the findings on 05/10/2023 at 01:10 pm.
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 a review of records and interview with the laboratory director and general supervisor (GS), the laboratory failed to ensure the MESACUP BP180 (Bullous pemphigoid) and BP230 ELISA (Enzyme-linked immunosorbent assay) kit was not used beyond its expiration date for six of six patients tested. Findings include: 1. On 05/10/2023 at 10:45 am, the GS stated the laboratory performed the MESACUP BP180 and BP230 ELISA kit for the detection of anti-BP autoantibodies; 2. On 05/10 /2023, a review of patient testing records between 02/21/2023 and 03/13/2023 revealed six of six patients were tested with an expired kit, Lot# 085FA expiration date 01/31/2023: a. Patient sample# 23-024216 tested on 02/21/2023. b. Patient sample# 23-026231 tested on 03/13/2023. c. Patient sample# 23-026233 tested on 03 /13/2023. d. Patient sample# 23-026425 tested on 03/13/2023. e. Patient sample# 23-026695 tested on 03/13/2023. f. Patient sample# 23-026276 tested on 03/13/2023. 3. The laboratory director confirmed the findings on 05/10/2023 at 11:45 am.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on a review of records, policies and procedures, and interview with general supervisor (GS), the laboratory failed to define a written function check protocol to

	ensure the plate rotator was functioning properly from January 2022 through December 2022. Findings include: 1. On 05/10/2023 at 01:00 pm, the GS stated the following: a. The laboratory performed the Buhlmann anti-SGPG (Sulfate-3-Glucuronyl Paragloboside) ELISA (Enzyme-linked immunosorbent assay) for the detection of IgM autoantibodies directed against SGPG; b. TMB (Tetramethylbenzidin) substrate was added to diluted serum and placed on a plate rotator set at 800-1000 rpm (revolutions per minute) for 30 minutes. 2. A function check protocol that defined the frequency of the plate rotator speed check, timer check, and acceptable limits for the checks could not be located. 3. During an interview on 05/10/2023 at 11:15 am, the GS stated the laboratory equipment was checked by an outside company at least annually. 4. The GS confirmed the findings on 05/10/23 at 01:20 pm, the laboratory did not have a written function check protocol for the plate rotator to ensure the plate rotator was functioning properly.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: A. Based on, lack of documentation and interview with the general supervisor, the laboratory failed to evaluate the relationship between 2 of 2 68D - kD Profiblots twice a year in 2022. Finding Include: 1. The QAP Number 060: The In-house Quality Assurance Proficiency Testing Program procedure states: 5.0 Procedure 5.2 "This will be performed at least twice a year for each test". 5.3 "If multiple instruments are used for a particular test, samples are to be run on each instrument to show consistency across units". 2. On the day of survey, May 10, 2023, the laboratory was unable to provide documentation for 2 of 2 - 68D - kD Profiblot performed on twice a year in 2022. 3. The GS confirmed the findings above on May 10, 2023 around 2:00 pm. 47272 B. Based on a review of records and interview with general supervisor (GS), the laboratory failed to have a system that twice a year evaluated and defined the relationship between test results for Celiac Disease testing performed using two test methods during the review period of January 2022 through December 2022. Findings include: 1. On 05/09/2023 at 09:45 am, the GS stated the laboratory performed Celiac Disease testing using two SQI Diagnostics Squidlite analyzers, denoted by the laboratory as "9006" and "9007". 2. On 05/10/2023, a review of records from January 2022 through December 2022 revealed the relationship between the two test methods had not been evaluated. 3. The GS confirmed the findings 05/10/2023 at 09:50 am, the relationship between the above test methods had not been evaluated at least twice annually as stated above.