Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D2151696	08/26/2021
Name of Provider or Supplier	**Street Address, City, State**	
Omni Laboratory Services	5862 N Lincoln Ave, Chicago, 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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on record review and interview, the laboratory failed to enroll in an HHS approved proficiency testing (PT) program for tests performed in the subspecialties of Bacteriology and General Immunology during the years of 2019 to 2021. Findings include: 1. Patients' test records from 12/2019 to 08/2021, the American Proficiency Institute (API)-PT documents for the years of 2019 to 2021, manufacturer's package insert, and procedures manual were reviewed. 2. The patients' final reports and manufacturer's package inserts revealed the following: *For 14 out of 14 selected patients, the laboratory performed and reported test results for these analytes: Heliobacter pylori (H.Pylori); Rheumatoid Factor (RF); Hepatitis C antibody (HCV); and Hepatitis B surface Antigen (HbsAg). *The methods used to test for H.Pylori, RF, HCV and HbsAg were all non-waived. 3. The laboratory's PT policy stated the following: "The laboratory will be enrolled in an approved Proficiency Testing for all regulated analytes as specified in Subpart I, Proficiency Testing Programs for Non-waived testing, ...". 4. The API-PT data records showed the laboratory failed to enroll in the subspecialties of Bacteriology and General Immunology for the analytes listed

	in findings #2. 5. On a Recertification survey conducted on 08/26/2021 at 4:00 PM, the general supervisor confirmed the above findings and stated he thought the tests were waived and did not require PT enrollment.
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on review of the American Proficiency Institute (API) proficiency testing (PT) reports and interview, the laboratory failed to successfully participate in their PT program for each Hematology analyte (D2130).
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 record review and interview, the laboratory failed to attain a score of at least 80 percent for SARS-CoV-2 IgM and C-Reactive Protein during the years of 2020 and 2021. Findings: 1. The American Proficiency Institute (API) proficiency testing (PT) Immunology results for the years of 2020 and 2021 and PT policies and procedures were reviewed. 2. The laboratory failed to achieve satisfactory performance scores for the following analytes: GENERAL IMMUNOLOGY *SARS-CoV-2 IgM - Event #3, 2020 = 33% - Unsatisfactory *C-Reactive Protein (qual) - Event #1, 2021 = 50% - Unsatisfactory 3. The laboratory's PT policy instructed the following: "When graded PT results are unsatisfactory, will evaluate the results and take appropriate corrective action as specified in Corrective Action Checklist:" 4. The laboratory failed to follow PT policies and procedures to investigate PT failures (unsatisfactory results) and take appropriate corrective action for SARS-CoV-2 IgM and C-Reactive Protein testing when failure scores were received. 5. On a Recertification survey conducted on 08/26/2021 at 10:45 AM, the general supervisor confirmed the above findings.

D2130	HEMATOLOGY CFR(s): 493.851(f) Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and interview, the laboratory failed to achieve satisfactory performance for the Hematology analytes erythrocyte count (RBC) and hematocrit (HCT) during the years of 2020 and 2021. Findings include: 1. The American Proficiency Institute (API) proficiency testing (PT) documents from 2019 to 2021 and procedures manual were reviewed. 2. The API-PT reports on 08/26 /2021 at 10:30 AM, revealed the laboratory received unsuccessful PT performance for the Hematology analytes as listed below: HEMATOLOGY Erythrocyte Count, RBC - Event #3, 2020 = 0% - Unsatisfactory Erythrocyte Count, RBC - Event #2, 2021 = 20% - Unsatisfactory Hematocrit (Hct) - Event #3, 2020 = 0% - Unsatisfactory Hematocrit (Hct) - Event #2, 2021 = 0% - Unsatisfactory 3. Further review showed the PT failures were noted but failed to provide documented evidence the failures were investigated and corrective actions implemented by the laboratory director (LD) or general supervisor (GS). 4. Review of the PT policy revealed the following instructions: "When graded PT results are unsatisfactory, will evaluate the results and take appropriate corrective action as specified in Corrective Action Checklist:" 5. The laboratory failed to follow PT policies and procedures to investigate PT failures (unsatisfactory results) and take appropriate corrective action for RBC and Hematocrit testing when failure scores were received. 6. On a Recertification survey conducted on 08/26/2021 at 4:00 PM, the GS confirmed the above 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 record review, lack of documentation, and interview, the laboratory failed to establish and follow written policies and procedures to assess employees performing Bacteriology and General Immunology testing for three out of three testing personnel (TP). Findings: 1. The Laboratory Personnel Report (CMS 209), the laboratory's policies, procedures and 14 randomly selected patients' final reports from 12/2019 to 08/2021 were reviewed. 2. CMS 209 lists three TP (TP1, TP2, and TP6) performing the following tests: GENERAL IMMUNOLOGY Anti-Streptolysin O (ASO) C-Reactive Protein (Crp) Rheumatoid Factor (RF). Hepatitis C antibody (HCV), and Hepatitis B surface Antigen (HbsAg). BACTERIOLOGY Heliobacter pylori (H. Pylori) 3. The personnel documents showed three out of three TP had not received competencies for the years of 2019 thru 2021 but were performing patient testing during this period. 4. The laboratory's manual failed to include the following criteria in their competency policy and step-by-step procedure for evaluating TP performing General Immunology and Bacteriology testing: a) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing, as applicable; b). Monitoring the recording and

	reporting of test results (for example, recording patients and their results in the labs' test log and EMR system); c). If applicable, review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records; d). Direct observation of performance of instrument maintenance and function checks; e). Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; f). Assessment of problem solving skills; and g). Evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. Thereafter, evaluations must be performed at least annually. 5. On a Recertification survey conducted on 08/26/2021 at 10:15 AM, the general supervisor confirmed the above findings.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, 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 analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of the procedures manual, quality control (QC) records, manufacturer's instructions, and an interview with the general supervisor (GS), the laboratory failed to have complete written procedures for seven out of seven assays and tests when the manufacturer's package inserts or operator's manuals are used as procedure manual (D5405); failed to establish the performance specifications for new analyzer for hematology analysis (D5421); failed to establish the performance specifications for two out of two laboratory developed tests (D5423); failed to establish control procedures for six out of eight tests performed (D5441); and failed to establish and follow written policies and procedures to perform quality assessment (QA) of all analytic systems (D5791).
D5405	PROCEDURE MANUAL CFR(s): 493.1251(c) Manufacturer's test system instructions or operator manuals may be used, when applicable, to meet the requirements of paragraphs (b)(1) through (b)(12) of this section. Any of the items under paragraphs (b)(1) through (b)(12) of this section not provided by the manufacturer must be provided by the laboratory. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory's procedure manual failed to include all the applicable requirements specified in 493.1251(b)(1) - (14) when the manufacturer's test system instructions or operator manuals are used for all tests and assays performed by the laboratory for General Immunology, Bacteriology, and Hematology testing, affect 24 out 24 patients. Findings Include: 1. The laboratory's procedure manual, manufacturer's package inserts, and randomly selected patient test records from 12/2019 to 08/2021 were reviewed. 2. The laboratory used the following

	testing system: HEMATOLOGY Cell-Dyne Emerald Cell Blood Count (CBC) analyzer GENERAL IMMUNOLOGY Instant-View Hepatitis B Surface Antigen (HbsAg) One-Step Serum Cassette test kit; Hepatitis C Virus Antibody (Anti-HCV) kit test (No brand name) Rheumatoid Factor (RF), Anti-Streptolysin-O (ASO), and C-Reactive Protein (CRP) slide test kits. BACTERIOLOGY Instant-View Heliobacter Pylori (H.Pylori) Serum Cassette test kit; 3. Review of the procedures manual and manufacturer's package insert revealed the laboratory failed to include the following written policies and procedures: *Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242 for each test system. * The Control procedures for each test system listed in findings #2. * Corrective action to take when control results fail to meet the laboratory's criteria for acceptability. * Reference intervals (normal values). * Imminently life-threatening test results, or panic or alert values, if applicable * The laboratory's system for entering results in the patient record and reporting patient results including, *When appropriate, the protocol for reporting imminently life-threatening results, or panic, or alert values; and * Description of the course of action to take if a test system becomes inoperable. 4. The final reports of 24 out of 24 patients selected for review included Hematology, Bacteriology, and General Immunology results. 5. On a Recertification survey conducted on 08/26/2021 at 4:00 PM, the general supervisor confirmed the above findings.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and interview, the laboratory failed to demonstrate that it could obtain performance specifications comparable to those established by the manufacturer before reporting patients' erythrocytes (RBC); lymphocytes (WBC); hematocrit (Hct); hemoglobin (Hgb) and platelets results, affecting 360 tests. Findings: 1. The Cell-Dyne Emerald validation records performed on 09/30/2020, quality control (QC) documents, patient results, and the Clinical Laboratory Improvement Amendments (CLIA) application were reviewed. 2. The laboratory used the Cell-Dyne Emerald Cell Blood Count (CBC) analyzer for the following analytes: RBC; WBC; Hct; Hgb and Platelets. 3. The laboratory failed to obtain the operator's manual for the CBC analyzer to ensure verification procedures were performed and manufacturer's performance specifications verified. 4. The laboratory failed to provide verification documentation to show the Cell Dyne analyzer's: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. 5. Review of the 09/30/2020 linearity data showed no evidence of review, adjustment, corrective action or approval by the laboratory director (LD). 6. The QC records and test results showed the laboratory had been testing since 12/2019. 7. The CLIA application signed

	by the LD on 08/26/2021 documents the laboratory performed an annual estimated volume of 360 Hematology tests. 8. On a Recertification survey conducted on 08/26 /2021 at 12:00 PM, the general supervisor confirmed the above findings.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on record, Food and Drug Administration website, lack of documentation, and interviews, the laboratory failed to establish the performance specifications for the Hepatitis B Surface Antigen (HbsAg) and Hepatitis C Antibody (Anti-HCV) laboratory developed test systems not approved or have clearance by the FDA, affecting four out of 14 patients. Findings Include: 1. The quality control (QC) records, manufacturer's package inserts, patient test records from 12/2019 to 08/2021, and procedures manual were reviewed. 2. The laboratory used the following unapproved and uncleared FDA kits for testing HbsAg and Hepatitis C Antibody: *Instant-View HbsAg One-Step Serum Cassette test and Anti-HCV kit (No brand name). 3. Review of QC records and manual revealed the laboratory failed to establishment and perform methods to provide evidence that, as applicable, the (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. accuracy, precision, analytical sensitivity, and analytical specificity of the procedure is adequate to meet the patients' needs as determined by the laboratory director and clinical consultant. 4. The final reports of four out of 14 patients selected for review were tested using the HbsAg and Anti-HCV kits. 5. On a Recertification survey conducted on 08/26/2021 at 4:00 PM, the general supervisor confirmed the above findings.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g)

	The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and an interview, the laboratory failed to establish control procedures that monitor the accuracy and precision of the complete analytic process for testing performed in the subspecialty of General Immunology and Bacteriology for 24 out of 24 patients. Findings include: 1. The laboratory's procedure manual, quality control (QC) records, and randomly selected patient test records from 12/2019 to 08/2021 were reviewed. 2. The laboratory used the following test systems: GENERAL IMMUNOLOGY Instant-View Hepatitis B Surface Antigen (HbsAg) One-Step Serum Cassette test kit; Hepatitis C Virus Antibody (Anti-HCV) kit test (No brand name) Rheumatoid Factor (RF), Anti-Streptolysin-O (ASO), and C-Reactive Protein (CRP) slide test kits. BACTERIOLOGY Instant-View Heliobacter Pylori (H.Pylori) Serum Cassette test kit; 3. Review of the procedures manual and QC records revealed for each test system listed in findings #2, the laboratory failed to establish and follow QC procedures each day of patient testing. 4. The final reports of 24 out of 24 patients selected for review included HbsAg, Anti-HCV, RF, ASO, CRP and H.Pylori results. 5. The laboratory failed to establish and implement QC procedures for all tests prior to testing patients. 6. On a Recertification survey conducted on 08/26/2021 at 4:00 PM, the general supervisor confirmed the above findings.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and interview, the laboratory failed to establish and follow written policies and procedures to perform quality assessment (QA) of all analytic systems during the years of 2019 to 2021, affecting 5770 patient tests. Findings Include: 1. The laboratory's procedures manual, quality control (QC) documents for the years of 2019 to 2021, the Clinical Laboratory Improvement Amendments (CLIA) application, and patients reports were reviewed. 2. Review of the QC records and patient reports showed the laboratory began performing the following: *Cell Blood Count (CBC) analysis testing on patients in 08/2020; and *Hepatitis B Surface Antigen (HbsAg); Hepatitis C Virus Antibody (Anti-HCV); Rheumatoid Factor (RF), Anti-Streptolysin-O (ASO), C-Reactive Protein (CRP); and Heliobacter Pylori (H.Pylori) patient testing in 12/2019; 3. The procedures manual revealed the laboratory policies and procedures failed to include an ongoing mechanism to monitor, assess, and when indicated, correct identified problems in the new test systems in the specialty and subspecialties of Hematology, Bacteriology and General Immunology. 4. Further review showed the laboratory failed to document any an ongoing review process that encompasses all facets of the laboratory's technical and non-technical functions. 5. The CLIA application signed by the LD on 08/26/2021 documents the laboratory performed an annual estimated total volume of 5770 patient

	tests. 6. On a Recertification survey conducted on 08/26/2021 at 2:00 PM, the general supervisor confirmed the above findings and admitted he had not provided day-to-day supervision and oversight since the beginning of 2020.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on record review and interview the laboratory failed to include the test reported date for seven out of 14 patients' final reports. Findings include: 1. The patients' final reports from the electronic medical record (EMR) system and manual were reviewed. 2. The review of 14 patients' final reports revealed the following: *Patient-X1, X2, X3, X4, X6, X7, and X14 final reports failed to include the date reported. 3. The laboratory failed to include in its policies and procedures to ensure the final patient test report indicate the date reported to the authorized person. 4. On a Recertification survey conducted on 08/26/2021 at 4:00 PM, the general supervisor confirmed the above findings.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on review of manuals, personnel records, lack of documentaion, and interview, the laboratory director (LD) failed to provide overall management to ensure proficiency testing enrollment for Rheumatoid Factor (RF) and Heliobacter Pylori (H. Pylori) (D6015); failed to establish quality assessment (QA) policies and procedures (D6021) and failed to ensure that an approved standard operating procedure manual was available to all personnel (See D6031).
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed.

	This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory director (LD) failed to ensure the laboratory was enrolled in an approved proficiency testing (PT) program for the Rheumatoid Factor (RF) and Heliobacter Pylori (H.Pylori) testing performed during the years of 2020 and 2021, affecting 14 out of 14 patients results. Findings: 1. The American Proficiency Institute (API) proficiency testing (PT) program documents, procedures manual, quality control (QC) log sheets and 14 patients reports were reviewed. 2. The laboratory performed and reported test results for these non-waived analytes: H.Pylori, RF. 3. The LD failed to include the above analytes in their API-PT program. See D2000. 4. On a Recertification survey conducted on 08/26/2021 at 4:00 PM, the general supervisor confirmed the above findings.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and interview, the laboratory director (LD) failed to establish and implement quality assurance (QA) procedures which monitor, assess, and when indicated, correct identified problems in the laboratory. Findings include: 1. The laboratory's standard operating procedures manual was reviewed. 2. The LD failed to establish written procedures that provide an ongoing review process that encompasses all facets of the laboratory's technical and non-technical functions for the following phases of the testing process: *Preanalytic - assessing practices/issues related to test requests, specimen submission, handling and referral. *Analytic - assessing: practices/issues related to test procedures; accurate and reliable test systems; equipment, instruments; reagents; materials; and supplies; specimen and reagent storage condition; equipment/instrument/test/system maintenance and function checks; control procedures; comparison of test results. Corrective actions; and test records. See D5400, D5405, D5421, D5423, & D5441. *Post-analytic -assessing practices/issues related to test reports. See D5801. 3. On a Recertification survey conducted on 08/26/2021 at 4:00 PM, the general supervisor confirmed the above findings.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process;

	This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and interview, the laboratory director (LD) failed to ensure six out of six testing personnel (TP) had an approved procedure manual available for any aspect of the testing process. Findings: 1. The laboratory's standard operating procedures manual and manufacturers' package inserts were reviewed. 2. The LD failed to establish and make available the following procedures for 6 out of 6 TP: *Complete written procedures for their laboratory developed tests (LDT) and when manufacturer's instructions/package inserts or operator's manuals are used as the test system's procedure. See D5405. *Control procedures for all analytic systems. See D5441. *Quality assurance procedures for preanalytic, analytic, and postanalytic phases of the tests. See D5791 and D6021. 3. On a Recertification survey conducted on 08/26/2021 at 4:00 PM, the general supervisor confirmed the above findings.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on record review, employee files, and interview, the laboratory failed to ensure one out of three individuals meet the education and training requirements to perform Routine Chemistry, Hematology, Bacteriology, and General Immunology moderately complex tests (D6065 and D6066).
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy 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; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on record review, lack of documentation, the Laboratory Personnel Report (CMS-209) and interview, the laboratory failed to ensure one out of three laboratory employees meet the education qualification requirements for performing Routine Chemistry, Bacteriology, General Immunology, and Hematology. Findings: 1. The employee files, quality control (QC) records, patient test results, and CMS-209 were reviewed. 2. The CMS 209 lists TP (TP1, TP2, and TP6) performing the following tests and test systems: *Blood Chemistry analysis; Cell Blood Count (CBC) analysis;

	Rheumatoid Factor (RF), Anti-Streptolysin-O (ASO), and C-Reactive Protein (CRP); and Heliobacter Pylori (H.Pylori). 3. The employee files of TP6 revealed the following: *TP6 failed to have training and written authorization to perform patient testing; and *TP6 failed to provide proof of education. 4. The QC records and patient results showed TP6 was performing and reporting patient results. 5. The laboratory failed to ensure TP6 met the education requirement for performing moderately complex testing prior to testing patients. 6. On a recertification survey conducted 08 /26/2021 at 3:45 PM, the general supervisor confirmed the above findings.
D6066	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(4)(ii) Have documentation of training appropriate for the testing performed prior to analyzing patient specimens. This STANDARD is not met as evidenced by: Based on record review, lack of documentation, the Laboratory Personnel Report (CMS-209) and interview, the laboratory failed to document one out of three training for each personnel performing Routine Chemistry, Bacteriology, General Immunology, and Hematology Findings: 1. The employee files, CMS-209, and competency policy and procedures were reviewed. 2. The CMS 209 lists TP (TP1, TP2, and TP6) performing the following test and test systems: *Blood Chemistry analysis; Cell Blood Count (CBC) analysis; Hepatitis B Surface Antigen (HbsAg); Hepatitis C Virus Antibody (Anti-HCV); Rheumatoid Factor (RF), Anti-Streptolysin-O (ASO), and C-Reactive Protein (CRP); and Heliobacter Pylori (H.Pylori). 3. The employee files of TP6 failed to have documented evidence of training to perform the tests listed in findings#2. 4. The competency policy failed to include procedures for training personnel in the performance and evaluation (D5209) of the tests performed. 5. On a recertification survey conducted 08/26/2021 at 3:45 PM, the general supervisor confirmed the above findings.
D6085	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3) The laboratory director must ensure that the test methodologies selected have the capability of providing the quality of results required for patient care. This STANDARD is not met as evidenced by: Based on record review, manufacturer's package inserts, and interview, the laboratory director (LD) failed to ensure the Hepatitis B Surface Antigen (HbsAg) and Hepatitis C Antibody tests used for four out of four patients have the capability of providing the quality of results required for patient care. Findings include: 1. The laboratory used the following FDA unapproved laboratory developed test (LDT) kits: *Instant-View HbsAg One-Step Serum Cassette test - Hepatitis B Surface Antigen (HbsAg) testing, and *Anti-HCV kit - Hepatitis C Antibody testing. 2. The LD failed to establish methods to provide evidence that the accuracy, precision, analytical sensitivity, and analytical specificity of the 2 new test procedures were adequate to meet patients' needs prior to testing patients. See D5423. 3. The laboratory begin reporting HbsAg and Anti-HCV results in 12/2019. 4. On a Recertification survey conducted on 08/26 /2021 at 4:00 PM, the GS confirmed the above findings.

D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and interview, the laboratory director (LD) failed to ensure three out of six personnel have the appropriate training and have demonstrated that they can perform COVID19-PCR, Hepatitis B Surface Antigen and Hepatitis C Antibody testing prior to testing patients' specimens, affecting 5000 patients' tests. Findings include: 1. The laboratory personnel documents, the Laboratory Personnel Report (CMS 209), patients' test results, and the Clinical Laboratory Improvement Amendments (CLIA) application were reviewed. 2. The CMS 209 list 6 testing personnel (TP) performing high complexity testing: VIROLOGY: COVID19-PCR were performed by TP3, TP4, and TP5 GENERAL IMMUNOLOGY: Hepatitis B Surface Antigen and Hepatitis C Antibody were performed by TP1, TP2, and TP6. 3. The personnel records and test results revealed TP4, TP5, and TP6 training and assessment for competency had not been performed prior to testing and reporting patient results. 4. The LD failed to establish and implement training and assessment procedures for COVID19-PCR, Hepatitis B Surface Antigen and Hepatitis C Antibody testing to ensure all TP were competent, prior to test patients. 5. The CLIA application signed by the LD on 08/26/2021 documents the laboratory performed an annual estimated volume of 5000 Virology tests. 6. On a Recertification survey conducted on 08/26/2021 at 4:00 PM, the general supervisor confirmed the above findings.
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, the Laboratory Personnel Report (CMS 209), and interview, the laboratory failed to employ 4 out of six individuals who meet the qualification requirements to perform COVID-19 PCR, Hepatitis B Surface Antigen and Hepatitis C Antibody testing (D6170), prior to testing patients.
D6170	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(a) Each individual performing high complexity testing must possess a current license issued by the State in which the laboratory is located, if such licensing is required. This STANDARD is not met as evidenced by:

	Based on record review, the Laboratory Personnel Report (CMS-209), and interview, the laboratory failed to ensure two out of six testing personnel (TP) meet the education requirements for performing highly complex testing in the subspecialty of General Immunology for 1 out of 3 testing personnel (TP). Findings: 1. The CMS 209 and employee files were reviewed. 2. The CMS 209 list 6 TP (TP3, TP4, and TP5) to performing the following highly complex tests: VIROLOGY: COVID19-PCR were performed by TP3, TP4, and TP5 GENERAL IMMUNOLOGY: Hepatitis B Surface Antigen and Hepatitis C Antibody were performed by TP1, TP2, and TP6. 3. The employee files of TP4 and TP6 revealed the following: *TP4 had written authorization to perform patient testing; *TP4 failed to provide proof of education. *TP6. See D6063 and D6065. 4. The laboratory failed to ensure TP4 and TP6 met the education requirement for performing highly complex testing. 5. On a recertification survey conducted 08/26/2021 at 3:45 PM, the GS confirmed the above findings.