Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D2151696	08/30/2019
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 an interview with the laboratory director (LD), the laboratory failed to enroll in an HHS approved proficiency testing (PT) program for the subspecialty of General Immunology, affecting 9 out of 9 patients. Findings include: 1. The laboratory's patients' test records, PT documents, manufacturer's package insert, and final reports were reviewed. 2. The patients' test logs and manufacturer's package insert showed the following: *The laboratory was performing patient testing for the analytes: antistreptolysin-O (ASO) and C-reactive protein (CRP). *The method used to test for ASO and CRP was non-waived. 3. The America Proficiency Institute (API) PT program receipt showed that the laboratory failed to enroll in the subspecialty of General Immunology for the ASO and CRP testing performed. 4. The final reports of 9 out of 9 patients selected for review, included ASO and CRP test results. 5. On an Initial survey conducted on 08/30/2019 at 2:30 PM, the LD confirmed the above findings and stated he thought the tests were waived and did not require PT enrollment.
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 direct observation and an interview with the laboratory director (LD), the laboratory failed to have sufficient equipment for the type and volume of testing it performs. Findings include: 1. On 08/30/2019 at 11:58 AM during a tour of the laboratory, the surveyor observed the following: *A centrifuge seated on the floor, against the wall, by the laboratory's entrance door; *No table or workbench for processing patients' requisitions and specimens; and *No table or workbench to aliquot and prep specimens for chemistry and immunology testing. 2. The LD confirmed the above findings.
D5309	TEST REQUEST CFR(s): 493.1241(e) If the laboratory transcribes or enters test requisition or authorization information into a record system or a laboratory information system, the laboratory must ensure the information is transcribed or entered accurately. This STANDARD is not met as evidenced by: Based on record review, manuals, and an interview with testing personnel (TP2) and the laboratory director (LD), the laboratory failed to ensure the information transcribed or entered into the laboratory's information system (LIS) is transcribed or entered accurately, affecting 9 out of 9 patients. Findings Include: 1. The patients' requisitions, final reports, and laboratory manual were reviewed. 2. The 9 randomly selected patients' requisitions and final reports revealed the following: * 4 (A1, A2, A3, & A4) out of 9 requisitions failed to indicate the sex of the patient; *However, the final reports of patients A1, A2, A3, & A4 included the sex; *The laboratory failed to provide documentation from the provider that confirmed the sex of patients A1, A2, A3, & A4, prior to entering the information into the patients' LIS records. *8 out of 9 patients' requisitions had requests for tests the laboratory did not perform. *The laboratory failed to send 8 out of 8 patients' specimens to a referral laboratory when tests requested were not performed. *1 out of 9 patients' final report had an incorrect collection date; and *1 out of 9 patients' received results that were not requested in their requisition. 3. The laboratory's manual failed to include a policy and procedure which would establish an ongoing process that would ensure the accuracy of manual into the LIS by personnel. 4. On an Initial survey conducted on 08/30/2019 at 2:30 PM, the LD and TP2 confirmed the above findings.
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 record review and an interview with testing personnel (TP2); the laboratory failed to establish written procedures for specimen submission, handling, and referral, prior to receiving patient specimens for Routine Chemistry and General Immunology. Findings include: 1. The laboratory procedures manual was reviewed. 2. The manual failed to include the following written step-by-step procedures: * The laboratory failed to have written details on how specimens are labeled. * The laboratory failed to have written details on how specimens are prepared/processed for chemistry and immunology testing. * The laboratory failed to have written details on how specimens are prepared for transport when referring to another testing laboratory. 3. On an Initial survey conducted on 08/30/2019 at 2:30 PM, the LD confirmed the above findings.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) 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. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) 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. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on record review and an interview with the laboratory director (LD), the laboratory's procedures manual failed to include all the applicable requirements specified in 493.1251(b)(1) - (14) for all tests, assays, and examinations performed by the laboratory in the subspecialty of General Immunology, affecting 9 out of 9 patients. Findings: 1. The laboratory procedures manual and patients results were reviewed. 2. The laboratory performs patient testing for the analytes: antistreptolysin-O (ASO) and C-reactive protein (CRP). 3. The procedures manual failed to include the following written policies and procedures: * The Control procedures for the ASO and CRP Assays. * Corrective action to take when control results fail to meet the laboratory's criteria for acceptability. * Imminently life-threatening test results, or panic or alert values. * 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 9 out of 9 patients selected for review included ASO and CRP test results. 5. On an Initial survey conducted on 08/30/2019 at 2:30 PM, the LD confirmed the above findings.

D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review, manuals, manufacturer's instructions, and an interview with the laboratory director (LD), the laboratory failed to include negative and positive control material at least once a day patient specimens are assayed for General Immunology testing, affecting 9 out of 9 patients. Findings: 1. The laboratory's manual, the antistreptolysin-O (ASO) and C-reactive protein (CRP) assay package inserts, and patients' test log were reviewed. 2. The final reports and test logs revealed the following: *The ASO and CRP test results of 9 selected patients were tested and reported on 06/10/19; 06/25/19; 07/08/19; 07/15/19; and 08/25/19 *The negative and positive controls were included on 2 out of 5 dates patients were tested. 3. The laboratory's manual failed to include control procedures for the ASO and CRP assays performed. 4. On an Initial survey conducted on 08/30/2019 at 2:30 PM, the LD 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, the Laboratory Personnel Report (CMS-209), and an interview with the laboratory director (LD), the laboratory failed to employ individuals who meet the qualification requirements of 493.1423 for testing personnel (TP). Finding: 1. The laboratory failed to ensure laboratory personnel meet the qualification requirements for performing moderately complex testing in the subspecialties of General Immunology and Routine Chemistry. See D6065
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 direct observation, lack of documentation, review of the Laboratory Personnel Report (CMS-209), and an interview with the laboratory director (LD), the laboratory failed to ensure laboratory employees meet the education qualification requirements for performing moderately complex testing in the subspecialties of General Immunology and Routine Chemistry, affecting 1 out of 2 testing personnel (TP). Findings: 1. The employee files and CMS-209 were reviewed. 2. The CMS 209 lists 2 TP (TP1 and TP2) performing antistreptolysin-O (ASO) and C-reactive protein (CRP) testing in the laboratory. 3. On 08/30/2019 at 2:00PM, the surveyor observed TP2 processing patient specimens and performing blood chemistry testing. 4. The laboratory failed to provide the documentation of Employee TP2's education, training and experience. 5. On an Initial survey conducted on 08/30/2019 at 2:30 PM, the LD confirmed the above findings.