Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D2184935	02/09/2021
Name of Provider or Supplier	**Street Address, City, State**	
Chicago Lab Services Inc	7422 N Western Ave - Ste 1, 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
D5301	TEST REQUEST CFR(s): 493.1241(a) The laboratory must have a written or electronic request for patient testing from an authorized person. This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and an interview with the owner and testing personnel (TP3), the laboratory failed to have, from an authorized person, a written or electronic request for patient testing, affecting 5 out of 5 patients. Findings Include: 1. The laboratory's specimen rejection criteria policy and procedure, patients' requisitions, and final reports were reviewed. 2. The 5 randomly selected patients' requisitions and final reports revealed the following: * 5 (A1, A2, A3, A4, & A5) out of 5 patient reports failed to have requisitions; *The final reports of patients A1, A2, A3, A4, & A5 list "NO DOCTOR" as authorized person. 3. The laboratory's policy and procedure failed to include the requirement to have a written or electronic request for patient testing from an authorized person prior to testing the patient's specimen(s). 4. On an Initial survey conducted on 02/09/2021 at 11:30 AM, the owner and TP3 confirmed the above findings.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on review of laboratory records and an interview with the owner and testing

	personnel (TP3), the laboratory director (LD) failed to provides overall management and direction in accordance with 493.1445 of this subpart in the subspecialty of General Immunology and Endocrinology. Findings: 1. The LD failed to ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method used. See D6086. 2. The LD failed to have an approved standard operating procedure manual available to all personnel. See D6106. 3. The LD failed to specify, in writing, the responsibilities and duties of each laboratory personnel. See D6107.
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method. This STANDARD is not met as evidenced by: Based on record review and an interview with the owner and testing personnel (TP3); the laboratory director (LD) failed to ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method used for COVID-19 testing, affecting 20 out of 20 positive patients. Findings include: 1. The Emergency Use Authorization (EUA) for Atila BioSystems, Inc, the laboratory's Critical Log, and procedures manual were reviewed. 2. The laboratory was using the iAMP COVID-19 Detection Kit. 3. The verification procedures and test logs revealed the following: *The LD failed to approve the verification procedures and test results from the COVID-19 Detection Kit prior to testing patients. *The LD failed to indicate if the laboratory's test results met the performance characteristics defined in the Food and Drug Administration (FDA)-EUA, prior to testing patients. *The laboratory begin reporting COVID-19 results on 01/23/2021. *From 01/23/2021 through 02/01/2021, the laboratory reported 20 COVID-19 positive results. 4. On an Initial survey conducted on 02/09/2021 at 11:30 AM, the owner and TP3 confirmed the above findings.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must 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 and an interview with the owner and testing personnel (TP3), the laboratory director (LD) failed to ensure that an approved procedure manual is available to the personnel responsible for any aspect of the testing process, affecting 3 out of 3 TP. Findings: 1. The laboratory's standard operating procedures manual and laboratory personnel records were reviewed. 2. The laboratory personnel report (CMS 209) list 3 TP (TP1, TP2, and TP3) performing tests in the laboratory. 3. The LD failed to ensure all policies and procedures implemented for use by TP1, TP2, and TP3 were reviewed and approved prior to testing patients. 4. On an Initial survey conducted on 02/09/2021 at 11:30 AM, the owner and TP3 confirmed the above findings.

D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) The laboratory director must 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 record review, the Laboratory Personnel Report (CMS 209); the lack of documentation and an interview with the owner and testing personnel (TP3), the laboratory director (LD) failed to specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the pre-analytic, analytic, and post-analytic 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, in the specialties and subspecialties of Chemistry and General Immunology, prior to reporting patient test results. Findings include: 1. The laboratory personnel documents, CMS 209, and manuals were reviewed. 2. The LD failed to assign the following the duties/responsibilities, in writing: *Technical Supervisor *Technical Consultant; and *General Supervisor 3. The LD failed to define, in writing, the following for TP1, TP2, and TP3: *The procedures each individual is authorized to perform, *The duties the TP are to perform in the pre-analytic, analytic, and post-analytic phases of testing; *Whether supervision is required for specimen processing, test performance or result reporting; and *Whether supervisory or director review is required, prior to reporting patients' test results. 4. On an Initial survey conducted on 02/09/2021 at 11:30 AM, the owner and TP3 confirmed the above findings.