Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D2291574	02/14/2025
Name of Provider or Supplier	**Street Address, City, State**	
L C Medical Supplies Inc	146 W Higgins Rd, Hoffman Est, 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
D3005	FACILITIES CFR(s): 493.1101(a)(3) (a)(3) Molecular amplification procedures that are not contained in closed systems have a uni-directional workflow. This must include separate areas for specimen preparation, amplification and product detection, and, as applicable, reagent preparation. This STANDARD is not met as evidenced by: Based on surveyor's direct observation, review of laboratory records, and interview with the data technician (DT), the laboratory failed to maintain a uni-directional workflow for molecular amplification procedures to prevent potential cross-contamination in specimen processing, preparation, amplification, and detection of five of five virology analytes, SARS-CoV-2 (Covid), Influenza A (Flu A), Influenza B (Flu B), Respiratory Syncytial Virus (RSV), and Human Metapneumovirus (HMPV) from January 2025 through February 2025 affecting 3672 patient tests. Findings include: 1. Review of the "Atila BioSystems iAMP COV/FLU/RSV Detection Kit ...Instructions for Use" revealed the following information. a) "Quality Control ...General Considerations ... - Maintain separate areas and dedicated equipment (e.g. pipettes, microcentrifuges) and supplies (e.g. microcentrifuge tubes, pipette tips, gowns and gloves) for assay reagent setup and handling of processed samples. - Workflow must always be from the clean area to the dirty area." 2. Review of the "Atila BioSystems iAMP Human Metapneumovirus Detection Kit (RUO) ... Instructions for Use" revealed the following information. a) "Quality Control ... General Considerations ... - Maintain separate areas and dedicated equipment (e.g. pipettes, microcentrifuges) and supplies (e.g. microcentrifuge tubes, pipette tips, gowns and gloves) for assay reagent setup and handling of processed samples. - Workflow must always be from the clean area to the dirty area." 3. On 02/14/2025, at 10:56 a.m., direct observation during a laboratory tour with the DT revealed the laboratory failed to maintain a uni-directional workflow for the molecular

	amplification of SARS-CoV-2, Influenza A, Influenza B, Respiratory Syncytial Virus (RSV) and Human Metapneumovirus (HMPV): a) The transfer of patient samples to the patient testing plates and the addition of positive and negative control samples to the patient testing plates all performed in one biosafety cabinet (BSC) "ESCO Class II BSC Serial No. 2021-169223" utilizing one set of pipettes. 4. On 02/14/2025, at 10:56 a.m., the DT confirmed the 3672 patient tests recorded on the "Laboratory Non-waived CLIA Tests Volumes Work Sheet" were conducted in the same BSC with one set of pipettes.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) (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: (b)(2)(i) Accuracy. (b)(2)(ii) Precision. (b)(2)(iii) Analytical sensitivity. (b)(2)(iv) Analytical specificity to include interfering substances. (b)(2)(v) Reportable range of test results for the test system. (b)(2)(vi) Reference intervals (normal values). (b)(2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on review of laboratory records, lack of documentation, and interview with the data technician (DT), the laboratory failed to establish the performance specifications for one of five virology analytes Human Metapneumovirus (HMPV) utilizing the Atila BioSystems iAMP Human Metapneumovirus Detection Kit on PCR instrumentation marked "Serial No. 552550". Findings include: 1. During a tour of the laboratory on 02/14/2025, at 10:42 a.m., the surveyor observed one PCR instrument marked, "Atila BioSystems - Name: Fluorescent Quantitative Detection System ...S N: MDA6.0.94-551875" 2. Review of laboratory records revealed a validation study marked: "LC Medical Supplies ...Machine Serial Number: MDA6094-551875 ...Atila power Gene 9600 using I-AMP Human Metapneumovirus Detection kit ...Approved by Lab Director: XXX Date: 01-19-2025". 3. Review of laboratory records revealed two of six patient test results for HMPV performed on PCR instrumentation marked "Serial No. 552550". a. MRN: 1904 Reported Date: 02/05/2025 Test: HMPV Result: Negative Instrument Serial No: 552550 b. MRN: 2226 Reported Date: 02/08/2025 Test: HMPV Result: Negative Instrument Serial No: 552550 4. Review of laboratory records revealed no documentation of Accuracy, Precision, Analytical sensitivity, Analytical specificity to include interfering substances, Reportable range of test results for the test system, Reference intervals (normal values), and any other performance characteristics required for the adequate test performance for HMPV for "Serial No. 552550". . 5. On 02/14/2025 at 3:43 p.m., the DT confirmed the validation study for Instrument Serial No: 552550 was not available for surveyor review.