Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D2252339	10/07/2024
Name of Provider or Supplier	**Street Address, City, State**	
Dupage County Diagnostics Llc	1315 Butterfield Rd - Unit 200, Downers Grove, 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
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on review of laboratory records, lack of documentation and interview with the technical supervisor (TS), the laboratory failed to perform American Proficiency Institute (API) proficiency testing (PT) sub-specialty virology samples (SARS-CoV-2, Influenza A, Influenza B and Respiratory Syncytial Virus (RSV)) with the laboratory's regular patient workload for five of five Microbiology PT Events from Event 1, 2023 to Event 2, 2024. Findings include: 1. Review of the "Dupage County Diagnostics Proficiency Testing" policy revealed the following information: " ...5. PT samples should be tested in the same manner as the patient's sample ...the lab director (or the designee) are required to attest that the PT samples were tested I the same manner as patient's samples." 2. Review of the laboratory's API PT instrument run printouts for Microbiology Events 1, 2, and 3, 2023 and Microbiology Events 1 and 2, 2024 revealed no patient samples included on the PT runs. a) API 2023 Microbiology - Event 1: Samples: COV - 01 (SARS-CoV-2), COV - 02 (SARS-CoV-2), COV - 03 (SARS-CoV-2), COV - 04 (SARS-CoV-2) b) API 2023 Microbiology - Event 2: Samples: COV - 03 (SARS-CoV-2), COV - 04 (SARS-CoV-2) c) API 2023 Microbiology - Event 3: Samples: COV - 05 (SARS-CoV-2), COV - 06 (SARS-CoV-2) d) API 2024 Microbiology - Event 1: Samples: SAR - 01 (SARS-CoV-2), SAR - 02 (SARS-CoV-2) e) API 2024 Microbiology - Event 2: Samples: SAR - 06 (SARS-CoV-2), SAR - 07 (SARS-CoV-2) Influenza A (SFR-06, SFR-07, SFR-08, SFR-09, SFR-10) Influenza B (SFR-06, SFR-07, SFR-08, SFR-09, SFR-10) RSV (SFR-06, SFR-07,

	SFR-08, SFR-09, SFR-10) SARS-CoV-2 (SFR-06, SFR-07, SFR-08, SFR-09, SFR-10) 3. On 10/07/2024, at 4:27 p.m., the TS confirmed the PT was not peformed with patient samples.
D3000	FACILITY ADMINISTRATION CFR(s): 493.1100 Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe. This CONDITION is not met as evidenced by: Repeat Deficiency Based on surveyor's direct observation, laboratory records, and interview with the technical supervisor (TS), 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 SARS-CoV-2, Influenza A, Influenza B, and Respiratory Syncytial Virus (RSV) from December 2022 through 2024, affecting over 77,500 patient tests (Refer to D3005) and failed to retain American Proficiency Institute (API) proficiency testing (PT) records for two years (Refer to D3037).
D3005	FACILITIES CFR(s): 493.1101(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: Repeat Deficiency Based on surveyor's direct observation, laboratory records, and interview with the technical supervisor (TS), 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 SARS-CoV-2, Influenza A, Influenza B, and Respiratory Syncytial Virus (RSV) from December 2022 through 2024, affecting over 77,500 patient tests. Findings include: 1. Review of the "Dupage County Diagnostics Molecular Testing, Quality Control and Quality Assessment Policy" revealed the following information: "Avoiding Contamination Policy: ...Avoid Cross Contamination between specimens ... ...two separate areas will be designated for PCR testing: Pre - and Post - PCR ... ... Sample Preparation and RNA Extraction will take place in Biosafety Cabinet (BSC) ... ...We will have one dedicated refrigerator/freezer for kit storage and another for storage of samples ... ...Tubes will be discarded after PCR amplification and analysis is complete. It will not be opened or will they be taken into the pre-PCR room ..." 2. On 10/07/2024, at 2:30 p.m., direct observation during a laboratory tour with the TS revealed the laboratory failed to maintain a uni-directional workflow for the molecular

	amplification of SARS-CoV-2, Influenza A, Influenza B, and Respiratory Syncytial Virus (RSV): 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 BSC (Baker SterilGARD SN: 127773); b. Transfer pipettes found on a storage shelf outside of the processing cabinet; c. Unmarked reagents, Laboratory B American Proficiency Institute (API) proficiency testing (PT) samples (SARS-CoV-2 liquid molecular CAT # 385 - Microbiology Events 1, 2, and 3, 2023, and five SARS-CoV-2 positive patient samples (ID Numbers: 52515, 80435, 62587, 81077 and 81083) stored in one freezer (Frigidaire SN:1K14671595). 3. On 10/07/2024, at 2: 30 p.m., the TS confirmed the laboratory did not follow uni-directional flow.
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 review of laboratory records, lack of documentation and interview with the technical supervisor (TS), the laboratory failed to retain American Proficiency Institute (API) proficiency testing (PT) records for one of five Microbiology PT events (Event 2) reviewed in 2024. Findings include: 1. Review of the "Dupage County Diagnostics Proficiency Policy" revealed the following guidelines: " - ...The laboratory's PT record keeping will include: All PT test records, such as instrument tapes and logs, PT Result Form, PT Attestation Statement and PT score Report. - ... All PT records will be retained for a minimum of two years ..." 2. Review of the submitted laboratory API PT instrument runs for Microbiology Event 2, 2024, revealed the surveyor was unable to determine the date of PT testing and the analyzer utilized to perform the following API PT samples: 2024 Event 2: SAR-06, SAR-07, SFR-06, SFR-07, SFR-08, SFR-09 SFR-10 (no documentation submitted) 3. On 10/07 /2024, at 1:30 p.m., the TS confirmed the laboratory faied to provide instrument run data for API PT Microbiology Event 2.
D5213	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1) The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with the technical supervisor (TS), the laboratory failed to examine the self-graded performance of sub-specialty virology analyte (COV - 05, SARS-CoV-2) on the American Proficiency Institute (API) proficiency testing (PT) Microbiology Event 3, 2023. Findings include: 1. Review of the "Dupage County Diagnostics Proficiency Testing" policy revealed the following information: " ...10. Upon receipt of evaluation results, review and investigate and document the finding for all unacceptable results. Self-grade specimens that were not graded by comparing expected values and/or peer group results." 2. Review of the laboratory's result sheet marked, "Proficiency Test 2023 Microbiology 3rd Event - Reagent Kit Lot: COVID20230419" revealed the following information: Sample ID - COV-05 Result - NEGATIVE Expected Result - POSITIVE

	3. Review of the API "Comparative Evaluation 2023 Microbiology - 3rd Event" report revealed the following information: Analyte / Method: SARS-CoV-2 Sample: COV-05 Reported Result: Not Detected Expected Result: See Data Summary Performance: Not Graded 4. Review of the API PT "2023 Microbiology - 3rd Event Performance Review and Corrective Action" form signed by the lab director on 11/14 /2023 revealed the following information: "The results were not graded, so no corrective action was taken." 5. On 10/07/2024, at 4:27 p.m., the TS confirmed the laboratory failed to perform the self-graded evaluation for Sample COV-05, API 2023 Microbiology Event 3.
D5305	TEST REQUEST CFR(s): 493.1241(c) The laboratory must ensure the test requisition solicits the following information: (1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (2) The patient's name or unique patient identifier. (3) The sex and age or date of birth of the patient. (4) The test(s) to be performed. (5) The source of the specimen, when appropriate. (6) The date and, if appropriate, time of specimen collection. (7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with the technical supervisor (TS), the laboratory failed to ensure patient test requisitions contained the required patient testing information on 3 of 15 test requests reviewed in 2022, 2023 and 2024. Findings include: 1. Review of the "Dupage County Diagnostics Test Orders Policy" revealed the following information: "All requisitions must be entered into the computer or Clinical Laboratory log and must include: Patient's name ...The patient's sex ... Date Ordered ...Tests: The test(s) to be performed ..." 2. Review of patient test requisitions revealed 3 of 15 (MRN: 109206, 118776 and 21137) test requests failed to indicate the name of the test(s) ordered. 3. Further review of MRN: 21137 revealed no sex of the patient documented on the submitted request form. 4. On 10/07/2024, at 4:03 p.m., the TS confirmed the patient test requisitions failed to contain the required patient testing information.
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 laboratory records, lack of documentation and interview with the technical supervisor (TS), the laboratory director (LD) failed to provide a written procedure manual for the testing of Influenza A, Influenza B, and Respiratory Syncytial Virus (RSV) samples (Refer to D5401); failed to follow the manufacturer's instructions for testing four of four virology analytes (SARS-CoV-2, Influenza A, Influenza B and Respiratory Syncytial Virus (RSV)) using the Atila BioSystems iAMP COV/FLU/RSV detection kit assay and the Atila BioSystems iAMP- COVID-19 detection kit assay (Refer to D5411); failed to have markings of identification on stored reagent vials (Refer to D5415); failed to establish the performance specifications for the Atila BioSystems iAMP COV/FLU/RSV detection kit assay and the Atila BioSystems iAMP- COVID-19 detection kit assay utilizing the Atila Biosystems, Inc. PowerGene 9600 Plus analyzer (Serial Number: MDA6094-552414) before reporting patient test results in 2022 through 2024, affecting 77,500 patient tests (Refer to D5423 A and B); failed to document quality control (QC) materials utilized for virology analyte Respiratory Syncytial Virus (RSV) testing for 3 of 15 patient test dates 03/11/2024, 05/01/2024 and 05/06/2024 (Refer to D5455).
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of laboratory records, lack of documentation and interview with the technical supervisor (TS), the laboratory failed to establish a written procedure manual for testing four of four virology analytes SARS-CoV-2, Influenza A, Influenza B, and Respiratory Syncytial Virus (RSV) utilizing the Atila BioSystems iAMP COV/FLU/RSV detection assay from March 2023 - October 2024, more than 64,500 patient tests affected. Findings include: 1. Review of patient test records revealed test results for four of four virology analytes SARS-CoV-2, Influenza A, Influenza B, and Respiratory syncytial virus (RSV) utilizing the Atila BioSystems iAMP COV/FLU/RSV detection assay. 2. Review of the "DuPage County Diagnostics Clinical Laboratory Policy and Procedure" revealed no documentation of procedures for testing utilizing the Atila BioSystems iAMP COV/FLU/RSV detection assay from March 2023 - October 2024, more than 64,500 patient tests affected. 3. On 10/7/2024, at 3:04 p.m., the TS confirmed the laboratory did not have documentation of procedures for utilizing the Atila BioSystems iAMP COV/FLU/RSV detection assay.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by:

	Based on review of laboratory records, direct observation, and interview with the technical supervisor (TS), the laboratory failed to reject specimen samples that were not collected using the Atila dry swab collection kits as directed for five of five patient samples for the Atila BioSystems iAMP COV/FLU/RSV Detection Kit assay and the Atila BioSystems iAMP- COVID-19 Detection Kit assay before reporting patient test results in 2022 through 2024. Findings include: 1. Review of the "Atila BioSystems iAMP COV/FLU/RSV Detection Kit - iAMP-COVFLURSV-100 Instructions for Use" manual revealed the following information. "SPECIMENS ... Acceptable Specimens - Direct nasopharyngeal or nasal dry swabs collected with Atila Sample Collection Device ... ...Specimen Rejection criteria ... - Inappropriate specimen type." 2. Review of the "Atila BioSystems iAMP COVID-19 Detection Kit iAMP-COVID19-100 Instructions For Use ...(EUA)" manual revealed the following information. "SPECIMENS ...Acceptable Specimens Nasal Swabs, nasopharyngeal swabs and/or oropharyngeal swabs collected dry with the Atila Sample Collection Device (iAMP-COVID19-SCD; provided in the kit). ...After sample collection, immediately insert swab into the collection tube provide with the Atila COVID-19 Sample Collection Device ... ...Specimen Rejection criteria - Inappropriate specimen type." 3. During the laboratory tour on 10/07/2024, at 2:41 p.m., the surveyor identified five of five patient samples marked as follows: a) 81077 (COV, FLA, FLB) Collected in "SNT BIOTECH Virus Transport Medium" b) 81083 (COV, FLA, FLB) Collected in "SNT BIOTECH Virus Transport Medium" c) 52515 (COV) Collected in "SNT BIOTECH Virus Transport Medium" d) 62587 (COV) Collected in "SNT BIOTECH Virus Transport Medium" e) 80435 (COV) Collected in "SNT BIOTECH Virus Transport Medium". 4. On 10/07/2024, at 4:06 p.m., the TS confirmed the five patient samples listed in Finding 3 were collected in "SNT BIOTECH Virus Transport Medium".
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on review of laboratory records, direct observation, and interview with the technical supervisor (TS), the laboratory failed to document storage requirements, preparation and expiration dates on three of three reagent vials utilized for molecular amplification procedures of virology analytes SARS-CoV-2, Influenza A, Influenza B, and Respiratory Syncytial Virus (RSV) from December 2022 through 2024, affecting 77,500 patient tests. Findings include: 1. Review of the "DuPage County Diagnostics Clinical Laboratory Policy and Procedure - Reagents" policy revealed the following information: "Reagents shall be stored and used according to the manufacturer's instructions. Labels for solutions shall include the following information: Contents Date changed/opened Expiration date ...Labels on containers for reagents prepared by laboratory staff shall contain the following information: SDS information The name of the individual who prepared the reagent Date of preparation and/or date of placement in service Date of expiration, as appropriate ..." 2. On 10/07 /2024, at 4:20 p.m., direct observation of three reagent vials in the laboratory freezer (Frigidaire Serial No. 1K14671595) utilized for molecular amplification procedures of

	virology analytes SARS-CoV-2, Influenza A, Influenza B, and Respiratory Syncytial Virus (RSV) failed to have the required markings described in Finding 1, affecting 77,500 patient tests.. 3. On 10/07/2024, at 4:21 p.m., the TS confirmed the observation of the unmaked reagent vials.
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: A. Based on review of laboratory records, lack of documentation, and interview with the technical supervisor (TS), the laboratory failed to establish the performance specifications for four of four virology analytes using the Atila BioSystems iAMP COV/FLU/RSV detection kit assay utilizing the Atila Biosystems, Inc. PowerGene 9600 Plus analyzer (Serial Number: MDA6094-552414) before reporting patient test results in 2024, affecting more than 64,500 patient tests. Findings include: 1. Review of patient test records revealed the reported results for four of four virology analytes SARS-CoV-2, Influenza A, Influenza B, and Respiratory Syncytial Virus (RSV) utilizing the high complexity iAMP COV/FLU/RSV Detection Kit assay. 2. Review of the "DuPage County Diagnostics Validation process: Machine (MDA6094-552414)" and lack of documentation revealed the laboratory failed to: a) provide documentation of instrument raw data validation runs for the "Atila Biosystems, Inc. PowerGene 9600 Plus analyzer (Serial Number: MDA6094-552414); b) identify 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 adequate test performance for virology analytes (SARS-CoV-2, Influenza A, Influenza B and Respiratory Syncytial Virus (RSV)) utilizing "SNT BIOTECH Virus Transport Medium" prior to reporting patient test results in 2024, affecting more than 64,500 patient tests. 3. On 10/07/2024, at 4:06 p.m., the TS confirmed the instrument raw data validation runs were not on file for surveyor review. B. Based on review of laboratory records, lack of documentation, and interview with the technical supervisor (TS), the laboratory failed to establish the performance specifications for SARS-CoV-2 testing with the Atila BioSystems iAMP- COVID-19 Detection Kit assay utilizing Atila Biosystems, Inc. PowerGene 9600 Plus analyzer (Serial Number: MDA6094-552414) prior to reporting patient test results in 2022 through 2024, affecting 77,500 patient tests. Findings include: 1. Review of patient test records revealed the laboratory performed testing for the virology analyte SARS-CoV-2, utilizing the Atila BioSystems iAMP- COVID-19 detection kit assay. 2. Review of the "DuPage County Diagnostics validation study Machine Serial Number MDA6094-552414" and lack of documentation revealed the laboratory failed to: a) provide documentation of instrument raw data validation runs for the "Atila Biosystems, Inc. PowerGene 9600

	Plus analyzer (Serial Number: MDA6094-552414); b) identify 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 adequate test performance for virology analyte (SARS-CoV-2) utilizing "SNT BIOTECH Virus Transport Medium" prior to reporting patient test results in 2022 through 2024, affecting 77,500 patient tests. 3. On 10/07/2024, at 4:06 p.m., the TS confirmed the instrument raw data validation runs were not on file for surveyor review.
D5455	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(v)(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 molecular amplification procedure, include two control materials and, if reaction inhibition is a significant source of false negative results, a control material capable of detecting the inhibition. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of laboratory records, lack of documentation and interview with the laboratory director (LD), the laboratory failed to document quality control (QC) materials utilized for virology analyte Respiratory Syncytial Virus (RSV) testing for 3 of 15 patient test dates 03/11/2024, 05/01/2024 and 05/06/2024. Findings include: 1. Review of the "DuPage County Diagnostics Molecular Testing, Quality Control and Quality Assessment Policy" revealed the following information: "Avoiding Contamination Policy: ...Include a positive external control to assure proper performance of extraction and amplification and functionality of the reagents ... ... Include a no-template control (NTC) to check for the absence of contamination in the reagents, consumables, and environment ..." 2. Review of laboratory records and patient test reports revealed no documentation of the QC materials utilized for virology analyte Respiratory Syncytial Virus (RSV) testing for 3 of 15 patient test dates 03/11/2024 (Lab #103327), 05/01/2024 (Lab #109206) and 05/06/2024 (Lab #110023). 3. Review of the instrumentation documentation printouts (sample run graphs) submitted by the LD on 11/11/2024 for testing dates 03/11/2024, 05/01/2024 and 05/06/2024 failed to include the instrument serial number, instrument run dates, and sample identifiers. 4. On 11/04/2024, at 10:42 a.m., the LD confirmed the RSV QC documentation was not provided for review during the survey.
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 the laboratory records and interview with the technical supervisor (TS), the laboratory director (LD) failed to provide the overall management and direction to maintain required high complexity laboratory standards. The LD failed to

	ensure the establishment and performance specifications for four of four virology analytes (SARS-CoV-2, Influenza A, Influenza B and Respiratory Syncytial Virus (RSV)) using the Atila BioSystems iAMP COV/FLU/RSV detection kit assay and the Atila BioSystems iAMP- COVID-19 detection kit assay utilizing the Atila Biosystems, Inc. PowerGene 9600 Plus analyzer (Serial Number: MDA6094-552414) before reporting patient test results in 2022 through 2024 (Refer to D6086); failed to ensure quality control (QC) materials were utilized for virology analyte Respiratory Syncytial Virus (RSV) testing for 3 of 15 patient test dates 03/11/2024, 05/01/2024 and 05/06/2024 (Refer to D6093); failed to ensure 9 of 15 patient test reports reviewed for SARS-CoV-2, Influenza A, Influenza B and Respiratory Syncytial Virus (RSV) testing included pertinent information required for the interpretation of Influenza A, Influenza B and RSV (Refer to D6098); failed to ensure training of high complexity testing personnel prior to testing and reporting SARS-CoV-2, Influenza A, Influenza B and Respiratory syncytial virus (RSV) from March 2023 through October 2024 (Refer to D6102).
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 review of laboratory records, lack of documentation and interview with the technical supervisor (TS), the laboratory director (LD) failed to ensure the establishment and performance specifications for four of four virology analytes (SARS-CoV-2, Influenza A, Influenza B and Respiratory Syncytial Virus (RSV)) using the Atila BioSystems iAMP COV/FLU/RSV detection kit assay and the Atila BioSystems iAMP- COVID-19 detection kit assay utilizing the Atila Biosystems, Inc. PowerGene 9600 Plus analyzer (Serial Number: MDA6094-552414) before reporting patient test results in 2022 through 2024. Findings include: 1. Review of laboratory records and lack of documentation revealed the laboratory failed to establish the performance specifications for four of four virology analytes (SARS-CoV-2, Influenza A, Influenza B and Respiratory Syncytial Virus (RSV)) using the Atila BioSystems iAMP COV/FLU/RSV detection kit assay utilizing the Atila Biosystems, Inc. PowerGene 9600 Plus analyzer (Serial Number: MDA6094-552414) before reporting patient test results in 2024, affecting more than 64,500 patient tests (Refer to D5423 A). 2. Review of laboratory records and lack of documentation revealed the laboratory failed to establish the performance specifications for SARS-CoV-2 testing with the Atila BioSystems iAMP- COVID-19 Detection Kit assay utilizing Atila Biosystems, Inc. PowerGene 9600 Plus analyzer (Serial Number: MDA6094-552414) prior to reporting patient test results in 2022 through 2024, affecting 77,500 patient tests (Refer to D5423 B).
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

	This STANDARD is not met as evidenced by: Based on review of laboratory records, lack of documentation and interview with the laboratory director (LD), the LD failed to ensure quality control (QC) materials were utilized for virology analyte Respiratory Syncytial Virus (RSV) testing for 3 of 15 patient test dates 03/11/2024, 05/01/2024 and 05/06/2024. Findings include: 1. Review of laboratory records and patient test reports revealed no documentation of the QC materials utilized for RSV testing for 3 of 15 patient test dates 03/11/2024 (Lab #103327), 05/01/2024 (Lab #109206) and 05/06/2024 (Lab #110023) (Refer to D5455).
D6098	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(8) The laboratory director must ensure that reports of test results include pertinent information required for interpretation. This STANDARD is not met as evidenced by: Based on review of laboratory records, patient test reports and interview with the technical supervisor (TS), the laboratory failed to ensure 9 of 15 patient test reports reviewed for SARS-CoV-2, Influenza A, Influenza B and Respiratory Syncytial Virus (RSV) testing included pertinent information required for the interpretation of Influenza A, Influenza B and Respiratory Syncytial Virus (RSV). Findings include: 1. Review of the "Dupage County Diagnostics Molecular testing, Quality Control and Quality Assessment Policy" revealed the following information. "COVID policy: CLIA Self-Assessment ...3. Does the molecular diagnostics laboratory provide ... Availability of consultation regarding test selection, results interpretation, and implication of results?" 2. Review of patient test reports and lack of documentation revealed 9 of 15 SARS-CoV-2, Influenza A, Influenza B and RSV final test reports failed to include pertinent information required for the interpretation of Influenza A, Influenza B and RSV. a) MRN: 102696 DATE: 03/06/2024 TESTS REPORTED: SARS-CoV-2, Influenza A, Influenza B and RSV b) MRN: 103327 DATE: 03/11 /2024 TESTS REPORTED: SARS-CoV-2, Influenza A, Influenza B and RSV c) MRN: 104363 DATE: 03/18/2024 TESTS REPORTED: SARS-CoV-2, Influenza A, Influenza B and RSV d) MRN: 109206 DATE: 05/01/2024 TESTS REPORTED: SARS-CoV-2, Influenza A, Influenza B and RSV e) MRN: 110023 DATE: 05/06 /2024 TESTS REPORTED: SARS-CoV-2, Influenza A, Influenza B and RSV f) MRN: 110742 DATE: 05/10/2024 TESTS REPORTED: SARS-CoV-2, Influenza A, Influenza B and RSV g) MRN: 116471 DATE: 09/03/2024 TESTS REPORTED: SARS-CoV-2, Influenza A, Influenza B and RSV h) MRN: 117270 DATE: 09/11 /2024 TESTS REPORTED: SARS-CoV-2, Influenza A, Influenza B and RSV i) MRN: 118776 DATE: 09/24/2024 TESTS REPORTED: SARS-CoV-2, Influenza A, Influenza B and RSV 3. On 10/07/2024, at 4:27 p.m., the TS confirmed the results of the final test results documented in Finding 1.
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 review of laboratory records, lack of documentation and interview with the technical supervisor (TS); the laboratory failed to ensure the training of two of two testing personnel (TP 1 and TP 2) listed on the CMS - 209 form for SARS-CoV-2, Influenza A, Influenza B and Respiratory Syncytial Virus (RSV) virology analytes utilizing the iAMP COV/FLU/RSV Detection kit in March 2023 until October 2024, affecting more than 64,500 patient tests. Findings include: 1. Review of laboratory personnel files revealed no documentation of training for two of two TP (TP 1 and TP 2) for SARS-CoV-2, Influenza A, Influenza B and Respiratory Syncytial Virus (RSV) testing utilizing the iAMP COV/FLU/RSV Detection kit in March 2023 until October 2024, affecting more than 64,500 patient tests. 2. On 10/07/2024, at 2:03 p.m., the TS confirmed TP 1 and TP 2 failed to have training records for utilizing the iAMP COV /FLU/RSV Detection kit.
D8100	INSPECTION REQUIREMENTS CFR(s): 493.1771 Each laboratory issued a CLIA certificate must meet the requirements in 493.1773 and the specific requirements for its certificate type, as specified in 493.1775 through 493.1780. All CLIA-exempt laboratories must comply with the inspection requirements in 493.1773 and 493.1780, when applicable. This CONDITION is not met as evidenced by: Based on review of laboratory records, lack of documentation and interview with the laboratory director (LD), the laboratory failed to allow the surveyor to assess Respiratory Syncytial Virus (RSV) quality control (QC) instrument run documentation for patient test dates, 03/11/2024, 05/01/2024 and 05/06/2024, establishment of performance specifications for the Atila BioSystems iAMP COV /FLU/RSV detection kit assay and the Atila BioSystems iAMP- COVID-19 detection kit assay utilizing the Atila Biosystems, Inc. PowerGene 9600 Plus analyzer (Serial Number: MDA6094-552414), Atila BioSystems iAMP COV/FLU/RSV detection kit assay training documentation for two of two testing personnel (TP 1 and TP 2), and documentation of patient testing performed on 10/03/2024, 10/04/2024, and 10/07 /2024 within a reasonable timeframe (Refer to D8103).
D8103	BASIC INSPECTION REQUIREMENTS CFR(s): 493.1773(b)(c)(d) (b) General Requirements. As part of the inspection process, CMS or a CMS agent may require the laboratory to do the following: (b)(1) Test samples, including proficiency testing samples, or perform procedures. (b)(2) Permit interviews of all personnel concerning the laboratory's compliance with the applicable requirements of this part. (b)(3) Permit laboratory personnel to be observed performing all phases of the total testing process preanalytic, analytic, and postanalytic). (b)(4) Permit CMS or a CMS agent access to all areas encompassed under the certificate including, but not limited to, the following: (b)(4)(i) Specimen procurement and processing areas. (b)(4)(ii) Storage facilities for specimens, reagents, supplies, records, and reports. (b)(4)(iii) Testing and reporting areas. (b)(5) Provide CMS or a CMS agent with copies or exact duplicates of all records and data it requires. (c) Accessible records and data. A

	laboratory must have all records and data accessible and retrievable within a reasonable time frame during the course of the inspection. (d) Requirement to provide information and data. A laboratory must provide, upon request, all information and data needed by CMS or a CMS agent to make a determination of the laboratory's compliance with the applicable requirements of this part. This STANDARD is not met as evidenced by: Based on review of laboratory records, lack of documentation and interview with the laboratory director (LD), the laboratory failed to provide requested Respiratory Syncytial Virus (RSV) quality control (QC) instrument run documentation for patient test dates, 03/11/2024, 05/01/2024 and 05/06/2024, establishment of performance specifications for the Atila BioSystems iAMP COV/FLU/RSV detection kit assay and the Atila BioSystems iAMP- COVID-19 detection kit assay utilizing the Atila Biosystems, Inc. PowerGene 9600 Plus analyzer (Serial Number: MDA6094-552414), Atila BioSystems iAMP COV/FLU/RSV detection kit assay training documentation for two of two testing personnel (TP 1 and TP 2), and documentation of patient testing performed on 10/03/2024, 10/04/2024, and 10/07/2024 within a reasonable timeframe. Findings include: 1. On 11/04/2024, at 10:00 a.m., a meeting was conducted with the LD to discuss the additional documentation required for review: a) Quality control (QC) instrument run documentation for Respiratory Syncytial Virus (RSV) patient test dates, 03/11/2024, 05/01/2024 and 05/06/2024; b) establishment of performance specifications for the Atila BioSystems iAMP COV/FLU/RSV detection kit assay and the Atila BioSystems iAMP- COVID-19 detection kit assay utilizing the Atila Biosystems, Inc. PowerGene 9600 Plus analyzer (Serial Number: MDA6094-552414 - Refer to D5423 A and B); c) Atila BioSystems iAMP COV/FLU/RSV detection kit assay training documentation for two of two testing personnel (TP 1 and TP 2 - Refer to D6102); d) documentation of patient testing performed on 10/03/2024, 10/04/2024, and 10/07/2024. 2. Review of the laboratory records submitted by the LD on 11/07 /2024 and lack of documentation revealed the laboratory failed to submit the documentation listed in Finding 1.