Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D2252339	11/20/2023
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
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: Based on surveyor's direct observation, laboratory documentation, and interview with the technical supervisor (TS), the laboratory failed to meet the requirements of this condition. The laboratory failed to provide a unidirectional workflow for molecular amplification procedures to minimize contamination of patient specimens, equipment, instruments, reagents, materials, and supplies. (Refer to D3005).
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: Based on surveyor's direct observation, manufacturers' instructions for use, 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 for SARS-CoV-2 for two of two testing years (2022 and 2023). Findings Include: 1. Review of the "iAMP - COVID19-100" (iAMP) Detection Kit Instructions for Use" revealed the following: a. "Personnel must be familiar with the protocol and equipment/instruments used." b. "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." c. "Workflow must always be from the clean area to the dirty area." 2. On 11/20/2023 at 11:35 a.m., direct observation of the TS demonstrating the testing procedures for the "iAMP - COVID19-100" (iAMP) assay revealed the following: a) the preparation of extraction buffer reagent, 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 utilizing the same pipettes in one biosafety cabinet ("SterilGARD SN: 127773"); b) patient samples stored with new patient samples in one refrigerator / freezer ("Frigidaire EVENTEMP Serial No. 1K14671595"). 3. Review of laboratory records and lack of documentation revealed the laboratory failed to ensure one of two (TP 2) was qualified for high complexity molecular biology testing of SARS- CoV-2 in 2023. (Refer to D6171). 4. On 11/20/2023, at 11:35 a.m., an interview with the TS revealed, "Run samples go back into fridge, keep for two days; positives for three days in the freezer."
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). 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 identify the personnel performing high complexity molecular biology SARS-CoV-2 assay on five of five patient test runs from 11/2022 to date of survey 11/20/2023. Findings include: 1. Review of patient test run data for the SARS-CoV-2 assay ("iAMP - COVID19-100" (iAMP) found five of five instrument printouts from 11/2022 to date of survey 11/20/2023 failed to identify the testing personnel that performed the test run. a) Instrument printout A (Date: 11/29/2022): "Experiment Name: COVID19 TEST_20221129_193437 - admin" b) Instrument printout B (Date: 02/27/2023): "Experiment Name: COVID19 TEMPLATE_20230227_173853 - admin" c) Instrument printout C (Date: 08/21/2023): "Experiment Name: COVID19 TEMPLATE_20230821_160114 - admin" d) Instrument printout D (Date: 09/13 /2023): "Experiment Name: COVID19 TEMPLATE_20230913_164102 - admin" e) Instrument printout E (Date: 11/07/2023): "Experiment Name: COVID19 TEMPLATE_20231107_180835 - admin" 2. On 11/20/2023, at 1:33 p.m., an interview with the TS revealed, "No way to enter which testing personnel did the run, not listed on raw data, enter as admin only."

D6026	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(8) 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)(8) 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.
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 review of laboratory records, lack of documentation, Laboratory Personnel Report (CMS-209), and interview with the technical supervisor (TS), the laboratory failed to retain education transcripts to qualify one of two testing personnel (TP 2) for high complexity SARS-CoV-2 testing from 01/16/2023 to date of survey 11/20/2023 affecting 7000 tests performed. (Refer to D6171).

D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry 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; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet

	the qualifications of 493.1449 (b) or (l) to perform tissue examinations. This STANDARD is not met as evidenced by: Based on review of laboratory records, lack of documentation, Laboratory Personnel Report (CMS-209), and interview with technical supervisor (TS), the laboratory failed to ensure one of two testing personnel were qualified for high complexity molecular biology testing of SARS- CoV-2 in 2023. Affecting 7000 test performed. Findings Include: 1. Review of the CMS-209 (11/20/2023) and lack of documentation revealed the laboratory failed to retain education transcripts to qualify one of two testing personnel (TP 2) for high complexity SARS-CoV-2 testing from 01/16/2023 to date of survey 11/20/2023 affecting 7000 tests performed. 2. On 11/20/2023, at 2:39 p.m., the TS confirmed the above finding.