Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D2237259	(X3) Date Survey Completed 07/06/2023
Name of Provider or Supplier Montys Clinical Lab	**Street Address, City, State** 1556 South River Rd, Des Plaines, 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 review of laboratory records, lack of documentation and interview with testing personnel (TP 1), the laboratory failed to enroll in an approved proficiency testing (PT) program for high complexity respiratory syncytial virus (RSV), and influenza A / B testing from 12/10/2022 to the date of survey (07/06/2023). Affecting 10,767 tests performed. Finding Include: 1. Review of proficiency testing records found no documentation of the laboratory's enrollment in a Centers for Medicare & Medicaid Services (CMS) approved PT program for testing RSV and influenza A / B from 12/10/2022 to the date of survey (07/06/2023). a. Total number of RSV and influenza A / B tests performed from 12/10/2022 - 07/06/2023 = 10,767. 2. On 07/06 /2023 at 10:39 a.m., TP 1 confirmed the laboratory failed to enroll in PT for RSV and influenza A / B.
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 direct observation, laboratory documentation, and interview with testing personnel (TP 1); 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 direct observation, manufacturers' package inserts (PI), laboratory records, interview with testing personnel (TP 1) and lack of documentation, 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, respiratory syncytial virus (RSV), and influenza A / B, for two of two testing years (2022 and 2023). Findings Include: 1. Review of the "iAMP COV/FLU/RSV Detection Kit (iAMP) Instructions for Use, QUALITY CONTROL, General Considerations" 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." d. "Wear clean disposable gowns and new, previously unworn, powder-free gloves during assay reagent setup and handing of processed samples. Change gloves whenever contamination is suspected." 2. Review of laboratory records and lack of documentation revealed the laboratory failed to record "iAMP CON/FLU/RSV Detection" assay training for TP 1. (See D6029). 3. On 07/06 /2023 at 11:12 a.m., direct observation of TP 1 performing the iAMP assay revealed the following: a. 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 in one biosafety cabinet ("LabMetrics, Serial # NA4FAT2012293"). b. Direct observation revealed the testing pipettes stored on a rack outside of the biosafety cabinet. c. Direct observation also revealed completed patient samples stored with new patient samples in one refrigerator. Surveyor observation also revealed the transport of initial patient samples through the amplification room containing thermal cycler ("analytikjena qTower3

	84G - SN: 3107G-0578") for entry to the extraction room. 4. On 07/06/2023 at 11:12 a.m., an interview with TP 1 revealed, "lab coats are worn in the extraction room, not in the amplification room".
D3039	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(5) Quality system assessment records. Retain all laboratory quality system assessment 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 general supervisor (GS), the laboratory failed to maintain laboratory quality system assessment records for monitoring room temperatures, room humidity values, refrigerator temperatures, and freezer temperatures for two of two dates reviewed for SARS-CoV-2, respiratory syncytial virus (RSV), and influenza A / B testing in 2023. Affecting 19 patient samples. Findings Include: 1. Review of the laboratory's "Daily Temperature Checks" procedures revealed the following: a. "Each thermometer in use is checked to monitor reagent storage temperature daily." b. "Any out-of-range documentation must include corrective action taken, a recheck of temperature to ensure corrective action remedy, and an evaluation of the integrity of the reagent or product contents before reagent or product can be used for laboratory testing." c. "All analyzers/testing environments that are sensitive to temperature and humidity are monitored daily and documented on the appropriate logs." 2. Review of the laboratory's "Daily Temperature and Humidity Logs" and lack of documentation revealed the following: a. Log marked "January 2023 (01/17/2023)"; no documentation of "Extraction Room Temparature[sic], Extraction Room Humidity, RT-PCR Room Temparature[sic], RT-PCR Room Humidity, Fridge #1, Freezer #1, Freezer #2, Initials." (16 patient samples tested) b. Log marked "July 2023 (7/04 /2023)"; no documentation of "Extraction Room Temparature[sic], Extraction Room Humidity, RT-PCR Room Temparature[sic], RT-PCR Room Humidity, Fridge #1, Freezer #1, Freezer #2, Initials." (3 patient samples tested) 3. On 07/06/2023 at 12:30 p.m., an interview with the GS 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 review of laboratory records and interview with the general supervisor (GS), the laboratory failed to outline all components of the testing procedures for one of one analytical system, "LumiraDx SARS-CoV-2 RNA STAR Complete" assay in 2022 and 2023. Findings Include: 1. Review of laboratory records revealed the laboratory's "SOP PCR - 384 Lumira Dx Procedure" failed to outline the following required components of the testing procedures for SARS-CoV-2 RNA (2022 and 2023): a. Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection. b. Limitations in the test methodology, including interfering substances. c. Pertinent literature references. d. 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. e. Description of the course of action to take if a test system becomes inoperable. 2. On 07/06/2023 at 11:19 a.m., an interview with the GS confirmed the above findings.
D5405	PROCEDURE MANUAL CFR(s): 493.1251(c) Manufacturer's test system instructions or operator manuals may be used, when applicable, to meet the requirements of paragraphs (b)(1) through (b)(12) of this section. Any of the items under paragraphs (b)(1) through (b)(12) of this section not provided by the manufacturer must be provided by the laboratory. This STANDARD is not met as evidenced by: Based on review of laboratory records, manufacturer's instructions for use, and interview with the general supervisor (GS), the laboratory failed to provide all components of the testing procedure that are not provided by the manufacturer for one of one analytical system, "iAMP COV/FLU/RSV Detection Kit" in 2022 and 2023. Affecting a total of 10,767 patient samples. Findings Include: 1. Review of the "iAMP COV/FLU/RSV Detection Kit Instructions for Use" failed to outline the following required components of the testing procedures for SARS-CoV-2, respiratory syncytial virus (RSV), and influenza A / B, (12/10/2022 to 07/06/2023): a. Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection. b. Pertinent literature references. c. 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. d. Description of the course of action to take if a test system becomes inoperable. 2. On 07/06/2023 at 2:30 p.m., an interview with the GS confirmed the above findings.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a

	maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on review of laboratory records, direct observation, lack of documentation, and interview with the general supervisor (GS); the laboratory failed to perform and document the service maintenance for one of one freezer containing "lumiraDx SARS-CoV-2 RNA STAR Complete" reagents from 03/23/2021 to date of survey (07/06/2023). Findings Include: 1. Review of laboratory records and lack of documentation revealed the laboratory failed to perform and document the service maintenance for one of one freezer ("FREEZER #1 - ABS American BioTech Supply Med Freezer") containing "lumiraDx SARS-CoV-2 RNA STAR Complete" reagents from 03/23/2021 to date of survey (07/06/2023). 2. Direct observation on 07/06/2023 at 11:19 a.m., revealed the following preventive maintenance record on "FREEZER #1 - ABS American BioTech Supply Med Freezer": a. "TRACE SERVICES INC. - 013883" b. "Service performed Date: 03/23/21" c. "Due Date 03/2022" 3. Direct observation on 07/06/2023 at 11:19 a.m., revealed the following assay kits stored in the freezer marked, "FREEZER #1 - ABS American BioTech Supply Med Freezer": a. "lumiraDx SARS-CoV-2 RNA STAR Complete, REF: L018180130096, LOT: M2300124, EXP: 2023-08-14, Store at 25C - 15C". b. "lumiraDx SARS-CoV-2 RNA STAR Complete, REF: L018180130096, LOT: M2300124, EXP: 2023-08-02, Store at 25C - 15C". c. "lumiraDx SARS-CoV-2 RNA STAR Complete, REF: L018180130096, LOT: M2300124, EXP: 2023-10-10-14, Store at 25C - 15C". 4. On 07/06/2023 at 11:19 a.m., an interview with the GS confirmed the above finding.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on review of laboratory records, lack of documentation, and interview with the general supervisor (GS), the laboratory failed to perform and document twice a year evaluations of the test results between three of three molecular biology patient testing assays utilized in 2022 and 2023 for SARS-CoV-2 (COVID - 19) testing. Findings Include: 1. Review of laboratory records revealed three molecular biology patient testing assays in use: a. "LumiraDx SARS-CoV-2 RNA STAR Complete" b. "iAMP COVID-19 Detection Kit" c. "iAMP COV/FLU/RSV Detection Kit" 2. Review of laboratory records and lack of documentation revealed that the laboratory failed to perform and document twice a year evaluation of the test results between the three COVID - 19 assay systems listed in Finding 1. 3. On 07/06/2023 at 2:30 p.m., an interview with the GS confirmed the above findings.
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, manufacturers' instructions, and interview with the general supervisor (GS); the laboratory director failed to ensure that one of one testing personnel (TP 1) listed on the Laboratory Personnel Report (CLIA) Form CMS - 209 received and demonstrated the appropriate training required for three of three assay procedures prior to performing and reporting high complexity molecular biology patient testing in 2022 and 2023. Findings Include: 1. Review of the laboratory's "Competency Assessment (COVID Testing)" forms for TP 1 failed to document training and competency for three of three molecular analytical systems in use; the LumiraDx SARS-CoV-2 RNA STAR Complete assay, the ATILA BioSystems iAMP COVID-19 Detection Kit, and the ATILA BioSystems iAMP COV /FLU/RSV Detection Kit in 2022 and 2023. a. "Name: TP 1" "Date: 3/7/2022" "Test: SARS COV 2 PCR" "Type of Assessment: SARS Cov-2 Test (x) Initial" b. "Name: TP 1" "Date: (not recorded)" "Test: SARS COV 2 PCR" "Type of Assessment: SARS Cov-2 Test (x) 6 month" c. "Name: TP 1" "Date: (not recorded)" "Test: SARS COV 2 PCR" "Type of Assessment: SARS Cov-2 Test (x) Annual" 2. Review of the manufacturer's "Intended Use" instructions for the "LumiraDx SARS-CoV-2 RNA STAR Complete" assay revealed the following: a. "LumiraDx SARS-CoV-2 RNA STAR Complete is intended for use by qualified clinical laboratory personnel specifically instructed and trained in the techniques of real-time PCR and in vitro diagnostic procedures." 3. Review of the "iAMP COVID-19 Detection Kit and the iAMP COV/FLU/RSV Detection Kit Instructions for Use, QUALITY CONTROL, General Considerations" revealed the following: a. "Personnel must be familiar with the protocol and equipment/instruments used." 4. On 07/06/2023 at 2:30 p.m., an interview with the GS confirmed the above findings.