Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2301956	02/28/2025
Name of Provider or Supplier	**Street Address, City, State**	
Abda Labs Llc	8006 Cameron Rd Ste A, Austin, TX	

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
D0000	The laboratory was found NOT to be in compliance with the CLIA regulations found at 42 CFR 493 CLIA requirements. The conditions not met were: D3000 - 42 C.F.R. 493.1101 Condition: Facility Administration; D5300 - 42 C.F.R. 493.1240 Condition: Preanalytic systems; D6076 - 42 C.F.R. 493.1441 Condition: Laboratories performing high complexity testing; laboratory director; D6108 - 42 C.F.R. 493.1447 Condition: Laboratories performing high complexity testing; technical supervisor.
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). This CONDITION is not met as evidenced by: Based on review of manufacturer's instructions, laboratory policy and procedure, observation and interview, the laboratory failed to meet the applicable requirements when it failed to provide a sink in the laboratory for hand washing after handling potentially hazardous material in the real-time reverse transcription polymerase chain reaction (RT-PCR) laboratory (refer to D3011).
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.

	This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, laboratory policy and procedure, observation and interview, the laboratory failed to provide a sink in the laboratory for hand washing after handling potentially hazardous material in the real-time reverse transcription polymerase chain reaction (RT-PCR) laboratory. Findings follow. A. Review of the Filtrous Direct ampPCR Flu A, Flu B, Covid, RSV A/B Combo q-PCR Detection Panel package insert, revision 03/20/2024, under Warnings and Precautions stated, "3. Follow Good Laboratory Practices: Wear appropriate protective clothing and use disposable gloves and protective eyewear. Do not eat, drink, or smoke in designated work areas. Wash hands thoroughly after handling samples and kit reagents." B. Review of the laboratory's policy and procedure titled Chemical Hygiene Plan, effective 11/18/2024 under 2.0 SCOPE stated, "2.1 The Chemical Hygiene Plan and Hazard Control Plan applies to all staff employed or undertaking work at ABDA Labs. Anyone working with chemicals and hazardous materials will follow the proper safety guidelines and guidelines defined in this plan." And under 5.0 HEALTH AND SAFETY at 5.2 stated, "The company provides proper safety equipment and materials to keep the employee safe for any task that is performed in the laboratory." And under 6.0 PROCEDURE at 6.1.1.5 stated, "Always wash hands after working with chemicals, even when gloves have been used." And under 6.0 PROCEDURE at 6.27 Protection from Particularly Hazardous Substances stated, "6.27.3.6 Persons working in the designated area shall remove protective equipment and wash their hands and forearms before engaging in other outside laboratories activities such as eating, drinking, smoking, vaping, using cosmetics, or using toilet facilities." C. During a tour of the laboratory on February 26, 2025 at 1345 hours, the surveyor requested a sink to wash her hands after removing gloves and observing there was no sink in the laboratory, was offered a sink in a storage closet down the hall from the laboratory containing no hand soap or paper towels. The sink did not appear to be used for hand washing. Surveyor washed her hands in the women's bathroom. D. Interview with Testing Personnel as listed on the CMS Form 209 on February 26, 2025 at 1350 hours in the laboratory for where he washed his hands, responded "I don't wash my hands, I just use gloves."
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. In addition, retain the following: This STANDARD is not met as evidenced by: I. Based on review of the laboratory's policies and procedures, laboratory records, reagent log, interview, and presurvey paperwork, the laboratory failed to retain the reagent name, lot number, expiration date, received date, and open date of the extraction kit used in the laboratory for real-time reverse transcription polymerase chain reaction (RT-PCR) testing for five of five test runs reviewed from 11/12/2024 - 01/15/2025. Findings follow. A. Review of the laboratory's policies and procedures did not discuss the documentation of its reagents. B. Review of the test run documentation from 11/12/2024 - 01/15/2025 was missing the reagent name, lot number, expiration date, received date, and open date for the Filtrous Universal DNA /RNA Extraction kit used for the 96 well plate. C. Review of the QLog-06 Reagent Tracking Log showed it was not being utilized. D. Interview with Testing Personnel

	as listed on the CMS Form 209 on February 26, 2025 at 1055 hours in the laboratory acknowledged he used the curve to judge whether the reagents worked and did not document the extraction kit on the documentation for the plate. E. Review of the CMS Form 116 showed an estimated annual volume of 7,680 tests and approximately 1,920 tests had been reported to date. II. Based on review of manufacturer's instructions, laboratory's validation procedure, laboratory records, observation, interview, and pre-survey paperwork, the laboratory failed to retain the curves from the RT-PCR test runs for four of five test runs reviewed from 11/12/2024 - 01/15/2025. Findings follow. A. Review of the Filtrous Direct ampPCR Flu A, Flu B, Covid, RSV A/B Combo q-PCR Detection Panel package insert, revision 03/20/2024, under QUALITY CONTROL stated, "NC (negative control) material: no obvious amplification curve for all detection channels. PC (positive control) material: obvious amplification curves for all active detection channels within Ct cutoff values. The above requirements must be met each time the experiment is performed; otherwise, the experiment is considered invalid. The reason for invalidation needs to be resolved and the test result needs to be repeated using residual samples stored appropriately." B. Review of the laboratory's policies and procedures titled Filtrous ampPCR FluA, FluB, Covid & RSV Combo Validation, effective 11/18/2024 under VALIDATION AND METHODOLOGY stated, "2.7. Differences in reaction conditions may lead to noise in negative controls and patient samples which contributes to Ct values. Noise may be present in forms such as but not limited to linear (non sigmoidal) amplification, nonsignificant amplification, and irregular curve shape. It is required to review the amplification curves for each sample and PCR mix combination to determine validity of the amplification curve. See instructions below for result interpretation. Do not result patient specimens without reviewing amplification curves for validity. 2.8. Targets are determined to be present for a particular analyte only if the following three criteria are met: 2.8.1. Ct value must be less than the cutoff value 2.8.2. Amplification curve in the linear view or multicomponent plot must have significant amplification. 2.8.2.1. Amplification Plots should be compared to amplification in positive and negative controls to determine if there is significant amplification. 2.8.3. Amplification curve must be sigmoidal. 2.9. A curve that does not meet the above criteria is determined to be 'Not amplified'." C. Review of laboratory records from 11 /12/2024 - 01/15/2025 showed qPCR testing was performed on the following dates: 1. 11/12/2024 2. 11/15/2024 3. 12/03/2024 4. 01/14/2025 5. 01/15/2025 D. During a tour of the laboratory on February 26, 2025 at 1415 hours the only curves from the test runs available for review was from the most recent test run: 01/15/2025. E. Interview with Testing Personnel as listed on the CMS Form 209 on February 26, 2025 at 1505 hours in the laboratory acknowledged only the curves from the most recent run was available for review, that the curves were not retained only the CT (cut off) values. F. Review of the CMS Form 116 showed an estimated annual volume of 7,680 tests and approximately 1,920 tests had been reported to date.
D5300	PREANALYTIC SYSTEMS CFR(s): 493.1240 Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, 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 preanalytic systems and correct identified problems as specified in 493. 1249 for each specialty and subspecialty of testing performed.

	This CONDITION is not met as evidenced by: Based on review of the manufacturer's instructions, laboratory's policies and procedures, laboratory records, interview, pre-survey paperwork, email, phone call and client collection instructions, the laboratory failed to monitor and evaluate the overall quality of the pre-analytic systems and correct identified problems. Findings follow. 1.The laboratory failed to follow manufacturer's instructions for specimen handling for its real-time reverse transcription polymerase chain reaction (RT-PCR) testing for Flu A, Flu B, Sars-CoV-2, RSV Combo A&B for 20 out of 37 specimens reviewed between 11/12/2024 - 01/15/2025 (refer to D5311 I). 2. The laboratory failed to provide its clients with specimen handling instructions for its real-time reverse transcription polymerase chain reaction (RT-PCR) testing for Flu A, Flu B, Sars-CoV-2, RSV Combo A&B for 106 of 106 days reviewed from 11/12/2024 - 02 /26/2025 (refer to D5311 II).
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) (a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (a)(1) Patient preparation. (a)(2) Specimen collection. (a)(3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (a)(4) Specimen storage and preservation. (a)(5) Conditions for specimen transportation. (a)(6) Specimen processing. (a)(7) Specimen acceptability and rejection. (a)(8) Specimen referral. This STANDARD is not met as evidenced by: I. Based on review of the manufacturer's instructions, laboratory's policies and procedures, review of laboratory records, interview, pre-survey paperwork, email and phone call, the laboratory failed to follow manufacturer's instructions for specimen handling for its real-time reverse transcription polymerase chain reaction (RT-PCR) testing for Flu A, Flu B, Sars-CoV-2, RSV Combo A&B for 20 out of 37 specimens reviewed between 11/12/2024 - 01/15/2025. Findings follow. A. Manufacturer's Instructions: 1. Review of the MSDS (material safety data sheets) for the viral transport media (VTM) tubes with and without neutralizing solution: a. Filtrous VTM Direct Formula (purple top), COV-30-3015-K1, under Storage Method stated, "Storage Notes After collection, the specimen is stable at room temperature between 5-30 degrees Celsius for up to 120 hours (5 days)." b. Filtrous VTM-N Neutralizing Formula (blue top), COV-10-L002-K1, under Storage Method stated, "Storage Notes After collection, specimen is stable at room temperature for 24-48 hours." 2. Review of the Filtrous Direct ampPCR Flu A, Flu B, Covid, RSV A/B Combo q-PCR Detection Panel package insert, revision 03/20/2024, under SAMPLE TYPE AND PRESERVATION under Sample Preservation stated, "Avoid freezing the viral transport media that contains the patient sample. The sample should be stored at 4 degrees Celsius and tested within 3 days of swabbing." B. Review of the laboratory's policies and procedures titled 1. Filtrous ampPCR FluA, FluB, Covid & RSV Combo Validation, effective 11/18/2024; 2. Swab DNA/RNA Extraction Kit Procedure, effective 11/18/2024; 3. ampPCR FluA, FluB, Covid and RSV Combo qPCR Detection Panel Procedure, effective 11/18/2024, did not specify the sample collection and handling requirements. A laboratory policy and procedure that discussed specimen collection and handling was requested on February 26, 2025 at 1355 hours but not provided. C. Review of laboratory records showed PCR testing was performed on the following dates: 1. 11/12/2024 2. 11/15/2024 3. 12/03/2024 4. 01/14/2025 5. 01 /15/2025 D. Interview with the Quality Manager on February 26, 2025 at 1355 hours

in the office stated the VTM tubes were good for 72 hours after collection. Interview with Testing Personnel as listed on the CMS Form 209 on February 26, 2025 at 1505 hours in the laboratory acknowledged the laboratory received about an equal number of blue and purple top [VTM] tubes, but remembered that for the run in December, all the tubes were blue tops. He confirmed he accessioned the samples and checked the collection dates. There was no documentation in the laboratory to identify which VTM tubes were received for each patient. He acknowledged the accession date on the test report was also the run date. E. Random review of patient reports revealed specimen stability was not followed as evidenced by the collection date and accession date (which also served as the test run date) as listed by laboratory accession number: Lab accession #|Collection Date& Time|Accession Date & Time|Elapsed Time Run on November 12: 1. 2411120100|11/05/2024@15:59|11/12/2024@11:24|6 days 19 hours 25 minutes 2. 2411120101|11/05/2024@12:20|11/12/2024@11:24|6 days 23 hours 4 minutes RUN in December using Blue top VTM: 3. 2412030044|11/29 /2024@10:28|12/03/2024@10:21|3 days 23 hours 53 minutes 4. 2412030045|11/29 /2024@10:28|12/03/2024@10:22|3 days 23 hours 54 minutes 5. 2412030046|11/29 /2024@11:33|12/03/2024@10:22|3 days 22 hours 49 minutes 6. 2412030047|11/29 /2024@11:09|12/03/2024@10:31|3 days 23 hours 22 minutes 7. 2412030048|11/29 /2024@11:11|12/03/2024@10:31|3 days 23 hours 20 minutes 8. 2412030049|11/29 /2024@09:03|12/03/2024@10:32|4 days 1 hour 29 minutes 9. 2412030050|11/29 /2024@11:10|12/03/2024@10:32|3 days 23 hours 22 minutes 10. 2412030051|11/29 /2024@13:15|12/03/2024@10:32|3 days 21 hours 17 minutes 11. 2412030052|11/29 /2024@11:15|12/03/2024@10:32|3 days 23 hours 17 minutes 12. 2412030053|11/29 /2024@10:39|12/03/2024@10:32|3 days 23 hours 53 minutes Run on January 14: 13. 2501140003|01/09/2025@17:21|01/14/2025@11:08|4 days 17 hours 47 minutes 14. 2501140004|01/09/2025@14:39|01/14/2025@11:08|4 days 20 hours 29 minutes 15. 2501140005|01/09/2025@16:03|01/14/2025@11:08|4 days 19 hours 5 minutes 16. 2501140006|01/09/2025@17:24|01/14/2025@11:08|4 days 17 hours 44 minutes 17. 2501140007|01/10/2025@14:32|01/14/2025@11:08|3 days 20 hours 36 minutes 18. 2501140008|01/10/2025@10:53|01/14/2025@11:08|4 days 0 hours 15 minutes 19. 2501140009|01/10/2025@10:47|01/14/2025@11:08|4 days 0 hours 21 minutes 20. 25011400010|01/10/2025@16:01|01/14/2025@11:08|3 days 19 hours 7 minutes * All of the test results were "not detected" for Flu A, Flu B, Sars-CoV-2, RSV Combo A&B with the exception of one report that was QNS (quantity not sufficient). F. Review of the CMS Form 116 showed an estimated annual volume of 7,680 tests, and approximately 1,920 tests had been reported to date. G. Email from the Quality Manager on February 28, 2025 at 0735 hours provided surveyor with an updated MSDS for the blue top vials. H. Review of the Filtrous VTM-N Neutralizing Formula (blue top) MSDS, COV-10-L002-K1, revised 5/25/2024, under Storage Method stated, "Storage Notes After collection, specimen is stable at room temperature for 28 days." I. Phone interview with the Quality Manager and manufacturer's customer support on February 28, 2025 at 1500 hours confirmed the package insert of the detection panel was a 3 day specimen handling requirement. Customer support stated that was intended to be preliminary and the facility was to do a stability study at validation to extend specimen handling beyond the three days. Interview with the Quality Manager confirmed a stability study was not performed. II. Based on review of the manufacturer's instructions, client collection instructions, review of laboratory records, interview, and pre-survey paperwork, the laboratory failed to provide its clients with specimen handling instructions for its real-time reverse transcription polymerase chain reaction (RT-PCR) testing for Flu A, Flu B, Sars-CoV-2, RSV Combo A&B for 106 of 106 days reviewed from 11/12/2024 - 02/26/2025. Findings follow. A. Review of the Filtrous Direct ampPCR Flu A, Flu B, Covid, RSV A/B Combo q-PCR Detection Panel package insert, revision 03/20/2024, under SAMPLE

	TYPE AND PRESERVATION under Sample Preservation stated, "Avoid freezing the viral transport media that contains the patient sample. The sample should be stored at 4 degrees Celsius and tested within 3 days of swabbing." B. Review of the laboratory's flier for Specimen Collection provided to its clients did not include specimen handling instructions. C. Review of laboratory records showed PCR testing was performed on the following dates: 1. 11/12/2024 2. 11/15/2024 3. 12/03/2024 4. 01/14/2025 5. 01/15/2025 D. Interview with the Quality Manager on February 26, 2025 at 1355 hours in the office stated the VTM tubes were good for 72 hours after collection. Further interview with the Quality Manager on February 26, 2025 at 1510 hours in the office confirmed the client specimen collection instructions did not include specimen handling. E. Random review of patient reports revealed specimen stability was not followed as evidenced by the collection date and accession date (which also served as the test run date) as listed by laboratory accession number: Lab accession #|Collection Date& Time|Accession Date & Time|Elapsed Time Run on November 12: 1. 2411120101|11/05/2024@12:20|11/12/2024@11:24|6 days 23 hours 4 minutes 2. 2411120100|11/05/2024@15:59|11/12/2024@11:24|6 days 19 hours 25 minutes RUN in December using Blue top VTM: 3. 2412030044|11/29/2024@10:28|12/03/2024@10:21|3 days 23 hours 53 minutes 4. 2412030045|11/29/2024@10:28|12/03/2024@10:22|3 days 23 hours 54 minutes 5. 2412030046|11/29/2024@11:33|12/03/2024@10:22|3 days 22 hours 49 minutes 6. 2412030047|11/29/2024@11:09|12/03/2024@10:31|3 days 23 hours 22 minutes 7. 2412030048|11/29/2024@11:11|12/03/2024@10:31|3 days 23 hours 20 minutes 8. 2412030049|11/29/2024@09:03|12/03/2024@10:32|4 days 1 hour 29 minutes 9. 2412030050|11/29/2024@11:10|12/03/2024@10:32|3 days 23 hours 22 minutes 10. 2412030051|11/29/2024@13:15|12/03/2024@10:32|3 days 21 hours 17 minutes 11. 2412030052|11/29/2024@11:15|12/03/2024@10:32|3 days 23 hours 17 minutes 12. 2412030053|11/29/2024@10:39|12/03/2024@10:32|3 days 23 hours 53 minutes Run on January 14: 13. 2501140003|01/09/2025@17:21|01/14/2025@11:08|4 days 17 hours 47 minutes 14. 2501140004|01/09/2025@14:39|01/14/2025@11:08|4 days 20 hours 29 minutes 15. 2501140005|01/09/2025@16:03|01/14/2025@11:08|4 days 19 hours 5 minutes 16. 2501140006|01/09/2025@17:24|01/14/2025@11:08|4 days 17 hours 44 minutes 17. 2501140007|01/10/2025@14:32|01/14/2025@11:08|3 days 20 hours 36 minutes 18. 2501140008|01/10/2025@10:53|01/14/2025@11:08|4 days 0 hours 15 minutes 19. 2501140009|01/10/2025@10:47|01/14/2025@11:08|4 days 0 hours 21 minutes 20. 25011400010|01/10/2025@16:01|01/14/2025@11:08|3 days 19 hours 7 minutes * All of the test results were "not detected" for Flu A, Flu B, Sars-CoV-2, RSV Combo A&B with the exception of one report that was QNS (quantity not sufficient). F. Review of the CMS Form 116 showed an estimated annual volume of 7,680 tests, and approximately 1,920 tests had been reported. G. Phone interview with the Quality Manager and manufacturer's customer support on February 28, 2025 at 1500 hours confirmed the package insert of the detection panel was a 3 day specimen handling requirement. Customer support stated that was intended to be preliminary and the facility was to do a stability study at validation to extend specimen handling beyond the three days [and refrigeration requirement]. Interview with the Quality Manager confirmed a stability study was not performed.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if

	applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, temperature charts, observation, and interview, the laboratory failed to ensure the temperature was monitored within manufacturer's specifications for 13 out of 13 days documented from December 2024 to February 2025 reviewed for the real-time reverse transcription polymerase chain reaction (RT-PCR) testing performed. Findings follow. A. Review of the Filtrous ampPCR Flu A, Flu B, Covid, RSV A/B Combo q-PCR Detection Panel package insert, revision 02/20/2025, under TRANSPORT AND STORAGE INSTUCTIONS stated, "Store the kit frozen at -20 +/- 5 degrees Celsius and avoid repeated freeze thaw cycles (less than 4 frozen - thaw times allowed)." B. Review of the temperature charts from December 2024 to February 26, 2025 revealed the documented temperatures ranged from -25.8 to -28.5 degrees Celsius as listed below by documented date and temperature in Celsius: 1. 12/02/2024 -27.6 2. 12/03/2024 -28.2 3. 12/09/2024 -26.1 4. 12/23/2024 -25.8 5. 01/13/2025 -27.1 6. 01/14/2025 -28.5 7. 01 /15/2025 -27.9 8. 01/20/2025 -28.5 9. 01/27/2025 -27.4 10. 02/03/2025 -27.1 11. 02/10 /2025 -28.2 12. 02/17/2025 -26.4 13. 02/24/2025 -27.5 C. During a tour of the laboratory on February 26, 2025 at 1340 hours, the surveyor observed 9 packages of the Filtrous ampPCR Flu A, Flu B, Covid, RSV A/B Combo q-PCR Detection Panels located in the freezer, Lot 240716001, expiration 07/16/2025. D. Interview with Testing Personnel as listed on the CMS Form 209 on February 26, 2025 at 1345 hours in the laboratory acknowledged the freezer was not capable of reaching -25 [degrees Celsius].
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 manufacturer's instructions, laboratory's policies and procedures, laboratory records, interview, pre-survey paperwork, email, phone call, client collection instructions, and observation, the laboratory director failed to provide overall management and direction of the laboratory. Findings follow. 1. The laboratory director failed to ensure the laboratory performed quality laboratory services for all aspects of test performance, including the preanalytic phase of testing (see D6082). 2. The laboratory director failed to provide a safe environment protecting employees from physical chemical and biological hazards (see D6084).
D6082	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1) (e) The laboratory director must-- (e)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic,

	and postanalytic phases of testing; This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions, laboratory's policies and procedures, laboratory records, interview, pre-survey paperwork, email, phone call and client collection instructions, the laboratory director failed to ensure the laboratory performed quality laboratory services for all aspects of test performance, including the preanalytic phase of testing. Findings follow. 1.The laboratory failed to follow manufacturer's instructions for specimen handling for its real-time reverse transcription polymerase chain reaction (RT-PCR) testing for Flu A, Flu B, Sars-CoV-2, RSV Combo A&B for 20 out of 37 specimens reviewed between 11/12/2024 - 01/15/2025 (refer to D5311 I). 2. The laboratory failed to provide its clients with specimen handling instructions for its real-time reverse transcription polymerase chain reaction (RT-PCR) testing for Flu A, Flu B, Sars-CoV-2, RSV Combo A&B for 106 of 106 days reviewed from 11/12/2024 - 02/26/2025 (refer to D5311 II).
D6084	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(2) provide a safe environment in which employees are protected from physical, chemical, and biological hazards; This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, laboratory policy and procedure, observation and interview the laboratory director failed to provide a safe environment protecting employees from physical chemical and biological hazards (see D3011).
D6108	LABORATORY TECHNICAL SUPERVISOR CFR(s): 493.1447 The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart. This CONDITION is not met as evidenced by: Based on review of the manufacturer's instructions, laboratory's policies and procedures, laboratory records, interview, pre-survey paperwork, email, phone call and client collection instructions, the technical supervisor failed to provide technical supervision of the laboratory (see D6112).
D6112	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451 The technical supervisor is responsible for the technical and scientific oversight of the laboratory. The technical supervisor is not required to be on site at all times testing is performed; however, he or she must be available to the laboratory on an as needed basis to provide supervision as specified in (a) of this section. This STANDARD is not met as evidenced by:

	Based on review of the manufacturer's instructions, laboratory's policies and procedures, laboratory records, interview, pre-survey paperwork, email, phone call, and client collection instructions, the technical supervisor failed to ensure the technical and scientific oversight of the laboratory. Findings follow 1.The laboratory failed to follow manufacturer's instructions for specimen handling for its real-time reverse transcription polymerase chain reaction (RT-PCR) testing for Flu A, Flu B, Sars-CoV-2, RSV Combo A&B for 20 out of 37 specimens reviewed between 11/12 /2024 - 01/15/2025 (refer to D5311 I). 2. The laboratory failed to provide its clients with specimen handling instructions for its real-time reverse transcription polymerase chain reaction (RT-PCR) testing for Flu A, Flu B, Sars-CoV-2, RSV Combo A&B for 106 of 106 days reviewed from 11/12/2024 - 02/26/2025 (refer to D5311 II).