

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2303412	(X3) Date Survey Completed 05/21/2025
Name of Provider or Supplier Cedar Diagnostics	Street Address, City, State 1464 E Whitestone Blvd Suite 2101, Cedar Park, 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 surveyed and found to be in compliance with the Conditions of the CLIA regulations found at 42 CFR 493.1 through 493.1780, and certification is recommended. Standard level deficiencies were cited.
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions, laboratory policy and procedure, temperature logs, laboratory records, interview, and pre-survey paperwork, the laboratory failed to ensure they were monitoring and performing testing within the manufacturer's requirements for the laboratory developed test (LDT) Real-Time Reverse Transcription Polymerase Chain Reaction (RT-qPCR) extraction phase for the Respiratory Panel for one of 11 extraction days reviewed from March 2025 to May 2025. A. Review of the Marina BioLab Total Nucleic Acid Isolation Kit Instructions for Use, MBLM03 (100Rxn), under Intended Use stated, " MarinaBioLab Total Nucleic Acid Isolation Kit designed for the rapid isolation of nucleic acids (DNA, RNA) from virus, bacteria, and yeast, fungi in biofluid and transport media samples. You can use the nucleic acid purified with this kit in a broad range of molecular biology downstream applications, such as sequencing and qPCR." And under General Guidelines stated "Perform all steps at room temperature (20-25Celsius</p>

(C)), unless otherwise noted." B. Review of the laboratory policy and procedure titled King Fisher Flex Extraction SOP (standard operating procedure), effective 10/11/2024 stated, "I. Purpose: This document presents the standard operating procedure for Extraction using Marina BioLab Extraction reagents and the King Fisher Extraction machine. Reagent Preparation: 1. Ensure the Pre-PCR room is within acceptable range listed on the Temperature and Humidity Log (Temperature 18-30C, Humidity 20-75%)." The policy and procedure had an incorrect acceptable room temperature range of 18-30C, C. Review of the Room Temperature and Humidity Logs from 03/07/2025 - 05/20/2025 showed temperatures outside of 20-25C in May 2025 for the Pre-PCR room. Compared against the 11 extraction days from 03/07/2025 - 05/20/2025 showed on 05/12/2025, the room temperature was 27C. D. Review of patient testing records showed 201 patients were extracted on May 12, 2025. A sampling is listed below by accession number: 1. TD000007351 2. TD000007771 3. TD000008341 4. TD000008741 5. TD000009281 E. Interview by phone with the Technical Supervisor (as listed on the CMS Form 209) on May 21, 2025 at 1110 hours confirmed the findings. Interview with the Technical Supervisor on May 20, 2025 at 0930 hours acknowledged they had tested approximately 600 panels of 22 viruses and bacteria (13,200 tests) since March 7, 2025. F. Review of the pre-survey paperwork of an attachment to the CMS Form 116 showed the Respiratory Panel included: 1. SARS CoV-2 2. Influenza A 3. Influenza B 4. Coronavirus 229E 5. Coronavirus OC43 6. Coronavirus NL63 7. Coronavirus HKU1 8. Respiratory Syncytial Virus A 9. Respiratory Syncytial Virus B 10. Human Rhinovirus 11. Enterovirus 12. Human Bocavirus 13. Human Metapneumovirus 14. Adenovirus 15. Epstein-Barr Virus 16. Parainfluenza Virus 1 17. Parainfluenza Virus 2 18. Parainfluenza Virus 3 19. Parainfluenza Virus 4 20. Streptococcus pyogenes 21. Moraxella catarrhalis 22. Staphylococcus aureus

D5423

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE
CFR(s): 493.1253(b)(2)

(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (b)(2)(i) Accuracy. (b)(2)(ii) Precision. (b)(2)(iii) Analytical sensitivity. (b)(2)(iv) Analytical specificity to include interfering substances. (b)(2)(v) Reportable range of test results for the test system. (b)(2)(vi) Reference intervals (normal values). (b)(2)(vii) Any other performance characteristic required for test performance.

This STANDARD is not met as evidenced by:

Based on review of the verification of performance specifications, interview, and pre-survey paperwork, the laboratory failed to select relative interfering substances for the verification of performance specifications of analytical specificity for interfering substances for the laboratory developed test (LDT) Real-Time Reverse Transcription Polymerase Chain Reaction (RT-qPCR) for the Respiratory Panel for 22 of 22 viruses and bacteria performed on 09/04/2024. Findings follow. A. Review of the LDT Marina BioLab Respiratory Panel verification of performance specifications for the analytical specificity to include interfering substances performed 09/04/2024, showed the interfering substances selected were ethanol and magnetic beads. B. Interview with the Technical Supervisor (as listed on the CMS form 209) on May 20, 2025 at

1120 hours in the office acknowledged they did not test for things such as nasal sprays, Vaseline, chap stick, or Vicks vapor rub for their respiratory panel. Interview with the Technical Supervisor on May 20, 2025 at 0930 hours acknowledged they had tested approximately 600 panels of 22 viruses and bacteria (13,200 tests) since March 7, 2025. C. Review of the pre-survey paperwork of an attachment to the CMS Form 116 showed the Respiratory Panel included: 1. SARS CoV-2 2. Influenza A 3. Influenza B 4. Coronavirus 229E 5. Coronavirus OC43 6. Coronavirus NL63 7. Coronavirus HKU1 8. Respiratory Syncytial Virus A 9. Respiratory Syncytial Virus B 10. Human Rhinovirus 11. Enterovirus 12. Human Bocavirus 13. Human Metapneumovirus 14. Adenovirus 15. Epstein-Barr Virus 16. Parainfluenza Virus 1 17. Parainfluenza Virus 2 18. Parainfluenza Virus 3 19. Parainfluenza Virus 4 20. Streptococcus pyogenes 21. Moraxella catarrhalis 22. Staphylococcus aureus