Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0693948	(X3) Date Survey Completed 08/15/2024
Name of Provider or Supplier Lehigh Regional Medical Center Laboratory	**Street Address, City, State** 1500 Lee Blvd, Lehigh Acres, FL	
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	An announced CLIA validation survey was conducted at Lehigh Regional Medical Center Laboratory on August 12, 2024 through August 15, 2024. The laboratory was surveyed under 42 CFR Part 493 CLIA requirements. Standard deficiencies cited are as follows:
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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: (1) Water quality. (2) Temperature. (3) Humidity. (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 observation of the Intensive Care Unit (ICU) and Clostridioides difficile rooms, record review of the operator's manual/guide, review of temperature and humidity logs, review of patient reports, and interview with the lead medical technologist, the laboratory failed to monitor temperature and humidity in accordance with operator instructions for the GEM 4000 instrument used in blood gas testing and the Revogene instrument used in Clostridioides difficile testing in 2022, 2023 and 2024. Findings Included: A tour of the Intensive Care Unit (ICU) room on 8/13/2024 at 11:34 AM revealed no temperature and humidity gauge to monitor the GEM 4000 instrument used in blood gas testing. A tour of the Clostridioides difficile room on 8 /14/2024 at 3:13 PM revealed no temperature and humidity gauge to monitor the Revogene instrument used in Clostridioides difficile testing. Review of temperature and humidity logs for the ICU and Clostridioides difficile room revealed no documentation of temperature and humidity in 2022, 2023 and 2024. Review of the

	Revogene Operator's Manual showed Temperature: 20 to 28 Celsius (C) (68-82 Fahrenheit [F]) and Humidity: 0 to 80 Relative Humidity (RH) (non-condensing). Review of the GEM 4000 Operator's Guide showed External Ambient Temperature: 12 C (53.6 F) to 28 C (89.6 F) Humidity:15 to 805 RH. Review of patient reports revealed the following: a. Patient#1 was tested for Clostridioides difficile on 8/14 /2024 b. Patient#2 was tested for blood gases on 8/11/2024 On 8/14/2024 at 3:13 PM, the lead medical technologist confirmed temperature and humidity were not monitored for the GEM 4000 instrument in the intensive care unit (ICU) and the Revogene instrument in the Clostridioides difficile room in 2022, 2023 and 2024.
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 observation, review of the package insert and procedure manual, and interview with a Technical Consultant, the laboratory failed to properly label quality control vials for Hematology on 8/12/2024. Findings Included: Review of the Clinical Laboratory Improvement Amendments (CLIA) Application for Certification, signed and dated by the Laboratory Director on 08/12/2024, revealed the laboratory had an estimated annual test volume for hematology of 278,257 tests per year. A tour of the laboratory on 8/12/2024 at 2:00 PM, revealed the XN-L Check controls Level (L)1 lot #41801401, L2 lot #41801402 and L3 lot #41801403 for the Sysmex XN 550 and Sysmex XN 450 Hematology analyzers did not have the open date and new expiration date on the opened vials. Review of the package insert for the XN-L Check controls showed "Open vials and vials which have been sampled by cap piercing will retain stability for 15 days if stored at 2 - 8 degrees C [Celsius] after being recapped." Review of the procedure titled Reagents and Control Handling and Storage stated "All open control vials are dated when opened. All open control vials have new expiration date recorded on vial if expiration date changes once control is opened." On 8/12/24 at 2:10 PM, Technical Consultant D confirmed the hematology control vials were not labeled with the open date or expiration date, and she did not know when the vials were opened.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on observation, review of policy and a patient report, and interview with the technologist, the laboratory failed to have chemistry saline in use that was not expired for Respiratory Syncytial Virus (RSV) testing from 5/22/24 - 8/13/24. Findings Included: A lab tour on 8/13/2024 at 10:06 AM revealed a chemistry saline bottle in

	use with an expiration date of 5/22/2024. Review of the RSV procedure policy formulated on 2/28/2020 revealed "Transport Media: Saline. Swab Sample Preparation procedure: Elute swab in 0.5-3.0 ml of a liquid transport system by rotating swab in the liquid." Review of patient reports revealed the following: a. Patient #1 was tested for RSV on 8/8/2024 at 1:13 PM. On 8/13/2024 at 2:03 PM, a technologist confirmed the chemistry saline was expired and used for RSV testing since the time of expiration.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review of patient reports, and interview with the Laboratory Director, the laboratory failed to ensure quality control (QC) results for immunohistochemistry (IHC) stains were documented by the Laboratory Director and Testing Personnel #B for acceptability before reporting patient results from 02/15/2023 - 02/13/2024. Findings Included: Review of four out of four patient reports (#1, #2, #3, and #4) revealed no documentation of IHC quality control. On 08/15/2024 at 9:30 AM, the Laboratory Director confirmed the IHC QC results were not documented. The Laboratory Director stated he thought the IHC QC documentation was part of the patients' pathology report.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of patient test reports and staff interview, the laboratory failed to identify the histopathology laboratory location where the technical component of immunohistochemistry staining was performed for 4 out of 4 (#1, #2, #3, #4) patient test reports reviewed. Findings Included: Review of four patient test reports (#1, #2, #3, and #4) revealed the patient reports did not have the name of the histopathology laboratory that performed the immunohistochemistry staining. On 08/15/2024 at 9:10 AM, the Laboratory Director confirmed the patient test reports did not have the name of the histopathology laboratory that performed the immunohistochemistry staining.