| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 40D0899990 | 08/23/2022 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Laboratorio Clinico Y Bacteriologico Santiago | Carretera 111 Km 51 Hm 7 Bo Caguana, Utuado, PR | |

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 |
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| **D5403** | PROCEDURE MANUAL<br>CFR(s): 493.1251(b)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on routine and special chemistry procedure manual review and laboratory supervisor interview; it was determined that the laboratory not have a procedure manual available for routine chemistry: The findings include: 1. The laboratory performed routine chemistry tests in RA 500 by technicon and uses a randox reagents. 2. Review of the routine chemistry procedure manual for RA 500 on August 23, 2022 at 11:30 am showed that no information regarding the following requirements was included: a. Requirements for patient preparation, specimen collection, storage, preservation, transportation, processing and referral criteria for specimen acceptability |

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| | and rejection. b. Normal values c. Limitations in the test methodology, including interfering substances d. Pertinent literature references e. Criteria to determine acceptable control results f. Preparation of control used in the test. g. Step by step performance or procedure, including test calculations and interpretation of results. h. Preparation of solutions, calibrators, control, reagents and other materials used in testing. i. Linearity procedure j. How to performed a calibration and frequency. 3. The laboratory supervisor confirmed on August 23, 2022 at 11:45 am that the procedure manual was not available. |
| **D5411** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(a)<br><br>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.<br><br>This STANDARD is not met as evidenced by:<br>Based on quality control records review, procedure manual review and laboratory general supervisor interview, it was determined that the laboratory failed to monitor and document the laboratory's room temperature since January 1, 2022 to August 23, 2022. The findings include: 1. On August 23, 2022 at 11:00 am the laboratory quality control and procedures manual was requested and review. 2. From January 1, 2022 to August 23, 2022 the laboratory did not monitor and document the daily the room temperature. A laboratory thermometer for monitor the room temperature in the testing area was requested and was not available at the time of inspection 4. The laboratory general supervisor confirmed on August 23, 2022 at 11:18 am, that the laboratory did not monitor and document the room temperature since January 1, 2022. |
| **D5471** | CONTROL PROCEDURES<br>CFR(s): 493.1256(e)(1)(g)<br><br>(e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed.<br><br>This STANDARD is not met as evidenced by:<br>Based on General Immunology quality control records review and laboratory general supervisor interview, it was determined that the laboratory did not evaluate the new lots of Rheumatoid factor (RA) test, Rapid Plasma Reagin (RPR) test prior to placed it in routine use. The findings include: 1. The laboratory quality control records were review on August 23, 2022 at 9:11 am, from January 1, 2022 to August 23, 2022. 2. The laboratory received the following reagent kit and no evaluation of their reactivity was performed: Test Lot Expiration Date RA 88920 1/31/2023 RPR 21222 10/31 /2023 3. The laboratory processed and reported 34 RPR (Rapid plasma reagin) patients and 4 RA (Rheumatoid factor) patients since January 1, 2022. |
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| **D6093** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(5)<br><br>The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.<br><br>This STANDARD is not met as evidenced by:<br>Based on Routine Chemistry and General Immunology quality control records review and laboratory general supervisor interview on August 23, 2022 at 12:05 pm, it was found that the laboratory director did not assure that quality control procedures. Refer to D5403, D 5411, D 5471 |