| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 40D0902422 | 07/14/2022 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Laboratorio Clinico Noy & Reference | 239 Arterial Hostos, Local 2 Y 1, San Juan, 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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| **D5421** | ESTABLISHMENT AND VERIFICATION OF PERFORMANCE<br>CFR(s): 493.1253(b)(1)<br><br>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.<br><br>This STANDARD is not met as evidenced by:<br>Based on lack of the performance specifications records for the sperm counting by hemocytometer method, procedures manual , sperm counting testing records review and interview with the general supervisor and laboratory director, it was determined that the laboratory failed to validate the sperm counting by hemocytometer method since July 14, 2020. The findings include: 1. On July 14, 2022 at 9:30 AM, the the sperm counting testing records showed that the laboratory performed the sperm counting by the hemocytometer method since July 14, 2020. The testing records did not include information about the dilution solution used to dilute the semen prior to perform the count. 2. On July 14, 2022 at 9:40 AM, the general supervisor stated that the laboratory used water to dilute the semen and used this protocol in the laboratory for at least 10 years. 3. On July 14, 2022 at 9:50 AM, the procedures manual showed the protocol of sperm counting by the hemocytometer method was revised by the laboratory director on 09/03/2020. The laboratory establish to dilute the sperm with water to perform the counting of the sperm cells by the hemocytometer. However, this protocol did not include a pertinent literature references. 4. On July 14, 2022 at 9:58 AM, the laboratory did not have available the validation of this method. 5. On July 14, 2022 at 10:15 AM, the laboratory director confirmed that the laboratory used water to dilute the sperm prior to counting and stated that this method were placed in routine |

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| | use since ten years ago. Also stated that the validation of this method is not available in the laboratory. 6. The laboratory performed five out of five sperm counting by the hemocytometer method from May 5, 2022 to June 29, 2022 (patients #37411, #377756, #183943, # 382018 and #186842). |
| **D5551** | IMMUNOHEMATOLOGY<br>CFR(s): 493.1271(a)(f)<br><br>(a) Patient testing. (a)(1) The laboratory must perform ABO grouping, D (Rho) typing, unexpected antibody detection, antibody identification, and compatibility testing by following the manufacturer's instructions, if provided, and as applicable, 21 CFR 606.151(a) through (e). (a)(2) The laboratory must determine ABO group by concurrently testing unknown red cells with, at a minimum, anti-A and anti-B grouping reagents. For confirmation of ABO group, the unknown serum must be tested with known A1 and B red cells. (a)(3) The laboratory must determine the D (Rho) type by testing unknown red cells with anti-D (anti-Rho) blood typing reagent. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section.<br><br>This STANDARD is not met as evidenced by:<br>Based on immunohematology quality control records review(years 2021 and 2022) and general supervisor interview on July 14, 2002, it was determined that the laboratory failed to follow quality control procedures when six out six patients specimens were testing for ABO group and Rh from January 20, 2022 to June 22, 2022. The findings include: 1. On July 14, 2002 at 10:00 am, the ABO group and Rh testing records showed that the laboratory did not perform the quality control procedures when six out six patients specimens were testing for ABO group and Rh the following days: Date Patient ID January 20, 2022 175277, 172570 and 172669 February 2, 2022 357260 April 21, 2022 371753 June 22, 2022 186634 2. On July 14, 2002 at 10:10 am, the general supervisor confirmed that those days the laboratory did not have quality control results. 3. The laboratory processed and reported six out six patients specimens for ABO group and Rh tests from January 20, 2022 to June 22, 2022. |
| **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 lack of the performance specifications records for the sperm counting by hemocytometer method, procedures manual , sperm counting testing records, Immunohematology quality control records review and interview with the general supervisor and laboratory director on July 14, 2022, it was determined that the laboratory director failed to ensure compliance with the analytic system requirements for the sperm counting and for the ABO group and Rh tests. Refer to D 5421 ( The laboratory failed to validate the sperm counting by hemocytometer method since July |

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| | 14, 2020). Refer to D 5551 ( The laboratory failed to follow quality control procedures when patients specimens were testing for ABO group and Rh from January 20, 2022 to June 22, 2022). |