

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0696875	(X3) Date Survey Completed 05/12/2022
Name of Provider or Supplier North Western Medical Laboratory	Street Address, City, State Ave Severiano Cuevas 24, Apartamento 101, Aguadilla, 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
D5024	<p>HEMATOLOGY CFR(s): 493.1215</p> <p>If the laboratory provides services in the specialty of Hematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1269, and 493.1281 through 493.1299.</p> <p>This CONDITION is not met as evidenced by: Based on hematology quality control records review (years 2021-2022) and laboratory director interview on May 12, 2022 at 10:30 AM, it was determined that the laboratory failed to meet the analytic system requirements for Hematology specialty (sperm cell counts). Refer to D5543 (the laboratory failed to include on control material each 8 hours of operation when manual sperm cell counts were performed by hemacytometer reviewed on May 12, 2022 at 10:15 AM.</p>
D5543	<p>HEMATOLOGY CFR(s): 493.1269(a)(d)</p> <p>(a) For manual cell counts performed using a hemocytometer-- (a)(1) One control material must be tested each 8 hours of operation; and (a)(2) Patient specimens and control materials must be tested in duplicate. (d) The laboratory must document all control procedures performed, as specified in this section.</p> <p>This STANDARD is not met as evidenced by: Based on sperm count testing records review (years 2021-2022), lack of quality control records and laboratory director interview on May 12, 2022 at 10:30 AM, it was determined that the laboratory failed to include one control material each 8 hours of operation when manual sperm cell counts were performed by hemocytometer. The</p>

	<p>findings include: 1. On May 12, 2022 at 10:00 AM, the records showed that the laboratory performed manual cell counts (sperm cell count) by the hemocytometer. 2. On May 12, 2022 at 10:15 AM , the records were reviewed from January 2021 to May 11, 2022 and showed that the laboratory did not include one control material each 8 hour of operation when 57 out 57 patients specimens were processed for sperm cell counts by the hemocytometer. 3. The laboratory processed and reported fifty seven (57) sperm count patient's samples from January 2021 to May 11, 2022. (2021=48 and 2022=9). 4. The laboratory director confirmed on May 12, 2022 at 10:30 AM, that the testing record not show any documentation of the control procedure.</p>
<p>D6076</p>	<p>LABORATORY DIRECTOR CFR(s): 493.1441</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on hematology quality control records review and laboratory director interview on May 12, 2022 at 10:30 AM, it was determined that the laboratory director failed to fulfill his responsibilities and duties to ensure compliance with the laboratory quality control requirements. Refer to D 6093.</p>
<p>D6093</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on hematology quality control records review (years 2021-2022) and laboratory director interview on May 12, 2022 at 10:30 AM, it was found that the laboratory director did not assure that the quality control procedures related to sperm cell counts were followed (The laboratory did not include any control material for sperm count test. Reviewed on May 12, 2022 at 10:15 AM). Refer D5543.</p>
<p>D6144</p>	<p>GENERAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1463</p> <p>The general supervisor is responsible for day-to-day supervision or oversight of the laboratory operation and personnel performing testing and reporting test results.</p> <p>This STANDARD is not met as evidenced by: Based on hematology quality control records review (years 2021-2022) and laboratory director interview on May 12, 2022 at 10:30 AM, it was determined that the general supervisor did not assure that quality control procedures were followed by the testing personnel. (The laboratory did not include any control material for sperm count test. Reviewed on May 12, 2022 at 10:15AM). Refer to D5443.</p>