

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0690738	(X3) Date Survey Completed 12/26/2019
Name of Provider or Supplier Lab Clin Referencia Cima	Street Address, City, State Calle Saturnino Rodriguez #7, Yabucoa, 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 2018-2019) and laboratory general supervisor interview on December 26, 2019 at 11:00 AM, it was determined that the laboratory failed to meet the analytic system requirements for Hematology specialty (sperm cell counts). Refer to D 5543 (the laboratory failed to include one control material each 8 hours of operation when manual sperm cell counts were performed by hemocytometer).</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 2018-2019), lack of quality control records and laboratory general supervisor interview on December 26, 2019 at 11:00 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 findings include: 1. The records showed that the laboratory</p>

	<p>performed manual cell counts (sperm cell count) by the hemocytometer. 2. From January 2018 to December 25, 2019, the records showed that the laboratory did not include one control material each 8 hours of operation when 27 out of 27 patients specimens were processed for sperm cells counts by the hemocytometer. 3. The laboratory processed and reported twenty seven sperm count patient's samples from January 2018 to December 25, 2019. (2018 = 15, 2019 = 12). 4. The laboratory general supervisor confirmed on December 26, 2019, 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 general supervisor interview on December 26, 2019 at 11:00 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 2018-2019) and laboratory general supervisor interview on December 26, 2019 at 11:00 AM , it was found that the laboratory director did not assure that the quality control procedures related to sperm cells counts were followed. Refer to D 5543.</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 2018-2019) and laboratory general supervisor interview on December 26, 2019 at 11:00 AM , it was determined that the general supervisor did not assure that quality control procedures were followed by the testing personnel. Refer to D6177.</p>
<p>D6177</p>	<p>TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1495(b)(3)</p>

Each individual performing high complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed.

This STANDARD is not met as evidenced by:

Based on hematology quality control records review (years 2018-2019) and laboratory general supervisor interview on December 26, 2019 at 11:00 AM , it was determined that testing personnel failed to follow quality control procedures. The finding includes: 1. The laboratory failed to include one control material each 8 hours of operation when manual sperm cell counts were performed by hemocytometer. The laboratory processed and reported twenty seven (27) sperm count patient's samples from January 2018 to December 25, 2019. (2018 = 15, 2019 = 12).