

<p>Statement of Deficiencies</p>	<p>(X1) Provider/Supplier/CLIA Identification Number</p> <p>40D2287572</p>	<p>(X3) Date Survey Completed</p> <p>03/20/2025</p>
<p>Name of Provider or Supplier</p> <p>Laboratorio Clinico Marina</p>	<p>Street Address, City, State</p> <p>Carretera 110, Km 19, Hm 6 Barrio Centro, Moca, PR</p>	
<p>For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.</p>		

<p>(X4) ID Prefix Tag</p>	<p>Summary Statement of Deficiencies</p>
<p>D5417</p>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on direct observation of the Human Chorionic Gonadotropin (hCG) box kit, quality control records and laboratory testing personnel interview on March 20, 2025 at 10:25 A.M., it was determined that the laboratory used an expired hCG kit from January 13, 2025 to March 14, 2025 on patient samples. The laboratory performed and reported three (3) patient samples. The findings include: 1. The laboratory used hCG by Alere hCG combo. A direct observation was performed and showed that the hCG kit that was in use, at the time of survey, was received on January 2, 2024 (Lot: 0000667202 exp. 2025-01-11) (reviewed on March 20, 2025 at 10:20 A.M). 2. Review of the hCG quality control records on March 20, 2025 at 10:25 A.M., showed that the laboratory used a expired hCG kit from January 13, 2025 to March 14, 2025. The laboratory processed and reported three (3) patients sample from January 13, 2025 to March 14, 2025. 3. The laboratory testing personnel confirmed on March 20, 2025 at 10:25 A.M., that the laboratory failed to used expired hCG kit from January 13, 2025 to March 14, 2025 on patient samples. The laboratory performed and reported three (3) patient samples.</p>
<p>D5445</p>	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g)</p> <p>(d) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the</p>

laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (d)(3) At least once each day patient specimens are assayed or examined perform the following for:

This STANDARD is not met as evidenced by:
Based on the Human Chorionic Gonadotropin (hCG) quality control records reviewed and laboratory testing personnel interview on March 20, 2025 at 10:17 A.M., it was determined that the laboratory did not include the external positive and negative control material each day of patient testing. The laboratory processed and reported four (4) patients sample from January 9, 2025 to March 14, 2025. The findings include: 1. Review of the hCG quality control records on March 20, 2025 at 10:00 A.M., showed that the laboratory did not include the external positive and negative control material each day of patient testing. The laboratory processed and reported four (4) patients sample from January 9, 2025 to March 14, 2025. 2. The laboratory testing personnel confirmed on March 20, 2025 at 10:17 A.M., that the laboratory failed to include the positive and negative external control material each day of patient testing. The laboratory processed and reported four (4) patients sample from January 9, 2025 to March 14, 2025.

D6020

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(5)

(e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;

This STANDARD is not met as evidenced by:
Based on direct observation, review of the quality control records, and interview with the laboratory testing personnel on March 20, 2025 at 11:30 AM; it was determined that the laboratory director did not ensure that the quality control that were establish were follow. D5414, D5445.