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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 40D0658307 | (X3) Date Survey Completed 11/09/2023 |
| Name of Provider or Supplier Lab Clinico Sagrado Corazon | Street Address, City, State San Claudio 370 Urb Sagrado Corazon, 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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| D5479 | <p>CONTROL PROCEDURES CFR(s): 493.1256(e)(5)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (5) Follow the manufacturer's specifications for using reagents, media, and supplies and be responsible for results. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on Human chorionic gonadotropin (hCG) manufacturer's instructions, worksheet records review and laboratory director interview on November 9, 2023 at 11:20 AM, it was determined that the laboratory failed to follow manufacturer's instructions to document the internal control each day of control testing when processing patient hCG samples. The findings include: 1. The laboratory performed (hCG) human chorionic gonadotropin by One step kit. 2. The manufacturer's instructions stated that the laboratory must monitor and document the internal control to ensure the validity of the hCG test performed. 3. The hCG test worksheet records showed on November 9, 2023 at 11:20 AM, that the laboratory did not document the observed results of the internal procedural control each day of control testing when processing patient hCG samples. 4. The laboratory processed and reported 461 hCG patient samples from January 1, 2022 to November 9, 2023. 5. The laboratory director confirmed on November 9, 2023 at 11:25 AM, that the laboratory failed to monitor and document the internal control each day of control testing when processing patient hCG samples.</p> |
| D6086 | <p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii)</p> <p>The laboratory director must ensure that verification procedures used are adequate to</p> |

determine the accuracy, precision, and other pertinent performance characteristics of the method.

This STANDARD is not met as evidenced by:

Based on Human chorionic gonadotropin (hCG) manufacturer's instructions, worksheet records review and laboratory director interview on November 9, 2023 at 11:20 AM, it was determined that the laboratory director failed to fulfill her responsibilities and duties to ensure compliance with the manufacturer's instructions and laboratory quality control requirements. Refer to D 5479.