| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 40D2048021 | 05/07/2019 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Laboratorio Clinico Caimito | Carretera 842, Km 5, Hm4 Caimito Alto, 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** | CONTROL PROCEDURES<br>CFR(s): 493.1256(e)(5)(g)<br><br>(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.<br><br>This STANDARD is not met as evidenced by:<br>Based on complete blood count (CBC) quality control records, Coulter Act 5 diff control plus manufacturer instructions review and laboratory director interview on May 7, 2019 at 9:40 AM, it was determined that the laboratory failed to follow the manufacturer's specifications for using the CBC controls materials when 232 patients specimens were tested and reported by the Coulter Act 5 diff system from January 8, 2019 to March 5, 2019. The findings include: 1. The laboratory analyzed and reported the CBC patient's specimens by the the Coulter Act 5 diff system . 2. The laboratory used the Coulter Act 5 diff control plus control materials. The manufacturer instructed the laboratory to use the control materials with 15 days open-vial stability. One box of this control material includes two vials of each levels (control materials for 30 days). 3. On May 7, 2019 at 9:40 AM, the CBC quality control records showed that the the laboratory opened one box of Coulter Act 5 diff control plus control and verified the following lots of control levels on December 20, 2019: lot 360119, lot 370119 and lot 380119, with the expiration date of March 5, 2019. 4. The CBC quality control records showed that the the laboratory used those lots of control material with exceeded open-vial stability from January 8, 2019 to March 5, 2019. The laboratory used one box of those control material for 62 days. 5. The laboratory director stated on May 7, 2019 at 9:40 AM, that the laboratory used the control materials until the |

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| | expiration date and not considered the open-vial stability. 6. The laboratory processed and reported 232 out of 232 CBC patients specimens from January 8, 2019 to March 5, 2019. |
| **D6020** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(5)<br><br>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided.<br><br>This STANDARD is not met as evidenced by:<br>Based on complete blood count (CBC) quality control records, Coulter Act 5 diff control plus manufacturer instructions review and laboratory director interview on May 7, 2019 at 9:40 AM, it was determined that laboratory director failed to ensure compliance with the requirements for the CBC analytic systems. The finding include: 1. Refer to D 5479 (The laboratory failed to follow the manufacturer's specifications for using the CBC controls materials when 232 patients specimens were tested and reported by the Coulter Act 5 diff system from January 8, 2019 to March 5, 2019). |