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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 40D2000974 | (X3) Date Survey Completed 02/11/2022 |
| Name of Provider or Supplier Laboratorio Clinico Figueroa | Street Address, City, State Carr Pr-155 Km 58 Hm 5 Barrio Pugnado Adentro, Vega Baja, 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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| 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 direct observation, hematology quality control records review and laboratory technical supervisor (# 1) interview on February 11, 2022 at 10:16 AM, it was determined that the laboratory failed to ensure compliance with the analytic system requirements for hematology (CBC) tests from December 6, 2021 to January 10, 2022. Refer to D 5417 (The laboratory laboratory used the CBC controls materials that have exceeded their expiration date when 246 out of 246 patients specimens were tested and reported for CBC tests from December 6, 2021 to January 10, 2022).</p> |
| D5417 | <p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>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, hematology quality control records review and laboratory technical supervisor (# 1) interview on February 11, 2022 at 10:16 AM, it was determined that the laboratory failed to used the CBC (complete blood count) controls materials that have exceeded their expiration date when 246 out of 246</p> |

patients specimens were tested and reported for CBC from December 6, 2021 to January 10, 2022. The findings include: 1. The laboratory analyzed and reported CBC patient's specimens by the DxH 520 system. 2. On February 11, 2022 at 10:16 AM, the Levy Jennings Charts showed that the laboratory used the following Coulter DxH series controls materials with exceeded their expiration date from December 6, 2021 to January 10, 2022: a. lot 372112911 exp date 12/05/2021. b. lot 372112912 exp date 12/05/2021. c. lot 372112913 exp date 12/05/2021. 3. The laboratory technical supervisor confirmed on February 11, 2022 at 10:16 AM, that the laboratory used those controls materials with exceeded their expiration date. She stated that due to the Covid Pandemic the laboratory had problems with those controls shipping. 4. The laboratory processed and reported 246 out of 246 patients specimens were tested for CBC from December 6, 2021 to January 10, 2022.

D6076

LABORATORY DIRECTOR
CFR(s): 493.1441

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.

This CONDITION is not met as evidenced by:
Based on direct observation, hematology quality control records review and laboratory technical supervisor (# 1) interview on February 11, 2022 at 10:16 AM, it was determined that the laboratory director failed to fulfill her responsibilities and duties to ensure compliance with the laboratory analytical system requirements for the CBC tests. Refer to D 6093.(The laboratory director failed to maintain the quality control procedures for the CBC tests from December 6, 2021 to January 10, 2022).

D6093

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(5)

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.

This STANDARD is not met as evidenced by:
Based on direct observation, hematology quality control records review and laboratory technical supervisor (# 1) interview on February 11, 2022 at 10:16 AM, it was determined that the laboratory director failed to maintain the quality control procedures for the CBC tests from December 6, 2021 to January 10, 2022. Refer to D 5024 (The laboratory failed to ensure compliance with the analytic system requirements for hematology (CBC) tests from December 6, 2021 to January 10, 2022).