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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 40D0658274 | (X3) Date Survey Completed 06/14/2023 |
| Name of Provider or Supplier Laboratorio Clinico El Monte Inc | Street Address, City, State 650 Ave Munoz Rivera Suite 103, Hato Rey, 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 |
|---------------------------|--|
| D5445 | <p>CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the 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. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on routine chemistry quality control records (year 2022-2023), chemistry procedure manual review, Federal Drug Administration access data base review and laboratory testing personnel interview at 10:00 AM on June 14,2023; it was determined that the laboratory did not process, two levels of control material, at least each day of testing, for the microalbumin and creatinine urine assay. The findings include: 1. The laboratory used Siemens DCA Vantage instrument to performs microalbumin and creatinine patient's samples. (Reviewed June 14,2023 at 10:00 AM.) 2. Review of Federal Drug Administration access data base on June 14, 2023, at 10:08 AM, showed that the microalbumin and creatinine test were classified as moderate complexity test. 3. Review of the chemistry procedure manual showed that for the microalbumin and creatinine test, the laboratory will process two levels of control material weekly. (Reviewed June 14, 2023, at 10:17A.M). 4. Review of the quality control records from January 9,2022 to June 14, 2023, showed that effectively, the laboratory included two levels of control material each week, instead of two levels of control material, at least each day of patients testing. (Reviewed June 14,2023 at 10:24 AM.) 5. The laboratory testing personnel confirmed on June 14,2023 at 10:32 AM, that the laboratory performed quality control procedure on a basis weekly. 6. The</p> |

laboratory processed and reported 704 patients tests for microalbumin and 556 patients tests for creatinine from January 9, 2022, to June 14, 2023. (Reviewed June 14, 2023, at 10:40 AM.)

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 routine chemistry quality control records review (2022-2023) and laboratory director interview on June 14, 2023 at 1:30 P.M.,it was determined that laboratory failed to ensure compliance with the requirements for analytic systems. Refer to D5445 (the laboratory did not process, two levels of control material, at least each day of testing, for the microalbumin and creatinine urine assay)