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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 40D2053476 | (X3) Date Survey Completed 07/11/2023 |
| Name of Provider or Supplier Laboratorio Clinico Yenimaris | Street Address, City, State Marginal Lomas De Carolina , Carr Pr-3 Km11 Hm 0, Carolina, 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 |
|---------------------------|--|
| D5783 | <p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.</p> <p>This STANDARD is not met as evidenced by: Based on Chemistry quality control records review, laboratory procedure manual and laboratory director interview on July 11, 2023 at 10:22 AM; it was determined that the laboratory failed to take and document remedial actions when control results fail to meet the laboratory's criteria for acceptability from March 10, 2023 to March 23, 2023 when 168 patient's was processed and reported for total bilirubin. The findings include: a. The laboratory performed total bilirubin (T Bil) in the Au480 by Beckman Coulter. b. On July 11, 2023 at 10:02 AM the quality control records were reviewed from January 2022 to June 2023. c. The laboratory procedure manual showed that if more than 6 control values fails above or below the one standard deviation (1SD), the laboratory must take and document a corrective action. d. Review of quality control graphs showed that the laboratory failed to take corrective action when the control material for T Bil (abnormal level) exceeded the laboratory limits with a trend above 1SD more than 6 plots. 168 patient samples were processed and reported. e. The laboratory director confirmed on July 11, 2023 at 10:22 AM, that no corrective actions were documented when 168 patient samples were processed and reported for TBil from March 10, 2023 to March 23, 2023.</p> |

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 Chemistry quality control review and laboratory director interview on July 11, 2023 at 10:30 AM; it was determined that the laboratory director fail to take corrective action when the control material exceeded the laboratory limits from March 10, 2023 to March 23, 2023 when 168 patient samples was processed and reported for Total Bilirubin. Refer to D5783.