| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 40D0705372 | 09/13/2018 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Laboratorio Clinico Del Mar | Calle Marginal Pr# 2 Urb Montecarlo #113, 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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| **D5421** | ESTABLISHMENT AND VERIFICATION OF PERFORMANCE<br>CFR(s): 493.1253(b)(1)<br><br>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the Sysmex XN 500 verification of performance specifications documents and interview with the laboratory supervisor on September 13, 2018, it was found that the laboratory did not perform the immature granulocytes method comparison prior to use. The findings include: a. The laboratory performed the Sysmex XN 500 instrument verification performance in January 2018. b. Review of the verification performance statistical data on September 13, 2018 at 10:15 AM, showed that the laboratory did not evaluate the immature granulocytes method comparison. c. The laboratory supervisor confirmed during survey that the parameter was not included. d. Since February 2018 the laboratory received and reported 2, 385 patient's samples. |
| **D5791** | ANALYTIC SYSTEMS QUALITY ASSESSMENT<br>CFR(s): 493.1289(a)(c)<br><br>(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The |

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| | laboratory must document all analytic systems assessment activities.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory Quality Assessment Program (QA) and interview with the laboratory director on September 13, 2018. it was determined that the laboratory did not follow the established written program for comparison of test results. The findings include: a. The QA program was reviewed on September 13, 2018 at 12:10 PM. b. The QA program that evaluation of patient's test results for inconsistencies (age, sex, diagnostic and others) must be evaluated using 10 patient's results and must be every six months. c. The QA program showed that the laboratory did not evaluate the patient's inconsistencies since year 2017. d. The laboratory director stated that the QA evaluation were not performed since year 2017. |
| **D6115** | TECHNICAL SUPERVISOR RESPONSIBILITIES<br>CFR(s): 493.1451(b)(2)<br><br>The technical supervisor is responsible for verification of the test procedures performed and establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the Sysmex XN 550 instrument verification of performance specification sand interview with the laboratory supervisor on September 13, 2018, it was determined that the technical supervisor did not assure to include the evaluation of the immature granulocytes parameter method comparison when the laboratory performed the instrument performance verification. The finding includes: a. The laboratory acquired a new hematology instruments (Sysmex XN 550) however did not perform the immature granulocytes parameter method comparison. Refer to D5421. |