

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 40D0658073	<b>(X3) Date Survey Completed</b> 06/27/2019
<b>Name of Provider or Supplier</b> Laboratorio Clinico Corozal Inc	<b>Street Address, City, State</b> 16 Gandara St, Corozal, PR	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5401</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on lack of Bacteriology manual, direct observation, bacteriology testing records (year 2019) and bacteriology incubator temperature chart (years 2018 and 2019) review and general supervisor interview on June 27, 2019 at 12:20 PM, it was determined that the laboratory failed to have the procedures manuals for the Bacteriology tests since July, 2017. The findings include: 1. The laboratory did not have available the procedures manual for the Bacteriology area. 2. The bacteriology testing records showed that the laboratory processed patient's urine cultures and reported the no growth and the colony count results in 48 hrs since year 2017. 3. On June 27, 2019 at 12:20 PM, it is observed and by interview with the general supervisor, that the laboratory processed patient's urine cultures with an sterile loops and streaks it across the MacConkey and blood agar culture plate media for the bacterial growth. The streaked plates were covered and incubated. 4. The bacteriology incubator temperature chart includes a temperature range of 35 C +/- 1 C. The incubator temperature charts showed temperatures results of 35 C during the years 2018 and 2019. No pertinent reference about the incubator temperature range was found. 5. The general supervisor confirmed on June 27, 2019 at 12:20 PM, that the procedures manual for the Bacteriology area was not available. 6. The laboratory processed 1,177 patient's urine cultures from January 2, 2019 to June 27, 2019.</p>
<b>D5421</b>	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p>

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.

This STANDARD is not met as evidenced by:  
Based on review of validation records of the Mindray system for complete cell count (CBC) test and general supervisor interview on June 27, 2019 at 11:00 AM, it was determined that the laboratory failed to complete the evaluation of the performance specifications of this new instruments on February 19, 2019, before processing and reporting 1,870 out of 1,870 patient's CBC specimens results from March 1, 2019 to June 27, 2019. The findings include: 1. On June 27, 2019 at 11:00 AM, the Mindray system validation records showed that the laboratory performed the validation of this instrument on February 19, 2019. However, the laboratory did not include the verification of the CBC reference intervals (normal values) in this validation procedure. 2. The laboratory includes the normal values of the former laboratory CBC's system (CellDyn 3200) in the CBC results reported by the Mindray system from March 1, 2019 to June 27, 2019. 3. The general supervisor confirmed on on June 27, 2019 at 11:00 AM, that the laboratory includes the normal values of the former laboratory CBC's system (CellDyn 3200) in the CBC results reported by the Mindray system from March 1, 2019 to June 27, 2019. She stated, that the laboratory is working to verify the normal range of the CBC tests reported by the Mandry system. 4. The laboratory processed and reported 1,870 out of 1,870 patient's CBC specimens results by the Mindray system from March 1, 2019 to June 27, 2019.

**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 review of validation records of the Mindray system for complete cell count (CBC) test and general supervisor interview on June 27, 2019 at 11:00 AM, it was determined that the laboratory failed to complete the evaluation of the performance specifications of this new instruments on February 19, 2019, before processing and reporting 1,870 out of 1,870 patient's CBC specimens results by the Mindray system from March 1, 2019 to June 27, 2019. Refer to D 5421.

**D6106**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(e)(14)

The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process.

This STANDARD is not met as evidenced by:  
Based on lack of Bacteriology manual and general supervisor interview on June 27, 2019 at 12:20 PM, it was determined that the laboratory director failed to ensure that an approved procedure manual for bacteriology procedures is available to all personnel responsible for any aspect of the testing process in the bacteriology and hematology areas since July, 2017. Refer to D 5401.

**D6144**

**GENERAL SUPERVISOR RESPONSIBILITIES**  
CFR(s): 493.1463

The general supervisor is responsible for day-to-day supervision or oversight of the laboratory operation and personnel performing testing and reporting test results.

This STANDARD is not met as evidenced by:  
Based on review of validation records of the Mindray system for CBC test and general supervisor interview on June 27, 2019 at 11:00 AM, it was determined that the general supervisor failed to perform day-to-day supervision for the personnel that performing the CBC since March 1, 2019. Refer to D 5421 (The laboratory did not complete the evaluation of the performance specifications of the new CBC system before processing and reporting 1,870 out of 1,870 patient's CBC specimens results by the Mindray system from March 1, 2019 to June 27, 2019).