

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0912552	(X3) Date Survey Completed 11/23/2022
Name of Provider or Supplier Laboratorio Clinico Baco Statlab Ii	Street Address, City, State Carr 2, Km 149 Hm 5, Bo Sabanetas Suite Num 15, Mayaguez, 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
D5020	<p>ENDOCRINOLOGY CFR(s): 493.1212</p> <p>If the laboratory provides services in the subspecialty of Endocrinology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, and 493.1281 through 493.1299.</p> <p>This CONDITION is not met as evidenced by: Based on serum Human Chorionic Gonadotropin (hCG) test quality control records (years 2021-2022) and interview with the laboratory general supervisor on November 23, 2022 at 10:45 a.m., it was determined that the laboratory failed to ensure compliance with the analytic system requirements for serum hCG qualitative tests. The finding includes: 1. The laboratory did not include each day of testing a negative and a positive control material when patients specimens were processed and reported for serum hCG qualitative test. Refer to D 5449 .</p>
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <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.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on hematology performance specifications records reviewed (1/10/2022) and laboratory general supervisor interview on November 23, 2022 at 10:09 a.m., it was determined that the laboratory failed to complete the evaluation of the performance specifications of the new hematology system. The findings include: 1. The laboratory acquired the system Mindray BC-5390 to perform (CBC) Complete Blood Count hematology tests on January 2022.(review on November 23, 2022 at 10:09 a.m.) 2. The laboratory began to use the hematology system on January 10, 2022. (review on November 23, 2022 at 10:12 a.m.) 3. From January 10, 2022 to November 23, 2022, the records showed that the laboratory did not verify the precision and manufacturer's reference intervals (normal values) appropriate for the laboratory's patient's sample prior to begin to test patient's samples.(review on November 23, 2022 at 10:15 a.m.) 3. The laboratory general supervisor confirmed on November 23, 2022 at 10:30 a.m. that the data evaluation of precision and manufacturer's reference intervals (normal values) were not include in the system validation. 4. The laboratory processed and reported 1,782 hematology patient's samples (CBC) since January 2022.

D5449

CONTROL PROCEDURES
CFR(s): 493.1256(d)(3)(ii)(g)

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-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on endocrinology quality control records review (year 2021-2022) and interview with the laboratory general supervisor on November 23, 2022 at 10:45 a.m. , it was determined that the laboratory failed to include a negative and positive control material when performed hCG test. The findings include : 1. The laboratory performed hCG (human chorionic gonadotropin) by Alere one step method.(review on November 23, 2022 at 10:45 a.m.) 2. Endocrinology quality control logs were reviewed from November 1, 2021 to November 23, 2022. (review on November 23, 2022 at 10:50 a.m.) 3. The records showed that the laboratory did not include a negative and positive control material from November 1, 2021 to October 31, 2022, when performed and reported 28 patient samples those days. (review on November 23, 2022 at 10:50 a.m.) 4. The laboratory general supervisor confirmed on November 23, 2022 at 10:55 a.m. , that the laboratory failed to include a negative and positive control material each day of testing when performed hCG test.

D5775

COMPARISON OF TEST RESULTS
CFR(s): 493.1281(a)(c)

(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.

This STANDARD is not met as evidenced by:
Based on hematology quality control records review in 2021-2022 and laboratory

	<p>general supervisor interview on November 23, 2022 at 9:30 AM, it was determined that the laboratory failed to evaluate and define twice a year the relationship between the manual cell differential and automatic cell differential. The findings include: 1. The laboratory performed automatic cell differential by Mindray hematology system. 2. Quality controls records were reviewed from February 19, 2021 to November 23, 2022. (review on November 23, 2022 at 9:35 A.M.) 3. The laboratory general supervisor confirmed on November 23, 2022 at 9:30 AM., that the laboratory failed to evaluate twice a year a relationship between the manual cell differential and automatic cell differential by hematology system since February 19, 2021.</p>
<p>D6072</p>	<p>TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(3)</p> <p>Each individual performing moderate complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed.</p> <p>This STANDARD is not met as evidenced by: Based on hCG test quality control records (year 2021-2022) and interview with the laboratory general supervisor on November 23, 2022 AM at 10:45 a.m., it was determined that the laboratory testing personnel failed to include a negative and positive control material when performed hCG test. The findings include: 1. The h CG quality control records showed that no positive neither negative control material were included each day of patient testing. Refer to D5449.</p>
<p>D6076</p>	<p>LABORATORY DIRECTOR CFR(s): 493.1441</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on hCG test quality control records review (year 2021-2022) laboratory supervisor interview on November 23, 2022 at 10:45 a.m., it was determined that the laboratory director failed to fulfill his responsibilities and duties to ensure compliance with the laboratory quality control requirements. Refer to D 6093 .</p>
<p>D6093</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on hCG test quality control records (year 2021-2022) and interview with the laboratory supervisor on November 23, 2022 AM at 10:45 a.m., it was determined that the laboratory director failed to ensure compliance with the requirements for analytic systems. The findings include: 1. The h CG quality control records showed</p>

that no positive neither negative control material were included each day of patient testing. Refer to D5449.