

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D2084733	(X3) Date Survey Completed 01/19/2018
Name of Provider or Supplier Cdt-Centro De Diagnostico Y Tratamiento	Street Address, City, State Calle Flor Gerena Final, Esq Sergio Pena, Humacao, 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
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: Based on review of Complete cells count (CBC) quality control records(2017, 2018), Mandry BC 5390 analyzer validation records(January 2017) review and general supervisor interview on January 19, 2018 at 11:35 AM, it was determined that the laboratory failed to complete the evaluation of the performance specifications of the new Mandry BC 5390 analyzer before reporting 605 out of 605 patients CBC test results from January 30, 2107 to December 31, 2017. The findings include: 1. On January 19, 2018 at 11:35 AM, the Mandry BC 5390 analyzer validation records showed that the laboratory performed and accepted the validation of the Mandry BC 5390 analyzer for patients CBC tests on January 30, 2017. 2. On January 19, 2018 at 11:35 AM, the Mandry BC 5390 analyzer validation records showed that the laboratory did not verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. 3. The general supervisor confirmed on January 19, 2018 at 11:40 AM, , that the laboratory did not verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population when it performed the validation procedures of the</p>

Mandry BC 5390 analyzer. 4. The general supervisor stated on January 19, 2018 at 11:40 AM, that the laboratory processed and reported 605 out of 605 patients CBC test results from January 30, 2107 to December 31, 2017.

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 Complete cells count (CBC) quality control records(2017, 2018), Mandry BC 5390 analyzer validation records(January 2017) review and general supervisor interview on January 19, 2018 at 11:35 AM, it was determined that the laboratory director failed to ensure compliance with the requirements for the analytic systems of the CBC tests from January 30, 2107 to December 31, 2017. The finding includes: 1. The laboratory failed to complete the evaluation of the performance specifications of the new Mandry BC 5390 analyzer before reporting 605 out of 605 patients CBC test results from January 30, 2107 to December 31, 2017. Refer to D 5421.

D6117

TECHNICAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1451(b)(4)

The technical supervisor is responsible for establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results.

This STANDARD is not met as evidenced by:
Based on review of Complete cells count (CBC) quality control records(2017, 2018), Mandry BC 5390 analyzer validation records(January 2017) review and general supervisor interview on January 19, 2018 at 11:35 AM, it was determined that technical supervisor failed to ensure compliance with the requirements for the analytic systems of the CBC tests from January 30, 2107 to December 31, 2017. The finding includes: 1. The laboratory failed to complete the evaluation of the performance specifications of the new Mandry BC 5390 analyzer before reporting 605 out of 605 patients CBC test results from January 30, 2107 to December 31, 2017. Refer to D 5421.