

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  40D1096293	<b>(X3) Date Survey Completed</b>  04/28/2023
<b>Name of Provider or Supplier</b>  Laboratorio Clinico Lorimar	<b>Street Address, City, State</b>  Carr Pr-115 Km 20 Hm 5 Barrio Guayabo, Aguada, 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>D5203</b>	<p><b>SPECIMEN IDENTIFICATION AND INTEGRITY</b> CFR(s): 493.1232</p> <p>The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results.</p> <p>This STANDARD is not met as evidenced by: Based on Quality Assessment records review ( 2022-2023) and laboratory director interview on April 28, 2023 at 9:50 a.m. it was determined that the laboratory failed to follow the written procedures to ensure the positive identification and sample integrity of patient specimen. The findings include: 1. The laboratory Quality Assessment written procedures showed that the laboratory perform an annual evaluation to ensure positive identification and optimum integrity of a patient's specimen. ( review on April 28, 2023 at 9:50 a.m.) 2. The Quality Assessment records showed that the laboratory failed to perform the evaluation to ensure positive identification and optimum integrity of a patient's specimen since march 2022. ( review on April 28, 2023 at 9:50 a.m.) 3. he laboratory director confirmed on April 28, 2023 at 10:00 a.m. , that the laboratory did not perform an evaluation to ensure positive identification and optimum integrity of a patient's specimen since 3/2022.</p>
<b>D5291</b>	<p><b>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT</b> CFR(s): 493.1239(a)</p> <p>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 general laboratory systems requirements specified at 493.1231 through 493.1236.</p>

This STANDARD is not met as evidenced by:  
Based on Quality Assessment (QA) records , QA written procedures review ( year 2022-2023 ) and laboratory director interview on April 28, 2023 at 11:45 a.m. it was determined that laboratory failed to monitor and evaluate the following QA activities: Specimen Identification and Integrity. Refer to D5203.

**D5391**

**PREANALYTIC SYSTEMS QUALITY ASSESSMENT**  
CFR(s): 493.1249(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 preanalytic systems specified at 493.1241 through 493.1242.

This STANDARD is not met as evidenced by:  
Based on Quality Assessment records review ( 2022-2023) and laboratory director interview on April 28, 2023 at 9:50 a.m. it was determined that the laboratory failed to follow the established Quality Assessment Program to monitor and evaluate the following requirements for preanalytic systems: patient test requests The findings include: 1. Review of the quality assessment program showed that evaluations to patient test request must be evaluated every year during the month of March. ( review on April 28, 2023 at 9:55 a.m. ) 2. Review of the quality assessment records showed that the last evaluation to patient test requests was performed in June 30, 2021. ( review on April 28, 2023 at 9:55 a.m. ) 3. The laboratory director confirmed that evaluations to test requests scheduled was not performed since June 2021. ( review on April 28, 2023 at 10:00 a.m. )

**D5413**

**TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT**  
CFR(s): 493.1252(b)

The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:  
Based on review of laboratory room, refrigerator, freezer temperature , relative humidity log records and interview with the laboratory director on April 28,, 2023 at 10:30 AM, it was determined that the laboratory did not document the daily temperatures not relative humidity. The findings include: 1. On April 28, 2023 at 10: 30 a.m., the refrigerator and freezer temperature log showed that even through the laboratory established a temperature range, the personnel in charge did not document the daily temperature. The personnel only document the word "DONE". 2. On April 28, 2023 at 10: 40 a. m. the room temperature and relative humidity log records were review. The log did not include any established range. The personnel only document

the word "DONE". 3. The laboratory director confirmed on April 28, 2023 at 10:35 a. m. that the laboratory did not document the room temperature, relative humidity, refrigerator and freezer temperatures in 2022.

**D5421**

**ESTABLISHMENT AND VERIFICATION OF PERFORMANCE**  
CFR(s): 493.1253(b)(1)

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:

A. Based on review of validation records of the Dimension ExL 200 system for comprehensive metabolic panel (CMP), lipid tests and laboratory director interview on April 28, 2023 at 10:40 AM, it was determined that the laboratory failed to verify that the manufacturer's CMP reference intervals (normal values) were appropriate for the laboratory's patient population before reporting 3,999 out of 3,999 patient CMP results from January 2023 to April 27, 2023. The findings include: 1. On April 28, 2023 at 10:40 A.M, the Dimension ExL 200 validation records showed that the laboratory laboratory performed the validation procedures in December 2022 and it did not verify that the manufacturer's reference intervals (normal values) were appropriate for the laboratory's patient population. 2. The laboratory director confirmed on April 28, 2023 at 10:45 A.M. , that the laboratory did not verify that the manufacturer's reference intervals (normal values) were appropriate for the laboratory's patient population before reporting routine chemistry patient results. 3. The laboratory processed and reported 3,999 out of 3,999 routine chemistry patient results from January 1, 2023 to April 27, 2023. B. Based on review of validation records of the Cell Dyn Ruby system for complete cell count (CBC) test and laboratory director interview on April 28, 2023 at 10:40 a.m., it was determined that the laboratory failed to complete the evaluation of the performance specifications of this new instruments on March 2022 before reporting 6,173 out of 6,173 CBC tests results from May 2022 to April 27, 2023. The findings include: 1. On April 28, 2023 at 10:40 AM, the Cell Dyn Ruby system validation records showed that the laboratory laboratory performed the validation procedures on March 2022 and it did not verify that the manufacturer's CBC reference intervals (normal values) were appropriate for the laboratory's patient population. 2. The laboratory director confirmed on April 28, 2023 at 10:45 AM, that the laboratory did not verify that the Cell Dyn Ruby system manufacturer's reference intervals (normal values) when it validated the system on on March 2022. The laboratory begin to process CBC patient samples on May 2022. 4. The laboratory processed and reported 6,173 out of 6,173 CBC patients specimens by the Cell Dyn Ruby system from May 2022 to April 27, 2023.

**D5471**

**CONTROL PROCEDURES**  
CFR(s): 493.1256(e)(1)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in

493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on endocrinology quality control records ( year 2022-2023 ) . patient test records review from May 25, 2022 to April 27, 2023 and laboratory director interview at 11:30 a.m. on April 28, 2023, it was determined that the laboratory did not evaluate the new lots of hCG- Human Chorionic Gonadotropin test for positive and negative reactivity prior to placed it in routine. The findings include: 1. Endocrinology tests quality control records were review from January 2022 to April 27, 2023. 2. The laboratory received the following reagent kit and no evaluation of their reactivity were performed: Test Lot Expiration Date First day of use hCG 079052 9/30/23 5/25/22 hCG 080370 1/31/24 2/3/23 3. The laboratory processed and reported: hCG- 57 patient samples since 5/25/22 to 12/31/22 ( lot : 079052 ) hCG- 29 patient samples since 2/3/23 to 4/27/23 ( lot : 080390 ) 4. The laboratory director confirmed on April 28, 2023 at 11:45 a.m. that the laboratory did not evaluate the new lots of hCG for positive and negative reactivity prior to placed it in routine use.

**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 laboratory preventive maintenance records review , performance specifications of Dimension and Cell Dyn system review and hCG quality control records review ( 2022-2023 ) and interview with the laboratory director on April 28, 2023 at 11:45 a.m., it was determined that the laboratory director failed to ensure compliance with the requirements for analytic systems. The findings include: 1. The laboratory failed to monitor and document the laboratory's room temperature, relative humidity, refrigerator and freezer temperature in 2022. Refer to D5413 2. The laboratory failed to verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. Refer to D 5421 3. The laboratory did not evaluate the new lots of hCG- Human Chorionic Gonadotropin test for positive and negative reactivity prior to placed it in routine. Refer to D5471.

**D6094**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality assessment 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 Quality Assessment (QA) records review ( year 2022-2023 ) and laboratory director interview on April 28, 2023 at 11:50 A.M., it was determined that laboratory

failed to ensure compliance with quality assessment (QA) requirements. The findings include: 1. Quality Assessment records ( 2022-2023 ) showed that the laboratory did not evaluate the established Quality Assessment Program to monitor and evaluate the requirements for laboratory general systems, preanalytic systems. ( review on April 28, 2023 at 11:50 a.m. ) 2. The laboratory director confirmed on April 28, 2023 at 11:50 a.m. , that failed to evaluate the requirements for laboratory general systems and preanalytic systems. Refer to D5291 and D5391.

**D6177**

**TESTING PERSONNEL RESPONSIBILITIES**  
CFR(s): 493.1495(b)(3)

Each individual performing high complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed.

This STANDARD is not met as evidenced by:  
Based on laboratory preventive maintenance records review , performance specifications of Dimension and Cell Dyn system review and hCG quality control records review ( 2022-2023 ) and interview with the laboratory director on April 28, 2023 at 11:45 a.m., it was determined that the laboratory testing personnel failed to ensure compliance with the requirements for analytic systems. The findings include: 1. The laboratory failed to monitor and document the laboratory's room temperature, relative humidity, refrigerator and freezer temperature in 2022. Refer to D5413 2. The laboratory failed to verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. Refer to D 5421 3. The laboratory did not evaluate the new lots of hCG- Human Chorionic Gonadotropin test for positive and negative reactivity prior to placed it in routine. Refer to D5471.