

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D1071152	(X3) Date Survey Completed 11/08/2023
Name of Provider or Supplier Laboratorio Clinico Llanadas	Street Address, City, State Carr 140 Km 67, Barceloneta, 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
D2094	<p>ROUTINE CHEMISTRY CFR(s): 493.841(e)</p> <p>(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.</p> <p>This STANDARD is not met as evidenced by: Based on Puerto Rico Proficiency Testing (PRPT) records review (year 2022-2023) and laboratory general supervisor interview on November 8, 2023 at 10:15 A.M. , it was determined that the laboratory failed to take and document corrective actions when it obtained an unsatisfactory results in routine chemistry test. The findings include: 1. Proficiency testing records review from February 2022 to October 2023. (review on 11/8/23 at 10:20 a.m.) 2. The PRPT review on 11/8/23 at 10:20 a.m. , showed that the laboratory did not take nor document corrective actions when it obtained an unsatisfactory results of 60 % in Total bilirubin test in the second testing event performed in May 2023. 3. The laboratory general supervisor confirmed on November 8, 2023 at 10:25 a.m., that the laboratory failed to take and document corrective actions when it obtained an unsatisfactory results in routine chemistry tests.</p>
D5311	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a)</p> <p>The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when</p>

appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.

This STANDARD is not met as evidenced by:

Based on observation , preservation of samples written policies review and laboratory nurse interview on November 8, 2023 at 9:00 A.M. , it was determined that the laboratory failed to follow written policies for urinalysis specimen processing and storing instructions. The findings include: 1. The Urinalysis written policies establishes that if the analysis cannot be perform within one hour of taking the sample, it should be kept in the refrigerator until the analysis is done. 2. During the survey perform on November 8, 2023 at 9:00 A.M. , the laboratory had over the counter six urine patient samples taken on November 7, 2023. The laboratory nurse establishes that the urine samples were in the refrigerator since last day , however, at 9: 00 a.m the urine samples were observed by the surveyor out of refrigerator and the laboratory did not have yet any testing personnel (general supervisor) to perform the test. 2. On November 8, 2023 at 9: 00 A.M. the laboratory had over the counter the following urinalysis samples perform on November 7, 2023 without processing :
Sample Id sample hour taken 1069152 7:50 AM 1069165 8:03 AM 1069169 8:05 AM 1069185 9:23 AM 1068487 10:36 AM 1069177 10:48 AM 3. The laboratory general supervisor confirmed on November 8, 2023 at 9:10 a.m.that the laboratory did not follow urinalysis specimen written procedures .

D5429

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:

1. Based on routine chemistry system manufacturer's instructions, routine chemistry preventive maintenance worksheets review (2022-2023) and laboratory general supervisor interview on November 8, 2023 at 11:13 AM, it was determined that the laboratory failed to follow written instructions for the preventive maintenance of Randox Analyzer. The findings include: a. The routine chemistry manufacturer's instructions establishes that the laboratory perform and document the preventive maintenance : before starting check, daily Check, weekly and monthly. (review on November 8, 2023 at 11:15 A.M.) b. Review of records showed on November 8, 2023 at 11:16 A.M. that the laboratory did not perform the following daily preventive maintenance in the Randox system since October 13, 2023: - removed condensation from RCU cahmber - clean outside of reagent and sample probes with alcohol swab - check cuvette water blanks - clean ISE module and condition electrodes - clean any stains from surface of instrument c. Review of records showed on November 8, 2023 at 11:18 A.M. that the laboratory did not perform the following weekly preventive maintenance in the Randox system since October 13, 2023: - clean the ASP and RCU units - clean the pipette covers, trough and mosaic plates - clean exterior sufaces of wash probes with alcohol swab - clean mixer paddles with alcohol swab d. The laboratory general supervisor confirmed on November 8, 2023 at 11:25 AM that the laboratory failed to perform and document the preventive maintenance since October 13, 2023. 2. Based on special chemistry system manufacturer's instructions,

preventive maintenance worksheets review (2022-2023) and laboratory general supervisor interview on November 8, 2023 at 11:50 AM, it was determined that the laboratory failed to follow written instructions for the preventive maintenance of TOSOH 360 Analyzer. The findings include: a. The special chemistry system manufacturer's instructions establishes that the laboratory perform and document the preventive maintenance : daily Check and monthly. (review on November 8, 2023 at 11:52 A.M.) b. Review of records showed on November 8, 2023 at 11:54 A.M. that the laboratory did not perform the following daily preventive maintenance in the TOSOH 360 system since October 16, 2023: - empty carousel - empty liquid waste - check diluent and wash fluids - replace ethanol with substrate - check paper supply - record results from substrate background - end of the day, replace substrate with ethanol c. The laboratory general supervisor confirmed on November 8, 2023 at 11:56 AM that the laboratory failed to perform and document the preventive maintenance since October 13, 2023.

D5431

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(a)(2)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted.

This STANDARD is not met as evidenced by:
Based on hematology system manufacturer's instructions , hematology preventive maintenance worksheets review (2023) and laboratory general supervisor interview on November 8, 2023 at 10:45 AM, it was determined that the laboratory failed to follow written instructions for the preventive maintenance of Sysmex XN-550 system. The findings include: a. The hematology manufacturer's instructions establishes that the laboratory perform and document the preventive maintenance : daily background check. (review on November 8, 2023 at 10:47 A.M.) b. Review of records showed on November 8, 2023 at 10:00 A.M. that the laboratory did not perform nor document the daily background check of the Sysmex system since November 1, 2023: c. The laboratory general supervisor confirmed on November 8, 2023 at 10:58 AM that the laboratory failed to perform and document the daily background check since October 13, 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 syphilis serology quality control records review (2023) and laboratory general supervisor interview at 10:50 a.m. on November 8, 2023, it was determined

that the laboratory did not evaluate the new lots of Rapid Plasma reagin (RPR) test for positive and negative reactivity prior to placed it in routine use. The findings include: 1. The laboratory syphilis serology quality control records were review from January 2022 to November 8, 2023. 2. The laboratory received the following reagent kit and no evaluation of their reactivity was performed: Test Lot open date RPR 31081 55 /2023 3. The laboratory processed and reported 231 RPR (Rapid plasma reagin) patient's samples since 5/5/2023. (Review on November 8, 2023 at 10:55 a.m.) 4. The laboratory general supervisor confirmed on November 8, 2023 at 10:58 a.m. that the laboratory did not evaluate the new lots of RPR for positive and negative reactivity prior to placed it in routine use.

D6091

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(4)(iii)

The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action.

This STANDARD is not met as evidenced by:
Based on laboratory Puerto Rico Proficiency Testing Program results review (year 2022-2033) and interview with the laboratory general supervisor on November 8, 2023 at 10:15 a.m., it was determined that the laboratory director did not take nor document any corrective action when the laboratory obtained 60 % score for the total bilirubin test in the second testing event of year 2023. Refer to D2094

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 routine chemistry and special chemistry system manufacturer's instructions preventive maintenance records review from January 2023 to November 2023, syphilis serology quality control records review (2023) and laboratory general supervisor interview at 11:30 AM on November 8, 2023, it was determined that laboratory director failed to ensure compliance with the requirements for analytic systems. Refer to D5429, D5431 and D 5471.

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 routine chemistry and special chemistry system manufacturer's instructions preventive maintenance records review from January 2023 to November 2023, syphilis serology quality control records review (2023) and laboratory general

supervisor interview at 11:30 AM on November 8, 2023, it was determined that laboratory general supervisor failed to ensure compliance with the requirements for analytic systems. Refer to D5429, D5431 and D 5471.