

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0658261	(X3) Date Survey Completed 10/12/2022
Name of Provider or Supplier Laboratorio Biomedico De Pr	Street Address, City, State # 550 Calle Soldado Ulises Arrigoitia,, Hato Rey, 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
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on the proficiency testing sample and the laboratory director interview the laboratory fail to test the proficiency for Syphilis Serology, Rapid Reagin Plasma (RPR) method as the same manner as it test patient specimen. Refer to D2006.</p>
D2006	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)</p> <p>The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing.</p>

This STANDARD is not met as evidenced by:
 Based on the Proficiency testing records review, worksheet records of Syphilis Serology, Rapid Reagin Plasma (RPR) method, (quantitative and qualitative) and interview of the laboratory director; it was determined that the laboratory failed to test the proficiency specimen as the same manner as it tests patient specimen (years 2021-2022). The findings include: a. On October 12, 2022 at 11:31 am the Proficiency test scores for syphilis Serology test were reviewed. The documents showed that the initially reactivities samples were later tested for the quantitative test twice. b. The proficiency test records showed that, on the first testing event of the year 2021 and the first testing event of the year 2022 the reactive samples were tested twice. For the third testing event of the year 2021 were tested three (3) times. c. On October 12, 2022 at 11:42 am the laboratory written protocol for syphilis serology patient testing was requested to the laboratory director. The laboratory director stated no written protocol was available. d. On October 12, 2022 at 12:05 pm syphilis serology patient testing worksheet was reviewed. The worksheet showed that the patient's samples with an initial reactive test result were diluted only once. The laboratory director stated that the patient samples were diluted only one time.

D2072

SYPHILIS SEROLOGY
 CFR(s): 493.835(d)

(1) For any unsatisfactory 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 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.

This STANDARD is not met as evidenced by:
 Based on the proficiency testing record review and laboratory director interview, it was determined that the laboratory failed to take a corrective action when obtain an unsatisfactory score in Rapid Reagin Plasma (RPR) in the first testing event of 2022. The findings include: a. On October 12, 2022 at 9:00 pm the Proficiency testing records were reviewed. b. In the first event of 2022 of Syphilis Serology Rapid Reagin Plasma (RPR) (Quantitative) method, the laboratory obtained 40% score. No corrective action was taken. c. The laboratory director confirmed on October 12, 2022 at 9:35 am that no corrective action was taken.

D5291

GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT
 CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236.

This STANDARD is not met as evidenced by:
 Based on the lack of Quality Assessment (QA) activities records and interview with the laboratory director; it was determined that the laboratory failed to evaluate and monitor the General system requirements since January 2021. The findings include: a. On October 12, 2022 at 9:22 am, the laboratory QA was requested. On October 12,

	<p>2022, at 9:34 am the laboratory QA was requested again. On October 12, 2022, at 9:47 am the QA was requested one more time. No QA was presented. b. Since January 2021 the laboratory did not evaluate practices related on: patient confidentiality, specimen identification and integrity, complaint investigation and communications. c. The Laboratory director confirmed on October 12, 2022 at 9:49am that the general laboratory system QA evaluations were not available.</p>
<p>D5391</p>	<p>PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(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 preanalytic systems specified at 493.1241 through 493.1242.</p> <p>This STANDARD is not met as evidenced by: Based on the lack of Quality Assessment (QA) activities records and interview with the laboratory director; it was determined that the laboratory failed to evaluate and monitor the pre-analytic system requirements since January 2021. The findings include: a. On October 12, 2022 at 9:22 am, the laboratory QA was requested. On October 12, 2022, at 9:34 am the laboratory QA was requested again. On October 12, 2022, at 9:47 am the QA was requested one more time. No QA was presented. b. Since January 2021 the laboratory did not evaluate practices related on: test request, specimen submission and handling, specimen referral. c. The Laboratory director confirmed on October 12, 2022 at 9:49am that the pre-analytic system QA evaluations were not available.</p>
<p>D5787</p>	<p>TEST RECORDS CFR(s): 493.1283(a)</p> <p>The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).</p> <p>This STANDARD is not met as evidenced by: Based on the Sedimentation Rate (SR) worksheet patient record review and interview with the laboratory director , it was determined that the laboratory failed to include any patient identification, when the laboratory tested samples for sed rate from July 2021 to October 2022 when 7 patient where processed and reported. The findings include: a. The laboratory use a Mini cube (non waived) analyzer for the sedimentation rate since september 10, 2021. b. On October 12, 2022 at 11:00 am the sedimentation rate patient's worksheet record was reviewed from July 2021 to October 2022. c. Review of records showed that no patient identification was documented. The laboratory processed and reported a total of seven (7) patient's samples on: 11/12 /2021; 2/8/2022; 2/11/2022; 3/21/2022; 4/22/2022; 6/8/2022 and 7/13/2022. d. On October 12, 2022 at 11:26 am the laboratory director confirmed that no name of the patient or record number was documented in the worksheet record when seven (7) patient were performed and reported.</p>

<p>D5791</p>	<p>ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c)</p> <p>(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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.</p> <p>This STANDARD is not met as evidenced by: Based on the lack of Quality Assessment (QA) activities records and interview with the laboratory director; it was determined that the laboratory failed to evaluate and monitor the analytic system requirements since January 2021. The findings include: a. On October 12, 2022 at 9:22 am, the laboratory QA was requested. On October 12, 2022, at 9:34 am the laboratory QA was requested again. On October 12, 2022, at 9:47 am the QA was requested one more time. No QA was presented. b. Since January 2021 the laboratory did not evaluate practices related on: equipment, instruments, reagents, materials, specimen and reagent storage conditions, system maintenance and function checks, verification of method performance specifications, calibration, control procedures, comparison of testresults, test records, corrective actions. c. The Laboratory director confirmed on October 12, 2022 at 9:49am that the analytic system QA evaluations were not available.</p>
<p>D5891</p>	<p>POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(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 postanalytic systems specified in 493.1291.</p> <p>This STANDARD is not met as evidenced by: Based on the lack of Quality Assessment (QA) activities records and interview with the laboratory director; it was determined that the laboratory failed to evaluate and monitor the post-analytic system requirements since January 2021. The findings include: a. On October 12, 2022 at 9:22 am, the laboratory QA was requested. On October 12, 2022, at 9:34 am the laboratory QA was requested again. On October 12, 2022, at 9:47 am the QA was requested one more time. No QA was presented. b. Since January 2021 the laboratory did not evaluate practices related on: test report, and turn around time. c. The Laboratory director confirmed on October 12, 2022 at 9:49am that the post-analytic system QA evaluations were not available.</p>
<p>D6094</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on lack of the Quality Assessment (QA) records, the laboratory director failed to ensure compliance with QA requirements. Refer to D5291, D5391, D5791 and D5891.