

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0658022	(X3) Date Survey Completed 02/08/2019
Name of Provider or Supplier Laboratorio Lomas Verdes	Street Address, City, State Ave Laurel Z39 Lomas Verdes, Bayamon, 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 PR Proficiency Testing records and laboratory director interview on February 8, 2019 at 12:35 PM, it was determined that the laboratory failed to enroll in an HHS approved Proficiency Testing Program for Bacteriology since December 2018. The findings include: 1. On February 8, 2019 at 12:35 PM, the laboratory PR Proficiency Testing records showed that the laboratory cancel the enrollment in in the PR Proficiency Testing Program for Bacteriology in December 2018. Refer to D 2016. 2. The laboratory PR Proficiency Testing records showed that the laboratory did not enroll in a HHS approved Proficiency Testing Program for Bacteriology for the year 2019. 3. The laboratory director confirmed on February 8, 2019 at 12:35 PM, that the laboratory canceled the enrollment of bacteriology in the PR Proficiency Testing program in December 2018 and did not yet enroll in an HHS approved Proficiency Testing Program for Bacteriology for the year 2019. She stated that the laboratory continue processing patients specimens in the bacteriology area. She stated that the laboratory reported the negative cultures results (no growth results for the urine culture and normal flora for throat and ulcer cultures) and referred the positive</p>

cultures from July 6, 2018 to February 7, 2019. 4. The laboratory reported 198 negative patient culture results out of 221 patients cultures processed from December 2018 to February 7, 2019.

D2016

SUCCESSFUL PARTICIPATION

CFR(s): 493.803(a)(b)(c)

(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.

This CONDITION is not met as evidenced by:

Based on Puerto Rico (PR) Laboratory Division Proficiency Testing (PT) desk review, PR Proficiency Testing records and laboratory director interview on February 8, 2019 at 12:35 PM, it was determined that the laboratory failed to perform a successful participation for bacteriology specialty and continue processing patients specimens from August 2018 to February 8, 2019. The findings include: 1. The P.R. Proficiency State Law requires that the laboratory to stop processing patient specimens when it gets two unsuccessful proficiency test results. 2. The Proficiency testing desk review was performed by the PR State office and sent a letter to the laboratory on January 8, 2019; this letter showed that the laboratory obtained unsuccessful proficiency test results for bacteriology in the first and the second event of year 2018. 3. On February 8, 2019 at 12:35 PM, the laboratory PR Proficiency Testing records showed that the laboratory obtained unsuccessful proficiency test results for bacteriology in the first event (0 per cent in April 2018) and in the second event (30 percent in August 2018) of year 2018. 4. The laboratory director confirmed on February 8, 2019 at 12:35 PM, that the laboratory obtained unsuccessful proficiency testing results for bacteriology in April 2018 and August 2018 events. She stated that the laboratory canceled the enrollment of bacteriology in the PR Proficiency Testing program in December 2018 and continue processing patients specimens in the bacteriology area. She stated that the laboratory reported the negative cultures results (no growth results for the urine culture and normal flora for throat and ulcer cultures) and referred the positive cultures from July 6, 2018 to February 7, 2019. 5. The laboratory reported 547 negative patient culture results out of 611 patients cultures processed from August 2018 to February 7, 2019.

D5026

IMMUNOHEMATOLOGY

CFR(s): 493.1217

If the laboratory provides services in the specialty of Immunohematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1271, and 493.1281 through 493.1299.

This CONDITION is not met as evidenced by:

Based on ABO group and D (Rho) type testing records, ABO group and D (Rho) type quality control records (years 2017, 2018 and 2019) review and general supervisor interview on February 8, 2019 at 11:55 AM, it was determined that the laboratory failed to meet the quality control requirements for the subspecialty of Immunohematology. Refer to D 5551 (The laboratory did not follow the quality control procedures when two out of two patients specimens were testing and reported for ABO group and D (Rho) type from January , 2017 to February 7, 2019).

D5405

PROCEDURE MANUAL
CFR(s): 493.1251(c)

Manufacturer's test system instructions or operator manuals may be used, when applicable, to meet the requirements of paragraphs (b)(1) through (b)(12) of this section. Any of the items under paragraphs (b)(1) through (b)(12) of this section not provided by the manufacturer must be provided by the laboratory.

This STANDARD is not met as evidenced by:

Based on review of Instant view - H. pylori test manufacturer's, H. pylori testing records review (years 2017, 2018 and 2019) and general supervisor interview on February 8, 2019 at 10:00 AM, it was determined that the laboratory failed to follow the Instant view - H. pylori test manufacturer's instructions when 1 out of 28 patients specimens were tested and reported for H. pylori by Instant view method from January 11, 2017 to September 13, 2017. The findings include: 1. On February 8, 2019 at 10:00 AM, the H. pylori testing records showed that the laboratory used the Instant view - H. pylori test method from January 24 , 2017 to January 26, 2019. 2 . The Instant view- H. pylori manufacture's insert showed that this assay has not been established for patients less that 19 years of age. 3. The H. pylori testing records showed that the laboratory tested and reported 1 out of 28 patients specimens of less that 19 years of age with the Instant view - H. pylori test kit; tested and reported from January 11, 2017 to September 13, 2017 (on August 21, 2017 the patient specimen #69299; 13 years old). 4. The laboratory supervisor confirmed on February 8, 2019 at 10:00 AM, that the laboratory processed and reported the patient specimen #69299 (13 years old) with the Instant view - H. pylori test method.

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 lack of room temperature records for the bacteriology area, bacteriology testing records review and general supervisor interview on February 8, 2019 at 9:10 AM, it was determined that the laboratory failed to monitor and document the room temperature of the bacteriology area from July 6, 2018 to February 7, 2019 when 691 out of 691 patients culture specimens were processing in this area. The findings include: 1. On February 8, 2019 at 9:10 AM, it is observed that the laboratory did not the monitor nor document the room temperature of the bacteriology area from July 6, 2018 to February 7, 2019. 2. The bacteriology testing records showed that the laboratory processed 691 patients culture specimens from July 6, 2018 to February 7, 2019. 3. The general supervisor confirmed on February 8, 2019 at 9:10 AM, that the laboratory did not monitor nor document the room temperature of the bacteriology area from July 6, 2018 to February 7, 2019.

D5551

IMMUNOHEMATOLOGY
 CFR(s): 493.1271(a)(f)

(a) Patient testing. (a)(1) The laboratory must perform ABO grouping, D (Rho) typing, unexpected antibody detection, antibody identification, and compatibility testing by following the manufacturer's instructions, if provided, and as applicable, 21 CFR 606.151(a) through (e). (a)(2) The laboratory must determine ABO group by concurrently testing unknown red cells with, at a minimum, anti-A and anti-B grouping reagents. For confirmation of ABO group, the unknown serum must be tested with known A1 and B red cells. (a)(3) The laboratory must determine the D (Rho) type by testing unknown red cells with anti-D (anti-Rho) blood typing reagent. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:
 Based on ABO group and D (Rho) type testing records, ABO group and D (Rho) type quality control records (years 2017, 2018, 2019) review and general supervisor interview on February 8, 2019 at 11:55 AM, it was determined that the laboratory failed to follow the quality control procedures when two out of two patients specimens were testing and reported for ABO group and D (Rho) type from January , 2017 to February 7, 2019. The findings include: 1. On February 8, 2019 at 11:55, AM, the ABO group and D (Rho) type testing records showed that the laboratory determined and reported 2 out of 2 patients specimens for ABO group and D (Rho) type : patients specimens # 101047 (A positive) on June 18, 2018 and patient specimen #113130 (O positive) on October 12, 2018. 2. The ABO group and D (Rho) type quality control records showed that the laboratory did not perform the quality control procedures when those patients specimens were tested and reported. 3. The general superviosr confirmed on February 8, 2019 at 11:55 AM, that the quality control records showed no control results those days.

D6076

LABORATORY DIRECTOR
 CFR(s): 493.1441

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>This CONDITION is not met as evidenced by: Based on Puerto Rico (PR) Laboratory Division Proficiency Testing (PT) desk review, PR Proficiency Testing records, ABO group and D (Rho) type testing records, ABO group and D (Rho) type quality control records (years 2017, 2018 and 2019) , Instant view - H. pylori test manufacturer's, H. pylori testing records, lack of room temperature records for the bacteriology area, bacteriology testing records review, laboratory director and general supervisor interview on February 8, 2019 at 12:35 PM, it was determined that the laboratory director failed to fulfill her responsibilities and duties to ensure compliance with the Proficiency Testing Program and the analytical system requirements. Refer to D 6888 (The the laboratory director failed to ensure that the laboratory is enrolled in an HHS approved Proficiency Testing Program for Bacteriology since December 2018). Refer to D 6889 (The laboratory director failed to ensure that the laboratory not processing patients specimens when it obtained unsuccessful proficiency test results for bacteriology). Refer to D 6093 (The laboratory director did not comply with the requirements of the analytic systems for the following specialties: Immunohematology, general serology and bacteriology).</p>
<p>D6088</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)</p> <p>The laboratory director must ensure that the laboratory is enrolled in an HHS-approved proficiency testing program for the testing performed.</p> <p>This STANDARD is not met as evidenced by: Based on PR Proficiency Testing records and laboratory director interview on February 8, 2019 at 12:35 PM, it was determined that the laboratory director failed to to ensure that the laboratory is enrolled in an HHS approved Proficiency Testing Program for Bacteriology since December 2018. Refer to D 2000.</p>
<p>D6089</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(i)</p> <p>The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on Puerto Rico (PR) Laboratory Division Proficiency Testing (PT) desk review, PR Proficiency Testing records and laboratory director interview on February 8, 2019 at 12:35 PM, it was determined that the laboratory director failed to ensure that the laboratory not processing patients specimens when it obtained unsuccessful proficiency test results for bacteriology. Refer to D 2016.</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:</p>

Based on ABO group and D (Rho) type testing records, ABO group and D (Rho) type quality control records (years 2017, 2018 and 2019) , Instant view - H. pylori test manufacturer's, H. pylori testing records, lack of room temperature records for the bacteriology area, bacteriology testing records review and general supervisor interview on February 8, 2019 at 11:55 AM, it was determined that laboratory director did not comply with the requirements of the analytic systems for the following specialties: Immunohematology, general serology and bacteriology. Refer to D 5026 (The laboratory failed to meet the quality control requirements for the subspecialty of Immunohematology). Refer to D 5405 (The laboratory failed to follow the Instant view - H. pylori test manufacturer's instructions). Refer to D 5413 (The laboratory failed to monitor the room temperature of the bacteriology area).

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 ABO group and D (Rho) type testing records, ABO group and D (Rho) type quality control records (years 2017, 2018 and 2019) , Instant view - H. pylori test manufacturer's, H. pylori testing records, lack of room temperature records for the bacteriology area, bacteriology testing records review and general supervisor interview on February 8, 2019 at 11:55 AM, it was determined that the general supervisor failed to perform day-to-day supervision for the personnel that performing testing and reporting test results. Refer to D 5026 (The laboratory failed to meet the quality control requirements for the subspecialty of Immunohematology). Refer to D 5405 (The laboratory failed to follow the Instant view - H. pylori test manufacturer's instructions). Refer to D 5413 (The laboratory failed to monitor the room temperature of the bacteriology area).

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 ABO group and D (Rho) type testing records, ABO group and D (Rho) type quality control records (years 2017, 2018 and 2019) , Instant view - H. pylori test manufacturer's, H. pylori testing records, lack of room temperature records for the bacteriology area, bacteriology testing records review and general supervisor interview on February 8, 2019 at 11:55 AM, it was determined that the testing personnel failed to follow manufacturer's instructions and quality control procedures. Refer to D 5026 (The laboratory failed to meet the quality control requirements for the subspecialty of Immunohematology). Refer to D 5405 (The laboratory failed to follow the Instant view - H. pylori test manufacturer's instructions). Refer to D 5413 (The laboratory failed to monitor the room temperature of the bacteriology area).