

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0663075	(X3) Date Survey Completed 08/29/2018
Name of Provider or Supplier Laboratorio Las Lomas	Street Address, City, State 1700 Ave J T Pinero Esq San Patricio, Rio Piedras, 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
D2047	<p>PARASITOLOGY CFR(s): 493.829(a)</p> <p>Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.</p> <p>This STANDARD is not met as evidenced by: Based on P. R. proficiency testing records review and technical supervisor interview on August 29, 2018 at 12:05 PM, it was determined that the laboratory failed to attain an overall testing event score of at least 80 percent for parasitology in April 2018. The Findings include: 1. The P. R. proficiency testing records showed laboratory failed to attain an overall testing event score of at least 80 percent for parasitology in April 2018. The laboratory obtained an unsatisfactory performance of 75 per cent for parasitology in April 2018 event. The laboratory did not take nor document corrective actions. 2. The technical supervisor confirmed on August 29, 2018 at 12:05 PM, that the laboratory obtained an unsatisfactory performance of 75 per cent for parasitology in April 2018 event and no corrective actions were taken.</p>
D2053	<p>PARASITOLOGY CFR(s): 492.829(d)</p> <p>(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) 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 P. R. proficiency testing records review and technical supervisor interview on August 29, 2018 at 12:05 PM, it was determined that the laboratory failed to take and document corrective actions when it obtained a event score of 80 percent for parasitology in April 2017 and December 17. The Findings include: 1. The P. R. proficiency testing records showed laboratory obtained a score of 80 percent for parasitology in in April 2017 and December 17. The laboratory did not take nor document corrective actions for those events. 2. The technical supervisor confirmed on August 29, 2018 at 12:05 PM, that the laboratory did not take nor documented corrective actions for those events.</p>
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 P. R. proficiency testing records review and technical supervisor interview on August 29, 2018 at 12:05 PM, it was determined that the laboratory failed to take and document corrective actions when it obtained a event score of 80 percent for cholesterol tests in February 2018. The Findings include: 1. The P. R. proficiency testing records showed laboratory obtained a score of 80 percent for cholesterol tests in February 2018. The laboratory did not take nor document corrective actions for those events. 2. The technical supervisor confirmed on August 29, 2018 at 12:05 PM, that the laboratory did not take nor documented corrective actions for these event.</p>
D5020	<p>ENDOCRINOLOGY CFR(s): 493.1212</p> <p>If the laboratory provides services in the subspecialty of Endocrinology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, and 493.1281 through 493.1299.</p> <p>This CONDITION is not met as evidenced by: Based on pregnancy qualitative tests testing records review (years 2017, 2018) and interview with the technical supervisor on August 29, 2018 at 11:25 AM, it was determined that the laboratory failed to meet the requirements of the subspecialty of Endocrinology for pregnancy qualitative test. The finding includes: 1. Refer to D 5449 (The laboratory did not include a negative nor a positive control material when patient specimens were assayed and reported for pregnancy qualitative test from January 15, 2018 to August 25, 2018).</p>
D5449	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g)</p>

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on pregnancy qualitative tests testing records review (years 2017, 2018) and interview with the technical supervisor on August 29, 2018 at 11:25 AM, it was determined that the laboratory failed to include at least once a negative and positive control material when 110 out of of 110 patient specimens were assayed and reported for pregnancy qualitative test from January 15, 2018 to August 25, 2018. The findings include: 1. The pregnancy qualitative tests testing records showed that the laboratory did not include a negative and positive control material when patient specimens were assayed and reported for pregnancy qualitative test from January 15, 2018 to August 25, 2018. 2 The technical supervisor stated that the laboratory included the control materials from January 15, 2018 to August 25, 2018, but not recorded the results. 3. The laboratory assayed and reported 110 out of of 110 patient specimens for pregnancy qualitative test from January 15, 2018 to August 25, 2018.

D5481

CONTROL PROCEDURES

CFR(s): 493.1256(f)(g)

(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on review of quality control graph record (years 2017 and 2018) for thyroxine (T4), calcium, chloride, urea nitrogen (BUN) and creatinine control material values and technical supervisor interview on August 29, 2018 at 10:45 AM, it was determined that the laboratory failed to take and document corrective action when control values failed to meet the laboratory's criteria for acceptability before reporting patient test results from July 11, 2018 to August 11, 2018. The findings include: 1. The laboratory processed and reported the calcium, chloride, BUN and creatinine tests by the Vitros 250 system and the T4 by the ECI system. 2. From July 17, 2018 to August 11, 2018, the quality control graph record for the following tests did not meet the laboratory's criteria for acceptability: July 17, 2018 (chloride); July 20, 2018 (creatinine and calcium) and August 11, 2018 (BUN). The laboratory did not took nor documented corrective actions. 3. From July 11, 2018 to July 26, 2018, the quality control graph record for T4 did not meet the laboratory's criteria for acceptability. The laboratory did not took nor documented corrective actions. 4. The laboratory processed the following patients specimens: 14 patients specimens for T4 from July 11, 2018 to July 26, 2018, 23 patients specimens for chloride on July 17, 2018, 26 patients specimens for creatinine and calcium tests on July 20, 2018 and 11 bun patients specimens on August 11, 2018.

D6042

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(4)

(b) The technical consultant is responsible for-- (b)(4) 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 pregnancy qualitative tests testing records review (years 2017, 2018), quality control graph record (years 2017 and 2018) for thyroxin (T4), calcium, chloride, urea nitrogen (BUN) and creatinine control material values and interview with the technical supervisor on August 29, 2018 at 11:25 AM, it was determined that the technical supervisor failed to ensure compliance with the analytic system requirements. Refer to D 5449 (The laboratory did not include a negative nor a positive control material when patient specimens were assayed and reported for pregnancy qualitative test from January 15, 2018 to August 25, 2018). Refer to D 5481 (The did not take and document corrective action when control values failed to meet the laboratory's criteria for acceptability before reporting patient test results).

D6072

TESTING PERSONNEL RESPONSIBILITIES

CFR(s): 493.1425(b)(3)

Each individual performing moderate 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 pregnancy qualitative tests testing records review (years 2017, 2018), quality control graph record (years 2017 and 2018) for thyroxin (T4), calcium, chloride, urea nitrogen (BUN) and creatinine control material values and interview with the technical supervisor on August 29, 2018 at 11:25 AM, it was determined that the testing personnel failed to follow quality control procedures. Refer to D 5449 (The laboratory did not include a negative nor a positive control material when patient specimens were assayed and reported for pregnancy qualitative test from January 15, 2018 to August 25, 2018). Refer to D 5481 (The did not take and document corrective action when control values failed to meet the laboratory's criteria for acceptability before reporting patient test results).

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.

This CONDITION is not met as evidenced by:

Based on P. R. proficiency testing records (years 2017 and 2018), pregnancy qualitative tests testing records review (years 2017, 2018), quality control graph record (years 2017 and 2018) for thyroxin (T4), calcium, chloride, urea nitrogen (BUN) and creatinine control material values and interview with the technical supervisor on August 29, 2018 at 11:25 AM, it was determined that the laboratory director failed to fulfil her responsibilities and duties to comply with the proficiency

	<p>testing and analytic system requirements. The findings include: 1. Refer to D 6092 (The laboratory director failed to ensure that a remedial action plan is follow when any proficiency testing results is found to be unacceptable or unsatisfactory). 2. Refer to D 6093 (The laboratory director failed to comply with the analytic system requirements).</p>
<p>D6092</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iv)</p> <p>The laboratory director must ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory.</p> <p>This STANDARD is not met as evidenced by: Based on P. R. proficiency testing records(years 2017 and 2018) review and technical supervisor interview on August 29, 2018 at 12:05 PM, it was determined that the laboratory that the laboratory director failed to ensure that a remedial action plan is follow when any proficiency testing results is found to be unacceptable or unsatisfactory. The Findings include: 1. Refer to D 2047 (The laboratory did not take nor document corrective actions when it obtained an unsatisfactory performance of 75 per cent for parasitology in April 2018 event). 2. Refer to D 2053 (The laboratory did not take nor document corrective actions when it obtained a events score of 80 percent for parasitology in April 2017 and December 17). 3. Refer to D 2094 (The laboratory did not take nor documented corrective actions when it obtained an event score of 80 percent for cholesterol tests in February 2018).</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: Based on pregnancy qualitative tests testing records review (years 2017, 2018), quality control graph record (years 2017 and 2018) for thyroxin (T4), calcium, chloride, urea nitrogen (BUN) and creatinine control material values and interview with the technical supervisor on August 29, 2018 at 11:25 AM, it was determined that the laboratory director failed to comply with the analytic system requirements. Refer to D 5020 (The laboratory failed to meet the requirements of the subspecialty of Endocrinology for pregnancy qualitative test). Refer to D 5481 (The did not take and document corrective action when control values failed to meet the laboratory's criteria for acceptability before reporting patient test results).</p>