

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D2112768	(X3) Date Survey Completed 05/07/2019
Name of Provider or Supplier Express Clinical Lab	Street Address, City, State Carr-Pr-3, Ave Los Veteranos, Solar B-11, Guayama, 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
D2067	<p>SYPHILIS SEROLOGY CFR(s): 493.835(b)</p> <p>Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events.</p> <p>This STANDARD is not met as evidenced by: Based on Puerto Rico Proficiency Testing Program (PRPTP) records reviewed (years 2017-2019) and laboratory director interview on May 7, 2019 at 9: 00 A.M., it was determined that the laboratory failed to participate in the syphilis serology second testing event performed in August 2018 and third testing event performed in December 2018. The findings include: 1. The laboratory was enrolled in the Puerto Rico Proficiency Testing Program in years 2017 to 2019. 2. The laboratory uses RPR Method by ASI to perform RPR (Rapid plasma reagin) syphilis serology patient's samples tests. 3. The Puerto Rico Proficiency Testing records were reviewed from years 2017 to 2019, the records showed that the laboratory did not participate in the second testing event of syphilis serology performed in August 2018 and third event performed in December 2018. The laboratory obtained a 0 % test score. 4. The laboratory director confirmed on May 7, 2019 at 9:00 A.M., that the laboratory failed to participate in the second testing event and third testing event of syphilis serology</p>

specialty in August 2018 and December 2018, respectively. 5. The laboratory processed and reported one hundred eighty nine (189) RPR (Rapid plasma reagin) patients samples tests since August 2018 to April 2019.

D2077

GENERAL IMMUNOLOGY

CFR(s): 493.837(c)

Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events.

This STANDARD is not met as evidenced by:

Based on Puerto Rico Proficiency Testing Program (PRPTP) records reviewed (years 2017-2019) and laboratory director interview on May 7, 2019 at 9: 00 A.M., it was determined that the laboratory failed to participate in the general immunology second testing event performed in August 2018 and third testing event performed in December 2018. The findings include: 1. The laboratory was enrolled in the Puerto Rico Proficiency Testing Program in years 2017 to 2019. 2. The laboratory uses ASI Method to perform RA (arthritis rheumatoid) and MONO (Monotest) qualitative patient's samples tests. 3. The Puerto Rico Proficiency Testing records were reviewed from years 2017 to 2019, the records showed that the laboratory did not participate in the second testing event of general immunology performed in August 2018 and third testing event performed in December 2018. The laboratory obtained a 0 % test score. 4. The laboratory director confirmed on May 7, 2019 at 9:00 A.M., that the laboratory failed to participate in the second testing event and third testing event of general immunology subspecialty in August 2018 and December 2018, respectively. 5. The laboratory processed and reported thirteen (13) RA (arthritis rheumatoid) and one (1) Monotest qualitative patients samples tests since October 2018 to March 2019.

D2089

ROUTINE CHEMISTRY

CFR(s): 493.841(c)

Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3)The laboratory participated in the previous two proficiency testing events.

This STANDARD is not met as evidenced by:

Based on Puerto Rico Proficiency Testing Program (PRPTP) records reviewed (years 2017-2019) and laboratory director interview on May 7, 2019 at 9: 00 A.M., it was

determined that the laboratory failed to participate in the routine chemistry third testing event performed in October 2018 and first testing event performed in February 2019. The findings include: 1. The laboratory was enrolled in the Puerto Rico Proficiency Testing Program in years 2017 to 2019. 2. The laboratory uses Architect 1000 SR to perform routine chemistry patient's samples tests. 3. The Puerto Rico Proficiency Testing records were reviewed from years 2017 to 2019, the records showed that the laboratory did not participate in the third testing event of routine chemistry performed in October 2018 and first event performed in February 2019. The laboratory obtained a 0 % test score. 4. The laboratory director confirmed on May 7, 2019 at 9:00 A.M., that the laboratory failed to participate in the third testing event 2018 and first testing event 2019 of routine chemistry specialty in October 2018 and January 2019, respectively. 5. The laboratory processed and reported ten thousand two hundred forty seven (10,247) routine chemistry patients samples tests since October 2018 to April 2019.

D2100

ENDOCRINOLOGY
CFR(s): 493.843(c)

Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events.

This STANDARD is not met as evidenced by:
Based on Puerto Rico Proficiency Testing Program (PRPTP) records reviewed (years 2017-2019) and laboratory director interview on May 7, 2019 at 9: 00 A.M., it was determined that the laboratory failed to participate in the endocrinology third testing event performed in October 2018 and first testing event performed in February 2019. The findings include: 1. The laboratory was enrolled in the Puerto Rico Proficiency Testing Program in years 2017 to 2019. 2. The laboratory uses Biosign Method to perform hCG (Human chorionic gonadotropin) qualitative patient's samples tests. 3. The Puerto Rico Proficiency Testing records were reviewed from years 2017 to 2019, the records showed that the laboratory did not participate in the third testing event of endocrinology performed in October 2018 and first event performed in February 2019. The laboratory obtained a 0 % test score. 4. The laboratory director confirmed on May 7, 2019 at 9:00 A.M., that the laboratory failed to participate in the third testing event 2018 and first testing event 2019 of endocrinology subspecialty in October 2018 and January 2019, respectively. 5. The laboratory processed and reported twenty three (23) hCG (Human chorionic gonadotropin) patients samples tests since October 2018 to April 2019.

D2123

HEMATOLOGY
CFR(s): 493.851(c)

Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended

during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events.

This STANDARD is not met as evidenced by:

A. Based on Puerto Rico Proficiency Testing Program (PRPTP) records review (years 2017 - 2019) and laboratory director interview on May 7, 2019 at 9:00 AM, it was determined that the laboratory failed to participate in an HHS approved Proficiency Testing Program for hematology in third event year 2018 and first event year 2019. The findings include: 1. The laboratory was enrolled in the Puerto Rico Proficiency Testing Program in years 2017 to 2019. 2. The laboratory uses a Cell Dyn Ruby hematology system to perform CBC (Complete blood count) hematology patient samples tests. 3. The Puerto Rico Proficiency Testing records were reviewed from years 2017 to 2019, the records showed that the laboratory did not participate in the third testing event of hematology performed in November 2018 and first event performed in March 2019. The laboratory obtained a 0 % test score. 4. The laboratory director confirmed on May 7, 2019 that the laboratory failed to participate in proficiency testing for hematology specialty for third event 2018 and first event 2019 in November 2018 and March 2019, respectively. 5. The laboratory processed and reported one thousand eight (1,008) CBC (Complete blood count) patients samples tests since October 2018 to April 2019. B. Based on Puerto Rico Proficiency Testing Program (PRPTP) records review (years 2017 - 2019) and laboratory director interview on May 7, 2019 at 9:00 AM, it was determined that the laboratory failed to participate in an HHS approved Proficiency Testing Program for coagulation tests (PT-PTT) (Prothrombin time and Partial tromboplastin time) in third event year 2018 and first event year 2019. The findings include: 1. The laboratory was enrolled in the Puerto Rico Proficiency Testing Program in years 2017 to 2019. 2. The laboratory uses a CA-600 Coagulation tests system to perform PT and PTT (Prothrombin time and Partial tromboplastin time) coagulation patient samples tests. 3. The Puerto Rico Proficiency Testing records were reviewed from years 2017 to 2019, the records showed that the laboratory did not participate in the third testing event of hematology performed in November 2018 and first event performed in March 2019. The laboratory obtained a 0 % test score. 4. The laboratory director confirmed on May 7, 2019 that the laboratory failed to participate in proficiency testing for hematology specialty for third event 2018 and first event 2019 in November 2018 and March 2019, respectively. 5. The laboratory processed and reported one hundred fourteen (114) PT and PTT (Prothrombin time and Partial tromboplastin time) patients samples tests since October 2018 to April 2019.

D6000

MODERATE COMPLEXITY LABORATORY DIRECTOR
CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:

Based on Puerto Rico Proficiency Testing Program (PRPTP) records review (years

2017 - 2019) and laboratory director interview on May 7, 2019 at 9:00AM, it was determined that the laboratory failed to participate in an HHS approved Proficiency Testing Program. Refer to D6015 and D6016.

D6015

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(4)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed.

This STANDARD is not met as evidenced by:

Based on Puerto Rico Proficiency Testing Program (PRPTP) records review (years 2017-2019) and laboratory director interview on May 7, 2019 at 9:00 AM, it was determined that the laboratory director failed to ensure that the laboratory is enrolled and participate in an HHS approved proficiency testing program for the following tests: RPR (Rapid plasma reagin), hCG qualitative (Human chorionic gonadotropin), routine chemistry, PT-PTT coagulation tests (Protrombin time and Partial Tromboplastin time, CBC hematology tests (Complete blood count) The findings include: 1. Review of Puerto Rico Proficiency testing records from June 2017 to March 2019, showed that the laboratory did not participate in the third testing event in 2018 and the first testing event in 2019 for teh following tests: RPR (Rapid plasma reagin), hCG qualitative (Human chorionic gonadotropin), routine chemistry, PT-PTT coagulation tests (Protrombin time and Partial Tromboplastin time and CBC hematology tests (Complete blood count). The laboratory obtained a 0% test score. 2. The laboratory did a late enrollment because the laboratory did not pay the Puerto Rico Proficiency Testing events for year 2019 until April 17, 2019. The Puerto Rico Proficiency Testing Program sent to the laboratory the first event testing for syphilis serology and general immunology in April 2019. 3. The laboratory director confirmed on May 7, 2019 at 9:00 A.M., that the laboratory failed to participate in the third testing event in 2018 and the first testing event in 2019 for RPR (Rapid plasma reagin), hCG qualitative (Human chorionic gonadotropin), routine chemistry, PT-PTT coagulation tests (Protrombin time and Partial Tromboplastin time and CBC (Complete Blood Count) hematology tests. The laboratory obtained a 0% test score. 4. The laboratory processed and reported one hundred eighty nine (189) patients specimens for RPR (Rapid plasma reagin), twenty three (23) patients specimens for hCG qualitative (Human chorionic gonadotropin), ten thousand two hundred forty seven (10,247) patients samples for routine chemistry, one hundred fourteen (114) patient samples tests for PT-PTT coagulation tests (Protrombin time and Partial Tromboplastin time and one thousand eight (1,008) patient samples tests for CBC hematology tests (Complete blood count).

D6016

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(4)(i)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory

director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:

Based on Puerto Rico Proficiency Testing Program(PRPTP) records review (years 2017-2019) and laboratory director interview on May 7, 2019 at 9:00 AM, it was determined that the laboratory director failed to ensure to participate in an HHS approved proficiency testing program. Refer to D2067, D2077, D2089, D2100 and D2123.