

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  40D1060233	<b>(X3) Date Survey Completed</b>  07/16/2021
<b>Name of Provider or Supplier</b>  Laboratorio Clinico Freytes	<b>Street Address, City, State</b>  Calle 1 B 1-9 Villas De Loiza, Loiza, PR	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D3009</b>	<p>FACILITIES CFR(s): 493.1101(c)</p> <p>The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements.</p> <p>This STANDARD is not met as evidenced by: Based on facility records review and laboratory director interview on July 16, 2021 at 9:45 AM, it was determined that the laboratory failed to be in compliance with the Puerto Rico State laboratory requirements. The findings include: 1. The laboratory Biomedical Generator Number (BGN) was due since September 14, 2020. 2. The laboratory director confirmed on July 16, 2021 at 9:45 AM, that the BGN was due since September 14, 2020.</p>
<b>D3039</b>	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(5)</p> <p>Quality system assessment records. Retain all laboratory quality system assessment records for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on lack of Quality Assessment (QA) records (year 2020) and laboratory director interview on July 16, 2021 at 10:15 AM, it was determined that the laboratory failed to maintain the established Quality Assessment Program to monitor and evaluate the laboratory activities (pre-analytic, analytic and post-analytic systems) during the year 2020. The findings include: 1. The laboratory did not maintain the Quality Assessment documentation during the year 2020. 2. The laboratory director confirmed on on July 16, 2021 at 10:15 AM, that the laboratory did not have available the Quality Assessment documentation corresponding the year 2020.</p>

<p><b>D5024</b></p>	<p><b>HEMATOLOGY</b> CFR(s): 493.1215</p> <p>If the laboratory provides services in the specialty of Hematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1269, and 493.1281 through 493.1299.</p> <p>This CONDITION is not met as evidenced by: Based on complete blood count (CBC) quality control records, manufacturer's instruction review and laboratory director interview on July 16, 2021 at 11:14 AM, it was determined that the laboratory failed to meet the analytic system requirements for Hematology specialty (CBC). Refer to D 5407 (The laboratory did not follow the manufacturer's instruction for quality control procedures when 140 out of 140 patients specimens were tested for CBC by the Act 5 system from February 8, 2021 to April 29, 2021. Refer to D 5417 (The laboratory used the CBC controls materials that have exceeded their expiration date from March 6, 2021 to March 8, 2021).</p>
<p><b>D5407</b></p>	<p><b>PROCEDURE MANUAL</b> CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on complete blood count (CBC) quality control records review and laboratory director interview on July 16, 2021 at 11:14 AM, it was determined that the laboratory failed to follow the manufacturer's instruction for quality control procedures when 140 out of 140 patients specimens were tested for CBC by the Act 5 system from February 8, 2021 to April 29, 2021. The findings include: 1. The laboratory analyzed and reported CBC specimens by the Act 5 system and the manufacturer require three levels of control materials (low, normal and high). 2. On July 16, 2021 at 11:14 AM, the CBC quality control records showed that the laboratory did not include the three levels of CBC control materials the following days: Date level of control CBC patients not included specimens reported 02/08/2021 normal 14 02/16/2021 low 23 02/22/2021 normal 23 03/01/2021 high 15 03/03/2021 normal 24 03/05/2021 normal 18 03/06/2021 normal 16 04/29/2021 normal nor 7 low 3. The laboratory director stated on July 16, 2021 at 11:14 AM, that the laboratory run every day of testing the three levels of control but the data of those days were lost in the system. 5. The laboratory tested and reported 140 out of 140 CBC patients specimens the following days: 02/08/2021, 02/16/2021, 02/22/2021, 03/01/2021, 03/03/2021, 03/05/2021, 03/06/2021 and 04/29/2021.</p>
<p><b>D5413</b></p>	<p><b>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT</b> CFR(s): 493.1252(b)</p> <p>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</p>

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 and room humidity records and laboratory director interview on July 16, 2021 at 12:00 PM , it was determined that the laboratory failed to monitor and document the room temperature and humidity of the laboratory since January 2020 to July 16, 2021. The findings include: 1. On July 16, 2021 at 12:00 PM, the laboratory did not monitor nor document the room temperature and humidity of the laboratory since January 2020. 2. The laboratory director confirmed on July 16, 2021 at 12:00 PM , that those records were not available. She stated that the days when the laboratory performed the RPR the room temperature and the room humidity was documented.

**D5417**

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT  
CFR(s): 493.1252(d)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:

Based on complete blood count (CBC) quality control records review and laboratory director interview on July 16, 2021 at 11:14 AM, it was determined that the laboratory used the CBC controls materials that have exceeded their expiration date from March 6, 2021 to March 8, 2021. The findings include: 1. The laboratory analyzed and reported CBC specimens by the Act 5 system. 2. The laboratory used the following control materials in March 6, 2021 and in March 8, 2021: lots 360121, 370121 and 380121 with the exceeded their expiration of March 5, 2021. 3. The laboratory director confirmed on July 16, 2021 at 11:14 AM that the records showed that the laboratory used those CBC controls materials that have exceeded their expiration. 4. The laboratory processed and reported 16 CBC patients specimens on March 6, 2021 and 15 CBC patients on March 8, 2021.

**D5449**

CONTROL PROCEDURES  
CFR(s): 493.1256(d)(3)(ii)(g)

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 test testing records review and interview with the laboratory director on July 16, 2021 at 11:40 AM, it was determined that the laboratory failed to include each day of testing a negative control material besides the positive control material when 38 out of 38 patients specimens were tested for qualitative hCG from January 15, 2021 to July 7, 2021. The findings include : 1. On July 16, 2021 at 11:40 AM, the pregnancy test testing records showed that the laboratory did not include each day of testing a negative control material besides the positive control material

	<p>when patients specimens were tested for qualitative hCG (Human Chorionic Gonadotropin) tests from January 15, 2021 to July 7, 2021. 2. The laboratory director confirmed on July 16, 2021 at 11:40 AM, that the laboratory did not include the external negative control material when patients specimens were tested for qualitative hCG. 3. The laboratory tested and reported 38 out of 38 patients specimens for qualitative hCG from January 15, 2021 to July 7, 2021.</p>
<p><b>D6000</b></p>	<p><b>MODERATE COMPLEXITY LABORATORY DIRECTOR</b> CFR(s): 493.1403</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on lack of clinical consultant personnel file, lack of room temperature and room humidity record, review of facility records, CBC quality control records, manufacturer's instruction and laboratory director interview on July 16, 2021 at 12:00 PM, it was determined that the laboratory director failed to fulfill her responsibilities and duties to comply with the administration of the laboratory, laboratory analytic system and quality assessment requirements. Refer to D 6010 (The laboratory director failed to comply with the administration of the laboratory). Refer to D 6020 (The laboratory director failed to comply with the laboratory analytic system requirements). Refer to D 6021 (The laboratory director failed to comply with the Quality Assessment Program during the year 2020).</p>
<p><b>D6010</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(2)</p> <p>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)(2) Ensure that the physical plant and environmental conditions of the laboratory are appropriate for the testing performed.</p> <p>This STANDARD is not met as evidenced by: Based on lack of clinical consultant personnel file, facility records review and laboratory director interview on July 16, 2021 at 9:45 AM, it was determined that the laboratory director failed to comply with the administration of the laboratory. Refer to D 3009 (The laboratory Biomedical Generator Number (BGN) was due since September 14, 2020). Refer to D 6056 (The laboratory director failed to have the Clinical Consultant position filled since 07/16/2019).</p>
<p><b>D6020</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(5)</p> <p>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</p>

director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on on lack of room temperature and room humidity records, review of pregnancy test testing records, complete blood count (CBC) quality control records, manufacturer's instruction and laboratory director interview on July 16, 2021 at 12:00 PM, it was determined that the laboratory director failed to comply with the laboratory analytic system requirements. Refer to D 5024 (The laboratory failed to meet the analytic system requirements for Hematology specialty). Refer to D 5413 (The laboratory failed to monitor and document the room temperature and humidity of the laboratory since January 2020 to July 16, 2021). Refer to D 5449 ( The laboratory failed to include each day of testing a negative control material besides the positive control material when 38 out of 38 patients specimens were tested for qualitative hCG from January 15, 2021 to July 7, 2021).

**D6021**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(5)

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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on lack of Quality Assessment (QA) records (year 2020) and laboratory director interview on July 16, 2021 at 10:15 AM, it was determined that the laboratory director failed to comply with the Quality Assessment Program during the year 2020. Referred to D 3039 (The laboratory did not maintain the established Quality Assessment Program during the year 2020).

**D6056**

**CLINICAL CONSULTANT**

CFR(s): 493.1415

The laboratory must have a clinical consultant who meets the qualification requirements of 493.1417 of this part and provides clinical consultation in accordance with 493.1419 of this part.

This CONDITION is not met as evidenced by:

Based on lack of clinical consultant personnel file and laboratory director interview on July 16, 2021 at 9:45 A.M., it was determined that the laboratory director failed to have the Clinical Consultant position filled since 07/16/2019. Refer to D 6057

**D6057**

**CLINICAL CONSULTANT QUALIFICATIONS**

CFR(s): 493.1417

The clinical consultant must be qualified to consult with and render opinions to the laboratory's clients concerning the diagnosis, treatment and management of patient

care. The clinical consultant must-- (a) Be qualified as a laboratory director under 493.1405(b)(1), (2), or (3)(i); or (b) Be a doctor of medicine, doctor of osteopathy or doctor of podiatric medicine and possess a license to practice medicine, osteopathy or podiatry in the State in which the laboratory is located.

This STANDARD is not met as evidenced by:

Based on lack of clinical consultant personnel file (credentials and competency records) and laboratory director interview on July 16, 2021 at 9:45 A.M, it was determined that the laboratory director failed to fill the Clinical Consultant position since 07/16/2019. The findings include: 1. The laboratory did not have the Clinical Consultant personnel file since 07/16/2019. 2. The laboratory director state on July 16, 2021 at 9:45 A.M, that the clinical consultant of the laboratory is the doctor of pediatric medicine that have an office near the laboratory but his personnel file was not available.