

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 40D0873472	<b>(X3) Date Survey Completed</b> 05/11/2021
<b>Name of Provider or Supplier</b> Cdt Policlínica Familiar Factor Inc	<b>Street Address, City, State</b> Carr Num 2 Km 65 Hm 6 Bo Factor I, Arecibo, 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>D2053</b>	<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 Puerto Rico Proficiency Testing Program records review ( 2020-2021) and laboratory director interview on May 11, 2021 at 9:20 A.M., it was determined that the laboratory failed to take and document corrective actions when it obtained an unsatisfactory results in parasitology specialties. The findings include: 1. Puerto Rico Proficiency Testing Program records and results were reviewed since 1/2020. 2. Review of Proficiency Testing records showed that the laboratory obtained unsatisfactory results of 60 % on Identification of Parasites test in the first testing event performed on May 2020. Remedial actions were not taken. 3 The laboratory director confirmed on May 11, 2021 at 9:20 A.M, that the laboratory failed to take and document corrective actions when it obtained an unsatisfactory results in parasitology tests in May 2020.</p>
<b>D2094</b>	<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,</p>

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 Puerto Rico Proficiency Testing Program records review ( 2020-2021) and laboratory director interview on May 11, 2021 at 9:20 A.M., it was determined that the laboratory failed to take and document corrective actions when it obtained an unsatisfactory results in routine chemistry tests. The findings include: 1. Puerto Rico Proficiency Testing Program records and results were reviewed since 1/2020. 2. Review of Proficiency Testing records showed that the laboratory obtained unsatisfactory results of 60 % in amylase test in the first testing event performed on February 2021. Remedial actions were not taken. 3. Review of Proficiency Testing records showed that the laboratory obtained unsatisfactory results of 60 % in phosphorus test in the third testing event performed on October 2020. Remedial actions were not taken. 4. The laboratory director confirmed on May 11, 2021 at 9:20 A.M, that the laboratory failed to take and document corrective actions when it obtained an unsatisfactory results in routine chemistry tests.

**D2128**

**HEMATOLOGY**

CFR(s): 493.851(e)

(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.

This STANDARD is not met as evidenced by:

Based on Puerto Rico Proficiency Testing Program records review ( 2020-2021) and laboratory director interview on May 11, 2021 at 9:20 A.M., it was determined that the laboratory failed to take and document corrective actions when it obtained an unsatisfactory results in hematology specialties. The findings include: 1. Puerto Rico Proficiency Testing Program records and results were reviewed since 1/2020. 2. Review of Proficiency Testing records showed that the laboratory obtained unsatisfactory results of 60 % in PTT ( Partial Thromboplastin time) test in the second testing event performed on July 2020. Remedial actions were not taken. 3 The laboratory director confirmed on May 11, 2021 at 9:20 A.M, that the laboratory failed to take and document corrective actions when it obtained an unsatisfactory results in hematology tests in July 2020.

**D5024**

**HEMATOLOGY**

CFR(s): 493.1215

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>This CONDITION is not met as evidenced by:  Based on hematology quality control records ( 2021-2021 ) , and interview with the laboratory director on May 11, 2021 at 10:50 A.M. it was determined that the laboratory failed to ensure compliance with the analytic system requirements for hematology. The finding included: 1. The laboratory failed to follow the manufacturer's instructions for calculating INR (International Normalized Ratio). ( D5405 )</p>
<p><b>D5291</b></p>	<p><b>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT</b>  CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236.</p> <p>This STANDARD is not met as evidenced by:  Based on quality assessment (QA) records review and laboratory director interview on May 11, 2021 at 9:40 A.M., it was determined that the laboratory failed to follow the established Quality Assessment Program to monitor and evaluate the requirement for the general laboratory systems. The findings include: 1. Review of the laboratory quality assessment manual showed that the laboratory establishes a monthly assessment for each general laboratory system process to keep track the laboratory performance. 2. From January 2018 to May 2021, the quality assessment (QA) records showed that the laboratory failed to follow the written procedures to monitor and evaluate the following QA activities: a. Patient Confidentiality b. Specimen identification and integrity c. Complaint investigations</p>
<p><b>D5391</b></p>	<p><b>PREANALYTIC SYSTEMS QUALITY ASSESSMENT</b>  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 quality assessment ( QA) procedures manual and laboratory director interview on May 11, 2021 at 9:40A.M., it was determined that laboratory failed to monitor and evaluate the following QA activities: test request. The findings include: 1. Review of the quality assessment procedure manual showed that evaluations to laboratory test request must be performed every three month. The laboratory did not evaluated the test request since January 25, 2019. 2. The laboratory director stated on May 11, 2021 at 9:20 A.M. that evaluations to test requisitions were not performed since January 2019.</p>
<p><b>D5405</b></p>	<p><b>PROCEDURE MANUAL</b>  CFR(s): 493.1251(c)</p> <p>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</p>

provided by the manufacturer must be provided by the laboratory.

This STANDARD is not met as evidenced by:

Based on hematology records review ( 2020-2021 ) and laboratory director interview on May 11, 2021 at 10:50 A.M. , it was determined that the laboratory failed to follow the manufacturer's instructions for calculating INR (International Normalized Ratio). The findings include: 1. . The laboratory perform PT ( Prothrombin time ) and PTT ( Partial thromboplastin time) tests by tilt tube method. 2. The laboratory had in routine use on May 11, 2021 the following neoplastine reagent: Lot. # 256487, exp. 11/2021. 3. The laboratory director ( testing personnel ) confirmed that the laboratory did not establish a normal population prothrombin (PT) mean when the laboratory began to use this lot on January 2021. 4. Hematology records were reviewed since January 2021 and showed that the laboratory processed and reported 22 PT ( Prothrombin time ) patient samples : dates PT patient 1/8/21 1 1/15/21 1 2/2/21 2 2/17/21 3 2/23/21 2 3 /17/21 2 4/13/21 2 4/16/21 3 4/20/21 3 5/4/21 1 5/6/21 2 5. The laboratory processed and reported twenty two (22) patient's samples since January 2021 with the incorrect INR. The laboratory uses the former laboratory PT mean of 12.0 sec's.

**D5791**

**ANALYTIC SYSTEMS QUALITY ASSESSMENT**

CFR(s): 493.1289(a)(c)

(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.

This STANDARD is not met as evidenced by:

Based on quality assessment procedures manual review and laboratory director interview on May 11, 2021 at 9:45 A.M. it was determined that the laboratory failed to follow the established Quality Assessment Program to monitor and evaluate the requirement for analytic systems. The findings include: 1. Review of the laboratory quality assessment records showed that the laboratory establishes a monthly assessment for each analytic process to keep track the laboratory performance. 2. Since January 2019, the quality assessment (QA) records showed that the laboratory did not perform the monthly evaluation of the analytic system. 3. The laboratory director confirmed on May 11, 2021 at 9:45 A.M., that the laboratory failed to perform the monthly evaluation of the analytic system.

**D5891**

**POSTANALYTIC SYSTEMS QUALITY ASSESSMENT**

CFR(s): 493.1299(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 postanalytic systems specified in 493.1291.

This STANDARD is not met as evidenced by:

Based on quality assessment procedures manual review and laboratory director interview on May 11, 2021 at 9:45 A.M., it was determined that the laboratory failed to follow the established Quality Assessment Program to monitor and evaluate the requirement for post-analytic systems. The findings include: 1. Review of the quality

	<p>assessment program showed that evaluations to patient's final test reports and turn around time ( TAT) must be evaluated annually. 2. Review of the quality assessment records showed that the last evaluations to patient's final test reports and turn around time did not performed since January 2019. 3. The laboratory director stated on May 11, 2021 at 9:45 A.M. that evaluations to patient's final test reports and turn around time were not performed since January 2019.</p>
<b>D6076</b>	<p><b>LABORATORY DIRECTOR</b> CFR(s): 493.1441</p> <p>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> <p>This CONDITION is not met as evidenced by: Based on hematology quality control records review ( 2020-2021) and interview with the laboratory director on May 11, 2021 at 11:30 A.M., it was determined that the laboratory director failed to fulfill his responsibilities and duties to ensure compliance with the laboratory analytical system requirements for hematology. The finding includes: 1. The laboratory director failed to ensure compliance with the hematology requirements. Refer to D6093.</p>
<b>D6089</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> 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 Proficiency Program testing records review ( 2019-2021 ) and laboratory director interview on May 11, 2021 at 9:20 A.M. it was determined that the laboratory director failed to ensure that proficiency testing samples were tested as required under Subpart H requirements. Refer to D2053, D2094 and D2128.</p>
<b>D6093</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> 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 hematology quality control records review( 2020-2021 ) and laboratory director interview on May 11, 2021 at 11:30 AM, it was determined that laboratory failed to ensure compliance with the requirements for analytic systems. Refer to D5405 .</p>
<b>D6094</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1445(e)(5)</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.

This STANDARD is not met as evidenced by:

Based on Quality Assessment (QA) records review ( 2019-2021 ) and laboratory director interview on May 11, 2021 at 10:00 A.M, it was determined that laboratory failed to ensure compliance with quality assessment (QA) requirements. The findings include: 1. Quality Assessment records showed that the laboratory did not evaluate the established Quality Assessment Program to monitor and evaluate the requirements for laboratory general systems, preanalytic, analytic and postanalytic systems. 2. The laboratory director confirmed on May 11, 2021 at 10:00 A.M., that failed to evaluate the requirements for laboratory general systems, preanalytic, analytic and postanalytic systems. Refer to D5291 , D5391, D5791 and D5891.