

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0873472	(X3) Date Survey Completed 03/13/2019
Name of Provider or Supplier Cdt Policlinica Familiar Factor Inc	Street Address, City, State 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.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D2121	<p>HEMATOLOGY CFR(s): 493.851(a)</p> <p>Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on Puerto Rico Proficiency Testing Program records review (2017-2018) and laboratory director interview on March 13, 2019 at 1:30 P.M., it was determined that the laboratory failed to attain a satisfactory results in hematology event. The findings include: 1. Puerto Rico Proficiency Testing Program records and results were reviewed from February 2017 to December 2018. 2. Review of Proficiency Testing records showed that the laboratory obtained unsatisfactory results of 0 % in the following tests : Partial prothrombin time (PTT) , prothombin time (PT) in the second testing event performed in July 2018. 3. Review of Proficiency Testing records showed that the laboratory obtained unsatisfactory results of 60 % in the Cell Identification test and 40 % in the White blood cell (WBC) test in the second testing event performed in July 2018. 4. The laboratory director confirmed on March 13, 2019 at 1:30 P.M, that the laboratory failed to attain a satisfactory results in the second hematology test event performed in July 2018.</p>
D5391	<p>PREANALYTIC SYSTEMS QUALITY ASSESSMENT 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:</p>

Based on Quality Assessment (QA) procedures manual review and laboratory director interview on March 13, 2019 at 11:45 A.M., it was determined that laboratory failed to monitor and evaluate the following QA activities: Test request. The findings include: 1. The quality assessment procedure manual showed that evaluations to laboratory test request must be performed every three month. The laboratory did not evaluate the test requisitions since March 2017. 2. On March 13, 2019 at 11:45 A.M., the quality assessment evaluation manual was reviewed with the laboratory director and no complete evaluation regarding test requisition was perform. 3. The laboratory director confirmed on March 13, 2019 at 12:15 P.M., that evaluations to patient's test request performed was a general evaluation and did not show the data that the laboratory use to perform the evaluations .

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 records review (2017-218) and laboratory director interview on March 13, 2019 at 12:15 P. 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 (test results and turn around time). The findings include: 1. Review of the quality assessment records showed that evaluations to patient's final test reports and turn around time must be evaluated annually. 2. Review of the quality assessment records(2017-2018) showed that the evaluations to patient's final test reports and turn around time did not include the data that the laboratory use to perform the evaluation. 3. The laboratory director confirmed on March 13, 2019 at 12:15 P.M., that evaluations to patient's final test reports and turn around time performed was a general evaluation and did not show the data that the laboratory use to perform the evaluations .

D6089

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(4)(i)

The laboratory director must ensure 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 Program testing records review (2017-2018) and laboratory director interview on March 13, 2019 at 1:30 P. 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 D2121.

D6094

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(5)

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 and laboratory director interview on March 13, 2019 at 1:30 P.M., it was determined that the 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 preanalytic and postanalytic systems. 2. The laboratory director confirmed on March 13, 2019 at 1:30 P.M., that laboratory failed to evaluate the requirements for preanalytic and postanalytic systems. Refer to D5391 and D5891.