

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D1079403	(X3) Date Survey Completed 06/04/2024
Name of Provider or Supplier Laboratorio Clinico Rq	Street Address, City, State Carr Pr 112 Km 5 Hm 3 Bo Arenales Altos, Isabela, 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
D5024	<p>HEMATOLOGY 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 sed rate patient data log records review (year 2023-2024) and interview with the laboratory testing personnel on June 4, 2024 at 10:15 A.M. it was determined that the laboratory failed to ensure compliance with the analytic system requirements for hematology. Refer to D5405.</p>
D5405	<p>PROCEDURE MANUAL 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 provided by the manufacturer must be provided by the laboratory.</p> <p>This STANDARD is not met as evidenced by: Based on Sedimat 15 manufacturer's instruction , sedimentation rate patient data log records review (2023-2024) .and laboratory testing personnel interview at 10:00 A. M. on June 4, 2024, it was determined that the laboratory did not include two levels control material (low and high) when they performed sedimentation rate (sed rate) tests by Sedimat 15 system. The findings include: 1. The laboratory uses Sedimat 15 system to perform sedimentation rate tests. 2. The manufacturer's establishes that two</p>

	<p>levels control material (low and high) must be included each day of testing for Sed Rate test. 3. Review of records from January 2023 to June 4, 2024, the sedimentation rate patient data log records showed that the laboratory did not include control material since January 2023. 4. The testing personnel confirmed on June 4, 2024 at 10:10 A.M., that the laboratory failed to include control material when sed rate tests were tested. 5. The laboratory processed and reported 1,030 sed rate patient's samples since January 2023.</p>
<p>D5421</p>	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Sysmex XN-350 and Mission U-500 performance verification results and laboratory testing personnel interview on June 4, 2024 at 9:27 A.M., it was determined that the laboratory failed to evaluate the obtained results from the performance verifications evaluations. The findings include: 1. The laboratory acquired the Sysmex XN-350 on November 2023. 2. The laboratory acquired the Mission U500 on November 2023. 2. On June 4, 2024 at 9:35 A.M., the systems performance verification procedures were reviewed and showed that the laboratory director did not evaluate and sign the performance verification of the Sysmex XN-500 hematology system and Mission U500- urinalysis system prior to begin to test patient samples. 4. The laboratory processed and reported 1,965 Complete blood count (CBC) from December 12, 2023 to June 4, 2024 and 2,349 urinalysis patient sample from August 17, 2023 to June 4, 2024. 5. The laboratory testing personnel confirmed on June 4, 2024 at 9:35 A.M. that the laboratory director failed to evaluate and sign the obtained results from the performance verifications evaluations of the Sysmex XN-350 and Mission U-500 systems.</p>
<p>D6000</p>	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR 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 review of sed rate patient data log records review (year 2023-2024) and laboratory testing personnel on June 4, 2024 at 11:00 A.M. , it was determined that the laboratory director failed to fulfill her responsibilities with the hematology analytic requirements. Refer to D6020.</p>
<p>D6020</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</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)(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 sed rate patient data log records review from January 2023 to June 4, 2024, and interview with the laboratory testing personnel on June 4, 2024 at 11:00 A.M., it was determined that the laboratory director did not follow manufacturers instructions for quality control procedure for the sed rate test by sedimat 15 system. Refer to D5405.

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

Based on personnel records review (2023-2024) and laboratory testing personnel interview on June 4, 2024 at 8:40 A.M., it was determined that the laboratory director (technical consultant) failed to provide annually the competence evaluation to the testing personnel that performed the moderate complexity tests since March 2022. The findings include: 1. On June 4, 2024 at 8:45 A.M., review the personnel records showed that the laboratory director did not evaluate annually the competence of the testing personnel; that include at least the following requirements: a. Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. b. Monitoring, recording and reporting of test results. c. Review of intermediate test results or worksheets, quality control records, proficiency testing results and preventive maintenance records. d. Direct observation of performance of instrument maintenance and function checks. e. Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. 2. On June 4, 2024 at 8:45 A.M. , the testing personnel confirmed that the technical consultant failed to perform the competence of the testing personnel since March 2022.