| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number**<br><br>40D0691230 | **(X3) Date Survey Completed**<br><br>04/10/2024 |
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| **Name of Provider or Supplier**<br><br>Stat Lab - Laboratorio Clinico Baco | **Street Address, City, State**<br><br>975 Avenida Hostos, Carretera#2, Km160, Hm 2, Mayaguez, 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** |
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| **D5437** | CALIBRATION AND CALIBRATION VERIFICATION<br>CFR(s): 493.1255(a)<br><br>Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.<br><br>This STANDARD is not met as evidenced by:<br>Based on hematology calibration records reviewed (years 2022-2024) and laboratory technical supervisor interview on April 10, 2024 at 9:15 A.M., it was determined that the laboratory failed to perform the calibration verification procedures with at least the frequency recommended by the manufacturer's (each six months) for the hematology tests performed by the Sysmex XS-1000 i hematology system. The findings include: 1. The laboratory uses a Sysmex XS-1000 i hematology system for CBC (Complete blood count) patient's tests. 2. The manufacturer's instructions establishes that the laboratory must perform the calibration verification procedures each six months. 3. From March 2022 to April 2024, the records showed that the laboratory did not perform at least every 6 months the calibration verification procedures for the Sysmex XS-1000 i hematology system. The calibration verification procedures were performed on March 2022, September 2022, March 2023 and December 2023. 4. The laboratory processed and reported 1091 Complete blood count (CBC) patient's samples from September 2023 to December 2023. 5. The laboratory technical |

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| | supervisor confirmed on April 10, 2024 at 10:00 A.M. that the laboratory did not perform at least every 6 months the calibration verification procedures for the Sysmex XS-1000 i hematology system. |
| **D6000** | MODERATE COMPLEXITY LABORATORY DIRECTOR<br>CFR(s): 493.1403<br><br>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.<br><br>This CONDITION is not met as evidenced by:<br>Based on review of laboratory director qualifications and laboratory technical supervisor interview on April 10, 2024 at 10 : 30 A.M. it was determined that the laboratory director failed to renew a current professional registry, as required by the state law. The findings include: a. The laboratory director record showed that the director failed to renew the current professional registry in 2024. b. The MT licence # 3844 and registry # 77613 expired on February 7, 2024. Refer to D6028. |
| **D6020** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(5)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on hematology calibration verification records review ( year 2022-2024 ) on April 10, 2024 at 9:20 A.M. and laboratory technical supervisor interview, it was determined that laboratory director failed to ensure compliance with the requirements for hematology analytic systems. The finding includes: 1. The laboratory failed to perform the calibration verification procedures with at least the frequency recommended by the manufacturer's (each six months) for the hematology tests performed by the Sysmex XS-1000 i hematology system. Refer to D5437. |
| **D6028** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(10)<br><br>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)(10) Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart; |

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| | This STANDARD is not met as evidenced by:<br>Based on review of personnel records and laboratory technical supervisor interview on April 10, 2024 at 10:A.M., it was determined that the laboratory director failed to renew a current professional registry, as required by the state law. The finding include: 1. The laboratory personnel records reviewed showed that the laboratory director state professional registry ( # 77613) was due since February 7, 2024. |
| **D6042** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413(b)(4)<br><br>(b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results;<br><br>This STANDARD is not met as evidenced by:<br>Based on hematology calibration verification records review ( year 2022-2024 ) on April 10, 2024 at 9:20 A.M. and laboratory technical supervisor interview, it was determined that laboratory technical supervisor ( testing personnel ) failed to ensure compliance with the requirements for hematology analytic systems. The finding includes: 1. The laboratory failed to perform the calibration verification procedures with at least the frequency recommended by the manufacturer's (each six months) for the hematology tests performed by the Sysmex XS-1000 i hematology system. Refer to D5437. |
| **D6103** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(13)<br><br>The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills.<br><br>This STANDARD is not met as evidenced by:<br>Based on personnel records review ( 2022-2023) and laboratory technical supervisor interview on April 10, 2024 at 11:00 A.M. , it was determined that the laboratory director failed to follow the written procedures to monitor and ensure the competency evaluations of the Clinical Consultant. The findings include: 1. The personnel records showed that the laboratory director did not evaluate annually the competence of the Clinical Consultant. 2. The last competence of the Clinical Consultant was performed on 12/2022. |