

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  40D0669861	<b>(X3) Date Survey Completed</b>  02/23/2021
<b>Name of Provider or Supplier</b>  Laboratorio Clinico Dr Agustin Stahl	<b>Street Address, City, State</b>  Carr 174 Bloque 21 No 2o Sta Rosa, Bayamon, 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>D6029</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(11)</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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.</p> <p>This STANDARD is not met as evidenced by: Based on personnel records review and laboratory director interview on February 23, 2021 at 9:10 AM, it was determined that the laboratory director did not make sure that the new testing personnel (# 1), had the necessary training before beginning to perform patient tests from December 2019 to February 23, 2021. The findings include: 1. The new testing personnel (#1) was hired and performed patient testing since December 2019. 2. The laboratory did not have any document related to testing personnel training. However, this testing personnel processed and reported patient's specimens in the following laboratory's areas: hematology, urinalysis, endocrinology, syphilis and general serology. 3. The laboratory director confirmed on February 23, 2021 at 9:10 AM, that the laboratory did not document the testing personnel training prior to perform patient tests.</p>
<b>D6030</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(12)</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</p>

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)(12) 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;

This STANDARD is not met as evidenced by:

Based on personnel records review and laboratory director interview on February 23, 2021 at 9:10 AM, it was determined that the laboratory director failed to fulfill her responsibilities to ensure that the new testing personnel(#1) is competent to perform laboratory test procedures from December 2019 to February 23, 2021. The findings include: 1. The new testing personnel (#1) was hired and performed patient's testing since December 2019. 2. The new testing personnel(#1) processed and reported patient's specimens in the following laboratory's areas from December 2019 to February 23, 2021: hematology, urinalysis, endocrinology, syphilis and general serology. 3. The laboratory director confirmed on February 23, 2021 at 9:10 AM, that she did not perform nor document the testing personnel competence from December 2019 to February 23, 2021.