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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 40D0932463 | (X3) Date Survey Completed 09/14/2018 |
| Name of Provider or Supplier Laboratorio Clinico Carraizo | Street Address, City, State 844 Str Km 5 6 Bo Carraizo, Trujillo Alto, 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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| D6103 | <p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on personnel files review, lack of technical supervisor competence records and technical supervisor interview on September 14, 2018 at 11:50 AM, it was determined that the laboratory director failed to ensure that policies and procedures were established for monitoring the technical supervisor competency since January 2017. The findings include: 1. The personnel files showed that the laboratory director did not perform technical supervisor competency since January 2017. 2. The technical supervisor confirmed on September 14, 2018 at 11:50 AM, that those competence records were not available in the laboratory.</p> |
| D6107 | <p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15)</p> <p>The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.</p> |

This STANDARD is not met as evidenced by:

Based on personnel files review, lack of technical supervisor competence records and technical supervisor interview on September 14, 2018 at 11:50 AM, it was determined that the laboratory director failed to specify, in writing, the responsibilities and duties of the technical supervisor competency since January 2017. The findings include: 1. The personnel files showed that the laboratory director did not specify, in writing, the responsibilities and duties of the technical supervisor competency since January 2017. 2. The technical supervisor confirmed on September 14, 2018 at 11:50 AM, that her personnel file did not specify in writing, her responsibilities and duties.