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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br>40D0658242    | <b>(X3) Date Survey Completed</b><br>11/27/2018 |
| <b>Name of Provider or Supplier</b><br>Laboratorio Clinico Doctor Center Miramar   | <b>Street Address, City, State</b><br>Ave Ponce De Leon 670, San Juan, 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>  |
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| <b>D5291</b>              | <p><b>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT</b><br/>CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on Quality Assessment (QA) records review and laboratory technical supervisor interview on November 27, 2017 at 12:00 PM, it was determined that laboratory failed to follow the established Quality Assessment Program to monitor and evaluate the personnel competence requirement from April 2017 to November 2018. The findings include: 1. The laboratory quality assessment records showed that personnel competence must be performed every year. 2. On November 27, 2017 at 12:00 PM, personnel file of the technical supervisor showed that the laboratory did not evaluate the her personnel competence annually. The last competence in record was performed in April 2017. 3. The technical supervisor confirmed on November 27, 2017 at 12:00 PM, that her personnel file includes the competence performed in April 2017.</p> |
| <b>D6094</b>              | <p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b><br/>CFR(s): 493.1445(e)(5)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by:</p>  |

Based on QA records review and laboratory technical supervisor interview on November 27, 2017 at 12:00 PM, it was determined that laboratory director failed to ensure compliance with QA requirements. Refer to D 5291 (the laboratory failed to follow the established QA Program to monitor and evaluate the personnel competence requirement from April 2017 to November 2018).