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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 40D0984583 | (X3) Date Survey Completed 06/21/2018 |
| Name of Provider or Supplier Lab Clinico Caribbean Medical Center | Street Address, City, State Ave Osvaldo Molina #151 Carr 194, Fajardo, 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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| D5209 | <p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on review of testing personnel files and interview with the laboratory supervisor on June 21, 2018, it was determined that the laboratory failed to follow their written policy regarding personnel competence. The findings include: a. The laboratory policy stated that personnel competence must be done annually. b. Review of personnel records showed that the last competence evaluation of testing personnel # 3668 was performed on 5/1/2017. c. The laboratory supervisor stated that the competence was not performed.</p> |
| D5217 | <p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based interview with the laboratory supervisor and review of the Wisconsin State Laboratory of Hygiene (WSLH) Proficiency Program test records, it was found that the laboratory did not verify, twice annually, the accuracy of the ammonia test. The findings include: a. The laboratory performed ammonia in patient samples. b. On June 21, 2018 the laboratory supervisor stated that they were enrolled in the WSLH Proficiency Program for ammonia. c. Review of the WSLH proficiency test records</p> |

did not include any evidence of participation for year 2017 not 2018. d. The laboratory did not evaluate the accuracy of the ammonia test since year 2017. e. The laboratory processed and reported 160 patient's samples for ammonia during year 2017 and 190 patient's samples since January 2018.

D6102

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(12)

The laboratory director must 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.

This STANDARD is not met as evidenced by:

Based on review of personnel file records and interview with the laboratory supervisor, it was determined that the laboratory director did not assure that the new hired testing personnel had the appropriate training prior to testing patient's samples. The findings include: a. Review of personnel file records showed that the medical technologist (MT) # 6004 was hired in August 2017 to perform non waived testing. b. The personnel record did not include evidence of training prior to testing patient's samples. c. The laboratory supervisor that the only training performed was for the Sofia analyzer.

D6107

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(15)

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.

This STANDARD is not met as evidenced by:

Based on review of personnel files and interview with the laboratory supervisor, it was determined that the laboratory director failed to specify the duties of the technical supervisor, and testing personnel. The findings include: a. The laboratory technical supervisor (MT # 5309) was hired on 3/16/2017. The technical supervisor file did not include written duties. b. The testing personnel MT # 8168 was hired in July 2017. The testing personnel file did not include written duties. c. The testing personnel MT # 6004 was hired in August 2017. The testing personnel file did not include written duties. d. The laboratory supervisor that the written duties were not included in the files.