| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 14D0691828 | 12/03/2020 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Illinois Department Of Public Health -Chicago | 2121 W Taylor St, Chicago, IL | |

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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| **D5400** | ANALYTIC SYSTEMS<br>CFR(s): 493.1250<br><br>Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.<br><br>This CONDITION is not met as evidenced by:<br>Based on review of patient test reports and laboratory procedure manuals, the laboratory failed to perform quality control testing each day of testing for one of one patient test reports and one of one laboratory procedure manuals reviewed. Findings include: 1) Refer to D5445. |
| **D5445** | CONTROL PROCEDURES<br>CFR(s): 493.1256(d)(1)(2)(g)<br><br>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.<br><br>This STANDARD is not met as evidenced by: |

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| | Based on review of patient test records and laboratory procedure manuals, the laboratory failed to perform quality control testing each day of testing for one of one patient test reports and one of one laboratory procedure manuals reviewed. Findings include: 1) Review of laboratory procedure manual #CCV012-01-0120, Titled, "Detection of Respiratory Pathogens via the Gen Mark ePlex Respiratory Pathogen Panel," section 8.2-External Controls, states, "Positive and Negative controls should be tested with each new lot of reagents or monthly, whichever occurs first." 2) Review of patient test report RP2020_XX shows a result of "no pathogens detected" tested on 4/14/20. 3) Review of Bench Worksheet for patient test report RP2020_XX , dated 04 /14/20, shows that the MMQCI control was tested on 3/28/20. 4) There was no evidence provided for daily quality control testing on 4/14/20. 5) In an interview on December 1, 2020, at 9:34 AM, TS#1 stated, "we only do monthly qc." |