| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 11D0675065 | 01/27/2022 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Fulton County Board Of Health | 10 Park Place South Se, Atlanta, GA | |

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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| **D0000** | A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on January 27, 2022. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited: |
| **D5213** | EVALUATION OF PROFICIENCY TESTING PERFORMANCE<br>CFR(s): 493.1236(b)(1)<br><br>The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program.<br><br>This STANDARD is not met as evidenced by:<br>Based on Proficiency Testing (PT) document review and staff interview, the laboratory failed to perform and submit results to the Medical Laboratory Evaluation Proficiency program. Findings include: 1. PT document review revealed that there were no results for the Immunology subspecialty testing for all events in 2020 and 2021. 2. During an interview with the Laboratory Manager and the Laboratory Director(CMS 209), in the conference room on January 27, 2022 at approximately 2: 15 PM, confirmed that there were no PT testing or results for Immunology in 2020 and 2021. |
| **D5293** | GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT<br>CFR(s): 493.1239(b)(c)<br><br>(b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities. |

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| | This STANDARD is not met as evidenced by:<br>Based on review of the laboratory procedure manual (SOP), quality assurance (QA) records, staff and laboratory director's interview, the laboratory failed to assess, monitor, and when indicated, correct problems identified in the laboratory from July 2019 to December 2021. Findings include: 1. Review of QA records revealed the laboratory director did not take necessary steps to identify and correct problems with missed Proficiency Testing (PT) for Quantiferon TB Gold Event 2 of 2021. 2. Corrective actions and QA activities were not documented properly in the laboratory to reflect all phases (Pre-Analytic, analytic and Post Analytic) of the QA policy from July 2019 to December 2021. 2. Interviews with the supervisor and the laboratory director on 01/27/ 2022 at approximately 2:00 PM in the review room confirmed that the laboratory was not monitoring QA activites appropriately from July 2019 to December 2021. |
| **D5311** | SPECIMEN SUBMISSION, HANDLING, AND REFERRAL<br>CFR(s): 493.1242(a)<br><br>The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory procedure manual and staff interview, the laboratory failed to establish written instructions for sending specimens to an outside reference laboratory for testing. The findings include: 1. The laboratory's procedure manual did not include a written policy and procedure (to include collection, preservation, storage, transport, testing schedule times, and how to obtain additional assistance) for staff to follow when sending specimens to reference laboratories (The State Lab, LabCorp, and Quest Diagnostics). 2. During an interview on January 27, 2022 at 2:00 PM with the Testing Personnel# 1(CMS 209), confirmed that the laboratory did not have a written policy and procedure for staff to follow when sending specimens to a reference laboratory. |
| **D5429** | MAINTENANCE AND FUNCTION CHECKS<br>CFR(s): 493.1254(a)(1)<br><br>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.<br><br>This STANDARD is not met as evidenced by:<br>Based on the laboratory tour and staff interview, the laboratory failed to have annual professional maintenance on the centrifuges as required. Findings include: 1. Observation during the laboratory tour revealed that the Horizon 642E Drucker Diagnostics centrifuge was NOT calibrated annually as required. The last calibration was performed on 03-22-2018. 2. The big Centra CL3 Thermo IEC 2 blood centrifuge |

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| | had no documented calibration dates. 3. An interview with the laboratory supervisor on 01/27/2022 during the lab tour at approximately 10:15 AM, confirmed the lack of the aforementioned professional maintenance on the centrifuges. |
| **D5451** | CONTROL PROCEDURES<br>CFR(s): 493.1256(d)(3)(iii)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Test procedures producing graded or titered results include a negative control material and a control material with graded or titered reactivity, respectively; 493.1256 (g) The laboratory must document all control procedures performed.<br><br>This STANDARD is not met as evidenced by:<br>Based on quality control (QC) document review and staff interview, the laboratory failed to document QC on syphilis testing (RPR) from July 2019 to January 2022. Findings include: 1. Based on review of QC documents at the main facility, located at 10 Park Place NE Atlanta GA, Quality Controls were not performed or documented on a QC log from July 2019 to January 2022. 2. During an interview with the laboratory director and laboratory supervisor, on January 27, 2022, at approximately 1: 45 PM, in the conference room, confirmed controls were not documented in a QC log from July 2019 to January 2022. |
| **D6021** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(5)<br><br>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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.<br><br>This STANDARD is not met as evidenced by:<br>Based on Quality Assurance(QA) manual review and interview with the staff, the Lab Director(LD) failed to review all QA documents on a monthly basis as required by Clinical Laboratory Improvement Amendments (CLIA). Findings include: 1. Quality Assurance (QA) documents review revealed the laboratory director did not review quality assurance documents including all maintenance logs, temperature logs, humidity logs, PT forms and corrective action logs as required in 2019, 2020 and 2021. 2. An interview with the lab director and supervisor ,in the review room, on 01 /27/2022, at approximately 1:50 PM, confirmed the LD did not review the aformentioned logs from July 2019 and December 2021. |
| **D6091** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(4)(iii)<br><br>The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. |

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| | This STANDARD is not met as evidenced by:<br>Based on Proficiency Testing(PT) document review and staff interview, the laboratory director (LD) failed to ensure all PT reports were reviewed by the appropriate staff to evaluate the laboratory's performance to identify any problems that require corrective action. Findings include: 1. PT document review revealed that the LD failed to ensure all PT reports were reviewed in 2020 and 2021. 2. During an interview with the laboratory manager and the LD, on January 27, 2022, at approximately 2:20 PM, in the conference room, confirmed the LD did not evaluate PT results in 2020 and 2021. |