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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 11D2194982 | (X3) Date Survey Completed 05/29/2024 |
| Name of Provider or Supplier Gold Coast Diagnostics | Street Address, City, State 4930 Governors Drive, Suite 407, Forest Park, 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 recertification survey was performed on May 29, 2024. The facility was found to be NOT in compliance with all applicable CLIA requirements for specialties /subspecialties for 42 CFR. |
| D5449 | <p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g)</p> <p>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-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on quality control (QC) document review and testing personnel (TP) interview, the laboratory failed to ensure the QC was within range for the Polymerase Chain Reaction (PCR) bacteriology test(s) before patient results were released. Findings : 1. Review of PCR QC for Staphylococcus Aureus (Staph. Aureus) and Citrobacter Freundii on the date of June 21, 2024 revealed the PTC control (positive control) failed. 2 of 2 patients ran were resultated as positive for Staph. Aureus. 2. Interview with TP #5 (CMS 209 page 2) on 5/29/24 at 1:46 PM in the lab confirmed the aforementioned finding.</p> |
| D5783 | <p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must</p> |

be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.

This STANDARD is not met as evidenced by:
Based on quality control (QC) document review and testing personnel (TP) interview, the laboratory failed to ensure the QC was within range for the Polymerase Chain Reaction (PCR) bacteriology test(s) before patient results were released. No corrective actions were documented. Findings : 1. Review of PCR QC for Staphylococcus Aureus (Staph. Aureus) and Citrobacter Freundii on the date of June 21, 2024 revealed the PTC control (positive control) failed. 2 of 2 patients ran were resulted as positive for Staph. Aureus without documentation of corrective action. 2. Interview with TP #5 (CMS 209 page 2) on 5/29/24 at 1:46 PM in the lab confirmed the aforementioned finding.

D6091

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(4)(iii)

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.

This STANDARD is not met as evidenced by:
Based on College of American Pathologist (CAP) proficiency testing (PT) record review and interview with the general supervisor (GS), the laboratory director (LD) failed to ensure PT was reviewed when results were received. Findings: 1. Review of the CAP PT result records revealed the 2023 Event B was not reviewed by the Laboratory Director. 2. Interview with the GS (CMS 209), on 5/29/24, in the laboratory, at 1 PM confirmed, the aforementioned finding.