| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 11D2085260 | 10/05/2021 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Northeast Georgia Physicians Group Urology | 1404 River Place, Suite 402, Braselton, 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** | On November 09, 2021 an off site followup review was completed. The report revealed that corrective action was found to be acceptable and corrected. The facility is now in compliance with with all regulations surveyed. |
| **D5447** | CONTROL PROCEDURES<br>CFR(s): 493.1256(d)(3)(i)(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-- Each quantitative procedure, include two control materials of different concentrations; (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, staff and laboratory coordinator's interview, the laboratory failed to perform and document QC on each day of patient testing for Sperm Analysis in the specialty of Hematology in 2020 and 2021. Findings include: 1. Based on review of QC documents, there were no commercial or in-house controls available or performed during patient testing on a daily basis in 2020 and 2021. 2. There was NO Individualized Quality Control Plan (IQCP) established by the laboratory. 3. During an interview with the laboratory coordinator on 10/05/2021 at approximately 11:30 AM in the conference room, it was confirmed that no controls were available or performed on a daily basis during patient testing in 2020 and 2021. |
| **D6070** | TESTING PERSONNEL RESPONSIBILITIES<br>CFR(s): 493.1425(b)(1)<br><br>Each individual performing moderate complexity testing must follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results. |

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| | This STANDARD is not met as evidenced by:<br>Based on review of the policy and procedure manual (SOP), observation during the lab tour, and staff interviews, the laboratory failed follow the policy for labeling specimens collected. Findings include: 1. Observation during the lab tour at 10:00 AM revealed 6 urine specimens on the lab counter to the right of the sink labeled with the patient's first and last name only. A second unique identifier was NOT on the labeled specimens. 2. Review if the SOP reveals the lab policy that specimens are to be labeled with two (2) or more unique identifying factors such as name, date of birth, or patient ID (identification) number. 3. Interviews with the laboratory coordinator and TP # 2 (CMS 209) on 10/05/2021 in the laboratory at approximately 10:03 AM, confirmed the urine specimens were not labeled with two(2) or more unique identifiers. |