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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 10D0719909 | (X3) Date Survey Completed 12/09/2020 |
| Name of Provider or Supplier All Womens Health Center Of Gainesville Inc | Street Address, City, State 1135 Nw 23rd Ave Ste N, Gainesville, FL | |
| 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 | At the time of the announced, on-site recertification survey, All Womens Health Center of Gainesville, Inc., was found to NOT be in compliance with the CLIA laboratory requirements of 42 CFR 493. |
| D5481 | <p>CONTROL PROCEDURES CFR(s): 493.1256(f)(g)</p> <p>(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the facility failed to ensure quality control testing was documented and in range before reporting patient results for 5 of 77 days reviewed in 2019 and 2020. The findings include: The 12/9/20 quality control record review showed: On 12/5/2019, no quality control (QC) was documented, and 9 patients were tested for Rhesus factor (Rh). On 3/31/20, no QC was documented, and 10 patients were tested for Rh. On 4/7/20, no QC was documented and 7 patients were tested for Rh. On 7/28/20, no QC was documented and 11 patients were tested for Rh. On 12/3/20, no QC was documented and 9 patients were tested for Rh. The interview with the office administrator on 12/9/20 at 11:30am confirmed the quality control had not been documented properly.</p> |