| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number<br>52D0389118 | (X3) Date Survey Completed<br>01/29/2019 |
|---|---|---|
| **Name of Provider or Supplier**<br>Aurora Health Center-Delavan | **Street Address, City, State**<br>1550 Hobbs Dr, Delavan, WI | |

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 |
|---|---|
| **D6072** | TESTING PERSONNEL RESPONSIBILITIES<br>CFR(s): 493.1425(b)(3)<br><br>Each individual performing moderate complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor review of quality control procedures and records, and patient results, and interview with the technical consultant, testing personnel performed serum human chorionic gonadotropin (hCG) testing on three days in January 2019 without testing serum quality control material as required in the laboratory's Individualized Quality Control Plan (IQCP). Findings include: 1. Review of the IQCP for serum hCG testing showed testing of Quidel low positive and negative serum control material on the first Monday of the month and with each new lot number of the test kit is required. 2. Review of the 2019 quality control log for the QuickVue+ hCG test showed no record of serum quality control testing in January 2019 on test kit lot number 704249. 3. Review of the "hCG Time of Testing - QuickVue+: One-Step hCG Combo" log for patient test results from January 2019 showed serum testing was performed on patient samples on January 4 (patient 1), January 18 (patient 2), and January 22 (patient 3). 4. Interview with the technical consultant on January 29, 2019 at 11:15 AM confirmed testing personnel did not follow the laboratory's quality control procedures when they performed patient serum hCG testing without testing serum quality control materials in January 2019. |