| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 24D0405602 | 12/28/2018 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Olivia Hospital & Clinic | 100 Healthy Way, Olivia, MN | |

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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| **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 document review and interview with laboratory personnel, the laboratory failed to ensure that an Individualized Quality Control Plan (IQCP) was reviewed annually. Findings are as follows: 1. The laboratory performed Serum Qualitative HCG* under the specialty of Immunology as confirmed by the General Supervisor (GS) during a tour of the laboratory on 12/27/18 at 8:05 a.m. 2. QC performance for Serum Qualitative HCG* was established in the Mono / Serum HCG Individualized Quality Control Plan (IQCP), dated 5/4/2016. 3. Annual reviews for 2017 and 2018 of the IQCP for Serum Qualitative HCG* were not found in laboratory records. The laboratory was unable to provide the documents upon request. 4. In an interview on 12 /27/18 at 3:30 p.m., the GS confirmed the above findings. * HCG = Human chorionic gonadotropin . |
| **D6086** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(3)(ii)<br><br>The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method. |

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| | This STANDARD is not met as evidenced by:<br>. Based on document review and interview with laboratory personnel, the laboratory failed to provide documentation of review and approval by the laboratory director of Performance Verification results prior to implementation of a new Immunology test method. Findings are as follows: 1. The laboratory performed Immunology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory on 12/27/18 at 8:05 a.m. 2. The Qiagen AmniSure Rupture of Fetal Membrane test kit was observed as present and available for use during the tour of the laboratory. 3. A Performance Verification (PV) report with verification of accuracy, performed 8/17 /2017, was found during review of laboratory records. 4. The Laboratory Director (LD) failed to sign and date the Performance Verification (PV) report. 5. In an interview on 12/27/18 at 3:00 p.m., the GS confirmed the above findings. . |