| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 52D0040259 | 04/23/2019 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Wisconsin Veterans Home | N2665 Cty Hwy Qq, King, 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 |
|---|---|
| **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 surveyor review of manual reticulocyte count analytic records and interview with the technical consultant, the laboratory did not test two levels of quality control material once each day of patient testing. Findings include: 1. Review of manual reticulocyte count analytic records showed no evidence testing personnel tested two levels of quality control material each day of patient testing. 2. Interview with the technical consultant on April 23, 2019 at 1:15 PM confirmed the laboratory does not test quality control material when performing manual reticulocyte counts on patient samples. |
| **D5449** | CONTROL PROCEDURES<br>CFR(s): 493.1256(d)(3)(ii)(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 qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.<br><br>This STANDARD is not met as evidenced by: |

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| | Based on surveyor review of quality control records and procedures, and interview with the technical consultant, the laboratory has not tested a positive and negative control material once each day of patient testing and has not approved an Individualized Quality Control Plan (IQCP) that provides equivalent quality testing for the Sofia Influenza A+B FIA (Fluorescent Immunoassay). Findings include: 1. Review of quality control records for the Sophia Influenza A+B FIA assay showed no evidence the laboratory tested positive and negative quality control material each day the laboratory tested patient samples. 2. Review of quality control procedures for the Sophia Influenza A+B FIA assay showed no evidence of an IQCP for the test system. 3. Interview with the technical consultant on April 23, 2019 at 11:15 AM confirmed the laboratory did not test quality control material each day of patient testing and confirmed the laboratory had not developed an IQCP for the test system. |