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|----------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------|-----------------------------------------------------|
| <b>Statement of Deficiencies</b>                                                                                           | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>52D0867947    | <b>(X3) Date Survey Completed</b><br><br>09/22/2021 |
| <b>Name of Provider or Supplier</b><br><br>Uw Health Central Laboratory                                                    | <b>Street Address, City, State</b><br><br>20 S Park St Suite 465, Madison, WI |                                                     |
| For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency. |                                                                               |                                                     |

| <b>(X4) ID Prefix Tag</b> | <b>Summary Statement of Deficiencies</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
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| <b>D5439</b>              | <p><b>CALIBRATION AND CALIBRATION VERIFICATION</b><br/>CFR(s): 493.1255(b)</p> <p>Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on surveyor review of calibration verification records and interview with the general supervisor, the laboratory did not perform calibration verification every six months for the Abbott Architect chemistry and immunoassay analyzers in 2020 and 2021. Findings include: 1. Review of calibration verification records showed calibration verification performed in July 2019, July 2020, April 2021 and July 2021 for all required analytes. Further review showed no additional documentation of</p> |

calibration verification for the Abbott Architect chemistry and immunoassay analyzers in 2020 and 2021. 2. Interview with the general supervisor on September 22, 2021 at 2:58 PM confirmed the laboratory did not perform calibration verification every six months for the Abbott Architect chemistry and immunoassay analyzers in 2020 and 2021. This is a repeat deficiency from August 7, 2013 and July 14, 2015.