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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 52D0388360 | (X3) Date Survey Completed 03/12/2020 |
| Name of Provider or Supplier Aurora Health Center - Hartford, E Sumner St | Street Address, City, State 1640 E Sumner St, Hartford, 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 |
|---------------------------|---|
| D5437 | <p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a)</p> <p>Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b) (3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of laboratory procedures and instrument records from 2019 and 2020, and interview with a technical consultant, the laboratory did not calibrate the D-Dimer assay on the Sysmex CA-600 coagulation analyzer within six months after the June 12, 2019 calibration, and tested four patient samples after the six-month calibration was due. Findings include: 1. The laboratory "D-Dimer, Innovance" procedure, Reference #3442, Version #5, Section VI, Calibration states, "A new curve should be prepared every 6 months". 2. Review of laboratory instrument records for the Sysmex CA-600 Analyzer shows the laboratory calibrated the D-Dimer assay on June 12, 2019 and January 2, 2020. Instrument tapes from December 13, 2019 through January 1, 2020 showed D-Dimer testing was performed on the following four patients after December 12, 2019 when the calibration was due, and before January 2, 2020 when the next calibration was performed. December 13, 2019, Patient 1 December 17, 2019, Patient 2 December 18, 2019, Patient 3 December 19, 2019, Patient 4 3. Interview with a technical consultant, staff A, on March 12, 2020 at 11:45 AM confirmed the laboratory did not calibrate the D-dimer assay within six months of</p> |

the calibration performed on June 12, 2019. Further interview confirmed the laboratory performed four patient tests more than six months after the June 12, 2019 calibration and before recalibration on January 2, 2020.