

| | | |
|--|--|---|
| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 52D2136461 | (X3) Date Survey Completed 06/26/2018 |
| Name of Provider or Supplier Aurora Health Center Oak Creek- Ryan Road | Street Address, City, State 200 E Ryan Road, Oak Creek, 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 |
|---------------------------|---|
| D5403 | <p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of hematology procedures and interview with the technical consultant, the Sysmex WAM Operating Procedure does not provide instructions for referral of specimens when testing is outside of the moderate complexity level and does not include appropriate limitations for moderate complexity testing. Findings include: 1. Review of Sysmex WAM Operating Procedure attachment "Significant Morphology to be Reported on Smear Review" showed the procedure for reporting abnormal smear review findings applies to all lab staff performing CBC (Complete Blood Count) wet work and differential testing and directs staff to report findings</p> |

| | |
|---------------------|--|
| | <p>from a smear review that would fall outside of normal parameters and are not included in the moderate complexity level scope of services for the laboratory. 2. Interview with the technical consultant on June 26, 2018 at 3:30 PM confirmed that the procedure allows reporting of abnormal differential results that are classified as high complexity testing.</p> |
| <p>D5409</p> | <p>PROCEDURE MANUAL CFR(s): 493.1251(e)</p> <p>The laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance as described in 493.1105(a)(2).</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of laboratory procedures and interview with the technical consultant, the laboratory's procedures do not include an initial date of use for the laboratory location. Findings include: 1. Review of laboratory procedures showed no initial date of use for the laboratory location. 2. Interview with the technical consultant on June 26, 2018 at 2:30 PM confirmed that the laboratory procedures do not include an initial date of use for the laboratory location.</p> |
| <p>D5421</p> | <p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of performance verification records for three Pochi 100i hematology analyzers and the Streck Auto Plus erythrocyte sedimentation rate (ESR) analyzer, and interview with the technical consultant, the laboratory did not evaluate the reportable ranges or verify the reference intervals of these test systems before reporting patient results. Findings include: 1. Review of the September 2017, December 2017, and April 2018 performance verification records for three different Pochi 100i hematology analyzers shows no evaluation of reportable ranges or verification of the manufacturer's reference intervals for the test system. Review of September 2017 performance verification records for the Streck Auto Plus instrument shows no evaluation of reportable ranges or verification of manufacturer's reference intervals for the test system. 2. Interview with the technical consultant on June 26, 2018 at 3:00 PM confirmed the reportable ranges and reference intervals of three Pochi 100i analyzers and the Streck Auto Plus instrument were not verified prior to use for patient testing.</p> |