Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D0389833	(X3) Date Survey Completed 01/31/2023
Name of Provider or Supplier West Suburban Center For Arthritis	**Street Address, City, State** 601 N Barker Rd Ste 110, Brookfield, 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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory policies and procedures and interview with the technical supervisor, the laboratory did not establish a procedure defining the method and frequency requirements for assessment of testing personnel and supervisory employee competence. Findings include: 1. Review of laboratory procedures showed no evidence of a procedure for assessing employee competence that identified the frequency of evaluation or the elements required for evaluation of testing and supervisory personnel. 2. Interview with the technical supervisor on January 31, 2023 at 10:30 AM confirmed the laboratory did not establish a procedure for assessing employee competence that defined the method and frequency of evaluation.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) 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. This STANDARD is not met as evidenced by: Based on surveyor review of the iSED procedure in the laboratory procedure manual and interview with the technical consultant, the laboratory did not have a procedure that included the reportable and reference ranges or control procedures since testing started on June 28, 2022. Findings include: 1. Review of the iSED procedure showed the laboratory initiated the procedure on June 28, 2022 for patient erythrocyte sedimentation rate (ESR) testing. Review of the procedure showed no evidence of control requirements, the reportable range, or reference ranges for the ESR test performed on the iSED analyzer. 2. Interview with the technical consultant on January 31, 2023 at 11:00 AM confirmed the procedure in the laboratory manual was not complete and did not include the required elements.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) 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. This STANDARD is not met as evidenced by: Based on surveyor review of validation studies completed for the iSED analyzer and interview with the technical consultant, the laboratory did not document the evaluation of the reference range or the reportable range for one of one test procedure performed on the analyzer. Findings include: 1. Review of the laboratory's iSED evaluation records showed the laboratory evaluated the erythrocyte sedimentation rate (ESR) test performed on the iSED analyzer. The review showed no evidence the laboratory evaluated the reference range provided by the manufacturer or had evaluated the continued use of the previous reference range from the manual ESR method. Further review showed the laboratory did not address the reportable range of the analyzer in their validation studies and did not test samples with results throughout the manufacturer's stated reportable range. 2. Interview with the technical consultant on January 31, 2023 at 11:00 AM confirmed the validation studies did not show the laboratory evaluated the reference range or the reportable range for ESR testing using the iSED analyzer.
D5813	TEST REPORT CFR(s): 493.1291(g)

	The laboratory must immediately alert the individual or entity requesting the test and, if applicable, the individual responsible for using the test results when any test result indicates an imminently life-threatening condition, or panic or alert values. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory reports and interview with the technical supervisor, the laboratory did not document that three of seven results identified as alert values were immediately reported to the physician on January 4, 2023. Findings include: 1. Review of the 'Out of Range Summary' report from January 4, 2023 showed the report incuded seven results identified as 'alert values'. Three of the seven results did not include a comment showing the physician was immediately alerted of the result. 2. Interview with the technical supervisor on January 31, 2023 at confirmed the laboratory has 'alert values' identified that are reported to the physicians as soon as the result is available. Further interview confirmed three of the seven alert values on the January 4, 2023 report did not include documentation that the physician was informed of the alert value.