

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  52D0989506	<b>(X3) Date Survey Completed</b>  07/22/2022
<b>Name of Provider or Supplier</b>  Oakleaf Clinics Sc	<b>Street Address, City, State</b>  3802 W Oakwood Mall Dr, Eau Claire, 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>
<b>D5403</b>	<p><b>PROCEDURE MANUAL</b> 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 survey review of laboratory procedures and interview with the laboratory supervisor, staff A, the chemistry procedures did not include reference intervals for testing performed on the Vitros XT 3400 chemistry analyzer. Findings include: 1. Review of the "Vitros XT 3400 Chemistry" procedure revealed reference range intervals were not included within the procedure. Further review of laboratory procedures showed no evidence the laboratory included reference intervals for testing performed on the Vitros XT 3400 chemistry analyzer in their procedures. 2. Interview with staff A, on July 22, 2022 at 12:40 PM confirmed the chemistry procedures did</p>

not include reference intervals for testing performed on the Vitros XT 3400 chemistry analyzer. This is a repeat deficiency from May 18, 2012.

**D6055**

**TECHNICAL CONSULTANT RESPONSIBILITIES**

CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing whenever test methodology or instrumentation changes. The individual's performance must be reevaluated to include the use of the new test methodology or instrumentation prior to reporting patient test results.

This STANDARD is not met as evidenced by:  
Based on surveyor review of laboratory records and training and competency evaluation records and interview with the laboratory supervisor, staff A, the technical consultant did not reevaluate competency after the implementation of the new chemistry analyzer prior to reporting patient test results for three of three testing personnel. Finding include: 1. Review of laboratory records showed the laboratory replaced the Vitros 350 chemistry analyzer with the Vitros XT 3400 chemistry analyzer effective May 17, 2022. 2. Review of training and competency records showed staff training occurred by the Ortho Diagnostics field service representative on the Vitros XT 3400 chemistry analyzer prior to the go-live of the new analyzer. Further review showed no evidence the technical consultant performed reevaluation for staff competency for use of the new analyzer prior to reporting patient test results. 3. Interview with staff A on July 22, 2022 at 11:50 AM confirmed the technical consultant did not reevaluate competency after the implementation of the new chemistry analyzer prior to reporting patient test results for three of three testing personnel.