

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 52D2171289	<b>(X3) Date Survey Completed</b> 03/16/2022
<b>Name of Provider or Supplier</b> Oakleaf Clinics- Chippewa	<b>Street Address, City, State</b> 855 Lakeland Drive, Chippewa Falls, 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>D5805</b>	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of laboratory information system (LIS) patient reports, Clinical Laboratory Improvement Amendments (CLIA) Application for Certification Form CMS-116 and interview with the laboratory supervisor, staff A, the test report did not include the correct testing address. Findings include: 1. Review of LIS test report for patient 1 showed the address of the laboratory as 855 Lakeland Drive, Eau Claire, WI 54701. 2. Review of the CLIA Form CMS-116 showed the address of the laboratory as 855 Lakeland Drive, Chippewa Falls, WI 54729. 3. Interview with staff A on March 16, 2022 at 9:40 AM confirmed the laboratory's address is 855 Lakeland Drive, Chippewa Falls, WI 54729 and the LIS test report did not include the correct testing address. Further interview confirmed LIS test reports were distributed to providers and patients when necessary.</p>
<b>D6072</b>	<p>TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(3)</p> <p>Each individual performing moderate complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument</p>

and procedural calibrations and maintenance performed.

This STANDARD is not met as evidenced by:

Based on surveyor review of the troponin procedure, Individualized Quality Control Plan (IQCP), quality control (QC) logs and interview with the laboratory supervisor, staff A, testing personnel did not perform and document quality control for the troponin test every thirty days according to the procedure from February 24 through November 15, 2021. Findings include: 1. Review of the I-Stat troponin procedure and IQCP showed testing personnel must test two levels of QC every thirty days. 2. Review of the troponin quality control logs showed: a. QC was performed February 24, 2021 and April 21, 2021 with no additional QC performed between those dates. QC was due to be performed March 26, 2021. b. QC was performed April 21, 2021 and June 11, 2021 with no additional QC performed between those dates. QC was due to be performed May 21, 2021. c. QC was performed June 11, 2021 and July 20, 2021 with no additional QC performed between those dates. QC was due to be performed July 11, 2021. d. QC was performed July 20, 2021 and September 23, 2021 with no additional QC performed between those dates. QC was due to be performed August 19, 2021. e. QC was performed September 23, 2021 and November 15, 2021 with no additional QC performed between those dates. QC was due to be performed October 23, 2021. 3. Interview with staff A on March 16, 2022 at 11:08 AM confirmed testing personnel did not perform and document quality control for the troponin test every thirty days according to the procedure from February 24 through November 15, 2021.