

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  24D2213829	<b>(X3) Date Survey Completed</b>  02/27/2023
<b>Name of Provider or Supplier</b>  Centracare Willmar Main Clinic Dermatology	<b>Street Address, City, State</b>  101 Willmar Ave Sw 2nd Floor E, Dermatology, Willmar, MN	
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>D5221</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d)</p> <p>All proficiency testing evaluation and verification activities must be documented.</p> <p>This STANDARD is not met as evidenced by:                      . Based on document review and an interview with laboratory personnel, the laboratory failed to document all proficiency testing evaluation activities on one of ten events performed in 2021 and 2022. Findings are as follows: 1. The laboratory performed Mohs Micrographic Surgery under the specialty Histopathology as confirmed by the Histotechnician (HT) during a tour of the laboratory at 10:10 a.m. on February 27, 2023. 2. To verify the accuracy of of the procedure, the laboratory twice per year had the Mohs slides of each Mohs surgeon peer reviewed in a blind review. 3. The MOHS Surgery procedure, found in the Mohs Laboratory Compliance Manual, established this biannual slide review in section 9.4. The procedure directed the laboratory surgeons to meet and discuss the results of the review if there was a conflict. 4. A Mohs Slide Review done on 10/4/21, Mohs # M21-493, found that both reviewing surgeons disagreed with the surgeon who had interpreted the patient slides. Review of the records did not find documentation of the discussion between the surgeons regarding the conflict/disagreement. 5. The laboratory was unable to provide the documentation upon request. 6. In an interview at 11:10 a.m. on February 27, 2023, the HT confirmed the above findings. .</p>
<b>D5433</b>	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1)</p> <p>For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a</p>

maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.

This STANDARD is not met as evidenced by:

Based on observation, document review, and an interview with laboratory personnel, the laboratory failed to document Histopathology biannual equipment maintenance activities on the cryostat during 2021 and 2022. Findings are as follows: 1. The laboratory performed Mohs Micrographic Surgery under the specialty Histopathology as confirmed by the Histotechnician (HT) during a tour of the laboratory at 10:10 a.m. on February 27, 2023. 2. A Leica CM1520 Cryostat was observed as present and available for use during the tour of the laboratory. 3. The Cryostat Procedure, found in the Mohs Laboratory Compliance Manual, established the following maintenance requirements: - that the Cryostat were to be defrosted and air dried every 6 months - that the air filter was to be replaced every 6 months 4. Review of the monthly Cryostat Maintenance Logs did not provide evidence that either of the 6 month maintenance protocols had been performed in 2021 or 2022. 5. The laboratory was unable to provide the documentation upon request. 6. In an interview at 11:10 a.m. on February 27, 2023, the HT confirmed the above findings.