

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0992852	(X3) Date Survey Completed 05/04/2018
Name of Provider or Supplier Centracare Clinic- Plaza Dermatology	Street Address, City, State 1900 Centracare Circle Suite 2575, Saint Cloud, MN	
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
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory failed to verify the accuracy of a Histopathology test procedure at least twice annually. Findings are as follows: 1. The laboratory performed Mohs Micrographic Surgery (MMS) testing under the subspecialty of Histopathology as confirmed by the Nurse Manager (NM) during a tour of the laboratory on 05/04/18 at 10:05 a.m. 2. Verification of accuracy requirements for the MMS testing were established in the Dermatology Quality Assurance Program policy provided by the laboratory. The laboratory required annual assessment of 1 case per Mohs physician. 3. Documentation of one 2017 MMS case verification was found in laboratory records. The laboratory was unable to provide additional MMS case verification records from 2017 upon request. A minimum of 2 cases must be verified annually. 4. In an interview on 05/04/18 at 12:15 p.m., the NM confirmed MMS accuracy had not been verified twice in 2017.</p>
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by:</p>

. Based on observation, document review and interview with laboratory personnel, the laboratory failed to ensure Histopathology and Mycology testing materials were not used after the expiration date had been exceeded. Findings are as follows: 1. The laboratory performed Mohs Micrographic Surgery under the subspecialty Histopathology and microscopic examinations for fungus under the subspecialty of Mycology as confirmed by the Nurse Manager (NM) during a tour of the laboratory on 05/04/18 at 10:05 a.m. 2. Expired tissue marking materials were observed as present and available for use during the tour of the laboratory. See below. -Cancer Diagnostics Tissue Marking Dye, Black Lot 15240 Expiration 07/2017 -Cancer Diagnostics Tissue Marking Dye, Violet Lot 15169 Expiration 12/2016 -Cancer Diagnostics Tissue Marking Dye, Orange Lot 15169 Expiration 12/2016 -Cancer Diagnostics Tissue Marking Dye Lot 16161 Expiration 12/2017 3. Expired fungal stain was observed as present and available for use during the tour of the laboratory. See below. -Chlorazol Black E Lot 5315 Expiration 11/11/2017 4. In an interview on 05/04/18 at 10:30 a.m., the NM confirmed the above materials were used after the expiration date had been exceeded.