

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 27D2187269	<b>(X3) Date Survey Completed</b> 06/17/2024
<b>Name of Provider or Supplier</b> Benefis Dermatology	<b>Street Address, City, State</b> 400 13th Ave South, Floor 2, Great Falls, MT	
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>D1001</b>	<p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e)</p> <p>Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.</p> <p>This STANDARD is not met as evidenced by: Based on record review, product inserts, and interview with a laboratory representative (not listed on the CMS-209 Laboratory Personnel Report), the laboratory failed to follow the manufacturer's instructions to document an external positive and negative quality control results as required by Sure Vue Serum/Urine human chorionic gonadotropin (hCG) product insert from June 17, 2022, to June 17, 2024. Findings: 1. A review of quality control (QC) records for hCG urine testing revealed the laboratory failed to document the results of an external positive and negative control performed monthly per the Sure Vue Serum/Urine hCG product insert from June 17, 2022, to June 17, 2024. 2. Based on the CMS 116 form, 75 urine pregnancy tests were performed from June 17, 2023, to June 17, 2024. 3. An interview with the laboratory representative (not listed on the CMS-209 form) on June 17, 2024, at 2:00 PM, confirmed the laboratory's QC documents did not contain the results for the external positive and negative QC per the Sure Vue Serum/Urine hCG product insert from June 17, 2022, to June 17, 2024.</p>
<b>D5217</b>	<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>

This STANDARD is not met as evidenced by:  
Based on a review of verification records, procedures and an interview with a laboratory representative (not listed on the CMS-209 Laboratory Personnel Report), the laboratory failed to perform twice-yearly accuracy verification of its MOHS testing procedures from June 17, 2022, to June 17, 2024. Findings: 1. A review of personnel records revealed the laboratory failed to perform one of the two accuracy verifications for its MOHS surgery procedures for the years 2022 and 2023. 2. Based on the CMS 116 form, 1500 MOHS testing procedures were performed from June 17, 2023, to June 17, 2024. 3. An interview on June 17, 2024, at 12:00 PM with a laboratory representative (not listed on the CMS-209 Laboratory Personnel Report) confirmed the laboratory failed to perform one of two twice-yearly accuracy verifications of its MOHS testing procedures for the years 2022 and 2023.

**D6091**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(e)(4)(iii)

The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action.

This STANDARD is not met as evidenced by:  
Based on a review of Wisconsin State Laboratory of Hygiene (WSLH ) Proficiency Testing records for 2022 and 2023, the CMS-209 Laboratory Personnel Report, and an interview with a laboratory representative (not listed on the CMS-209 form), the laboratory director failed to ensure all proficiency testing reports received were reviewed and approved by the appropriate staff from June 17, 2022, to June 17, 2024. Findings: 1. A review of WSLH proficiency testing events 2022-MiscQA POC1 and POC2, 2023-MiscQC POC1 and POC2 for Provider Performed Microscopy and Urinalysis/Urine Human Chorionic Gonadotropin (hCG) revealed two personnel not listed on the CMS 209 form signed in place of the laboratory director to approve the proficiency test results and/or attest the attestations. 2. An interview with the laboratory representative (not listed on the CMS-209 form) on June 17, 2024, at 2:00 PM confirmed the signatures were of two personnel from another laboratory and that the laboratory director listed on the CMS-209 form failed to ensure all proficiency testing reports received were reviewed and approved by the appropriate staff from June 17, 2022, to June 17, 2024.