

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  36D0656150	<b>(X3) Date Survey Completed</b>  05/03/2021
<b>Name of Provider or Supplier</b>  Skin Pathology Services Inc	<b>Street Address, City, State</b>  2660 E Market St, Warren, OH	
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>D2016</b>	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.</p> <p>This CONDITION is not met as evidenced by: Based on record review and an interview with the Office Manager, the laboratory failed to successfully participate in a PT (proficiency testing) program for the non-waived Gram stain testing, performed under the subspecialty of Bacteriology. All patients who had Gram stain testing in this laboratory from the third WSLH (Wisconsin State Laboratory of Hygiene) PT event of 2020 to the first WSLH PT event of 2021 had the potential to be affected by this deficient practice. Findings Include: 1. The laboratory failed to achieve satisfactory PT performance for the analyte of Gram Stain in two out of three consecutive PT testing events, which resulted in subsequent unsuccessful analyte performance. All patient Gram stain</p>

specimens tested from the third WSLH PT event of 2020 to the first WSLH PT event of 2021 had the potential to be affected by this deficient practice. (Refer to D2028)

**D2028**

**BACTERIOLOGY**

CFR(s): 493.823(e)

Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:

Based on record review and an interview with the Office Manager, the laboratory failed to achieve satisfactory (Proficiency Testing) PT performance for the analyte of Gram Stain in two out of three consecutive PT testing events, which resulted in subsequent unsuccessful analyte performance. All patient Gram stain specimens tested from the third WSLH (Wisconsin State Laboratory of Hygiene) PT event of 2020 to the first WSLH PT event of 2021 had the potential to be affected by this deficient practice. Findings Include: 1. Review of the WSLH PT documentation for the third testing event of 2020 found the laboratory received an overall score of 60%. The laboratory received a result of "Fail" on the Gram stain specimens GS-11 and GS-13. 2. Review of the WSLH PT documentation for the first testing event of 2021 found the laboratory received an overall score of 60%. The laboratory received a result of "Fail" on the Gram stain specimen GS-3 and GS-5. 3. The Office Manager confirmed, via a telephone interview on 05/04/2021, that the laboratory routinely used Gram stain on histological specimens to visualize bacteria that may be present. Patient results are routinely reported as 'positive' (bacteria present), and 'negative' (bacteria absent). The PT results were reported as such; however, the PT provider stated the specific Gram stain reaction should be reported for each specimen. For PT results, 'positive' should be reported when Gram positive organisms were present, and 'negative' should be reported when Gram negative organisms were present. Thus, due to this miscommunication of reporting structure, the Office Manager confirmed, via a telephone interview on 05/04/2021, that the laboratory failed to achieve satisfactory PT performance for the analyte of Gram stain on the third WSLH PT event of 2020 and the first WSLH PT event of 2021.