

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 28D1016805	(X3) Date Survey Completed 04/25/2019
Name of Provider or Supplier Strnot Dermatology	Street Address, City, State 600 North Cotner Blvd Suite 308, Lincoln, NE	
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 the list of tests performed, review of proficiency testing and interview with the testing personnel at 9:45 AM on 4/23/2019, the laboratory failed to verify the accuracy of KOH for 2017 and 2018. Findings are: 1. Review of the list of tests performed provided by the laboratory revealed KOH performed at this laboratory with an annual volume of 23 tests. 2. Review of proficiency testing all 3 events of 2017 and 2018 for KOH, Microbiology, revealed failures on 2017 2nd event (50%), 2017 3rd event (50%), and 2018 2nd event (50%). 3. Interview with the testing personnel confirmed the laboratory had failed events and had not submitted any other challenges through either PT or another laboratory to verify the accuracy of this testing.</p>
D6022	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur.</p> <p>This STANDARD is not met as evidenced by: Based on review of proficiency testing results and interview with testing personnel the</p>

laboratory director failed to identify failures in quality as they occur. The findings include: 1. Review of proficiency testing all 3 events of 2017 and 2018 for KOH, Microbiology, revealed failures on 2017 2nd event (50%), 2017 3rd event (50%), and 2018 2nd event (50%). These failures were not identified and no investigation was initiated. Refer to D5217. 2. Interview with the testing personnel confirmed the laboratory had failed events and had not identified these failures.