

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D1019312	(X3) Date Survey Completed 04/17/2018
Name of Provider or Supplier Skin Diagnostics Inc	Street Address, City, State 9201 Montgomery Rd, Cincinnati, OH	
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
D5211	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's records and an interview with the Laboratory Director (LD), the laboratory failed to review test accuracy verification results. Findings were as follows: 1. The surveyor was presented with the "Skin Diagnostics Inc, Policy and Procedure Manual", updated April 2018. 2. During a review of test accuracy verification records, five selected cases for accuracy assessment were forwarded to AccuPath/DermPath for peer review. Five cases selected: D17-674 D17-51 D17-24 D17-77 D17-009 2. The LD provided an "AccuPath Quality Management" peer review sheet which did not contain any dates of submission, peer review signature dates or dates of LD review. The laboratory director confirmed no review of the AccuPath/Derm peer reviewed cases was documented. The interview occurred on 04/17/2018 at 9:53 AM.</p>
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: REPEAT DEFICIENCY Based upon a review of lab policies, proficiency and accuracy assessment testing records and an interview with the Laboratory Director (LD), the laboratory failed to perform test accuracy verification twice annually.</p>

Findings were as follows: 1. The surveyor was presented with the "Skin Diagnostics Inc, Policy and Procedure Manual", updated April 2018. 2. During a review of test accuracy verification records, five selected cases for accuracy assessment were forwarded to AccuPath/DermPath for peer review. Five cases selected: D17-674 D17-51 D17-24 D17-77 D17-009 2. The LD provided an "AccuPath Quality Management" peer review sheet which did not contain any dates of submission, peer review signature dates or dates of LD review. The laboratory director verified no dates for peer review had been documented during 2016, 2017 and 2018. The interview occurred on 04/17/2018 at 9:53 AM.

D6092

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(4)(iv)

The laboratory director must ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's records and an interview with the Laboratory Director (LD), the laboratory failed to have an approved corrective action plan established when any test accuracy verification results are found to be unacceptable. Findings were as follows: 1. During a review of test accuracy verification records, five selected cases for accuracy assessment were forwarded to AccuPath/DermPath for peer review. No date was documented for the submission of the peer reviewed cases. 2. The surveyor was presented with the "Skin Diagnostics Inc, Policy and Procedure Manual", updated April 2018. No test accuracy verification corrective action policy and procedure was found. 3. The laboratory director confirmed no corrective action policy and procedure was established. The interview occurred on 04 /17/2018 at 9:55 AM.