

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D0211849	(X3) Date Survey Completed 03/13/2018
Name of Provider or Supplier Sona Dermatology	Street Address, City, State 6500 Rock Spring Dr Ste 105, Bethesda, MD	
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 procedure manual and quality assurance (QA) review and interview with the laboratory director (LD), the laboratory did not ensure that proficiency testing (PT) was performed at least twice annually. Findings: 1. The procedure, "Proficiency Testing" states that "At a minimum of twice of a year, quality control proficiency testing shall be performed on slides for Toluidine Blue (T-Blue) and Hematoxylin and Eosin (H&E)." 2. A review of QA records showed that 8 slides were sent out to another doctor to evaluate for PT on 8/3/17 and 4 slides were sent out for PT on 2/14/18; and 3. At the time of the survey, there was no documentation of PT being sent out in 2016. 3. During an interview on 3/13/18 at 12:30 PM, the LD confirmed that PT had not been performed twice a year.</p>
D5473	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Note: This is a repeat deficiency. The laboratory was cited during the re-certification</p>

survey on 3/30/2016 for not recording the daily stain quality control, recording the staining characteristics of the Hematoxylin and Eosin stain and the Toluidine Blue stain. The plan of correction stated that this would be corrected. Based on quality control (QC) and patient log record review and interview with the laboratory director (LD), the laboratory did not ensure that daily stain QC was consistently documented, recording the quality of the staining characteristics of the Hematoxylin and Eosin (H&E) stain and the Toluidine Blue (T-Blue) stain. Findings: 1. The laboratory performs H&E and T-Blue staining procedures to evaluate histopathology slides. Daily stain QC for H&E and T-Blue stains are recorded on the "Mohs Frozen Section Daily Technical Quality Assurance Report." 2. A review of daily stain QC logs from 110 days of testing from 1/4/17 to 12/18/17 showed that for 4/110 days QC logs were present, but the results of the stain QC were not documented on the log sheet; and 3. The signature of the LD was missing for 2/110 days. 4. There was no QC log present for the H&E stain on 2/27/17, and there were no QC logs present for the T-Blue stain on 4/5/17 and 8/16/17; and 5. A review of patient logs showed that on these 3 days patient testing was performed using these stains. 6. During an interview on 3/13/18 at 12:30 PM, the LD confirmed that daily slide QC was not consistently documented.