

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 07D0096640	(X3) Date Survey Completed 01/19/2018
Name of Provider or Supplier Shoreline Mohs Surgery	Street Address, City, State 5 Durham Rd, Ste B2, Guilford, CT	
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
D0000	The Shoreline MOHS Surgery Laboratory was surveyed pursuant to 42CFR Part 493 of the Clinical Laboratory Improvement Amendments of 1988 (CLIA) on January 19, 2018.
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: Based on record review and staff interview, the laboratory failed to provide evidence that the laboratory evaluated the Hematoxylin & Eosin (H&E) stain for acceptable staining characteristics in the subspecialty of histopathology. Findings include: 1. Record review of the laboratory procedure manual on 1/19/18 revealed the manual did not include a procedure for daily evaluation of the H&E stain. 2. Record review of the H&E slides on 1/19/18 revealed documentation was not available for daily H&E stain quality and acceptability. 3. Staff interview with the laboratory director on 1/19/18 at 10:00 AM confirmed the following: a. The laboratory does not have a procedure for evaluation of stain reactivity. b. The laboratory does not document stain reactivity to ensure stain acceptability. 4. The laboratory performs 1,400 histopathology tests annually.</p>