

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  14D1029865	<b>(X3) Date Survey Completed</b>  11/07/2019
<b>Name of Provider or Supplier</b>  Chicago Cosmetic Surgery & Dermatology	<b>Street Address, City, State</b>  515 N State - Ste 900, Chicago, IL	
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>D5471</b>	<p><b>CONTROL PROCEDURES</b> CFR(s): 493.1256(e)(1)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and an interview with the laboratory staff, the laboratory failed to document each lot number of commercially prepared reagents and stains, when opened, to perform Hematoxylin and Eosin (H&amp;E) staining procedures. Findings include: 1. The laboratory procedures manual, patients test logs, and "Got Mohs" quality control (QC) and maintenance logs for the years of 2018 and 2019 were reviewed. 2. The "Got Mohs" and patients' test logs revealed the following: *Seven (7) Mohs procedures dates were selected for QC and maintenance logs review: 01/09/2018; 04/13/2018; 08/17/2018; 12/07/2018; 02/15/2019; 06/21/2019; and 09/20/2019. *The QC logs failed to include the documenting of the reagents and stains it brings to the laboratory for tissue processing for the above dates. 3. The laboratory failed to ensure the travel Mohs service provided the laboratory with the list of reagents, their lot numbers and expiration dates, when brought by the TP into the laboratory, to perform H &amp; E staining. 4. On an Recertification survey conducted on 11/07/2019 at 1:50 PM, the laboratory staff confirmed the above findings.</p>