

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 07D2116007	(X3) Date Survey Completed 10/29/2018
Name of Provider or Supplier Ct Skin Health, Llp	Street Address, City, State 4 Corporate Dr, Suite 386, Shelton, 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
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview the laboratory failed to document routine maintenance and function checks for laboratory equipment in the specialty of pathology. Findings include: 1. Record review of the laboratory's automated cover-slipper (model # 4764) maintenance records on 10/29/18 revealed weekly and monthly function checks were not documented since August 2017. 2. Staff interview with testing personnel # 2 on 10/29/18 at 11:30 AM confirmed the above findings. 3. The laboratory performs 10,450 tests annually in the specialty of pathology.</p>
D6102	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12)</p> <p>The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview the laboratory director failed to ensure testing personnel (TP) were trained prior to testing patient samples. Findings include: 1. Record review of the laboratory's testing personnel report (CMS-209) dated 7/16/18</p>

on 10/29/18 revealed the laboratory employed 1 new TP since last onsite survey. Record review of the laboratory's personnel records revealed the date of hire was 5/15 /17. Training records for the new TP were not available for review. 2. Staff interview with the general supervisor on 10/29/18 at 10:00 AM confirmed training records for the new TP were not available.