

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D1052801	(X3) Date Survey Completed 01/02/2018
Name of Provider or Supplier Dermcare Physicians And Surgeons	Street Address, City, State 154 East Central St, Natick, MA	
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	A CLIA recertification survey was conducted for the Dermcare Physicians and Surgeons laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493. .
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 and record review and interview, the laboratory failed to verify at least twice annually procedures it performs that are not included in subpart I of this part as evidenced by the following: A review of the laboratory's policies and procedures revealed that their was no twice annual accuracy verification procedure for the following tests that were implemented after the last CLIA recertification survey: 1. Potassium Hydroxide (KOH); 2. Wet prep; and, 3. Tzanck smear. The histotechnician interviewed on 1/2/18 at 9:15 AM confirmed that twice annual accuracy verification procedures had not been set up for the above examinations. .</p>
D5407	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on procedure manual review and interview, the laboratory director failed to approve, sign, and date all laboratory procedures as evidenced by the following: A</p>

review of the laboratory procedure manual revealed that the laboratory director had not documented a review and approval of the following newly implemented procedures: 1. Potassium Hydroxide (KOH); 2. Wet prep; and, 3. Tzanck smear. The histotechnician confirmed in an interview on 1/2/18 at 9:08 AM that the laboratory director had not documented a review and approval of the procedures.