

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D1094366	(X3) Date Survey Completed 01/26/2018
Name of Provider or Supplier Westgate Dermatology And Laser Center, Pa	Street Address, City, State 2020 Peace Haven Road, Winston Salem, NC	
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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, review of personnel records, and interview with the laboratory director 1/26/18, the laboratory failed to establish written policies and procedures for evaluating the competency of all testing personnel. Findings: Review of the laboratory's policies and procedures revealed the laboratory had not established a written procedure for evaluating the competency of providers who perform KOH (potassium hydroxide) and scabies preps. Review of personnel records revealed the laboratory's providers had participated in a quiz to identify elements found in KOH and scabies preps twice a year during 2016 and 2017. There was no written policy describing how the process is conducted, including the elements required by CLIA (Clinical Laboratory Improvement Amendments), the criteria for acceptability, and how unacceptable evaluations are handled. During interview at approximately 1:15 p.m., the laboratory director confirmed the laboratory did not have a written competency evaluation policy for providers that included the six elements required by CLIA.</p>
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>

This STANDARD is not met as evidenced by:
Based on review of manufacturer's instructions, the absence of records, and interview with TP (testing personnel) 1/26/18, the laboratory failed to perform and document all maintenance specified by the manufacturer for the IntelliPATH FLX Automated Slide Stainer. The procedure manual for the IntelliPATH FLX Automated Slide Stainer states on page 49 "System Cleaning When the IntelliPATH FLX software notifies operator that cleaning is necessary, follow on-screen instructions. This cleaning cycle should be performed at a minimum of once per week if the user has not reached the maximum slide count allowed. ...". The procedure also describes additional cleaning procedures to be performed daily, weekly, and monthly. There were no records available to indicate that the laboratory performed the cleaning procedures at the frequency specified by the manufacturer 1/1/16 - 1/26/18. During interview at approximately 12:25 p.m., TP #1 stated that he had performed the required maintenance but had not documented it.

D5475

CONTROL PROCEDURES
CFR(s): 493.1256(e)(3)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (3) Check fluorescent and immunohistochemical stains for positive and negative reactivity each time of use. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's policies and procedures, the absence of records, and interview with TP (testing personnel) and the laboratory director 1/26/18, the laboratory failed to check IHC (immunohistochemical) stains for negative reactivity each time of use. The laboratory's "IHC Policy" states "... Policy: For each primary antibody run on the IntelliPATH FLX a known positive control is run on the same slide as the patient test tissue. ... For each primary antibody run on the IntelliPATH FLX a negative control is run if the tissue has pigment that may interfere with interpretation of IHC staining, and when the tissue contains only tumor and there are no cells/tissues that serve as a suitable internal negative control. ..." During interview at approximately 1:05 p.m., TP #1 and the laboratory director confirmed that they do not run a negative control to check negative reactivity for each antibody tested.