

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D1041929	(X3) Date Survey Completed 10/16/2018
Name of Provider or Supplier Dermopath Diagnostics Bay Area	Street Address, City, State 10500 University Center Dr Ste 200, Tampa, FL	
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
D5415	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.</p> <p>This STANDARD is not met as evidenced by: Based on observation and interview with the Laboratory Manager, the laboratory failed to label small plastic transfer bottles (for mobile van) with expiration dates for the Bluing reagent and the 100% reagent alcohol. Findings Included: 1. A tour of the main laboratory to observe reagents for the mobile van on 10/16/18 at approximately 12:15 PM revealed that two small plastic transfer bottles that were labeled with the reagent name and vendor but did not have expiration dates on top of each. 2. Interview on 10/16/18 at 12:15 PM with the Laboratory Manager confirmed that the two bottles did not have expiration dates.</p>
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on observation of reagents and interview with the Laboratory Manager, the laboratory failed to ensure the Clear Rite was removed from use after the expiration</p>

date. Findings Included: 1. Observation of reagents in the flammable cabinet on 10/16 /18 at approximately 12:15 PM revealed an open bottle of Clear Rite (Lot#344767) with an expiration date of 09/2017 that was in segregated reagents for the mobile van. 2. Interview on 10/16/18 at 12:15 PM with the Laboratory Manager confirmed the Clear Rite was expired.