

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D0418238	(X3) Date Survey Completed 01/23/2025
Name of Provider or Supplier Forefront Dermatology S C	Street Address, City, State 3253 S Harlem Ave - Ste 1a, Berwyn, IL	
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
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>(d) 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 review of laboratory policies and procedures, direct observation of laboratory testing supplies, and interview with the laboratory representative; the laboratory failed to ensure five of five margin marking dye vials and one of one mounting media vial were not used when they had exceeded their expiration dates. Findings include: 1. Review of laboratory policies and procedures revealed the policy titled, "Quality Control Policies and Documentation", which stated, under "Reagents", "This office will practice the following policies 2. All outdates/ expired [reagents] will be disposed of properly." 2. Upon a tour of the laboratory on 01/23/2025, at 9:47 am, direct observation of laboratory testing supplies found five of five margin marking dyes, used for demonstrating tissue margins in the grossing process of histopathology, and one of one mounting media vial, used for attaching the sample to the slide for microscopic evaluation, to be expired. Margin Marker Dye: Lot #: Expiration: Green, 2 oz 21245 09/30/2023 Red, 2 oz 21238 08/31/2023 Black, 2 oz 125196 05/31/2023 Blue, 2 oz 21235 08/31/2023 Yellow, 2 oz 125197 04/30/2024 Mounting Media: Lot #: Expiration: epredia REF: 4112 110544 09/2023 3. Interview with the laboratory representative on 01/23/2025, at 10:53 am, confirmed the laboratory failed to ensure five of five marking dye vials and one of one mounting media vial were not used when they had exceeded their expiration dates.</p>
D6054	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p>

(b)(9) Thereafter, evaluations must be performed at least annually

This STANDARD is not met as evidenced by:

Based on review of laboratory policies and procedures, laboratory records, CMS-209 (Laboratory Personnel Report), lack of documentation, and interview the laboratory representative; the technical consultant failed to ensure competency evaluations were performed annually for one of two testing personnel (TP) performing Provider-Performed Microscopy (PPM) testing at the laboratory in the year of 2024. Findings include: 1. Review of laboratory policies and procedures revealed the policy titled, "Personnel Competency Testing", which stated, under "Procedure", "All testing personnel must have an annual review stating that they have reviewed all three phases of testing (pre analytic, analytic & post analytic) that are required for monitoring and testing competency" 2. Review of the CMS-209 revealed two TP performing PPM testing of Potassium Hydroxide (KOH) and Scabies. 3. Review of laboratory competency evaluation records revealed that one of two TP (TP #2) performing PPM testing lacked documentation of competency evaluation performed at the testing laboratory in 2024. 4. Interview with the laboratory representative on 01/23/2025, at 10:53 am, confirmed the technical consultant failed to ensure competency evaluations were performed annually for one of two TP performing PPM testing.