

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 15D0971895	(X3) Date Survey Completed 10/05/2022
Name of Provider or Supplier Franklin Dermatology	Street Address, City, State 18 E State Road 44, Franklin, IN	
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>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, record review and interview, the laboratory failed use mineral oil (expiration 7/2019) that was not expired for two out of two patients (PT#1 and PT#2) reviewed for scabies testing in 2021 and 2022. Findings included: 1.) A laboratory tour on 10/3/2022 at 9:56 AM, revealed three patient examination rooms contained small bottles of mineral oil that had no expiration dates marked. The storage room contained one large bottle of mineral oil in use for scabies which had expired on 7/2019. 2.) Review of "Storage, Use and Handling" policy on page 17 read, "do not use reagents after expiration date." Policy was signed by laboratory director on 6/22 /01. 3.) Review of scabies testing showed the following patients were tested using expired mineral oil: a) PT#1 tested on June 21, 2022. b) PT#2 tested on May 25, 2021. 4.) During interview on 10/3/2022 at 12:00 PM, SP#1 (office manager) confirmed the small bottles of mineral oil located in the patient examination rooms were not marked for with an expiration date, but they are filled from the large bottle located in storage that was expired. 5.) Annual Test Volume for scabies is less than 60.</p>
D5473	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The</p>

laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory failed to document Hematoxylin and Eosin (H&E) stain quality (quality control) for four out of four patients (PT#3, PT#4, PT#5, PT#6) reviewed for Dermatopathology. Findings included: 1.) Review of Dermatopathology patient reports indicated the following patients had H&E stains completed and the slides were read without documented stain quality review: a) PT#3 slides read on 9/7/2022, b) PT#4 slides read on 9/8/2022, c) PT#5 slides read on 3/19/2021, d) PT#6 slides read on 3/23/2021. 2.) Review of "Quality Control" policy indicated the following: a) Page 19 requires the laboratory to check all that applied. b) 6.1.1 has an x marked. c) 6.1.1 lists which laboratory specimens are sent to for processing, but only initials were listed. d) 6.1.1 also requires the laboratory to "Add laboratory name, address, telephone number, contact person and documentation of laboratory's Quality Control procedures after V-5 -page 40." e) Page 40 is blank. f) The laboratory did not update the policy for which processing laboratory is performing the technical component and it did not contain a quality procedure for Dermatopathology. g) The policy was not signed or dated by the laboratory director. 3. During an interview on 10/3/2022 at 12:00 PM, SP#1 (office manager) and SP#2 (Laboratory Director) confirmed the laboratory failed to document H&E stain quality and the quality control policy had not been updated. 4. Annual test volume for dermatopathology is 690.