Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D2302894	08/26/2024
Name of Provider or Supplier	**Street Address, City, State**	
Davishire Dermatology	1900 Patterson Street, #205, Nashville, TN	

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	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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. This STANDARD is not met as evidenced by: Based on laboratory observation, patient test records, and staff interviews, the laboratory failed to ensure that it did not use potassium hydroxide (KOH) reagent beyond its expiration for the fungal testing of 23 patients since April 2024. The findings include: 1. Observation of the laboratory on 08/26/2024 at 8:50 a.m. revealed one bottle of EKI 20% potassium hydroxide (Lot: 2104347) used for dermatological fungal exams with an expiration date of 02/16/2023. 2. A review of patient test records revealed the laboratory performed KOH testing on 23 patients from 04/11 /2024 to the survey date (08/26/2024). 3. An interview with the Laboratory Director on 08/26/2024 at 11:30 a.m. confirmed that the laboratory used the observed KOH reagent for patient testing after the reagent's expiration date.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (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 laboratory must document all control procedures performed. This STANDARD is not met as evidenced by:

	Based on laboratory observation, a review of patient test records, quality control (QC) records, and staff interviews, the laboratory failed to document daily Hematoxylin and Eosin (H&E) staining QC for one of the four testing days reviewed in 2024. The findings include: 1. Observation of the laboratory on 08/26/2024 at 8:50 a.m. revealed a Rushabh Instruments HistoPro 414 linear slide stainer (ID: LS0524) using Mercedes Scientific Hematoxylin (Lot: 2409524) and Eosin (Lot: 2409626) reagents for the staining of patient tissues removed from the micrographically oriented hectographic surgery (MOHS) procedure. 2. A review of patient test records revealed the laboratory performed H&E staining on tissues obtained during MOHS procedures on 06/28/2024 (8 patient cases), 07/19/2024 (9 patient cases), 08/09/2024 (5 patient cases), and 08/23 /2024 (10 patient cases). 3. A review of daily H&E staining records revealed no documented QC recorded for 06/28/2024. 4. An interview with the Laboratory Director on 08/26/2024 at 11:30 a.m. confirmed that the June 2024 daily H&E QC log was missing during the survey.