Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0214109	06/30/2023
Name of Provider or Supplier	**Street Address, City, State**	
Bernstein & Robinson Dermatology	1115 South Main Street, Bel Air, MD	

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
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: Based on review of the quality control log for the potassium hydroxide preparation test (KOH), review of the patient test logs, and interview with the office manager (OM), the laboratory failed to ensure that patients' identification matched the specimen accession numbers for quality control activities. Findings: 1. The laboratory performed a quarterly proficiency check on each physician performing KOH evaluations which was documented on the "Log for Quality Control of KOH" (KOH QC log). 2. There was a KOH QC log for Dr. R reviewing Dr. B and for Dr. B reviewing Dr. R. Each log documented the patient accession number (#), the patient name, and whether the reviewing doctor agreed with the original results. 3. The KOH QC logs for 2021-2023 were reviewed. 4. Six of six patients documented on the KOH QC logs for 2022 listed accession #s with patient names that did not match what was documented on the patient test logs. 5. For the 2022 Dr. R reviewing Dr. B KOH QC log: a. The patient name listed next to accession # 22-01 was not found on the patient test log. Review of the patient's electronic medical record (EMR) determined that the patient did not have a KOH performed. Accession # 22-01 on the patient log documented a KOH that was read by Dr. R not Dr. B. b. The patient name listed next to accession # 22-12 was listed as accession # 22-08 on the patient test log. 6. For the 2022 Dr. B reviewing Dr. R KOH QC log: a. The patient name listed next to accession # 22-03 was listed as accession # 22-02 on the patient test log. b. The patient name listed next to accession # 22-17 was listed as accession # 22-13 on the patient test log. c. The patient name listed next to accession # 22-21 was listed as

	accession #s 22-17 and 22-18 on the patient test log. d. The patient name listed next to accession # 22-45 was listed as accession # 22-41 on the patient test log. Accession # 22-45 had no patient name assigned to it. 7. The OM explained that the accession #s were not used for patient identification and were not documented in the EMR to be able to confirm if the patient test log was accurate. 8. During the survey 06/30/2023 at 11:50 AM, the OM confirmed that the accession numbers and patient names from the KOH QC log did not match what was recorded on the patient test log to ensure positive patient identification.
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 review of the media quality control log, review of the patient test log, and interview with the office manager (OM), the laboratory failed to ensure that dermatophyte test medium (DTM) was not used beyond the expiration date. Findings: 1. The laboratory performed quality control checks on each lot of DTM by documenting the lot number, expiration date, date received, and results from the visual inspection. 2. The dates each lot number was put into use were not documented. 3. Lot number 477580 expired on 07/17/2021 and the next lot number, 489214, was not received until 08/10/2021. Accession number 21-24 was inoculated on 07/20/2021 and accession number 21-26 was inoculated on 07/27/2021 and both had negative results. 4. During the survey on 06/30/2023 at 11:50 AM, the OM confirmed that the date in use for each DTM lot number was not documented and two patients were potentially tested using expired DTM.