Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0914494	10/11/2023
Name of Provider or Supplier	**Street Address, City, State**	
Gold Skincare Center	2000 Richard Jones Rd Ste 200, 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
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 patient requisitions, final patient test reports, tissue slides, Mohs procedure manual and staff interview, the laboratory failed to follow the procedure to ensure positive patient identification and labeling of histological slides for one of six histopathology (1 of 1 Mohs) cases reviewed. The findings include: 1) Review of six randomly selected patient requisition, final test reports, and histopathology slides revealed the last name and first initial on the slide for case M23-40 (Patient ID 314130) were different from the first and last names on the final report and test requisition for case M23-40 (Patient ID 314130). 2) Review of the "Test Days and Procedures" section of the laboratory's Mohs procedure manual revealed the specimen "is labeled with the patients last name, first initial, Mohs accession number" 3) Interview on 10/11/23 at 3:00 pm with the Chief Operating Officer and testing personnel confirmed that the laboratory failed to follow the procedure to ensure positive patient identification and labeling of slides for case M23-40 (Patient ID 314130).
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or

	examining specimens. This STANDARD is not met as evidenced by: Based on review of patient test records, procedure manual, and staff interview, the laboratory failed to have a written procedure for the scabies test on the date of the survey (10/11/23). The findings include: 1. Review of the patient scabies testing logs (January 2021 to October 2023) revealed patient testing for scabies on 1/13/21, 1/21 /21, 8/30/21, 12/27/22, 1/10/23 (two patient's tested), 5/4/23, 8/9/23, and 9/19/23. 2. Review of the laboratory's procedure manual revealed no procedure was available for scabies testing. 3. Interview on 10/11/23 at 3:00 pm with the Chief Operating Officer and testing personnel confirmed that the laboratory did not have a written policy for scabies testing at the time of the survey.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) 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. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the procedure manual and staff interviews, the laboratory failed to label secondary reagent containers used for histopathology processing of patient tissues with lot numbers and expiration dates. The findings include: 1. Observation of the laboratory on 10/11/23 at 8:05 am revealed the following : -An Avantik Biogroup tissue processor (SN 137550094) using 95% Alcohol, Xylene, Formalin, 80% Alcohol, and 100% Alcohol for use in the automated processing of patient dermatopathology tissues. -A Histopro 414 automated stainer (SN 137751194) using water, Hematoxylin, Bluing, Eosin, 95% Alcohol, Xylene, Formalin, 80% Alcohol, and 100% Alcohol for use in the automated staining of patient tissues removed during the Mohs surgical procedure. -A manual tissue processing station using water, Hematoxylin, Bluing, Eosin, 95% Alcohol, Xylene, Formalin, 80% Alcohol, and 100% Alcohol for use in the manual processing and staining of patient dermatopathology tissues. - None of the reagent containers used with the Avantik Biogroup tissue processor, Histopro 414 stainer, or manual processing station were labeled with the reagent lot numbers or expiration dates. 2. Review of the laboratory's "Quality Control Program" procedure revealed the following statement: "All reagents and other supplies will be labeled to indicate: 1. Identity and, when significant, strength or concentration. 2. Recommended storage requirements. 3. Preparation and expiration dates. 4. Safety data. 5. Other pertinent information." 3. Interview on 10/11/23 at 3:00 pm with the Chief Operating Officer and testing personnel confirmed that the laboratory did not label secondary containers of reagents used in the automated and manual processing and staining of patient dermatopathology tissues with reagent lot number and expiration dates.
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 observation of the laboratory, review of the procedure manual, review of patient testing logs, and staff interview, the laboratory failed to ensure mineral oil used for patient scabies testing was not used past the expiration date, with nine patient test results for scabies reported in the two years reviewed (January 2021 to October 2023). The findings include: 1. Observation of the laboratory on 10/11/23 at 8:40 am revealed one bottle of Sunmark Heavy Mineral Oil (Lot: HR6112CA) with an expiration date of 8/2015 in use for scabies examination. 2. Review of the laboratory's "Quality Control Program" procedure revealed the following statement: "Reagents and other supplies are not used when they have exceeded their expiration dates, have deteriorated or are of substandard quality." 3. Review of the patient scabies testing logs (January 2021 to October 2023) revealed patient testing on 1/13/21, 1/21/21, 8/30 /21, 12/27/22, 1/10/23 (two patient's tested), 5/4/23, 8/9/23, and 9/19/23. 3. Interview with the Chief Operating Officer and testing personnel on 10/11/23 at 3:00 p.m. confirmed the mineral oil observed in the laboratory was used for scabies examination of patient specimens after the reagent expiration date of 8/2015.