Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D2047551	11/28/2022
Name of Provider or Supplier	**Street Address, City, State**	
Skincare Drs Pa	7373 France Ave So Suite 304, Edina, MN	

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
D5006	MYCOLOGY CFR(s): 493.1203 If the laboratory provides services in the subspecialty of Mycology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1263, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: . Based on observation, document review and an interview with laboratory personnel, the laboratory failed to meet all requirements specified in 493.1230 through 493.1256, 493.1263, and 493.1281 through 493.1299 for the sub-specialty of Mycology. The laboratory performs approximately XX non-waived mycology tests per year. Findings are as follows: 1. The laboratory failed to perform and document fungal microscopic examination testing accuracy verification activities at least twice annually . See D5217 2. The laboratory failed to establish required procedures for fungal microscopic examinations and associated required activities. See D5403 3. The laboratory failed to ensure solutions used for fungal microscopic examinations were not used after the expiration date had been exceeded. Dee D5417 4. The laboratory failed to maintain an information or record system (patient testing log) for fungal microscopic examinations. See D5787 5. The Technical Consultant failed to ensure testing personnel were evaluated for fungal microscopic examination competency. See D6046 .
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.

	This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the laboratory failed to perform and document testing accuracy verification activities at least twice annually for one of one moderate complexity microscopic examination procedures performed by the laboratory. Findings are as follows: 1. The Mycology Subspecialty was removed from the laboratory's CLIA certification on 10/11/18 as indicated on the Form CMS-116 submitted by the laboratory during the routine CLIA survey performed on 10/11/18. 2. The following fungal microscopic testing materials were observed as present and available for use during a tour of the laboratory with the Clinical Operations Manager (COM) at 1:10 p.m. on 11/28/22: Micromaster microscope and Olympus CX-41 microscope Potassium Hydroxide (KOH) solution - 2 bottles Chlorazol Black stain Glass slides and cover slips Butane lighter Waste container labeled KOH Slides containing 141 unlabeled slides with milky or gray residue The KOH solution and Chlorazol Black stain were expired - see D5417 3. Laboratory Testing Personnel 1 indicated she performed approximately two fungal microscopic examinations each of the last 5.5 years during a telephone interview at 1: 33 p.m. on 11/28/22. 4. The laboratory's fungal microscopic patient testing log, found the the KOH Log, Edina manilla folder, indicated patient samples received fungal microscopic examinations in 2018, 2019, and 2020. See below. Year Number of tests 2018 5 2019 2 2020 1 Testing records were not found for 2021 or 2022. See D5787. 5. A procedure for twice annual verification of fungal testing accuracy was not found in laboratory documents. The laboratory was unable to provide this procedure upon request. See D5403 6. Verification of fungal testing accuracy documents from 2018 through 2022 were not found found during review of laboratory records. The laboratory was unable to provide testing accuracy verification records upon request. 7. In an interview at 1:40 p.m. on 11/28/22, the COM confirmed the above finding. .
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the laboratory failed to establish required procedures for one of one moderate complexity microscopic examination procedures performed by the laboratory.

	Findings are as follows: 1. The Mycology Subspecialty was removed from the laboratory's Clinical Laboratory Improvement Amendments (CLIA) certification on 10 /11/18 as indicated on the Form CMS-116 submitted by the laboratory during the routine CLIA survey performed on 10/11/18. 2. The following fungal microscopic testing materials were observed as present and available for use during a tour of the laboratory with the Clinical Operations Manager (COM) at 1:10 p.m. on 11/28/22: Micromaster microscope and Olympus CX-41 microscope Potassium Hydroxide (KOH) solution - 2 bottles Chlorazol Black stain Glass slides and cover slips Butane lighter Waste container labeled KOH Slides containing 141 unlabeled slides with milky or gray residue The KOH solution and Chlorazol Black stain were expired - see D5417 3. Laboratory Testing Personnel 1 indicated she performed approximately two fungal microscopic examinations each of the last 5.5 years during a telephone interview at 1:33 p.m. on 11/28/22. 4. The laboratory's fungal microscopic patient testing log, found the the KOH Log, Edina manilla folder, indicated patient samples received fungal microscopic examinations in 2018, 2019, and 2020. See below. Year Number of tests 2018 5 2019 2 2020 1 Testing records were not found for 2021 or 2022. See D5787. 5. Procedures for fungal microscopic testing and associated CLIA required activities were not found in laboratory documents. The laboratory was unable to provide procedures upon request. 6. In an interview at 1:40 p.m. on 11/28/22, the COM confirmed the above finding. .
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, document review, and interview with laboratory personnel, the laboratory failed to ensure solutions used for fungal microscopic examinations were not used after the expiration date had been exceeded in 2018 through 2022. Findings are as follows: 1. The Mycology Subspecialty was removed from the laboratory's CLIA certification on 10/11/18 as indicated on the Form CMS-116 submitted by the laboratory during the routine CLIA survey performed on 10/11/18. 2. The following fungal microscopic testing materials were observed as present and available for use during a tour of the laboratory with the Clinical Operations Manager (COM) at 1:10 p.m. on 11/28/22: Micromaster microscope and Olympus CX-41 microscope Potassium Hydroxide (KOH) solution - 2 bottles Chlorazol Black stain Glass slides and cover slips Butane lighter Waste container labeled KOH Slides containing 141 unlabeled slides with milky or gray residue 3. Laboratory Testing Personnel 1 indicated she performed approximately two fungal microscopic examinations each of the last 5.5 years during a telephone interview at 1:33 p.m. on 11 /28/22. 4. The laboratory's fungal microscopic patient testing log, found the the KOH Log, Edina manilla folder, indicated patient samples received fungal microscopic examinations in 2018, 2019, and 2020. See below. Year Number of tests 2018 5 2019 2 2020 1 Testing records were not found for 2021 or 2022. See D5787. 5. The (KOH) solution and Chlorazol Black stain were used for testing patient specimens after the expiration date had been exceeded in 2018 through 2022. See below. Solution: KOH 10% with DMSO Lot #: 17257 Expiration Date: 09/14/18 Solution: KOH 10% with

	DMSO Lot #: 1811506 Expiration Date: 04/25/19 Solution: Chlorazol Black Lot #: 7044 Expiration Date: 02/13/19 6. In an interview on at 1:35 p.m. on 11/28/22, the COM confirmed the above findings. .
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the laboratory failed to maintain an information or record system (patient testing log) for microscopic examinations for one of one moderate complexity microscopic examination procedures performed by the laboratory in 2021 and 2022. Findings are as follows: 1. The Mycology Subspecialty was removed from the laboratory's Clinical Laboratory Improvement Amendments (CLIA) certification on 10/11/18 as indicated on the Form CMS-116 submitted by the laboratory during the routine CLIA survey performed on 10/11/18. 2. The following fungal microscopic testing materials were observed as present and available for use during a tour of the laboratory with the Clinical Operations Manager (COM) at 1:10 p.m. on 11/28/22: Micromaster microscope and Olympus CX-41 microscope Potassium Hydroxide (KOH) solution - 2 bottles Chlorazol Black stain Glass slides and cover slips Butane lighter Waste container labeled KOH Slides containing 141 unlabeled slides with milky or gray residue The KOH solution and Chlorazol Black stain were expired. See D5417 3. Laboratory Testing Personnel 1 indicated she performed approximately two fungal microscopic examinations each of the last 5.5 years during a telephone interview at 1: 33 p.m. on 11/28/22. 4. The laboratory's fungal microscopic patient testing log, found the the KOH Log, Edina manilla folder, indicated patient samples received fungal microscopic examinations in 2018, 2019, and 2020. See below. Year Number of tests 2018 5 2019 2 2020 1 5. A fungal microscopic examination patient testing log was not found in laboratory records for 2021 or 2022. The laboratory was unable to provide a patient testing log upon request. 6. In an interview at 1:40 p.m. on 11/28/22, the COM confirmed the above finding. .
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the Technical Consultant failed to ensure four of four testing personnel were evaluated for competency on the single moderate complexity microscopic examination performed by the laboratory in 2018 though 2022. Findings are as follows: 1. The

	Mycology Subspecialty was removed from the laboratory's Clinical Laboratory Improvement Amendments (CLIA) certification on 10/11/18 as indicated on the Form CMS-116 submitted by the laboratory during the routine CLIA survey performed on 10/11/18. 2. The following fungal microscopic testing materials were observed as present and available for use during a tour of the laboratory with the Clinical Operations Manager (COM) at 1:10 p.m. on 11/28/22: Micromaster microscope and Olympus CX-41 microscope Potassium Hydroxide (KOH) solution - 2 bottles Chlorazol Black stain Glass slides and cover slips Butane lighter Waste container labeled KOH Slides containing 141 unlabeled slides with milky or gray residue The KOH solution and Chlorazol Black stain were expired. See D5417 3. Laboratory Testing Personnel 1 indicated she performed approximately two fungal microscopic examinations each of the last 5.5 years during a telephone interview at 1:33 p.m. on 11 /28/22. 4. The laboratory's fungal microscopic patient testing log, found the the KOH Log, Edina manilla folder, indicated patient samples received fungal microscopic examinations in 2018, 2019, and 2020. See below. Year Number of tests 2018 5 2019 2 2020 1 Fungal testing records were not found for 2021 or 2022. See D5787 5. A fungal microscopic testing competency assessment procedure was not found in laboratory documents. The laboratory was unable to provide this procedure upon request. See D5403 6. Competency assessments for four of four testing personnel were not found during review of laboratory records from 2018 through 2022. The laboratory was unable to provide testing accuracy verification records upon request. 7. In an interview at 1:40 p.m. on 11/28/22, the COM confirmed the above finding. 8. In an email received at 4:27 p.m. on 12/07/22, the COM confirmed four testing personnel performed fungal microscopic examinations in the laboratory.