Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D0414140	11/04/2025
Name of Provider or Supplier	**Street Address, City, State**	
Goldin Skin Dermatology	4709 W Golf Rd - Ste 600, Skokie, IL	

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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of the laboratory policy and procedure manuals, lack of documentation, and interview with testing personnel (TP) #2; the laboratory failed to follow the established competency procedure in place to assess employee competency for 3 of 3 TP who perform potassium hydroxide (KOH) testing. Findings include: 1. Review of the laboratory's policy and procedure manual identified the procedure titled "Testing Procedure for KOH" that stated "Initial training will occur when a new clinician joins the practice. Training will occur again at the 6-month mark and then annually thereafter." 2. Review of laboratory records revealed laboratory failed to have documented competency assessments for TP #3, TP #4, and TP #5 who perform KOH testing. 3. Interview with TP #2 on 11/04/2025, at 12:05 pm, confirmed that the laboratory failed to have a competency reviews completed for three of three TP in place for microscopic KOH testing.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) (d) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493. 1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the

	laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (d)(3) At least once each day patient specimens are assayed or examined perform the following for: This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, record review, review of patient log, and interview with testing personnel (TP) #2; the laboratory failed to perform control procedures specified by the laboratory for potassium hydroxide (KOH) testing from 01/02/2023 though the survey date of 11/04/2025. Findings include: 1.Review of the laboratory's policy and procedure manual identified the procedure titled "KOH QC policy" that stated "Procedure: Each morning a quality control slide will be read under the microscope. A KOH control for Mycology is a suspension of inactivated fungal spores and mycelia that can be used to verify the quality of a potassium hydroxide (KOH) preparation. The preparation will include placing the mycology control on a clean glass slide, Adding one drop of the KOH preparation and then reviewing the slide. Expected Daily result: Fungal mycelia appear as reflected strands under bright field microscopy or phase contrast microscopy. Few if any epithelial cells should be present." 2. Review of records titled "QC form" revealed the laboratory had failed to document the use of QC slides from 01/02/2023 to the date of survey 11/04/25 3. An interview with TP #2 at 12:27 pm on 11/04/2025 confirmed the laboratory failed to follow the laboratories established quality control procedure for KOH testing. 4. Review of laboratory patient log titled "KOH Log" revealed that 238 patients had KOH testing performed from 1/5/2023 to 9 /12/25.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with testing personnel (TP)#2; the laboratory failed to perform corrective actions for out of range temperature/ humidity readings for 14 of 36 dates when histopathology testing was performed. 1. The laboratory's 2023, 2024 and 2025 "Room Temperature" log indicated temperature should be 68-76 F and humidity should be "60% >". 2. Review of the 2023, 2024, and 2025 "Room Temperature" records identified that the temperature was outside than the laboratory's established acceptability criteria for 14 of 36 histopathology testing dates. Testing Date Temperature Reading 1. 07-13-2023 76.1 F 2. 08-17-2023 76.1 F 3. 09-14-2023 76.1 F 4. 10-12-2023 76.1 F 5. 11-16-2023 78.8 F 6. 12-14-2023 76.8 F 7. 01-11-2024 76.1 F 8. 03-07-2024 76.6 F 9. 05-23-2024 77.2 F 10. 08-18-2024 78.6 F 11. 09-12-2024 76.3 F 12. 10-10-2024 76.4 F 13. 02-06-2025 76.6 F 14. 10-16-2025 76.8 F 3. On survey date 11-04-2025, at 02:25 pm, TP #2 confirmed no corrective

	actions were taken for out of range humidity/temperature readings when histopathology testing was performed.
D5805	TEST REPORT CFR(s): 493.1291(c) (c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of laboratory policy and procedures, review of patient test reports and interview with testing personnel (TP)#2; the laboratory failed to include all the required components of a laboratory test report for three of four patient test reports reviewed for testing using the potassium hydroxide (KOH) process. Findings Include: 1. Review of the laboratory's policy and procedure manual identified the procedure titled "Testing Procedure for KOH" that stated "5. System for entering results into the patient record- Results are to be documented in the physical documentation binder as well as within the patient EMR showing positive or negative results along with the date the test was conducted. 2. Review of one of four patient test reports (MRN: 148276) for KOH testing found the laboratory failed to indicate the test result /interpretation, on the laboratory's test report. 3. Review of two of four patient test reports (MRN: 312798 and 316287) for KOH testing found the laboratory failed to report patient results as the laboratory approved reportable range of positive or negative. MRN 312798 KOH results reported as "hyphae" MRN 316287 KOH results reported as "hyphae" 4. On survey date 11-04-25, at 02:45 pm, TP #2 confirmed one patient test report failed to indicate the test results/interpretation on the rest report. 5. On survey date 11-04-25, at 03:00 pm, TP #2 confirmed two patient test reports failed to report the results of KOH testing as established by the laboratory.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (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. The procedures for evaluation of the competency of the staff must include, but are not limited to-- This STANDARD is not met as evidenced by: Review of laboratory personnel records, the CMS-209 (laboratory personnel report), lack of documentation, review of policy and procedure, and interview with Testing Personnel (TP) #2; the technical consultant (TC) failed to ensure competency evaluations were completed for three of three testing personnel (TP) that performed potassium hydroxide (KOH) preparations and scabies wet preparations. Findings Include: 1. Review of the laboratory policy and procedure revealed a document titled "KOH/Scabies Clinician Training" which stated: "Initial training will occur when a

	new clinician joins the practice. Training will occur again at the 6-month mark and then annually thereafter. Training includes reviewing 5-10 slides to ensure the differences between a positive and negative slide prep can be identified. In addition to this the KOH and Scabies testing procedure work document will be reviewed with the clinician." 2. Review of laboratory personnel records revealed no competency assessments for three of three TP listed on the CMS-209 as TP #4, #5, and #6 for KOH preparations and scabies wet preparations. 3. Interview with Testing personnel #2 on survey date 11-04-25, at 12:05 pm, confirmed that the laboratory TC failed to perform competency assessments for three of three TP that perform KOH and scabies wet preparations.