Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2047508	02/23/2021
Name of Provider or Supplier	**Street Address, City, State**	
Skin Md, Pa	750 Eureka St, Suite A, Weatherford, TX	

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
D0000	Laboratory representatives were present at the entrance conference conducted 02/23 /2021. The survey process was discussed. An opportunity for questions and comments was given. The exit conference was held with the laboratory representatives on 02/23 /2021. The laboratory was found to be in substantial compliance for the specialties /subspecialties for which it was surveyed. The standard level deficiencies cited were discussed. The process for submitting the corrections was explained. CMS form 2567 will be emailed from the Texas State Health and Human Services Commission, Health Facility Compliance Arlington Group.
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: I. Based on review of Centers for Medicare and Medicaid Services (CMS)-116 form, laboratory records and confirmed by staff interview, the laboratory failed to verify the accuracy of non-regulated potassium hydroxide (KOH) procedures at least twice annually for 2 of 2 testing events in 2019 and 2 of 2 testing events in 2020. Findings: 1. Review of the CMS-116 form submitted at survey by the laboratory revealed the laboratory performed KOH procedures. 2. Review of the laboratory's proficiency testing records for 2019 and 2020 revealed the laboratory failed to verify the accuracy of KOH procedures at least twice annually for 2 of 2 testing events in 2019 and 2 of 2 events in 2020. 3. During an interview on 02/23/2021 at 10:35 am, the practice manager was asked for documentation of twice annual accuracy for KOH procedures for 2019 and 2020. The practice manager stated that there were no twice annual accuracy assessments for 2019 or 2020. This confirmed the above findings. II. Based on review of laboratory policy, the laboratory's twice annual accuracy assessments for Mohs testing, and confirmed in staff interview, the laboratory failed to have

	documentation of evaluating the results of the peer reviews to determine accuracy for 1 of 2 events in 2019 and 2 of 2 events in 2020. Findings: 1. Review of the laboratory's policy and procedure manual page 16 stated: "B. Proficiency Testing Purpose: To evaluate the diagnostic abilities of the Mohs surgeon and the quality of the slides produced by the Mohs Tech. Methods: Every 12-month period, we will confirm that testing provided the correct results. For Mosh [sic] surgery specimen slides will be submitted for review by an out of house pathologist. Slides should represent both those called positive and negative by the Mosh [sic] surgeon. The results of proficiency testing are reviewed by an out house pathologist. Any errors encountered will be addressed to determine any pre-analytical, analytical or post-analytic errors that may be contributing." 2. Review of the laboratory's twice annual accuracy assessment for 2019 and 2020 revealed the following: 04/2019 Mohs Technique number: SMD19-063 Stage 1: Normal slrn Mohs Technique number: SMD19-066 Stage 1: Normal srln Mohs Technique number: SMD19-074 Stage 1: Normal srln The form was signed by the peer reviewer. There was no documentation of the results from the peer reviewer being evaluated by the Mohs surgeon for accuracy. 01/2020 Mohs Technique number: SMD20-003 Stage 1: No tumor Mohs Technique number: SMD20-009 Stage 1: + near blue niar Stage 2: No tumor Mohs Technique number: SMD20-015 Stage 1: No tumor The form was signed by the peer reviewer. There was no documentation of the results from the peer reviewer being evaluated by the Mohs surgeon for accuracy. 05/2020 Mohs Technique number: SMD20-057 Stage 1: Negative Mohs Technique number: SMD20-063 Stage 1: Negative Mohs Technique number: SMD20-068 Stage 1: Negative The form was signed by the peer reviewer. There was no documentation of the results from the peer reviewer being evaluated by the Mohs surgeon for accuracy. The laboratory failed to have documentation of evaluating the results of the peer reviews to determine accuracy for the above-mentioned testing events. 3. During an interview on 02/23 /2021 at 11:40 am, the practice manager was asked how twice annual assessments were performed and she stated that she did not know. She stated that she was going to send a text message to the histotechnician, who was at another location, for clarification. The histotechnician responded and stated that that Mohs maps and slides were sent to a peer reviewer for twice annual assessments. The practice manager confirmed the results of the twice annual assessments were not evaluated by the Mohs surgeon for accuracy.
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: I. Based on direct observation, review of laboratory policy, patient records and confirmed in interview, the laboratory failed to follow their own written policy for labeling Mohs slides for 4 of 4 patients in 2019 (random review), 4 of 4 patients in 2020 (random review) and 3 of 3 patients in 2021 (random review). Findings: 1. Review of the laboratory's policy and procedure manual page 7 stated: "D. Labeling of Frozen Section Slides Purpose: To provide a standard for labeling of slides Slides are to be labeled before frozen sections are cut a. Information to be written with a slide marking pen on the frosted end of the slide b. Line 1- Surgery Accession (Case)

	# c. Line 2- Patient last name and first initial d. Line 3- Patient ID # e. Line 4- Stage # (Stage 1 is implied and is not noted on the slide)/lesion designation (A, B, etc.), Tissue Piece # f. A second or third slide on the same piece of tissue is noted with A, B, or C as well g. Slides are to be labeled IA1-I, IA1-2, IA2-1, IA2-2" 2. A random review of patient Mohs slides from 2019, 2020 and 2021 were observed to be labeled with surgery accession #, patient last name and first initial, tissue piece #/slide letter, and stage number: 12/13/2019 Patient IDs: SMD19-208 (8 of 11 slides) SMD19-209 (4 of 5 slides) SMD19-210 (2 of 3 slides) SMD19-211 (2 of 3 slides) 01/17/2020 Patient IDs: SMD20-001 (5 of 7 slides) SMD20-002 (2 of 3 slides) SMD20-003 (2 of 3 slides) SMD20-004 (2 of 3 slides) 02/13/2021 Patient IDs: SMD21-031 (5 of 5 slides) SMD20-032 (7 of 7 slides) SMD20-033 (6 of 6 slides) A random review of patient Mohs slides from 2019 and 2020 were observed to be labeled with surgery accession #, tissue piece #/slide letter, and stage number: 12/13/2019 Patient IDs: SMD19-208 (3 of 11 slides) SMD19-209 (1 of 5 slides) SMD19-210 (1 of 3 slides) SMD19-211 (1 of 3 slides) 01/17/2020 Patient IDs: SMD20-001 (2 of 7 slides) SMD20-002 (1 of 3 slides) SMD20-003 (1 of 3 slides) SMD20-004 (1 of 3 slides) The laboratory failed to follow their own written policy for labeling Mohs slides with surgery accession (Case) #, patient last name and first initial, patient ID #, stage # /lesion designation, Tissue Piece #. 3. During the exit interview on 02/23/2021 at 12: 30 pm, the practice manager confirmed the above findings. II. Based on review of laboratory procedure manual and confirmed in interview, it was revealed the laboratory failed to have documentation for potassium hydroxide (KOH) procedures. Findings: 1. Review of the laboratory's procedure manual revealed the manual failed to contain procedures for how to perform KOH procedures. 2. The laboratory was asked to provide documentation of procedure for KOH procedures. No documentation was provided. 3. During an interview on 02/23/2021 at 10:35 am, the practice manager confirmed the above findings.
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 direct observation and confirmed in interview, the laboratory failed to ensure potassium hydroxide reagents did not exceed their expiration date. Findings: 1. During a tour of the laboratory on 02/23/2021 at 11:22 am, the surveyor observed the following expired reagents in the laboratory cabinet: 2 bottles of Potassium Hydroxide, 10% w/v Lot# 7438-00, expiration date 08/31/2019 Lot# 8369-00, expiration date 05/31/2020 2. During an interview on 02/23/21 at 11:40 am, the practice manager confirmed the above findings.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(14) Specify, in writing, the responsibilities and duties of each

	consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of the CMS 209 form, laboratory personnel records, and confirmed in interview, the Laboratory Director failed to specify in writing the responsibilities and duties 1 of 2 Testing Persons (TP-2) performing moderate complexity testing. Findings: 1. Review of the CMS 209 form listed TP-2 as a testing person performing moderate complexity procedures in the area of: provider performed microscopy (KOH). The laboratory director did not specify, in writing, which procedures TP-2 was authorized to perform. 2. During the exit interview on 02/23/2018 at 12:30 pm, the practice manager confirmed the above findings. Word key: CMS: Centers for Medicare and Medicaid Services KOH: potassium hydroxide
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on review of Centers for Medicare and Medicaid (CMS-209) form, personnel records, and confirmed in interview, the technical consultant failed to perform annual personnel competency assessment for 1 of 2 testing persons (TP-2) who perform moderate complexity testing in 2019 and 2020. Findings: 1. Review of CMS 209 form revealed moderate complexity potassium hydroxide (KOH) procedures were performed by Testing Person-2. 2. Review of personnel records revealed annual competency assessment was not performed for TP-2 in 2019 and 2020. 3. The laboratory was asked to provide documentation of competency assessments for 2019 and 2020 and none were provided. 4. During an interview on 02/23/2021 at 10:35 am, the practice manager confirmed the above findings.