

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2015671	(X3) Date Survey Completed 02/09/2021
Name of Provider or Supplier Skin Md, Pa	Street Address, City, State 804 Ne Mall Blvd, Hurst, 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	An entrance conference was held 02/09/2021 with the Practice Manager. The survey process was discussed. An opportunity for questions and comments was given. Based upon the onsite survey conducted 02/09/2021, this facility was found NOT to be compliance with CLIA regulations found at 42 CFR for the specialties/subspecialties in which it was surveyed. 493.1403 Moderate Complexity - Laboratory Director An exit conference was held on 02/09/2021 with the Practice Manager. The exit conference attendees were advised the laboratory was out of compliance and advised of conditions and deficiencies found during the survey. An opportunity for questions and comments was provided. CMS form 2567 will be emailed from the Texas State Health and Human Services Commission, Health Facility Compliance Arlington Group.
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: 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 included: 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 02/09/2021 at 10:31 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</p>

annual accuracy assessments for 2019 or 2020. This confirmed the above findings. This was a repeat deficiency for a recertification survey conducted on 12/08/2016. 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 2 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 6-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: 02/2019 Mohs Technique number: SMD19-001 Stage 1: Negative Mohs Technique number: SMD19-002 Stage 1: Negative Mohs Technique number: SMD19-005 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. 05/2019 Mohs Technique number: SMD19-021 Stage 1: Negative Mohs Technique number: SMD19-0030 Stage 1: Negative Mohs Technique number: SMD19-0035 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. 02/2020 Mohs Technique number: SMD20-003 Stage 1: No tumor Mohs Technique number: SMD20-007 Stage 1: No tumor Mohs Technique number: SMD20-012 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. 04/2020 Mohs Technique number: SMD20-014 Stage 1: Negative Mohs Technique number: SMD20-015 Stage 1: Negative Mohs Technique number: SMD20-017 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 02/09/2021 at 10:17 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. There was no response received from the histotechnician.

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) and 4 of 4 patients in

2020 (random review). Findings: 1. Review of the laboratory's policy and procedure manual pages 5-7 stated: "III. Test Specimens ... 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 and 2020 were observed to be labeled with surgery accession #, patient last name and first initial, tissue piece #/slide letter, and stage number 12/14/2019 Patient IDs: SMD19-082 (1 of 2 slides) SMD19-088 (5 of 6 slides) SMD19-089 (4 of 6 slides) SMD19-090 (9 of 10 slides) 02/15/2020 Patient IDs: SMD20-001 (2 of 3 slides) SMD20-002 (2 of 3 slides) SMD20-003 (2 of 3 slides) SMD20-004 (4 of 5 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 12/14/2019 Patient IDs: SMD19-082 (1 of 2 slides) SMD19-088 (1 of 6 slides) SMD19-089 (2 of 6 slides) SMD19-090 (1 of 10 slides) 02/15/2020 Patient IDs: SMD20-001 (1 of 3 slides) SMD20-002 (1 of 3 slides) SMD20-003 (1 of 3 slides) SMD20-004 (1 of 5 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 an interview on 02/09/2021 at 11:04 am, 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 02/09/2021 at 10:17 am, the practice manager confirmed the above findings.

D6000

MODERATE COMPLEXITY LABORATORY DIRECTOR
CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:
Based on review of Centers for Medicare and Medicaid Services (CMS)-116 form, laboratory records and confirmed by staff interview, the laboratory director failed to provide overall management and direction of the laboratory services. Refer to D6007.

D6007

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(1)

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)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of

test performance, which includes the preanalytic, analytic, and postanalytic phases of testing;

This STANDARD is not met as evidenced by:

Based on review of Centers for Medicare and Medicaid Services (CMS)-116 form, laboratory records and confirmed by staff interview, the laboratory director failed to ensure that testing systems performed in the laboratory provided quality laboratory services for all aspects of test performance as evidenced by: 1. 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. Refer to D5217. This was a repeat deficiency for a recertification survey conducted on 12/08/2016.

D6053

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 semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Based on review of Centers for Medicare and Medicaid (CMS-209) form, personnel files and confirmed in interview the technical consultant (TC) failed to evaluate and document the performance 1 of 3 Testing Persons (TP-2) responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. Findings: 1. Review of the CMS 209 form revealed 2 Testing Persons (TP #2 - TP#3) performing moderate complexity testing for potassium hydroxide procedures (KOH). 2. TP-2; hire date 03/02/2020; no initial training and no documentation of semiannual performance for KOH procedures in 2020 The laboratory was asked to provide the semiannual performance assessment, none was provided. 3. During an interview on 02/09/2021 at 10:31 am, the practice manager confirmed the above findings.

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 3 testing persons (TP-3) 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 and Testing Person-3. 2. Review of personnel records revealed annual competency assessment was not performed for TP-3 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 02/09/2021 at 10:31 am, the practice manager confirmed the above findings.