Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0922048	02/22/2023
Name of Provider or Supplier	**Street Address, City, State**	
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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. The survey process was discussed. An opportunity for questions and comments was given. The exit conference was held with the laboratory representatives. 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 Health and Human Services Commission, Health Facility Compliance Arlington Group. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Southern Operations Branch-Dallas for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
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 review of the Centers for Medicare and Medicaid Services (CMS)-116 form, laboratory policy, laboratory proficiency testing (PT) records, and confirmed in interview, the laboratory failed to verify the accuracy of scabies examinations at least twice annually in 2022. The findings include: 1. Review of the CMS-116 form revealed the laboratory performed scabies examinations. 2. Review of the laboratory's policy manual revealed: "Comparison of Test Results Tests performed in the laboratory for which proficiency testing is not available will be verified at least twice

	a year by an outside laboratory (see various sections in the CLIA handbook) and the results will be reviewed by the Laboratory Director." 3. Review of the laboratory's proficiency testing records for 2022 revealed no documentation of twice annual accuracy assessments for scabies examinations. The surveyor requested documentation of twice annual accuracy assessments for scabies examinations. None was provided. 4. During an interview on 02/22/2023 at 09:57 a.m., the Office Manager confirmed the above findings.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on the laboratory procedure manual, patient test records, and confirmed in interview, the laboratory failed to ensure patient histopathology slides were labeled with at least 2 unique patient identifiers for 69 of 69 slides in November and December 2022 (random sampling). The findings include: 1. Review of the laboratory's "Specimen Processing Procedure" revealed: "B. Slide Processing (performed by the technician) ... 2. Slides are cover slipped and labeled with the patient's name, Mohs section, and Mohs number using indelible ink ... C. Slide evaluation (performed by physician) ... 3. Prepared glass slides are evaluated by the dermatologic surgeon in the following manner: a. First, slides are checked for proper labeling of patient's last name and specimen numbers matching those on the patient's map ..." The "Specimen Processing Procedure" did not include labeling instructions to reliably identify patients with the same last name using unique patient identifiers to distinguish between specimens. 2. A random review of patient slides from November and December 2022 revealed 69 slides labeled with the patient's last name, Mohs case number, and Mohs sections. The laboratory failed to ensure patient histopathology slides were labeled with at least 2 unique patient identifiers. 3. During an interview on 02/22/2023 at 11:28 a.m., the Office Manager confirmed the above findings.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of laboratory records, laboratory policy, and confirmed in interview, the laboratory failed to define intended reactivity to ensure predictable staining characteristics of the Melan A stain in 2022. The findings include: 1. Review of laboratory records revealed the laboratory performed Melan-A stains. 2. Review of

	the laboratory policy titled "Melan A Stain Procedure" revealed: "Tissue is processed according to the routine processing procedure outlined in the CLIA lab manual with the following changes ... Three slides per section depth are made. One H&E, one positive slide, and one negative slide ...." The policy failed to define the staining characteristics for intended reactivity of the Melan A stain. The surveyor requested documentation of defined staining characteristics for the Melan A stain. None was provided. 3. During an interview on 02/22/2023 at 10:49 a.m., the Office Manager confirmed the above findings. Key: H&E: Hematoxylin and Eosin
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on review of laboratory policy, patient records, and confirmed in interview, the laboratory failed to ensure 11 of 11 patient Tzanck smear and KOH preparation results (random review) were transcribed accurately to the final test report in 2021 (September and October) and 2022 (January, March, and May through October). The findings include: 1. Review of page 28 of the laboratory policy titled "V.10 Laboratory Procedure Manual Tzanck (Cytodiagnostic) Smear" revealed: "9.2 REPORTABLE RANGE 9.2.1 A normal result is negative 9.2.2 The reportable range of this test is either positive or negative." 2. Review of page 31 of the laboratory policy titled "V-8. Laboratory Procedure Manual for Potassium Hydroxide (KOH) Examination" revealed: "9.2 REPORTABLE RANGE 9.2.1 A normal result is negative 9.2.2 The reportable range of this test is either positive or negative." 3. A random review of 11 Tzanck smear and KOH patient final reports from 2021 (September and October) and 2022 (January, March, and May through October) revealed the laboratory failed to accurately transcribe the following patient results: A. Tzanck Smears 09/30/2021 Test number: 2021-03 Tzanck Log: BLANK Final Report: "multi-nucleated giant cells" 10/25/2021 Test number: 2021-04 Tzanck Log: "positive" Final Report: "multi-nucleated giant cells" 01/27/2022 Test number: 2022-01 Tzanck Log: "positive" Final Report: "multi-nucleated giant cells" 03/31/2022 Test number: 2022-02 Tzanck Log: "Positive" Final Report: "multi-nucleated giant cells" 05/25/2022 Test number: 2022-04 Tzanck Log: "Negative" Final Report: "no balloon or multi-nucleated giant cells" 09/01/2022 Test number: 2022-05 Tzanck Log: "positive" Final Report: "multi-nucleated giant cells" 10/03/2022 Test number: 2022-06 Tzanck log: "positive" Result: "No [sic] convinced has multinucleated giant cells, it does however have numerous diplococci present." B. KOH Preparations 06/15/2022 Test numbers: 2022-06, 2022-07, 2022-08 KOH log: "Positive" Final Report: "branching hyphae" 07/20/2022 Test number: 2022-09 KOH log: "Positive" Final Report: "branching hyphae" 08/04/2022 Test number: 2022-10 KOH log: "Positive" Final Report: "branching hyphae" 10/27/2022 Test number: 2022-15 KOH log: "Positive" Final Report: "branching hyphae" The laboratory failed to accurately transcribe results of Tzanck smears and KOH preparations to the final reports. 4.

	During the exit conference on 02/22/2023 at 12:45 p.m., the Office Manager confirmed the above findings. Key: KOH: potassium hydroxide
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 review of Centers for Medicare and Medicaid Services (CMS)- 209 form, laboratory policy, personnel records, and confirmed in staff interview, the Technical Consultant failed to evaluate and document competency assessments for 1 of 2 Testing Persons (TP2) in 2021 and 2022. The findings include: 1. Review of the CMS-209 form revealed TP2 performed moderately complexity laboratory testing. 2. Review of laboratory policy titled "DERMATOLOGY LABORATORY COMPETENCY TESTING POLICY" revealed: "The director is responsible for evaluating the competency of all testing personnel. The staff must maintain their competency to perform testing procedures and prepare specimens promptly, accurately, and proficiently. Current employees and new employees will be tested on any new procedure prior to the employee performing the task. All employees will be evaluated annually ..." 3. Review of personnel records revealed a hire date for TP2 as 05/10/2017. Further review of personnel records revealed no documentation of annual competency assessments for TP2 for 2021 and 2022. The surveyor requested documentation of annual competency for TP2. None was provided. 4. During an interview on 02/22/2023 at 10:22 a.m., the Office Manager stated that there were no documented competency assessments for TP2. This confirmed the above findings.