

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0671567	(X3) Date Survey Completed 03/16/2022
Name of Provider or Supplier Us Dermatology Partners Sherman	Street Address, City, State 815 Pecan Grove Road East, Sherman, 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	<p>An entrance conference was held with the laboratory representatives. The survey process was discussed and survey forms were provided. An opportunity for questions and comments was given. Noted deficiencies and plans of correction were discussed with the laboratory representatives at the exit conference. The laboratory representatives were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in COMPLIANCE with applicable Conditions of Participation in the CLIA program, and recertification is recommended. 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 Dallas Regional Office (RO) 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.</p>
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 the CMS (Center for Medicaid & Medicare Services) 116 form, laboratory policy, proficiency testing records, and confirmed by staff interview, the laboratory failed to verify the accuracy of non-regulated KOH procedures at least twice annually for 1 of 4 testing people in 2021. Findings: 1. Review of CMS 116 application (Submitted on 03/16/2022) revealed the laboratory performed 60 KOH tests annually. 2. Review of the laboratory policy titled "KOH Quality Assurance" stated the following: "Each provider who performs KOH must have two cases reviewed by another provider in the practice twice a year." 3. Review of the</p>

laboratory's proficiency testing records revealed the laboratory performed proficiency testing events for KOH at two-time periods annually for each testing person. Further review revealed Testing Person 4 on CMS- 209 (TP-4) did not perform 2 of 2 proficiency testing events in 2021. The laboratory failed to verify the accuracy of KOH procedures at least twice annually for 1 of 4 testing people in 2021. 4. During an interview with Testing Person 3 (TP-3) on 03/16/2022 at 10:48 a.m. in the facility breakroom, TP-3 confirmed the above findings.

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(b)

The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

I. Based on review of the submitted Centers for Medicare and Medicaid (CMS) 116 Application, manufacturer's instructions, random review of laboratory environmental records (05/2021 through 02/2022), and confirmed in interview, the laboratory failed to ensure room temperature ranges were within storage specifications for the Remel 10% Potassium Hydroxide (KOH) for 8 of 12 months in 2021 (05/2021 through 12/2021) and 2 of 2 months in 2022 (01/2022 and 02/2022). Findings Included: 1. Review of CMS 116 application (Submitted on 03/16/2022) revealed the laboratory performed 60 KOH tests annually. 2. Review of manufacturer's instructions for the Remel 10% Potassium Hydroxide revealed the following: "Storage This product is ready for use and no further preparation is necessary. Store product in its original container at 2-30 C until used. Allow product to equilibrate to room temperature before use." 3. Review of laboratory environmental logs, "MOH's Laboratory Room Temp and Humidity Log" revealed the laboratory temperature range was 5-35 C. 4. During an interview with Testing Person 3 (TP-3) on 03/16/2022 at 10:34 a.m. in the facility breakroom, TP-3 was asked where the Remel 10% Potassium Hydroxide for KOH testing was stored. TP-3 stated the KOH reagent was stored in the "MOH's Laboratory". This confirmed the laboratory failed to ensure room temperature ranges were within storage specifications for the Remel 10% Potassium Hydroxide (KOH) for 8 of 12 months in 2021 (05/2021 through 12/2021) and 2 of 2 months in 2022 (01/2022 and 02/2022). II. Based on review of the submitted Centers for Medicare and Medicaid (CMS) 116 Application, manufacturer's instructions, random review of laboratory environmental records (01/2022 through 02/2022), and confirmed in interview, the laboratory failed to ensure room temperature ranges were within storage specifications for the Sigma-Aldrich Hematoxylin Gill Stain for 8 of 12 months in 2021 (05/2021 through 12/2021) and 2 of 2 months in 2022 (01/2022 and 02/2022). Findings Included: 1. Review of CMS 116 application (Submitted on 03/16/2022) revealed the laboratory performed 1,069 histopathology tests annually. 2. Review of manufacturer's instructions for the Sigma-Aldrich Hematoxylin Gill Stain reagents revealed the following: "Storage and Stability: Store reagents at room temperature (18-26 C) protected from light. Reagents are stable until expiration date show on label." 3. Review of laboratory environmental logs, "MOH's Laboratory Room Temp and Humidity Log" revealed the laboratory temperature range was 5-35 C. 4. During an

interview with Testing Person 3 (TP-3) on 03/16/2022 at 11:00 a.m. in the facility breakroom, TP-3 was asked where the Sigma-Aldrich Hematoxylin Gill Stain for histopathology staining was stored. TP-3 stated the Hematoxylin Stain was stored in the "MOH's Laboratory". This confirmed the laboratory failed to ensure room temperature ranges were within storage specifications for the Sigma-Aldrich Hematoxylin Gill Stain for 8 of 12 months in 2021 (05/2021 through 12/2021) and 2 of 2 months in 2022 (01/2022 and 02/2022).