Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0877602	08/18/2023
Name of Provider or Supplier	**Street Address, City, State**	
West Houston Dermatology Pa	2925 Briarpark Dr, Ste 150, Houston, 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	The laboratory was found out of compliance with applicable CLIA regulations (42 CFR Part 493, Requirements for Laboratories). The facility representative was given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility was found in compliance with applicable CLIA conditions, 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 CMS Southern Operations Branch-Dallas for referral to the Office of Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
D3013	FACILITIES CFR(s): 493.1101(e) Records and, as applicable, slides, blocks, and tissues must be maintained and stored under conditions that ensure proper preservation. This STANDARD is not met as evidenced by: Based on surveyor's observations, review of laboratory's policies and procedures, and staff interview, the laboratory failed to define and monitor storage conditions for proper preservation of processed histopathology slides for one of one room where processed sliders were stored. Findings included: 1. Surveyor's observations on 08/18 /2023 at 1030 hours revealed previously processed histopathology slides were stored in a storage room which was not monitored for either temperature or humidity to ensure their proper preservation. 2. Review of laboratory's policies and procedures revealed the laboratory did not have protocols in place defining storage conditions or monitoring requirements to ensure proper preservation of processed slides. 3. In an

	interview on 08/18/2023 at 1030 hours in the storage room, the facility's Lead Medical Assistant (as indicated on submitted Survey Entrance/Exit Conference document), confirmed the 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: Based on surveyor's observations, review of laboratory's temperature records for 2022 and 2023, and staff interview, the laboratory failed to monitor and document storage temperature for one of one reagent used in the laboratory, Potassium Hydroxide 10% (KOH). Findings included: 1. Surveyor's observations in the laboratory on 08/18/2023 at 0945 hours revealed two bottles of Medical Chemical Corporation KOH reagent (Lot: 2545-03, Expiration date: 2023-08-31) stored in a drawer under the microscope. The storage requirements listed on the bottles indicated storage temperature requirements of 15-35C. 2. Review of the facility's temperature records for 2022 and 2023 revealed there was no documentation of monitoring temperature where the KOH was stored. 3. In an interview on 08/18/2023 at 0955 hours in the patient room, the facility's Lead Medical Assistant (as indicated on submitted Survey Entrance/Exit Conference document), confirmed the findings. Key: C - Degrees Celsius
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on surveyor's observations, review of the Olympus KHC Microscope user manual, review of laboratory's policies/procedures, review of the laboratory's microscope maintenance records and staff interview, the laboratory failed to define and document protocols for microscope maintenance (cleaning) for one of one microscope in use. Findings included: 1. Surveyor's observations on 08/18/2023 at 1020 hours in the laboratory in the laboratory revealed the laboratory used the Olympus KHC Microscope, serial number 202206, placed in use in 1999. No user manual was available on the premises. 2. Review of the Olympus KHC Microscope user manual (copy found at www.manualslib.com was shared with the laboratory) revealed: Section E, page 5: "Upon completion of observations, carefully wipe off

	Cargile oil on the oil immersion objective with a piece of gauze moistened with xylol." And, Section IX, page 8: "Cleaning must be performed with utmost care." The Olympus KHC Microscope user manual did not specify specific maintenance protocol or its required frequency. 3. Review of laboratory's policies/procedures revealed the laboratory did not have protocols in place that addressed microscope maintenance and its frequency. 4. Review of the laboratory's microscope maintenance records revealed the laboratory employed a third-party vendor to perform preventive maintenance on an annual basis. There were no maintenance records for the days the microscope was in use available for review. 5. In an interview on 08/18/2023 at 1020 hours in the hallway, the facility's Lead Medical Assistant (as indicated on submitted Survey Entrance/Exit Conference document), confirmed the findings.
D5471	CONTROL PROCEDURES CFR(s): 493.1256(e)(1)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on surveyor's observations, review of laboratory's quality control records for 2021, 2022 and 2023, policies and procedures and staff interview, the laboratory failed to document verification of reactivity for each new lot/batch/shipment for one of one reagent used by the laboratory, Potassium Hydroxide 10% (KOH). Findings included: 1. Surveyor's observations on 08/18/2023 at 1020 in the laboratory revealed two bottles of KOH solution in use: Medical Chemical Corporation Potassium Hydroxide, 10% w/v Lot: 2545-03 Expiration date: 2023-08-31 The bottles did not have receipt date or date of placement in use (date opened) documented. 2. Review of laboratory's quality control records from 2021 to 2023 revealed no documentation of verification of KOH reagent reactivity. 3. Review of laboratory's policies/procedures revealed the policies/procedures did not address KOH reagent reactivity verification. 4. In an interview on 08/18/2023 at 0955 hours in the patient room, the facility's Lead Medical Assistant (as indicated on submitted Survey Entrance/Exit Conference document), confirmed the findings.