Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2148077	11/23/2020
Name of Provider or Supplier	**Street Address, City, State**	
Pdp Of Texas Pllc	7445 Las Colinas Blvd, Irving, 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 with the laboratory representative. 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 representative at the exit conference. The laboratory representative was 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.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on laboratory policy, direct observation and confirmed in staff interview, the laboratory failed to ensure aliquoted containers of multiple reagents were labeled to indicate reagent identity/lot number, storage requirements and expiration dates to ink for grossing histopathology slides. Findings included: 1. The laboratory policy titled "Mohs Lab Daily Task" stated, "Remove caps on the paint containers and place a

	toothpick in each container. If paint is moderately low, add a small amount of water to paint until it is full. If container is completely empty add a solution of no more than paint and of water." The policy failed to ensure aliquoted containers were labeled with the reagent identity/lot number, an expiration date or storage requirements. 2. A tour of the laboratory on 11/23/2020 at 10:40am revealed inks were stored in plastic containers on the bench top. The containers were not labeled with a reagent identity /lot number, an expiration date or storage requirement. 3. An interview with the histotechnician on 11/23/2020 at 10:42am in the laboratory confirmed the findings. He confirmed that the containers were not labeled with the reagent identity/lot number, an expiration date or storage requirement.
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 policy, laboratory quality control records, and confirmed in staff interview, the laboratory failed to document the intended reactivity for Hematoxylin and Eosin (H & E) staining to ensure predictable staining characteristics of quality control slides for Hematoxylin and Eosin (H & E) staining on each day of patient testing from 12/11/2019 to 11/23/2020. Findings included: 1. The laboratory policy titled "Mohs Lab Daily Task" stated, "Complete daily quality control forms which are all located on a single clipboard found in the second cabinet over the cryostats ..." The policy failed to define the intended reactivity for Hematoxylin and Eosin (H & E) staining to ensure predictable staining characteristics of quality control slides. 2. The laboratory quality control record titled "Hematoxylin and Eosin Staining-Quality Control" provided the following documentation: "Slide #; Date; Time; Accept; Unaccept; Tech; Action Taken" The quality control record failed to define the intended reactivity for Hematoxylin and Eosin (H & E) staining to ensure predictable staining characteristics of quality control slides. The quality control record failed to provide documentation of testing persons' evaluation of the H&E quality control slide. 3. In an interview on 11/23/2020 at 10:06am in the laboratory, the histotechnician was asked to explain the H&E control slide procedure and to provide documentation of the intended reactivity for the H&E stain. He stated that the first stained slide each day of patient testing was used as the quality control slide. No documentation was provided for the intended reactivity for the H&E stain. The histotechnician was asked who evaluated the H&E control slide. He stated that he evaluated the slide for acceptability. This confirmed the above findings.