

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2080454	(X3) Date Survey Completed 11/06/2023
Name of Provider or Supplier Adg Houston Path Pllc	Street Address, City, State 2525 W Bellfort Ave, Ste 194, 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	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility was found to be in compliance with applicable Conditions in the CLIA program, and recertification is recommended.
D5475	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(3)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (3) Check fluorescent and immunohistochemical stains for positive and negative reactivity each time of use. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on the review of the laboratory's IHC stain test menu, the laboratory's IHC QC records from May 2023 to October 2023, patient results, and confirmed in an interview, the laboratory failed to have documentation of negative control reactivity for IHC stains for 13 of 13 days reviewed. The findings were: 1. Review of the laboratory's IHC stain test menu revealed the laboratory performed 13 IHC stains. Adipophilin CD3 CD4 CD7 CD8 CD34 CK 7 H. Pylori Mart-1 Red (or Melan A) p63 S-100 SOX-10 (Monoclonal) SOX-10 (Polyclonal) 2. Random review of the laboratory's IHC QC records from May 2023 to October 2023 revealed no documentation of negative control reactivity for IHC stains for 13 of 13 days reviewed. 5/10/23 5/25/23 6/20/23 7/11/23 8/16/23 8/24/23 9/20/23 10/18/23 10/25/23 10/26/23 10/27/23 10/30/23 10/31/23 3. Review of patient results for the above dates revealed 111 patients had IHC stains. 5/10/2023 Case ID Slide ID IHC stain ADG23-15487 00000471 Melan A (Mart-1 Red) ADG23-15510 00000470 Melan A (Mart-1 Red) ADG23-15349 00000469 Melan A (Mart-1 Red) ADG23-15428 00000468 Melan A (Mart-1 Red) ADG23-15418 00000418 Melan A (Mart-1 Red) 5/25/23 ADG23-17577 00000604 Melan A (Mart-1 Red) ADG23-17587 00000603 Melan A (Mart-1 Red) ADG23-17684 00000602 Melan A (Mart-1 Red) ADG23-17907</p>

00000601 Melan A (Mart-1 Red) ADG23-17939 00000599 Melan A (Mart-1 Red) ADG23-17822 00000598 Melan A (Mart-1 Red) ADG23-17802 00000597 Melan A (Mart-1 Red) ADG23-17874 00000596 Melan A (Mart-1 Red) ADG23-17909 00000600 Melan A (Mart-1 Red) ADG23-17469 00000588 Melan A (Mart-1 Red) ADG23-17676 00000591 Melan A (Mart-1 Red) ADG23-17554 00000590 Melan A (Mart-1 Red) ADG23-17331 00000592 CD7 ADG23-17494 00000589 CD34 6/20/23 R23-002026 00000809 Melan A (Mart-1 Red) ADG23-21516 00000810 Melan A (Mart-1 Red) ADG23-21307 00000806 Melan A (Mart-1 Red) ADG23-21337 00000802 Melan A (Mart-1 Red) ADG23-21225 00000801 Melan A (Mart-1 Red) ADG23-21222 00000800 Melan A (Mart-1 Red) ADG23-21547 00000811 S-100 ADG23-21395 00000808 S-100 ADG23-21323 00000796 S-100 ADG23-20860 00000807 CD34 7/11/23 ADG23-24409 00000935 Melan A (Mart-1 Red) ADG23-24394 00000933 Melan A (Mart-1 Red) ADG23-24300 00000932 Melan A (Mart-1 Red) ADG23-24412 00000931 Melan A (Mart-1 Red) 8/16/23 ADG23-29415 00001325 Melan A (Mart-1 Red) ADG23-29295 00001323 Melan A (Mart-1 Red) ADG23-29546 00001319 Melan A (Mart-1 Red) 00001318 p63 ADG23-29621 00001324 SOX-10 (Polyclonal) ADG23-29502 00001322 CD8 00001321 CD4 00001320 CD3 8/24/23 ADG23-30824 00001427 SOX-10 (Polyclonal) ADG23-30683 00001423 SOX-10 (Polyclonal) ADG23-30453 00001416 SOX-10 (Polyclonal) 00001417 p63 ADG23-30661 00001426 p63 ADG23-30684 00001424 CD3 R23-002712 00001418 CD3 ADG23-30783 00001425 Melan A (Mart-1 Red) ADG23-30817 00001422 Melan A (Mart-1 Red) ADG23-30841 00001419 Melan A (Mart-1 Red) ADG23-30634 00001421 Adipophilin 9/20/23 ADG23-34690 00001761 SOX-10 (Polyclonal) ADG23-34383 00001760 SOX-10 (Polyclonal) 00001759 p63 ADG23-33932 00001758 CD8 00001756 CD4 00001755 CD3 00001757 CD7 ADG23-34016 00001746 CD34 R23-002917 00001745 S-100 00001744 p63 00001743 CK7 ADG23-34932 00001742 Melan A (Mart-1 Red) ADG23-34505 00001739 H. Pylori 10/18/23 ADG23-38852 00002057 SOX-10 (Polyclonal) ADG23-38855 00002058 SOX-10 (Polyclonal) ADG23-38767 00002056 S-100 00002055 CD34 ADG23-38797 00002050 p63 ADG23-38651 00002054 Melan A (Mart-1 Red) ADG23-38723 00002053 Melan A (Mart-1 Red) ADG23-38798 00002052 Melan A (Mart-1 Red) ADG23-38722 00002051 Melan A (Mart-1 Red) ADG23-38664 00002048 H. Pylori ADG23-38666 00002046 H. Pylori 10/25/23 ADG23-39808 00002122 SOX-10 (Monoclonal) ADG23-39834 00002121 SOX-10 (Monoclonal) ADG23-39711 00002120 S-100 ADG23-39802 00002119 SOX-10 (Polyclonal) ADG23-39755 00002118 Melan A (Mart-1 Red) 00002117 Melan A (Mart-1 Red) ADG23-39787 00002116 Melan A (Mart-1 Red) ADG23-39680 00002115 Melan A (Mart-1 Red) 10/26/23 ADG23-40164 00002133 Melan A (Mart-1 Red) ADG23-40105 00002132 Melan A (Mart-1 Red) ADG23-40006 00002128 Melan A (Mart-1 Red) ADG23-39958 00002127 Melan A (Mart-1 Red) ADG23-39770 00002126 Melan A (Mart-1 Red) ADG23-39721 00002125 Melan A (Mart-1 Red) ADG23-40066 00002123 Melan A (Mart-1 Red) ADG23-40011 00002131 SOX-10 (Monoclonal) 00002130 SOX-10 (Monoclonal) ADG23-40007 00002129 SOX-10 (Monoclonal) ADG23-40073 00002124 CD3 10/27/23 ADG23-40356 00002140 Melan A (Mart-1 Red) ADG23-40349 00002139 Melan A (Mart-1 Red) ADG23-40314 00002138 Melan A (Mart-1 Red) ADG23-40207 00002137 Melan A (Mart-1 Red) ADG23-40087 00002134 Melan A (Mart-1 Red) ADG23-40322 00002136 SOX-10 (Monoclonal) ADG23-40191 00002135 S-100 10/30/23 ADG23-40511 00002154 Melan A (Mart-1 Red) ADG23-40638 00002153 Melan A (Mart-1 Red) ADG23-40309 00002152 Melan A (Mart-1 Red) ADG23-40430 00002151 Melan A (Mart-1 Red) ADG23-40296 00002150 Melan A (Mart-1 Red) ADG23-40379 00002149 Melan A (Mart-1 Red) ADG23-40503 00002148 Melan A (Mart-1 Red) ADG23-40605 00002147 Melan A (Mart-1 Red) ADG23-40506

00002146 Melan A (Mart-1 Red) ADG23-40489 00002145 Melan A (Mart-1 Red) ADGS23-03572 00002144 Melan A (Mart-1 Red) ADG23-40342 00002142 SOX-10 (Monoclonal) ADG23-40245 00002141 SOX-10 (Monoclonal) 10/31/23 ADG23-40598 00002168 Melan A (Mart-1 Red) ADG23-40787 00002166 Melan A (Mart-1 Red) ADG23-40712 00002165 Melan A (Mart-1 Red) ADG23-40549 00002164 Melan A (Mart-1 Red) ADG23-40598 00002167 Melan A (Mart-1 Red) MPHS23-4135 00002160 Melan A (Mart-1 Red) ADG23-40657 00002162 S-100 ADG23-40866 00002161 CD34 ADG23-40767 00002163 CD3 4. An interview with the general supervisor and the testing personnel #8 on 11/6/2023 at 11:05 am in the conference room confirmed the above findings. Key: IHC=Immunohistochemical QC=Quality Control CK=Cytokeratin MART-1=Melanoma Antigen Recognized by T cells 1 Melan A=Melanoma Antigen