Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2080454	04/17/2018
Name of Provider or Supplier	**Street Address, City, State**	
Adg Houston Path Pllc	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 representative(s) 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.
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 a review of laboratory proficiency testing records, test volume documentation, and an interview with facility personnel, it was revealed that the laboratory failed to verify the accuracy of all test procedures it performs that are not regulated analytes, at least twice annually. Findings were: 1. A review of laboratory proficiency testing records from for 2017 revealed no documentation of the laboratory verifying the accuracy of the following 15 special stains used in histopathology: AFB, AFB-FITE, Colloidal Iron, Congo Red, Geimsa, GMS, Gram, Iron, Melanin-Fontana Masson, Mucin, PAS, Steiner, Tricrome, VVG, Warthin Starry. 2. A review of the facility test volume documentation revealed the facility performed 2493 special stains in 2017. 3. During an interview with the general supervisor on 4/17/2018 at 1426

	hours in the conference room, the above findings were confirmed. Key: AFB- Acid Fast Bacilli PAS- periodic acid-Schiff GMS- Gomori Methenamine-Silver Nitrate Stain VVG- Verhoeff-Van Gieson stain
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 observation, review of manufacturer's operating manuals, and interview of laboratory personnel, it was revealed that the laboratory failed to document the room temperature or humidity of the area where slides were stored. Findings were: 1. During a tour of the laboratory, it was observed that there was no chart for recording room temperature or humidity of the slide storage area available for review at the time of the survey. 2. A review of the Sakura Tissue Teck Coverslipper manual (Revised 10 /31/2012) revealed that the manufacturer stated: "Avoid humidity greater than 50%" "Avoid temperatures greater than 77F and less than 67F." 3. An interview of the general supervisor on 04/17/2018 at 1523 hours in the facility conference room confirmed that the facility was not documenting the room temperature or humidity of the slide storage area. Key: F- Fahrenheit
D5821	TEST REPORT CFR(s): 493.1291(k) When errors in the reported patient test results are detected, the laboratory must do the following: (k)(1) Promptly notify the authorized person ordering the test and, if applicable, the individual using the test results of reporting errors. (k)(2) Issue corrected reports promptly to the authorized person ordering the test and, if applicable, the individual using the test results. (k)(3) Maintain duplicates of the original report, as well as the corrected report. This STANDARD is not met as evidenced by: Based on a review of patient results and staff interview, it was revealed that the laboratory failed to provide documentation of ensuring that corrected results are evident of a discrepancy. The findings were: 1. A review of patient record for ADG18-07387 revealed a report date of 4/17/2018. The report included a statement that it was an "Amendment" due to "change in diagnosis". The report did not include: The date of the original report The original report diagnosis A statement that this was a corrected report 2. An interview with the laboratory director on 04/17/2018 at 1609 hours in the conference room confirmed the above findings.