Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2080454	10/21/2020
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.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies, a review of the laboratory's Boekel Oven Logs from 2018 and 2019, a random review of patient test records, and staff interview, it was revealed the laboratory's quality assurance system failed to ensure the Boekel Oven was operating at the acceptable temperature for processing patient's slides per the laboratory's policy for 18 of 18 months from July 2018 to December 2019. Findings include: 1. A review of the laboratory's policy titled 'Standard Operating Procedure Microtomy/Cutting Procedure' revealed the following: " Put all slides in tissue basket and place in oven for 20 minutes on 65C (acceptable range is 55

	- 65C)." 2. A review of the laboratory's Boekel Oven Logs from July 2018 to December 2019 revealed the following 18 months where the laboratory was operating outside of the acceptable temperature range of 55 - 65C per the laboratory's policy: a) July 2018 Temperatures documented for 20 days 1 of 20 days recorded at 66C 1 of 20 days recorded at 69C 1 of 20 days recorded at 70C 2 of 20 days recorded at 71C 14 of 20 days recorded at 72C 1 of 20 days recorded at 73C b) August 2018 Temperatures documented for 23 days 6 of 23 days recorded at 69C 8 of 23 days recorded at 70C 1 of 23 days recorded at 71C 7 of 23 days recorded at 72C 1 of 23 days recorded at 74C c) September 2018 Temperatures documented for 19 days 1 of 19 days recorded at 68C 5 of 19 days recorded at 71C 12 of 19 days recorded at 72C 1 of 19 days recorded at 74C d) October 2018 Temperatures documented for 23 days 20 of 23 days recorded at 70C 3 of 23 days recorded at 71C e) November 2018 Temperatures documented for 21 days 21 of 21 days recorded at 70C f) December 2018 Temperatures documented for 18 days 1 of 18 days recorded at 69C 17 of 18 days recorded at 70C g) January 2019 Temperatures documented for 22 days 22 of 22 days recorded at 70C h) February 2019 Temperatures documented for 20 days 20 of 20 days recorded at 70C i) March 2019 Temperatures documented for 19 days 18 of 19 days recorded at 70C j) April 2019 Temperatures documented for 22 days 3 of 22 days recorded at 66C 7 of 22 days recorded at 67C 5 of 22 days recorded at 68C 1 of 22 days recorded at 69C 2 of 22 days recorded at 70C k) May 2019 Temperatures documented for 21 days 6 of 21 days recorded at 68C 4 of 21 days recorded at 69C 8 of 21 days recorded at 70C 1 of 21 days recorded at 72C l) June 2019 Temperatures documented for 20 days 1 of 20 days recorded at 71C 5 of 20 days recorded at 72C 13 of 20 days recorded at 74C 1 of 20 days recorded at 75C m) July 2019 Temperatures documented for 21 days 17 of 20 days recorded at 70C 3 of 20 days recorded at 72C n) August 2019 Temperatures documented for 17 days 1 of 17 days recorded at 67C 6 of 17 days recorded at 69C 6 of 17 days recorded at 70C 1 of 17 days recorded at 71C 3 of 17 days recorded at 72C o) September 2019 Temperatures documented for 17 days 1 of 17 days recorded at 67C 5 of 17 days recorded at 68C 1 of 17 days recorded at 69C 10 of 17 days recorded at 70C p) October 2019 Temperatures documented for 22 days 22 of 22 days recorded at 70C q) November 2019 Temperatures documented for 21 days 21 of 21 days recorded at 70C r) December 2019 Temperatures documented for 24 days 24 of 24 days recorded at 70C 3. A random review of patient test records revealed the following 10 patient's slides were processed and read on days when the Boekel oven was outside of the acceptable temperature range: Date: 11/27 /18 Result ID: ADG18-28419 Oven Temperature Reading: 70C Date: 11/27/18 Result ID: ADG18- 28426 Oven Temperature Reading: 70C Date: 12/21/18 Result ID: ADG18- 30591 Oven Temperature Reading: 70C Date: 12/21/18 Result ID: ADG18-30532 Oven Temperature Reading: 70C Date: 2/18/19 Result ID: ADG19- 03267 Oven Temperature Reading: 70C Date: 2/18/19 Result ID: ADG19- 03166 Oven Temperature Reading: 70C Date: 3/7/19 Result ID: ADG19- 04625 Oven Temperature Reading: 70C Date: 3/7/19 Result ID: ADG19- 04522 Oven Temperature Reading: 70C Date: 10/31/19 Result ID: MPH19- 04852 Oven Temperature Reading: 70C Date: 10/31/19 Result ID: ADG19- 23442 Oven Temperature Reading: 70C 4. An interview with the director of histology on 10/21/20 at 1:00 p.m. in the conference room, after review of the records, 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: Based on surveyor observation, a review of the operations manual for the Olympus BX43 System Microscope, and staff interview it was revealed the laboratory failed to have documentation of monitoring the temperature and humidity in 3 of 3 offices of testing personnel where laboratory equipment was stored in 2018 and 2019. Findings include: 1. During a tour of the facility on 10/21/20 at 1:30 p.m. the following laboratory equipment was found in 3 of 3 offices of testing personnel: a) Office of testing person #1: Olympus BX43 System Microscope SN: 7D04312 b) Office of testing person #2: Olympus BX43 System Microscope SN: 7D04864 c) Office of testing person #9 Olympus BX43 System Microscope SN: 7B49747 2. A review of the operations manuals for the laboratory equipment stored in the testing personnel's offices revealed the manufacturer required the following conditions for operation: Olympus BX43 System Microscope (M 010-01, April 2010) "Ambient temperature: 5C to 40C (41 to 104 F) Maximum relative humidity: 80% for temperatures up to 31C (88F) , decreasing linearly through 70% at 34C (93F), to 60% at 37C (99F), to 50% relative humidity at 40C (104F)." 3. The laboratory was asked to provide documentation of monitoring the temperature and humidity in the offices for compliance with the manufacturer's instructions. No documentation was provided. 4. An interview with the director of histology on 10/21/20 at 1:30 p.m. in the conference room revealed the facility did not monitor the temperature or humidity in the offices. This confirmed the above findings.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on a review of the Sakura Tissue-Tek Film Automated Coverslipper Operating Manual, a review of the laboratory's maintenance records for the Sakura Tissue-Tek Film Automated Coverslipper from August 2018 - September 2020, and staff interview, it was revealed the laboratory failed to have documentation of performing the required maintenance for 12 of 25 months from August 2018 to September 2020. Findings include: 1. A review of the Sakura Tissue-Tek Film Automated Coverslipper Operating Manual (0002470-01 REV E, 2012) states the following maintenance is required: a) The film waste tray should be emptied and cleaned at least once each month. b) Inspect the slide baskets for wear and evidence of stress weekly. 2. A review of the laboratory's maintenance records for the Sakura Tissue-Tek Film Automated Coverslipper from August 2018 - September 2020 revealed the following 12 of 25 months when the required maintenance was not documented as being performed: a) August 2018 There was no documentation of inspecting the slide baskets for wear and evidence of stress for 4 of 4 weeks. b) September 2018 There was no documentation of emptying and cleaning the film waste tray for the month of

	September. There was no documentation of inspecting the slide baskets for wear and evidence of stress for 4 of 4 weeks. c) October 2018 There was no documentation of emptying and cleaning the film waste tray for the month of October. There was no documentation of inspecting the slide baskets for wear and evidence of stress for 4 of 4 weeks. d) November 2018 There was no documentation of emptying and cleaning the film waste tray for the month of November. There was no documentation of inspecting the slide baskets for wear and evidence of stress for 4 of 4 weeks. e) December 2018 There was no documentation of inspecting the slide baskets for wear and evidence of stress for 4 of 4 weeks. f) January 2019 There was no documentation of inspecting the slide baskets for wear and evidence of stress for 2 of 4 weeks. g) February 2019 There was no documentation of emptying and cleaning the film waste tray for the month of February. There was no documentation of inspecting the slide baskets for wear and evidence of stress for 4 of 4 weeks. h) March 2019 There was no documentation of inspecting the slide baskets for wear and evidence of stress for 2 of 4 weeks. i) May 2019 There was no documentation of inspecting the slide baskets for wear and evidence of stress for 3 of 4 weeks. j) September 2019 There was no documentation of inspecting the slide baskets for wear and evidence of stress for 2 of 4 weeks. k) October 2019 There was no documentation of emptying and cleaning the film waste tray for the month of October. There was no documentation of inspecting the slide baskets for wear and evidence of stress for 4 of 4 weeks. l) November 2019 There was no documentation of emptying and cleaning the film waste tray for the month of November. There was no documentation of inspecting the slide baskets for wear and evidence of stress for 4 of 4 weeks. 3. An interview with the director of histology on 10/21/20 at 2:15 p.m. in the conference room, after review of the records, confirmed the above findings.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies, a random review of the laboratory's Temperature and Humidity logs for 2018, 2019, and 2020, a random review of patient test records, and staff interview, it was revealed the laboratory failed to have documentation of performing corrective actions when the room's humidity was documented outside the laboratory's acceptable range for 24 of 24 times from October 2018 to September 2020. Findings include: 1. A review of the laboratory's policy titled 'Standard Operating Procedure Operating Temperature & Relative Humidity Ranges' states the following laboratory instrumentation requires a humidity range of 30% - 80%: a) Sakura Tissue Tek Prisma Stainer b) Sakura Tissue Tek Coverslipper 2. A random review of the laboratory's Temperature and Humidity logs for 2018, 2019, and 2020 revealed the following 24 days where the documented room humidity was outside the laboratory's acceptable range of 30% - 80% which is required for the

	laboratory's instrumentation: Date Recorded Humidity 11/13/18 28% 11/14/18 26% 11 /15/18 26% 11/16/18 26% 11/27/18 27% 12/4/18 29% 12/11/18 29% 12/14/18 29% 12 /21/18 27% 2/8/19 26% 2/18/19 28% 3/4/19 27% 3/5/19 26% 3/7/19 26% 3/15/19 89% 3/18/19 89% 3/19/19 89% 10/31/19 28% 1/3/20 29% 1/6/20 29% 1/7/20 27% 1 /20/20 26% 1/21/20 28% 1/31/20 29% 3. The laboratory was asked to provide documentation of performing corrective actions when the laboratory's room humidity was outside of the acceptable range. No documentation was provided. 4. A random review of patient records revealed the following 12 patient's specimens were processed and resulted when the laboratory's room humidity was outside of the acceptable range for the laboratory's instrumentation: Date: 11/27/18 Result ID: ADG18-28419 Date: 11/27/18 Result ID: ADG18- 28426 Date: 12/21/18 Result ID: ADG18- 30591 Date: 12/21/18 Result ID: ADG18- 30532 Date: 2/18/19 Result ID: ADG19- 03267 Date: 2/18/19 Result ID: ADG19- 03166 Date: 3/7/19 Result ID: ADG19- 04625 Date: 3/7/19 Result ID: ADG19- 04522 Date: 10/31/19 Result ID: MPH19- 04852 Date: 10/31/19 Result ID: ADG19- 23442 Date: 1/21/20 Result ID: ADG20- 01296 Date: 1/21/20 Result ID: ADG20- 01309 5. An interview with the director of histology on 10/21/20 at 1:00 p.m. in the conference room, after review of the records, confirmed the above findings.
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on a review of the laboratory's personnel records and staff interview, it was revealed the laboratory failed to have documentation of the technical supervisor performing two competency assessments within the first year for 1 of 9 testing personnel for high complexity testing. Findings include: 1. A review of the laboratory's personnel records revealed the laboratory failed to have documentation of the technical supervisor performing two competency assessments within the first year for testing person #5 (as indicated on the CMS 209 form, signed by the laboratory director on 10/19/20) a) Testing person #5 - Hire date: 9/5/17 - Competency assessment done: 1/15/18 - No documentation of a second competency assessment prior to October 2018 2. The laboratory was asked to provide documentation of two competency assessments being performed within the first year for the identified testing personnel. No documentation was provided. 3. An interview with the director of histology on 10/21/20 at 11:00 a.m. in the conference room, after review of the records, confirmed the above findings.