Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2119325	11/05/2019
Name of Provider or Supplier	**Street Address, City, State**	
Mid-Valley Pathology, Llc	505 Angelita Drive, Suite 6, Weslaco, 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 at the entrance and exit conferences. 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. 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.
D5219	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(2) At least twice annually, the laboratory must verify the accuracy of any test or procedure listed in subpart I of this part for which compatible proficiency testing samples are not offered by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: Based on a review of the laboratory's test menu, a review of the laboratory's twice annual accuracy assessments for 2018 and staff interview, it was revealed the laboratory failed to verify the accuracy of each non-regulated test performed by the facility. Findings include: 1. A review of the laboratory's test menu revealed the laboratory performs the following tests: H & E stain AB/PAS (Alcian Blue/Periodic acid-Schiff) FE (Iron) H. Pylori (Helicobacter Pylori) PAS (Periodic acid-Schiff) Trichrome Gastrin AE1/AE3 Desmin Chromogranin A Synaptophysin Grossing 2. A review of the laboratory's twice annual accuracy assessments for 2018 revealed the laboratory failed to have records of performing twice annual accuracy assessments on

	the following tests: H & E stain AB/PAS (Alcian Blue/Periodic acid-Schiff) FE (Iron) H. Pylori (Helicobacter Pylori) PAS (Periodic acid-Schiff) Trichrome Gastrin AE1 /AE3 Desmin Chromogranin A Synaptophysin Grossing 3. An interview with Testing Personnel #1 (as listed on Form CMS-209) on November 5, 2019 at 14:45 hours in the laboratory confirmed the findings.
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 surveyor observation, and confirmed in interview of facility personnel, the laboratory failed to ensure aliquot containers of reagents were properly labeled with lot number and expiration date. The findings were: 1. Surveyor observation in the laboratory on November 5, 2019 at 09:30 hours revealed two aliquot (squirt) containers. One bottled was labled "80% Alcohol" and the 2nd bottle was labled, "95% Dehydrant." The bottles were not labeled with lot number or expiration date. 2. Interview with the histotechnologist on November 5, 2019 at 09:30 hours in the laboratory confirmed the findings.
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of laboratory's submitted CMS Form-209, review of personnel records, and confirmed in interview of facility personnel, the laboratory director failed to specify in writing the responsibilities of each consultant and testing person. The findings were: 1. Review of the laboratory's submitted Form CMS-209, approved by the laboratory director on November 5, 2019 revealed the laboratory had designated 1 clinical consultant, 1, technical supervisor, 1 general supervisor, and 8 testing persons. 2. Review of laboratory records revealed no job descriptions available for review for each consultant and testing person. 3. The findings were confirmed in interview with Testing Personnel #1 (as listed on Form CMS-209) on November 5, 2019 in the laboratory.
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 review of personnel records, and confirmed in interview of facility personnel, the technical supervisor failed to perform competency assessments on testing personnel #1 (as listed on Form CMS-209) at least twice during his first year of patient testing (grossing). The findings were: 1. Review of personnel records for Testing Personnel #1 (as listed on Form CMS-209) revealed he had a patient testing start date of May 18, 2018. 2. Further review of the personnel records revealed no competency assessments available for review. 3. An interview with Testing Personnel #1 (as listed on Form CMS-209) on November 5, 2019 at 11:30 hours in the conference room confirmed the findings.