Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0503924	03/15/2018
Name of Provider or Supplier	**Street Address, City, State**	
Mid Valley Family Practice Associates Pa	1710 East 8th Street, 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	The laboratory was found to be out of compliance based on the following CONDITION LEVEL DEFICIENCY: D5400 - 42 C.F.R. 493.1250 Condition: Analytic Systems Noted deficiencies and plans of correction were discussed with the laboratory representative at the exit conference. The facility representative was given an opportunity to provide evidence of compliance with noted deficiencies and no such evidence was provided prior to survey exit. 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.
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions for the HemoCue Glucose 201 microcuvettes, surveyor observation of microcuvettes currently in use, and staff interview, it was revealed the laboratory failed to document the opened expiration date of the microcuvettes. The findings were: 1. A review of the manufacturer's instructions for the HemoCue Glucose 201 microcuvettes (150702 150311) under the section titled "Storage for microcuvettes kept in a vial" revealed: "Microcuvettes kept in an opened vial are stable for 30 days when stored in a refrigerator at 35 - 46F." 2. Surveyor observation of supplies currently in use in the laboratory on 03/15/2018 at 1215 hours revealed an open vial of microcuvettes in the refrigerator: Lot: 17051464

	The vial did not have documentation of an opened date or of the opened expiration date. 3. The laboratory was asked to provide documentation of when the vial was opened or when the microcuvettes would be expired. No documentation was provided. 4. An interview with testing personnel number 3 (as listed on Form CMS 209) on 03/15/2018 at 1230 hours in the conference room revealed she did not know when microcuvettes were opened and did not know they were only good for 30 days once opened. This confirmed the findings. NOTE: THIS IS A REPEAT DEFICIENCY FROM THE SURVEY CONDUCTED ON 05/04/2016.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of the laboratory's American Proficiency Institute's proficiency testing records from 2016, 2017, and 2018, and staff interview, it was revealed the laboratory failed to have documentation of the laboratory director signing 3 of 12 attestation statements and of testing personnel signing 12 of 12 attestation statements. The findings were: 1. A review of the laboratory's American Proficiency Institute's proficiency testing records from 2016, 2017 and 2018 revealed the laboratory failed to have documentation of the following required signatures on attestation statements: a) Laboratory Director (missing on 3 of 12 events) 2016 Chemistry Group 2 Event 3 2017 Chemistry Core Kit 1 Event 1 2018 Chemistry b) Testing Personnel (missing on 12 of 12 events) 2016 Hematology Event 2 2016 Hematology Event 3 2016 Chemistry Group 2 Event 2 2016 Chemistry Group 2 Event 3 2017 Hematology Event 1 2017 Hematology Event 2 2017 Hematology Event 3 2017 Chemistry Core Kit 1 Event 1 2017 Chemistry Core Kit 1 Event 2 2017 Chemistry Core Kit 1 Event 3 2017 Chemistry Core Kit 2 Event 1 2018 Chemistry Core Kit 1 Event 1 2. The laboratory was asked to provide documentation of the laboratory director and testing personnel signing the identified attestation statements. No documentation was provided. 3. An interview with the business officer on 03/15/2018 at 1330 hours in the conference room revealed the laboratory would have the laboratory director sign the attestation statements, but did not know testing personnel were to also sign them. This confirmed the findings.
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 review of the laboratory's test menu, review of the laboratory's records, and staff interview, it was revealed the laboratory failed to have documentation of twice annual accuracy assessment for KOH preps and Wet Preps. The findings were: 1. A review of the laboratory's test menu revealed the laboratory performed KOH preps and Wet Preps in 2016 and 2017. 2. A review of the laboratory's records revealed the laboratory participated in proficiency testing for KOH and Wet Preps for 2017 Event

	3. There wasn't documentation of the laboratory participating in proficiency testing for any other events in 2016 and 2017. 3. The laboratory was asked to provide documentation performing twice annual accuracy assessments for KOH and Wet Preps for 2016 and an addition one in 2017. No documentation was provided. 4. An interview with the business officer on 03/15/2018 at 1330 hours in the conference room - after her review of the records - confirmed the findings.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of the laboratory's records, and staff interview, it was revealed the laboratory failed to meet the requirements in analytic systems. The findings were: 1. The laboratory failed to ensure manufacturer-required maintenance was performed and documented (refer to D5429) NOTE: THIS IS A REPEAT DEFICIENCY FROM THE SURVEY CONDUCTED 05/04/2016) 2. The laboratory failed to ensure function checks were performed as required by laboratory policy (refer to D5435). NOTE: THIS IS A REPEAT DEFICIENCY FROM THE SURVEY CONDUCTED 05/04/2016) 3. The laboratory failed to ensure quality control testing was performed each day of patient testing for serum hCG testing (refer to D5449). Key hCG - human chorionic gonadotropin
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 review of the manufacturer's instructions for the Cell-Dyn Emerald hematology analyzer, review of the manufacturer's instructions for the Alfa Wasserman Ace Alera chemistry analyzer, review of the laboratory's maintenance logs from 2016, 2017, and 2018, and staff interview, it was revealed the laboratory failed to have documentation of performing the required maintenance. The findings were: 1. A review of the manufacturer's instructions for the Cell-Dyn Emerald hematology analyzer (9140853F- August 2012) under the section titled "Preventive Maintenance Schedule" revealed: a) Monthly - Bleach Cleaning b) Semi-annual - Lubricating the Pistons 2. A review of the manufacturer's instructions for the Alfa Wasserman Ace Alera chemistry analyzer revealed the manufacturer required the following maintenance: a) daily start up - remove condensation from reagent compartment and camera lenses - check fluid levels - clean touch plate and probe pathway - check probe alignment - clean, condition, Wash ISE b) daily shut down - remove and discard used sample cups and seglets - empty the cuvette waste box -

	clean exterior of probe - clean touch plate and probe pathway - perform disk backup c) weekly - inspect air filters - clean if required - clean exterior surfaces of system and ISE Module - clean ISE Sample Port - Perform Tough Plate Assembly cleaning procedure d) monthly - rinse probe and fluid lines with 10% bleach - clean bottle caps and cap connectors - perform sample delay, optical calibration and table offset - clean reference housing e) bi-annual - replace ISE pump tubing - inspect ISE electrodes f) annual - replace all ISE tubing 2. A review of the laboratory's Cell Dyn Emerald maintenance records from November 2016 to February 2018 revealed the laboratory failed to have documentation of the performing following maintenance: a) Monthly November 2016 May 2017 June 2017 November 2017 February 2018 b) Semi-annual No documentation for 2017 3. A review of the laboratory's Alfa Wasserman Ace Alera maintenance records from January 2017 to February 2018 revealed the laboratory failed to have documentation of performing the following maintenance: a) daily startup 23 of 23 days in January 2018 20 of 20 days in February 2018 b) daily shutdown 23 of 23 days in January 2018 20 of 20 days in February 2018 c) weekly 4 of 4 weeks in January 2017 2 of 4 weeks in February 2017 2 of 5 weeks in March 2017 2 of 4 weeks in April 2017 1 of 5 weeks in August 2017 1 of 3 weeks in September 2017 1 of 5 weeks in November 2017 1 of 4 weeks in December 2017 5 of 5 weeks in January 2018 4 of 4 weeks in February 2018 d) monthly January 2017 March 2017 June 2017 September 2017 November 2017 January 2018 February 2018 e) annual no annual documented in 2017 4. The laboratory was asked to provide documentation of performing the identified maintenance procedures. No documentation was provided. 5. An interview with testing personnel number 3 (as listed on Form CMS 209) on 03/15/2018 at 1130 hours in the laboratory - after her review of the records- confirmed the findings. NOTE: THIS IS A REPEAT DEFICIENCY FROM THE SURVEY CONDUCTED 05/04/2016
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, review of the laboratory's records, and staff interview, it was revealed the laboratory failed to have documentation of verifying the speed of the centrifuges used by the laboratory. The findings were: 1. A review of the laboratory's policy titled "Centrifuge Speed and Timer Policy" revealed: "Frequency When a new general lab centrifuge is placed in service, after a major repair, and semi-annually thereafter." 2. A review of the laboratory's records revealed the laboratory failed to have documentation of verifying the speed of the centrifuges in 2016 and 2017. 3. The laboratory was asked to provide documentation of verifying the speed of its centrifuges as required by its policy. No documentation was provided. 4. A phone interview with the technical consultant on 03/15/2018 at 1230 hours revealed the laboratory had performed one verification of centrifuge speed in 2016, but had not done it in 2017. She stated she was unsure where the records for the

	verification were located. This confirmed the findings. NOTE: THIS IS A REPEAT DEFICIENCY FROM THE SURVEY CONDUCTED 05/04/2016
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality control records, review of patient hCG test records, and staff interview, it was revealed the laboratory failed to have documentation of performing quality control testing each day of patient testing. The findings were: 1. A review of the laboratory's serum hCG quality control records from June 2016 to January 2018 revealed the laboratory performed quality control testing on the following days: 06/23/2016 09/09/2016 11/30/2016 02/10/2017 11/30/2017 01 /15/2018 01/24/2018 2. A review of the laboratory's hCG patient test records from July 2016 to February 2018 identified the following days were patient samples were tested without documentation of quality control being performed: Date Specimen ID 07/20/2016 165280 08/22/2016 150586 09/08/2016 150012 09/13/2016 159489 09/23 /2016 152684 05/17/2017 168448 07/25/2017 138818 08/30/2017 170927 01/23/2018 3-19-67 01/29/2018 8-2-89 01/30/2018 169228 02/12/2018 148309 3. The laboratory was asked to provide documentation of performing quality control testing each day of patient testing or of an Individualized Quality Control Plan (IQCP) to modify the frequency of quality control testing. No documentation was provided. 4. An interview with testing personnel number 3 (as listed on Form CMS 209) on 03/15/2018 at 1100 hours in the conference room - after her review of the records - confirmed the findings. Key hCG - human chorionic gonadotropin
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on review of the laboratory's personnel records, and staff interview, it was revealed the laboratory failed to have documentation of the technical consultant performing annual competency assessments in 2016 and 2017 for 2 of 5 testing personnel. The findings were: 1. A review of the laboratory's personnel records revealed Testing personnel number 4 (as listed on Form CMS 209) performed KOH testing and testing personnel number 5 (as listed on Form CMS 209) performed urine microscopic testing. 2. The laboratory was asked to provide documentation of the technical consultant performing competency assessments on testing personnel number 4 and number 5 in 2016 and 2017. No documentation was provided. 3. An interview

	with the business officer on 03/15/2018 at 1300 hours in the conference room revealed the technical consultant did not perform competency assessments in 2016 and 2017 on the identified personnel. This confirmed the findings.