Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0678048	02/19/2019
Name of Provider or Supplier	**Street Address, City, State**	
Mt West Family Health Center	6151 Dew Street Suite 410, El Paso, 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 surveyed and failed to meet the following conditions of the CLIA regulations found at CFR 42 493.1 through 493.1780: 493.1250 Condition: Analytic Systems 493.1403 Condition: Laboratories Performing Moderate Complexity Testing; laboratory director 493.1409 Condition: Laboratories Performing Moderate Complexity Testing; technical consultant
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: Review of package inserts, policies and procedures, observations, quality control records and interview of facility personnel found that the laboratory failed to test external quality control materials as defined by the manufacturer when using the Siemens 10 SG Urinalysis Reagent strips lot 804050 expiration 2019-10-31. THIS IS A REPEAT DEFICIENCY CITED IN THE AUGUST 2011 and the JANUARY 26, 2017 INSPECTION. Findings included: 1. Review of the package insert for the Siemens 10 SG urinalysis reagent strips found under the heading QUALITY CONTROL - "Test known negative and positive specimens or controls whenever a new bottle is first opened." 2. Review of the laboratory's own written policy titled Urinalysis found under the heading Quality Control: "run a control and a microscopic first working day of the week before running a urinalysis. When the control does not meet the standards, check for any deterioration. If the problem is uncorrected send urine to the reference lab (refrigerated)." 3. Observations made during the tour the laboratory found that the laboratory was currently using Siemens 10 SG Urinalysis Reagent Strips lot 804050 expiration 2019-10-31. There was no documentation of the date opened on the bottle. 4. Review of quality control records for 2018 found no

	documentation of quality control procedures for the Siemens 10 SG urinalysis reagent strips lot 804050 expiration 2019-10-31. 5. Interview of the laboratory quality manager conducted on February 19, 2019 at 10:08 AM confirmed that the laboratory did not document the date of opening of the Siemens 10 SG urinalysis reagent strips and there was no documentation of quality control for this lot number.
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: Review of proficiency testing records and interview of facility personnel found that the laboratory testing personnel failed to attest to the integration of proficiency testing specimens into the routine, patient workflow for urinalysis in five of six testing events in 2017 in 2018. THIS IS A REPEAT DEFICIENCY CITED IN THE JANUARY 26, 2017 INSPECTION. The findings included: 1. Review of the American Association of Family Practitioners (AAF P) proficiency testing records for urinalysis found that the testing personnel failed to sign three of three testing events in 2017 for urinalysis and two of three testing events in 2018. 2. Interview of the laboratory quality manager conducted on February 19, 2019 at 12:00 PM confirmed that attestation statements had not been signed by testing personnel and that testing personnel were no longer employed. She confirmed that the previous nurse manager left in October 2018 and failed to ensure that proficiency testing records were complete.
D5018	URINALYSIS CFR(s): 493.1211 If the laboratory provides services in the subspecialty of Urinalysis, the laboratory must meet the requirements specified in 493.1230 through 493.1256, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on review of the laboratory's policy and procedures, procedure manuals, maintenance records, surveyor observations, and staff interview, the laboratory failed to follow written policies and procedures to monitor, assess and correct problems in the analytic laboratory systems specified at 493.1251 through 493.1283. The findings included: 1. The laboratory failed to follow their own procedure for centrifuge speed and time when preparing urine specimen sediment for microscopic analysis, and failed to include pertinent literature references in the procedure. Refer to D5403. 2 .The laboratory failed to define a maintenance protocol to ensure centrifuge performance that is necessary to prepare urine specimen sediment for microscopic analysis. Refer to D5433.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling,

	storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, and confirmed in interview with the laboratory quality Manager, the laboratory failed to include pertinent literature references for centrifuge speed and time in the procedure titled Urinalysis. The findings included: 1. Review of the laboratory's procedure titled Urinalysis found under the heading Procedure - Step 5. "Centrifuge specimen sample for 3 minutes on 3300 RPM's, for STAT centrifuge for two minutes." 2. When asked if the laboratory had a pertinent literature resource available for performing urinalysis, the laboratory quality manager stated she did not know of one." 3.Interview of the laboratory quality Manager conducted on February 19, 2019 at 1.1 p.m. confirmed that the laboratory's procedure for performing urinalysis did not include pertinent literature references for determining centrifuge speed and time and it was unknown if the centrifuge used to prepare the urine sediments met the speeds defined in the procedure available to testing personnel.
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: Observations and interview of facility personnel found that the laboratory failed to ensure that the aliquot of methylene blue stain (used for stool examinations for leukocytes) found in the laboratory was clearly labeled to indicate storage requirements, preparation and expiration dates and any other pertinent information required for proper use. The findings included: 1. Observations made during the tour the facility found that the laboratory had a bottle of blue liquid labeled methylene blue. There was no other documentation on this bottle. Location of the stock reagent was requested but no one knew where that was kept. 2. Interview of the laboratory

	quality manager conducted on February 19, 2019 at 10:08 AM confirmed that the aliquot of methylene blue stain was not labeled with pertinent information. She confirmed that the location of the stock reagent was unknown.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) 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 establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on surveyor observations, review of laboratory policies and maintenance records, and confirmed in interview with the Laboratory Quality Manager, the laboratory failed to establish a maintenance protocol to ensure the centrifuge used to prepare urine sediment for microscopic analysis met the defined speed in their own laboratory procedure; necessary for accurate and reliable urinalysis testing. The findings included: 1. Observations made during the inspection found that the laboratory used the ultra 8V centrifuge (serial number V121127) to prepare urine sediment specimens for Microscopic analysis. 2. Review of the laboratory policy /procedure titled Urinalysis found under the heading Procedure, step 5." Centrifuge specimen sample for 3 minutes on 3300 RPM's for STAT centrifuge for 2 minutes." Interview of the Laboratory Quality Manager conducted on February 19, 2019 at 1:21 PM confirmed that the laboratory had not established a maintenance protocol to ensure the centrifuge performance met the speed criteria as written in their own procedure.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: The Laboratory Director failed to provide overall management and direction. 1. The laboratory Director failed to ensure that the centrifuge available to testing personnel for use in preparing urine sediments for microscopic analysis met the speed and time requirements as defined in their own procedure was available .(See D 6014) 2. The laboratory director failed to ensure that proficiency testing specimens were tested as required. (See D6016 and 6017) 3. The laboratory director failed to ensure that all testing personnel met the minimum education requirements before performing non-waived testing. (See D6028) 4. The laboratory director failed to ensure that all testing personnel received the appropriate training prior to testing patient specimens. (See D6029) 5. The laboratory director failed to ensure that all testing personnel were evaluated for competency semiannually during the first year of testing and annually every year thereafter. (See D6030)

D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Review of policies and procedures, observations and interview of facility personnel found that the laboratory director failed to ensure that testing personnel prepared urine sediment for Urine microscopic examination as required for accurate and reliable results. (See D5403)
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Review of proficiency testing records and interview of laboratory quality manager found that the laboratory director failed to ensure that testing personnel attested to the routine integration of specimens into the patient workflow in five of six testing events. THIS IS A REPEAT DEFICIENCY CITED IN THE JANUARY 26, 2017 INSPECTION. The findings included: 1. Review of the 2017 and 2018 AAFP proficiency testing records found that the laboratory failed to ensure that testing personnel attested to the routine integration of proficiency specimens into the patient workload in five of six testing events. 2. Interview of the laboratory, quality manager conducted on February 19, 2019 at 12:00 PM confirmed that the laboratory did not test and submit results to the proficiency testing agency for this event.
D6017	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(ii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(ii) Ensure that results are returned within the timeframes established by the proficiency testing program. This STANDARD is not met as evidenced by: Review of proficiency testing records and interview of laboratory quality manager

	found that the laboratory director failed to ensure that proficiency testing samples were tested, and returned to the proficiency testing agency before the submission date for grading in the AAFP 2018-A proficiency testing event for urinalysis. The findings included: 1. Review of the 2017 and 2018 AAFP proficiency testing records found that the laboratory failed to participate and submit results to the proficiency testing agency before the results submission deadline of March 27, 2018 resulting in an overall score of 0% for the testing event. 2. Interview of the laboratory, quality manager conducted on February 19, 2019 at 12:00 PM confirmed that the laboratory did not test and submit results to the proficiency testing agency for this event.
D6028	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(10) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(10) Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart; This STANDARD is not met as evidenced by: The Laboratory director failed to ensure that one of four testing personnel listed on the CMS report 209 Laboratory Personnel Report held the minimum education required to perform urine microscopic analysis. (See D6065)
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Review of the CMS report 209 Laboratory Personnel Report, personal records and interview facility personnel found that the laboratory director failed to ensure that two of four testing personnel had received the appropriate training prior to testing patient specimens for urinalysis sediment examination. (See D6066)
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently

	and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Review of the CMS report 209 Laboratory Personnel Report, personnel records and interview of facility personnel found that the laboratory director failed to ensure that four of four testing personnel were evaluated for competency in performing urine sediment microscopic examination, semiannually in the first year of testing and annually every year thereafter. Findings included: 1.Review of the CMS report 209 Laboratory Personnel Report found the laboratory designated four testing personnel performing moderate complexity procedures (urine sediment microscopic examination). 2. Review of personnel records found no documentation of semiannual competency assessments for testing persons one and two. Testing person one (hired July 17, 2017) had no documentation of semiannual competency assessment in the first year of testing. Testing person two (hired October 30, 2017) had no documentation of semiannual competency assessment in the first year of testing. Testing person three (hired February 4, 2008) had no documentation of annual competency assessment for 2017, 2018 or 2019. Testing person four (hired February 17, 2014) had no documentation of annual competency assessment for 2017 or 2018. 3. Interview of the Laboratory Quality Manager conducted on February 19, 2019 confirmed the above findings.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Review of the CMS 209 Laboratory Personnel Report, testing personnel records and interview of facility personnel found the laboratory failed to ensure that one of for testing personnel met the minimum education requirements and two of four testing personnel failed to have documentation of training for moderate complexity procedures (urinE microscopic sediments examination) prior to testing patient specimens. THIS IS A REPEAT DEFICIENCY CITED IN THE JANUARY 26, 2017 INSPECTION. (See D6065 and D6066)
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a

	chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Review of the CMS report 209, personnel records and interview of facility personnel found that the laboratory failed to ensure that one of four testing personnel performing moderate complexity procedures held the appropriate education prior to testing patient specimens for urinalysis procedures. THIS IS A REPEAT DEFICIENCY CITED IN THE JANUARY 26, 2017 INSPECTION. The findings included: 1. Review of the CMS report 209 Laboratory Personnel Report found the laboratory designated for testing personnel performing moderate complexity testing (urinalysis microscopic examination). 2. Review of personnel records found no documentation of education for testing person one listed on the CMS report 209. Education records were requested but not provided. 3. Interview of the laboratory, quality manager conducted on February 19, 2019 at 11:37 AM confirmed that education records were not available for testing person one. She offered the MA certificate as evidence of education.
D6066	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(4)(ii) Have documentation of training appropriate for the testing performed prior to analyzing patient specimens. This STANDARD is not met as evidenced by: Review of the CMS report 209 Laboratory Personnel Report, personal records and interview facility personnel found that two of four testing personnel had no documentation of initial training prior to testing patient specimens for urine sediment microscopic examination. The findings included: 1. Review the CMS report 209 Laboratory Personnel Report found that the laboratory designated for testing personnel performing moderate complexity testing procedures (urine sediment microscopic examination). 2. Review of personnel files found no documentation of initial training for testing persons one and two listed on the CMS report 209 Laboratory Personnel Report . 3. Interview of the laboratory, quality manager conducted on February 19, 2019 at 10:41 AM confirmed that there was no documentation of initial training other than the test given to testing personnel.