Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	51D2098204	10/30/2018
Name of Provider or Supplier	**Street Address, City, State**	
Medtest	3860 Teays Valley Road, Suite 2, Hurricane, WV	

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
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on review of the laboratory's records and interview with Testing Personnel #2 (TP2), the laboratory failed to certify the proper functioning of their fume hood annually. The findings include: 1. Review of the laboratory's records identified no documentation of fume hood maintenance. 2. Review of the laboratory's fume hoods identified that the fume hoods were installed on 08/18/17 and there was no recertification sticker for 2018. 3. On 10/30/18 at approximately 9:15 AM TP2 confirmed the findings.
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: Based on laboratory policies and procedures, observation and interview with testing personnel, it was determined that the laboratory did not have a written policy that ensured optimum integrity of a patient's specimen in transit. Findings include: 1. Observed on Oct 30, 2018 at approximately 11AM, the laboratory received a

	shipment of approximately 10 urine specimens sent in transit via UPS which originated from a sole medical provider in Oklahoma. The tests ordered for every patient received were Urinalysis/Microscopy and urine drug screens. 2. The transit time for the urinalysis specimens varied between 2- 5 days which made the specimen integrity questionable. 3. The laboratory personnel stated they test all specimens received and have no time related policy for acceptance of urinalysis specimens. 4. The laboratory specimen collection devices did not appear to contain any preservative additives. 5. The specimen collection tubes where the date of expiration is located was covered by an adhesive label that contained the identity of the patient. The personnel did not check the expiration date on the tube and placed another bar code label on top of the original label. 6. There was no documentation of specimen rejection. 7. There was no documentaion of pre-analytic test method establishment and the impact of transit time on urine specimens for a newly introduced test.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on personnel competency record review and interview with the testing personnel, the laboratory personnel competency policies did not contain the initial training documentation and assurance of competency prior to performing laboratory testing. Findings include: 1. The laboratory was in the process of documenting the annual personnel competency assessment for Urinalysis/Microscopy, urine drug screens. However, the initial training and competency assessment verification prior to performing patient tests were not found on all 3 testing personnel. 2. On October 30, 2018 at approximately, 2:00PM, the testing personnel stated that they had not had the initial training and competency assessment performed prior to reporting patient testing and were unaware of that portion of the policy.
D5317	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(d) If the laboratory accepts a referral specimen, written instructions must be available to the laboratory's clients and must include, as appropriate, the information specified in paragraphs (a)(1) through (a)(7) of this section. This STANDARD is not met as evidenced by: Based on review of the policy and procedure manual and interview with testing personnel, the laboratory failed to provide referring clients with written instructions for Urinalysis/Microscopy patient preparation, specimen collection, specimen storage and preservation, and specimen transportation. Findings include: 1. The laboratory Client Handbook signed by the director on 10/15/2018 did not contain written instructions on patient preparation, specimen collection, storage/preservation and timelines for specimen transport to maintain the quality of the Urinalysis/Microscopy specimens. It contained guidelines for urine toxicology, respiratory and blood which were not the types of specimens being tested at the time of the survey. 2. There were no guidelines for urinalysis/microscopy specimen rejection. 3. The inspectors

	observed the receipt and testing of referred Urinalysis/Microscopy specimens that had been collected five days prior to receipt with no cooling packs/preservatives used in transit to preserve urine quality. 4. On 10/30/18 at approximately 11AM, the testing personnel stated that the urine's are not preserved and sometimes the urines arrived with cold packs and sometimes they did not. They only reject samples that are leaking or missing patient information. 5. On 10/30/2018 at approximately 11AM, the testing personnel stated they were not aware of any instructions provided to the Oklahoma originated primary care provider.
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 policy and procedure manual and interview with the testing personnel, the laboratory failed to provide a procedure for the analysis of steroid hormones in serum using LC-MS/MS which included the following: Step-by-step performance of the procedure, including test calculations and interpretation of results; reportable range for test results; quality control procedure; corrective action to take when controls or calibration fail to meet the criteria for acceptability; reference intervals (normal ranges); panic or alert values; the laboratory's system for reporting results; and description of actions to take when the Shimadzu 8060 LC-MS/MS becomes inoperable. Findings include: 1. Review of the laboratory's policy and procedure manual identified no policy or procedure for the validation runs for the LC-MS/MS. 2. The testing personnel stated the laboratory was using "The Analysis of Steroid Hormones in Serum using LC-MS/MS" procedure as the only "SOP" for running the validations for this method on the LC-MS/MS. 3. Review of "The Analysis of Steroid Hormones in Serum using LC-MS/MS" procedure identified a procedure which failed to include the following: Step-by-step performance of the procedure, including test calculations and interpretation of results; reportable range for test results; quality control procedure; corrective action to take when controls or calibration fail to meet the criteria for acceptability; reference intervals (normal ranges); panic or alert values; the laboratory's system for reporting results; and

	description of actions to take when the Shimadzu 8060 LC-MS/MS becomes inoperable. 4. On 10/30/18 at approximately 1:15 PM, testing personnel #3 confirmed the findings.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on review of the laboratory's reagents and interview with testing personnel #1 (TP1), the laboratory failed to ensure that reagents/solutions were not used past their expiration date. Findings include: 1. Inspector observed the MPA Hormone Reagent on the Shimadzu 8060 LC-MS/MS had an expiration date of 10/18/18. 2. Inspector observed a "MPB30/MPA20" control for the LC-MS/MS validation runs was made on 10/24/18. 3. On 10/30/18 at approximately 9:30 AM, TP1 stated that they only use that reagent once a week, they use the MPB more often. TP1 confirmed that the expired reagent needed replaced.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on review of laboratory policies and records for Urinalysis/Microscopy, the laboratory had not established the performance specifications for the newly introduced test system. Findings include: 1. According to patient test records for Urinalysis /Microscopy, the laboratory had begun reporting patient testing on Oct 13, 2018. 2. There was no records found to support the performance specifications had been established prior to reporting patient testing.
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 Urinalysis/Microscopic test record logs and interview with testing personnel, the laboratory failed to perform daily quality control or have photographs /chart available for manual microscopic urinalysis examination. Findings include: 1. Laboratory test records for urinalysis from October 13, 2018 to present, demonstrated no documentation of quality control each day of patient testing. 2. The laboratory personnel described that they were not aware of quality control procedures for urinalysis/Microscopic. 3. There were no charts/photographs of urine microscopic elements displayed for testing personnel use.
D5777	COMPARISON OF TEST RESULTS CFR(s): 493.1281(b)(c) (b) The laboratory must have a system to identify and assess patient test results that appear inconsistent with the following relevant criteria, when available: (b)(1) Patient age. (b)(2) Sex. (b)(3) Diagnosis or pertinent clinical data. (b)(4) Distribution of patient test results. (b)(5) Relationship with other test parameters. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on record review of procedure manual, urinalysis patient records and interview with testing personnel, the laboratory had no policy addressing the correlation between the Urinalysis analyzer results and the reflexed urine microscopy. Findings include: 1. The Urinalysis Reflex Microscopy log dated 10/16/18 documented all microscopy patient test results and the Bayer Clinitek printouts were compared for correlation. Patients tested on the Bayer Clinitek on 10/13/2018 appear on the Urinalysis Reflex Microscopy log for 10/16/18. 2. In a demonstration of the urinalysis testing process at approximately 9:30 AM, the testing personnel described that reflex urine microscopy testing is performed on the same day as the Clinitek analysis. 3. There was no policy or validation available establishing criteria for when to perform the Urine Microscopic reflex testing. 4. On Oct. 30, 2018 at approximately 2:00 PM, the testing personnel were not aware of any document that outlined spefiic criteria for when to reflex the Clinitek Urinalysis patient testing to Urinalysis Microscopy
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on record review of test reports, observation and interview of the testing personnel, the laboratory failed to include the name and address of the MedTest

	testing laboratory location on the test report. Findings include: 1. During a review of laboratory records for patient test management from Oct 15, 2018 to present, none of the laboratory test reports contained the name and address of the testing laboratory as required by 493.1291(c)(2). 2. Observation of the testing personnel performing the specimen accessioning for Urinalysis/Microscopy and urine drug screen specimens on 10/30/18 showed that the Vitas LIMSABC Laboratory Information Management System did not demonstrate the capability of generating the name and address on the test reports. 3. The laboratory Quality Assessment policy signed by the director on Oct 15, 2018 states the report shall have the laboratory name and address. 4. On 10/30 /2018 at approximately 11:30AM, The testing personnel stated that that name and address was not on the test reports selected for review on the date of the survey.
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: Based on review of laboratory policies and records regarding personnel, quality control, quality assessment and performance specifications establishment, the laboratory director failed to provide proof of overall management, direction and administration of the laboratory in accordance with 493.1407. Findings include: 1. The laboratory director did not determine performance specifications for newly introduced tests. Refer to D6013 for details. 2. The laboratory director did not establish a quality control program for urinalysis/Microscopy testing. Refer to D6020 for details. 3. The laboratory director did not implement quality assessment policies. Refer to D6021 for details. 4. The laboratory director did not assure employee training and competency prior to introducing a newly introduced test methodology. Refer to D6029 for details.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on review of laboratory policies/records, the laboratory director failed to ensure that the Urinalysis/Microscopy method had been initially verified/established for accuracy, precision, reportable range, reference/normal range, sensitivity and specificity for a non-FDA approved test. Findings include: 1. Laboratory records indicate that Urinalysis/Microscopic patient testing was reported in October 12, 2018. 2. There were no records to support the laboratory director had ensured the method was initially verified/validated for accuracy, precision, reportable range and

	establishment of normal/reference values prior to initiating patient testing. 3. The laboratory had been verifying GCMS methodology for hormone and toxicology testing since 2017 with no patient testing being reported as of the date of the survey (Oct 30, 2018). However, on Oct 30, 2018, they were establishing (validating) the procedure using expired reagent
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of urinalysis test records and interview with testing personnel, the laboratory director failed to ensure that quality control program was maintained. Findings include: 1. There was a log of patients tested for urinalysis/Microscopy test records from Oct 12, 2018 to Oct 30, 2018, but no record of any quality control performed during that period was available. 2. There were no photos or charts of urinary elements available for staff to assess for Microscopic quality. 3. There was no record of a control used to monitor the proper use of the Microscope.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of the laboratory quality assessment program policy and interview with testing personnel, the laboratory director failed to ensure that quality assessment program was maintained. Findings include: 1. The laboratory had a Quality Assessment Program policy which established employee training/evaluation, pre-analytic, analytic and post-analytic criteria to monitor. The laboratory did not maintain records on any of the Laboratory Quality Assessment Forms. 2. Initial training of the laboratory staff prior to initiating patient testing was not completed. 3. The patient test management monitor which was part of the QA Program had not been established. 4. There were no records of patient specimen rejection. 5. Monthly staff meetings were not documented. 6. No documentation of QA activities 7. On 10/30 /2018 at approximately 11:30AM, the testing personnel stated that they were not aware of any of the QA meetings, QA patient test management, specimen rejection documentation or the previous 2016 CLIA survey plan of correction plan had been implemented.

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: Based on review of personnel records and interview with testing personnel, the laboratory director failed to assure that personnel received the proper initial training for Urinalysis/Microscopy Finding include: 1. There were 3 testing personnel identified by the laboratory documentation. None of the 3 laboratory testing personnel had documentation of initial training and follow-up initial competency. 2. On October 30, 2018 at approximately 1:00 PM, the laboratory testing personnel stated they did not have documentation of initial competency. 3. The Laboratory Personnel Competency Assessment policy did not address the specifics of personnel training or initial competency verification prior to reporting patient testing.