Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2021947	01/22/2019
Name of Provider or Supplier	**Street Address, City, State**	
Murray E Joiner Jr, Md, And Associates	2726 Electric Road, Suite -#203, Roanoke, VA	

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	An announced CLIA Recertification survey was conducted at Murray E Joiner Jr, MD and Associates in Roanoke, Virginia on January 22, 2019 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows:
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on the review of manufacturer's package inserts (PI), policy and procedures (P&P), and interviews, the laboratory failed to follow the established policy for specimen handling for nine hundred (900) urine samples from November 20, 2018 and up to the date of survey on January 22, 2019. Findings include: 1. Review of the Thermo Scientific PI's for the assays of amphetamines, buprenorphine, cocaine metabolite, methadone, opiates, and oxycodone revealed the following statement: "Samples within a pH range of 3 to 11 are suitable for testing with this assay." 2. Review of the P&P for "Specimen collection and handling" page 3 (signed by the laboratory director on 09/18/2018 and 01/17/2019) revealed the following statement: "4. Urine must be validated for a. pH b. specific gravity c. creatinine and d. general oxidants." During an interview with the primary testing personnel (TP) at approximately 12:00 PM, the inspector asked the TP how the lab tests and documents the pH of urine samples according to P&P and manufacturer's instructions. She/he stated that they did not test for the pH of samples. The laboratory assayed 900 urine

	samples from November 20, 2018 and up to the date of survey on January 22, 2019. 3. Interview with the technical consultant and primary TP at approximately 2:30 PM confirmed the above-listed 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 the review of manufacturer's package inserts (PI), operator's guide, available temperature documents, and interview, the laboratory failed to monitor and document room temperature, relative humidity, and refrigerator temperatures according to manufacturer's specifications from November 20, 2018 and up to January 3, 2019. Findings include: 1. Review of the Thermo Scientific PI's for the assays of amphetamines, benzodiazepines, buprenorphine, cocaine metabolite, methadone, opiates, and oxycodone revealed the following statement: "Store reagents at 2-8 degrees Celsius." Review of the Thermo Scientific Indiko Plus analyzer operator's guide revealed the following statement: "Indiko instrument operation conditions-ambient room temp 18-30, relative humidity 40-80%." Review of the UTAK Laboratories DAU Urine Toxicology Control (Level 1 and 2) PI revealed the following statement: "Store liquid control materials at 2-8 degrees Celsius." 2. Review of the available laboratory temperature documents revealed that the testing personnel (TP) began recording room temperature, relative humidity and refrigerator temperature on January 3, 2019. There was no other temperature documentation available for review from November 20, 2018 and up to January 3, 2019. 3. Interview with the technical consultant and primary TP at approximately 2:30 PM confirmed the above-listed 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 the review of the operator's guide, available maintenance documentation, and an interview, the laboratory failed to follow manufacturer's instructions for performing and documenting instrument maintenance procedures from November 20, 2018 to January 3, 2019. 1. Review of the Thermo Scientific Indiko Plus analyzer operator's guide revealed the following statements: " Daily maintenance to include, but limited to: beginning of Day- wipe up condensed water from reagent storage, check and/or fill DI water container, check reagent volume. End of the Day- run stand by procedure, clean reagent/sample rack, empty and clean solid waste and waste water

	container. Weekly- backup database to USB flash drive/hard drive, wash liquid and solid waste containers thoroughly, clean the probes and the mixer, clean wash wells. Monthly- clean water containers and tubing (follow instructions from the manual), exit software and power down workstation and instrument and clean incubator cuvette positions." 2. Review of the available maintenance documentation revealed that there was no documentation of daily, weekly or monthly maintenance performed by testing personnel from November 20, 2018 to January 3, 2019. 3. Interview with the technical consultant and primary TP at approximately 2:30 PM confirmed the above-listed findings.
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 the review of policy and procedures (P&P), quality assurance (QA) documents, the Laboratory Personnel Report Form (CLIA) (CMS-209 Form), testing personnel (TP) records, and interview, the laboratory director failed to 1) follow the P&P for QA reviews (Cross Reference D6021); 2) ensure laboratory temperatures were monitored and documented and instrument maintenance was performed (Cross Reference D6023); and 3) ensure TP were trained and competent prior to performing testing procedures (Cross Reference D6029).
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 the review of policy and procedures (P&P), available quality assurance (QA) documents and interview, the laboratory director failed to follow the established QA policy for performing quality control (QC) reviews at least monthly from November 20, 2018 to January 16, 2019. Findings include: 1. Review of the P&P for QA (signed by the lab director on 09/18/2018 and 01/17/2019) revealed the following statement: "Monitoring QC results- the Laboratory director or designee reviews QC results of each test at least monthly. Any trends are documented." 2. Review of available QA documents revealed that, from November 22, 2018 to January 15, 2019, the laboratory director did not review QC results on at least a monthly basis as specified in the P&P. The QA documents revealed that the review of QC results took place on January 16, 2019 and QC results were not within the laboratory acceptable range on November 20 and 30, 2018 and December 28, 2018. The laboratory director

	signed the corrective action documentation for the dates on January 16, 2019. 3. Interview with the technical consultant and primary TP at approximately 2:30 PM confirmed the above-listed findings.
D6023	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(6) 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)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system; This STANDARD is not met as evidenced by: Based on the review of manufacturer's package inserts and operator's guide, available temperature and maintenance documentation, and interview, the laboratory director failed to: 1) ensure the monitoring and documentation of room temperature, relative humidity, and refrigerator temperatures (Cross Reference D5413); and 2) ensure the staff followed manufacturer's instructions for performing and documenting instrument maintenance procedures (Cross Reference D5429).
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 the review of the Laboratory Personnel Report Form (CLIA) (CMS-209 Form), testing personnel (TP) records, policy and procedures (P&P), and interviews, the laboratory director failed to follow the established written policies to ensure that one (1) of one (1) new TP had documented training and competency assessments prior to performing patient testing procedures from November 22, 2018 to January 16, 2019. Findings include: 1. Review of CLIA CMS-209 form revealed that TP A was a new TP (See attached TP Code Sheet). 2. Review of TP records and an interview with TP A at approximately 11:30 AM revealed, that just prior to on-site survey, the training and competency assessment documents for TP A were completed. There was no documentation of training or competency assessments by the laboratory director prior to patient testing on November 22, 2018. 3. Review of the P&P's revealed the following: "Quality Control and Assessment - Personnel Quality Assurance (signed by the lab director 09/12/2018): 1. Personnel performing analysis will be properly trained prior to analysis. 2. Personnel will be instructed and must show competency of all lab policies prior to analysis. 3. Personnel will be instructed and must show competency in operation of all lab equipment and maintenance of equipment prior to

	analysis." "Personnel Competency Assessment Policy (signed by lab director on 01/13 /2019): Competency assessment is the means to confirm that training is effective and that personnel are capable of following established procedures to accurately perform laboratory testing that produces quality results. These assessment will occur at the onset of testing, following training, after 6 months of employment, and then annually on the anniversary of their hire date." 3. Interview with the technical consultant and primary TP at approximately 2:30 PM confirmed the above-listed findings.