

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 49D2021947	<b>(X3) Date Survey Completed</b> 12/01/2020
<b>Name of Provider or Supplier</b> Murray E Joiner Jr, Md, And Associates	<b>Street Address, City, State</b> 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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	An announced CLIA Recertification on-site survey was conducted at Murray E. Joiner Jr, MD, and Associates on December 1, 2020 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. The initial contact and entrance interview with the laboratory was conducted on October 19, 2020 with an off-site record review of documentation on November 17, 2020 and a follow-up phone conference on November 20, 2020. Specific deficiencies cited are as follows:
<b>D5217</b>	<p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b> CFR(s): 493.1236(c)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on the review of proficiency testing (PT) records, lack of documentation, and interview with the technical consultant, the lab failed to verify the accuracy twice a year for urine pH in 2019. Record review included all three PT events in 2019 and the first two events in 2020. Findings include: 1. Review of the College of American Pathologists (CAP) PT records revealed lack of documentation for the urine pH analyte in 2019 for all three events. The inspector requested to review twice a year accuracy verification by a secondary method for the above-mentioned analyte. The documentation was not available for review. 2. An interview with the technical consultant at approximately 11:40 AM on December 1, 2020 confirmed the findings.</p>
<b>D5407</b>	<p><b>PROCEDURE MANUAL</b> CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p>

This STANDARD is not met as evidenced by:

Based on the tour of the laboratory, review of policy and procedures (P&P), review of six (6) patient reports, proficiency testing (PT) records, and interviews, the lab director failed to update the P&P for general specimen collection and handling to reflect current lab procedures for urine validation and urine storage. Findings include:

1. Tour of the lab at approximately 9:15 AM on December 1, 2020 revealed the lab receives urine specimens via FedEx. The lab also had a small refrigerator located within the lab for storage of reagents and quality control materials. No urine samples were stored within the refrigerator.
2. Review of the P&P manual revealed the following policy (signed by the lab director 1/17/19 and 1/5/20) "Standard Operating Procedure for General Specimen Collection and Handling, Per Laboratory Policies and Procedures: 4. Urine must be validated for a) pH, b) specific gravity, c) creatinine and d) general oxidants. 5. Once urine is validated, two separate samples are stored for 7 days and 30 days at 2-8 degrees Celsius prior to disposal."
3. Review of 6 patient reports and the College of American Pathologists (CAP) PT records for all three events in 2019 and the first two events in 2020 revealed no results for the creatinine analyte. An interview with the primary testing personnel and technical consultant at approximately 10:40 AM on December 1, 2020 revealed the lab has not tested for the creatinine analyte and that the procedure had not been updated since the last survey performed 1/22/19. The inspector inquired about the storage of urine samples according the aforementioned procedure. They stated that the lab does not store urine samples for the timeframe specified. Once the lab tests the samples, the samples are shipped to a reference lab for confirmation testing. The technical consultant stated that the procedure does not reflect lab practices and would be updated immediately.
4. An interview with the lab director at approximately 11:45 AM on December 1, 2020 confirmed the findings.

**D5439**

**CALIBRATION AND CALIBRATION VERIFICATION**

CFR(s): 493.1255(b)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:  
Based on the review of calibration records, policy and procedures (P&P), lack of documentation, and interview with the technical consultant, the lab failed to follow the established P&P for performing calibration verification every six months for the drug of abuse analytes in 2019. Dates of record review include 2019 and up to the date survey on December 1, 2020. Findings include: 1. Review of the calibration verification records for 2019 and 2020 revealed lack of documentation of performance every six months in the calendar year 2019. The following records were available for review: December 5, 2019, March 9, 2020 and September 4, 2020. The inspector requested to review additional documents for the calendar year 2019. The documents were not available for review. 2. Review of the P&P "Linearity Testing (Reportable Range) Calibration Verification" (signed by the lab director 9/12/18 and 1/17/19) revealed the following statements "Calibration Verification: For analyzers and analytes that are not calibrated with a minimum of three calibrators verifying the low, midpoint, and high end of the reportable range, a calibration verification must be performed to substantiate the continued accuracy of the monitor throughout the reportable range, after the initial validation studies are performed with the setup of the analyzer. Calibration verification is performed every 6 months, as stated in current CLIA regulations." 3. An interview with the technical consultant at approximately 11: 40 AM on December 1, 2020 confirmed the findings.

**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 Laboratory Personnel Report Form (CLIA) (CMS-209 Form), testing personnel (TP) records, the quality assurance (QA) policy and interview, the lab director failed to ensure the established written policy for performance and documentation of initial competency assessment was followed for one (1) of 1 TP in 2020. Findings include: 1. Review of the CMS-209 form revealed that there was 1 new TP performing patient testing in 2020. See attached list. 2. Review of the TP A records revealed no documentation of initial competency assessment performed after training and prior to testing patients. Date of training and patient testing 4/29/20. 3. Review of the QA policy revealed the following statement, "Personnel Policy (signed 11/1/20) - each employee will have competency assessed and documented for each procedure the employee performs. This is done at initial training, six months after initial employment and annually thereafter." Review of retired QA Policy (retired 11/1 /20) revealed the following statements: "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." 4. An interview with the primary testing personnel and technical consultant at approximately 11:40 AM confirmed the findings.