

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 51D2155274	(X3) Date Survey Completed 03/05/2019
Name of Provider or Supplier Mountain State Health & Wellness	Street Address, City, State 400 South Ruffner Road, Charleston, 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
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure and policy manuals, analyte package inserts, and electronic instrument manual, the laboratory failed to include normal ranges and the result reporting protocol on the procedures for the Indiko Plus Liquid Chemistry Analyzer. Findings: 1. Review of the binder titled "Sample Preparation and Analysis Using the Indiko Plus Liquid Chemistry Analyzer" found that the procedure was missing the following elements: a. Step-by-step performance of the test b. Reportable range c. Limitations d. Normal range e. Reporting protocol 2. Review of the manufacturer's package insert titled "DRI Cocaine Metabolite Assay" in the binder</p>

titled "Indiko Plus Chemistry Analyzer Validation Study," found that the document was missing the following elements: a. Step-by-step performance of the test b. Reagent preparation c. Calibration procedures d. Reportable range e. Quality control procedures f. Corrective action procedures g. Normal values h. Action to take when system becomes inoperable 3. Review of the electronic Indiko Plus Operation Manual found that the instructions were missing the following elements: a. Limitations b. Normal range c. Reporting protocol 4. A cumulative review of the above documents demonstrated that the following elements were missing: a. Normal range b. Reporting protocol