

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 51D1100953	(X3) Date Survey Completed 05/14/2025
Name of Provider or Supplier Renal Consultants Pllc	Street Address, City, State 24 Maccorkle Avenue Sw Suite 201, South 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
D0000	A routine recertification survey was conducted at Renal Consultants PLLC on May 14, 2025, by the West Virginia Office of Laboratory Services. The laboratory was surveyed to assess for compliance with the CLIA regulations under 42 CFR 493, Requirements for Laboratories. Specific noncompliance, cited as deficiencies, are explained below.
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>(b) The procedure manual must include the following when applicable to the test procedure: (b)(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. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(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. (b)(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:</p>

Review of chemistry policies and procedures, Orchard patient test reports, lack of documentation, interview with the technical consultant (TC1), and exit interview with the TC1 and testing personnel (TP2), the laboratory failed to include the (b)(10) reference intervals (normal values) for 6 of 37 analytes and calculations in the Vitros 5600 analyzer procedure manual. Findings: 1. Review of chemistry policies and procedures identified "Operation of the Vitros 5600" stating reference intervals (normal values) for 31 analytes currently tested on the Vitros 5600 analyzer. 2. Review of 11 Orchard patient reports for chemistry (428542, 428362, 4285441, 428364, 428564, 428363, 428567, 428550, 428565, 428365, 428566) identified a total of 37 analytes and calculations resulted. No documentation for the reference intervals for 6 of the 37 could be located in the procedure: anion gap, creatinine clearance, transferrin, TIBC, % transferrin saturation, and estimated glomerular filtration rate (eGFR). 3. During an interview with TC1, 5/14/25 at 10:00 AM, TC1 agreed the procedures for the Vitros 5600 chemistry analyzer lacked the reference intervals (normal values) for the 6 analytes and calculations. 4. An exit interview with TC1 and TP2, 5/14/25 at 12:30 PM, confirmed the findings.

D5801

TEST REPORT
CFR(s): 493.1291(a)

(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.

This STANDARD is not met as evidenced by:
Based on a review of policies and procedures, quality assessment (QA) documents, lack of documentation, and an interview with technical consultant (TC1), the laboratory failed to (a)(1) document the evaluation of accuracy for results reported from calculations in the Orchard laboratory information system (LIS) from January 2024 thru date of survey. Findings: 1. Review of laboratory QA policies identified "Result Verification" stating "Once annually every lab report format within the LIS or EHR will be verified for accuracy. This will include individual tests as well as calculations." 2. Review of QA documents (January 2024 thru date of survey) revealed no documented evaluation of test results reported from calculations in the Orchard LIS system. 3. During an interview with TC1, 5/14/25 at 11:15 AM, TC1 stated the result verification QA for results reported from calculations could not be located. 4. An exit interview with TC1 and testing personnel (TP2), 5/14/25 at 12:30 PM, confirmed the findings.