

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 51D0661843	(X3) Date Survey Completed 12/14/2018
Name of Provider or Supplier Wvu Dental	Street Address, City, State 64 Medical Center Drive, Morgantown, 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
D5207	<p>COMMUNICATIONS CFR(s): 493.1234</p> <p>The laboratory must have a system in place to identify and document problems that occur as a result of a breakdown in communication between the laboratory and an authorized person who orders or receives test results.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedure manual, the electronic specimen tracking log system introduced in 2018, and interview with testing personnel /Laboratory Director, the laboratory failed to maintain documentation of communication with medical providers regarding problems or critical alert values for 2017 and 2018. Findings: 1. The CLIA protocol and procedure manual demonstrated no written policy for the documentation of notification of problems to authorized persons who order or receive test results. 2. The laboratory's electronic specimen tracking spreadsheet system implemented by the director in 2017 did not contain any information documenting communications with medical providers. 3. On 12/14/18 at approximately 12:45 PM, the laboratory director stated that she verbally communicated critical values to the medical providers. But, she did not document the conversation detail, time, date or to whom she spoke and did not have a critical alert or communication policy.</p>
D5407	<p>PROCEDURE MANUAL 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> <p>This STANDARD is not met as evidenced by:</p>

Based on review of the Laboratory Procedure Manual titled CLIA Protocol and Procedure Manual and interview with laboratory director, the laboratory director had not signed and dated the review and approval of the current CLIA Protocol manual for the laboratory. Findings: 1. The CLIA Protocol and Procedure manual was not signed or dated by the current laboratory director at the time when the manual was initially put into use. 2. On 12/14/18 at approximately 9:30 AM, the laboratory director agreed that she had not signed and dated the CLIA Protocol and Procedure Manual at the time she became the Laboratory Director in 2017

D5433

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(b)(1)

For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's maintenance records for 2017 and 2018, interview with the laboratory director and observation during the laboratory tour, the laboratory failed to document preventive maintenance and service for the microscope used for oral pathology testing. Findings: 1. The laboratory procedure manual did not include a procedure or policy for servicing of the microscope. 2. There was no service report records found for the oral pathology microscope for 2017 and 2018. 3. The oral pathology microscope did not contain a sticker documenting the last maintenance performed. 4. On 12/14/18 at approximately 9:10 AM, the laboratory director stated that the Oral pathology Microscope annual maintenance had not been performed for 2017 and 2018.