Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	51D0666165	02/23/2021
Name of Provider or Supplier	**Street Address, City, State**	
Wv Office Of Laboratory Services	167 11th Avenue, 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
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: 1.Based on interview and review of documentations the laboratory failed to document daily maintenance checklist for GeneXpert System Maintenance Log: a.The GeneXpert System Maintenance Log on "Daily Maintenance" on "clean work area, close all module doors and discard used cartridge" the boxes did not check. Eight out of ten months range from October 2020 to February 2021 reviewed. For the months of November and December 2020 & January and February 2021, the maintenance logs for GeneXpert Serial Number 838589-Rana & Serial Number 838594-Q missing daily maintenance check boxes. b.During an interview on 2/23/2021 at approximately 11 AM, the laboratory' Virology Technical Supervisor # 3 stated that the testing personnel completed the task daily but did not document the activity. 2.Based on observation, staff interview and lack of documentation, the laboratory failed to perform and document maintenance for the Evolis prep area and Rapid Plasma Reagin (RPR) section Ranin pipettes in the diagnostic immunology section of the laboratory. Finding include: a.A tour of the laboratory on February 22, 2021 at approx. 10:45am, revealed pipettes in the Evolis prep area and RPR without service labels and lack of documentation for last calibration of pipettes. i.7 of 7 pipettes lacked a service maintenance label. b.During an interview at approx. 10:50am with technical supervisor (TS1), the CMS surveyor requested maintenance documents for the

	pipettes in the testing area of the diagnostic immunology section of the lab. TS1 stated, "I guess we don't have a schedule on the pipettes, since they are new. We don't have any documents from the contractor". c.During the exit interview on February 24, 2021 at appox. 2:30 pm, the Laboratory Director confirmed the above findings.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of laboratory's Quality Assurance (QA) documentation in Diagnostic Immunology section, interview with the section supervisor, the laboratory failed to document actual Quality Control (QC) reaction results for RPR (rapid plasma reagin) for Rotator Quality Assurance, control cards results on July, August, September, October, November and December 2019 as evidenced by: 1. In review of the laboratory's Rotator QA, the laboratory did not document the actual reactions of the QC tested, they check marked the following: Control card, NR; normal range NR: QC check marked Control card, R Min.; normal range R: QC check marked Control card, R; normal range R: QC check marked 2. In interview with the Diagnostic Immunology section supervisor, on 2/22/2021 at 12:30 PM she confirmed the finding.
D6124	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(iv) The procedures for evaluation of the competency of the staff must include, but are not limited to direct observation of performance of instrument maintenance and function checks. This STANDARD is not met as evidenced by: 1. Based on staff interview and review of Quality Assessment (QA) Plan, the technical supervisor failed to perform maintenance and calibration function checks on the Evolis and Rapid Plasma Reagin (RPR) section testing pipettes. Findings include: a. During an interview at approx. 10:50am on February 22, 2021 with technical supervisor (TS1), the CMS surveyor requested maintenance documents for the pipettes in the testing area of the diagnostic immunology section of the lab. TS1 stated, "I guess we don't have a schedule on the pipettes, since they are new. We don't have any documents from the contractor". b. The Authority and Responsibility for QA Plan: Supervisor section in the West Virginia OLS QA Manual states, "Monitoring all phases of laboratory sample/specimen integrity, instrument calibration and maintenance , analytical procedures, controls and corrective action, documentation, reports of analyses performed in the laboratories for compliance with technical procedures and QA plans." c..QA Plan 4.7 Equipment Calibration section states the responsibility of equipment calibration lies on the section supervisor and other Laboratory Scientist using the equipment. i. 4.7.3 Pipettes section states "all pipettes are calibrated every six months by an outside vendor or replaced as needed." d. During the exit interview on February 24, 2021 at approx. 2:30 pm, the Laboratory Director confirmed the above findings.