Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2122950	03/17/2021
Name of Provider or Supplier	**Street Address, City, State**	
Wellmont Medical Associates, Inc	743 Island Road, Bristol, VA	

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	An announced CLIA Recertification on-site survey was conducted at the Wellmont Medical Associates, Inc (Bristol) on March 17, 2021 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 laboratory conducted on February 19, 2021 with off-site record review of documentation and a follow-up phone conference on March 16, 2021. Specific deficiencies cited are as follows: The laboratory is performing COVID-19 testing and in compliance with the applicable COVID-19 reporting requirements.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on the review of manufacturer's Food and Drug Administration's (FDA) Emergency Use Authorizations (EUA), available patient/quality control (QC) logs, lack of documentation and interviews, the laboratory failed to perform external positive and negative QC for six (6) of 8 days and 11 patients reviewed. 1. Review of the Cepheid Xpert Xpress SARS-CoV-2/Flu/RSV manufacturer's FDA EUA revealed the following statement "Testing of nasopharyngeal swab, nasal swab, or nasal wash /aspirate specimens using the Xpert Xpress SARS-CoV-2/Flu/RSV test run on the GeneXpert Dx and GeneXpert Infinity systems is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. 263a, that meet requirements to perform high or moderate complexity tests." 2. In an interview with the primary testing personnel and lab manager on 03/17/21 at 11:40

	AM and review of records, it was revealed the lab utilizes the GeneXpert DX instrument (serial number 738085) and began testing patients on 02/01/21. In addition, the lab performed external QC procedures on 02/01/21 and 03/03/21. 3. Review of available patient and QC logs revealed the following dates and patients tested: 02/09/21- Patient 1, 02/10/21- Patient 1, 02/16/21- Patient 1 and 2, 02/26/21- Patient 1 and 2, 03/01/21- Patient 1 and 03/05/21- Patient 1, 2, 3 and 4. The inspector requested to review the daily external positive and negative QC documents for the above-specified dates. The lab lacked documentation of the requested QC. 4. An interview with the primary testing personnel and lab manager on 03/17/21 at 11:45 AM confirmed the findings.