

VIRGINIA DEPARTMENT OF FORENSIC SCIENCE

**VALIDATION OF THE VERITIPRO™ THERMAL CYCLER: PERFORMANCE
CHECK OF FIRMWARE UPDATE V1.2.1**

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PURPOSE

This performance check was conducted to test the function of the Applied Biosystems® VeritiPro™ PCR System (VP) for amplifying DNA samples, following the update of the firmware to v1.2.1.

MATERIALS AND METHODS

The Applied Biosystems® VeritiPro™ PCR System Firmware (ThermoFisher Scientific, Waltham, MA) is used on the Applied Biosystems® VeritiPro™ thermal cycler (ThermoFisher Scientific). Amplification programs currently in use at the Virginia Department of Forensic Science (VDFS) on casework and will be used with the VP system are: the PowerPlex® Fusion 5C System (Fusion; Promega Corp., Madison, WI) and AmpFℓSTR™ Yfiler™ PCR Amplification Kit (Yfiler; ThermoFisher Scientific, Waltham, MA). The firmware update from the previously installed v1.1.2 to v1.2.1 did not have any algorithm changes or affect performance except for the following new features/changes and fixes:

Fixed run error encountered when the first step of protocol is 25 deg C

Fixed auto delta hold time out of range message

Fixed error message displayed when supply voltage is not stable

Set maximum stages and steps within thermal protocol to 50

Fixed incorrect NVRAM key corrupt error during protocol run

Fixed incorrect run started with unsaved changes message in run report under Restricted Mode 2

Implemented new computer module due to part obsolescence

Added feature to allow run to start before the heated cover setpoint is reached

The fixes and features described above from the firmware developer's release notes were evaluated. The firmware is a software component of the thermal cycler instrument. The feature to allow the run to start before the heated cover setpoint is reached is an optional feature that our laboratory does not employ and, as such, was not tested. The remaining changes were determined to be minor revisions to the firmware, such as fixing error messages. Since these revisions were minor in nature, as opposed to impacting the analytical process, a functional test

of the firmware was performed on the VP instrument following the firmware update. Additional regression and reliability testing, required for major revisions to instrumentation software, were not applicable.

Two male bloodstain samples were previously extracted and purified using DNA IQ™ (Promega Corp.) on the Biomek® NXP Automation Workstation (Beckman Coulter, Fullerton, CA). The DNA extracts were previously quantitated using the Plexor® HY System (Promega Corp.) and Stratagene Mx3005P instrument (Agilent Technologies, La Jolla, CA) for amplification and detection.

A manual half-reaction setup was performed for Fusion and Yfiler and amplification was carried out in 0.2mL tubes using the VP with updated firmware. Amplified samples (1 µL) were separated on the Applied Biosystems™ 3500xL Genetic Analyzer (ThermoFisher Scientific) and analysis was performed using GeneMapper™ ID-X Software (ThermoFisher Scientific) v1.4. All methods were performed as described in the Virginia Department of Forensic Science Procedures Manuals.¹

RESULTS

DNA profiles were compared to those previously developed using the GeneAmp™ PCR System 9700 (ThermoFisher) and to published proficiency test data. Correct profiles were obtained for all samples (data not shown). The amplification controls performed as expected.

CONCLUSION

A functional check of the VP thermal cycler was performed, following a minor revision to the instrument firmware (to v1.2.1). It demonstrated that the instrument works as expected when used to perform Fusion and Yfiler DNA amplification.

¹ <http://www.dfs.virginia.gov/documentation-publications/manuals/> (accessed September 4, 2024).