Thermo Fisher Scientific performed developmental validation experiments in accordance with the DNA Advisory Board (DAB) Quality Assurance Standards (July 1, 2020) and guidelines from the Scientific Working Group on DNA Analysis Methods (SWGDAM, December 5, 2016) to evaluate the performance of the Applied Biosystems™ PrepFiler™ and PrepFiler™ BTA Automated Forensic DNA Extraction Kits on the Applied Biosystems HID NIMBUS Presto System. Results from these instrument-reagent system developmental validation studies have demonstrated that they are fit for Human Identification testing.

Each laboratory using the PrepFiler and PrepFiler BTA Automated Forensic DNA Extraction Kits should perform its own appropriate internal validation studies to establish interpretation criteria and demonstrate that the PrepFiler kits are appropriate and fit for its own Human Identification uses.