COMPARITIVE PERFORMANCE EVALUATION OF VIRAL STABILITY WITH UNIVERSAL TRANSPORT MEDIUM DEVICES (ALSO BRANDED AS TRANSPRO™ CVM)

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Detection of clinical viruses requires specific equipment and training that are not always readily available. Swabs represent an alternative tool that require little training and equipment; however, recovery and detection of pathogens after collection has proven to be inconsistent. This derives the need for a transport medium that will preserve viability, inhibit propagation and ensure quantitative detection via culture, PCR, immunostaining, etc. We compared the performance of a non-propagating transport medium test device with a similar commercial predicate device. Quantitation of nine viruses (Human adenovirus 1, Cytomegalovirus [CMV], Echovirus Type 30, Herpes Simplex Virus Types I [HSV-1] and II [HSV-2], Influenza A, Parainfluenza 3, Respiratory Syncytial Virus [RSV], and Varicella Zoster Virus [VZV]) was tested in triplicate for two dilutions, two temperatures (room temperature [20-25°C] and refrigerated [4°C]), over the course of four time points (0, 24, 48, 72h) between a predicate and test Universal Transport Media (UTM) device (branded as TransPRO™ CVM). Following UTM storage, samples were inoculated onto shell vials containing a confluent monolayer of permissive cells and incubated 24 to 48h. Shell vial cover slips were collected, mounted and stained with strain specific fluorescent antibodies and visualized with a fluorescent microscope. Individual foci were counted for quantitative analysis. For both devices, test viruses could be quantified through 72h of storage at two separate temperatures. In general, refrigerated storage resulted in higher test strain recoveries. Adenovirus, CMV, Echovirus 30, HSV-1, Parainfluenza 3, and RSV were all relatively stable during the 72h time course, while HSV-2, Influenza A, and VZV decreased in stability. One-way ANOVA demonstrated statistical differences ($P<0.05$) in the two devices under certain conditions, concluded to be indicative of normal microbiological variability and swab manufacturing inconsistency. Specifically, Adenovirus demonstrated significantly lower recovery for 48-72h at both temperatures for the predicate device. Echovirus 30 demonstrated significantly higher test device counts from 24-72h at 4°C. The test device evaluating HSV-2 resulted in significantly lower counts in the 1:10 dilution at 48h and 20-25°C. Parainfluenza 3 analysis resulted in significantly lower counts at 4°C for both dilutions at the 48h timepoint. VZV test device results were significantly higher at 0h and 48h for both temperatures and both dilutions. No significant differences were found testing CMV, HSV-1, Influenza A, and RSV. From a clinical perspective, no differences were noted between the two devices, the test device performed in an equivalent fashion to the predicate thus making it a valid system for the collection, storage, and transport of clinical specimens.