CLINICAL VALIDATION OF MICROBRUSH TEST SWAB

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INTRODUCTION

Since the beginning of the SARS-CoV-2 pandemic, there has been a shortage of nasopharyngeal (NP) swabs. These swabs are utilized to collect the optimal specimen for RT-PCR detection of the virus. NP swabs are an FDA Class I exempt device requiring FDA registration and production following current good manufacturing practices (21 CFR Part 820). Young Innovations, a manufacturer of micro-applicators, has developed an NP swab, Microbrush® Test Swab. Based on studies on the performance of 3D printed swabs [1], a similar analysis was performed. This study was undertaken to assess the performance characteristics of the Microbrush Test Swab including the molecular detection of respiratory viruses.

MATERIALS AND METHODS

Physical Characteristics. Size measurements of the head, neck, shaft, breakpoint, swab surface characteristics, flexibility, durability and strength were assessed. Flexibility was assessed by bending the tip. Durability and strength were assessed by bending back on itself 20 times, by bending 90^{o} at the tip and neck and by the ability to revert to original shape after bending to 90^{o}.

Specimen collection. The ability to collect cells was assessed by scraping the interior cheek. Gram stain was performed and analyzed for the presence of epithelial cells.

Molecular detection. The ability to detect influenza a, influenza b (FLUAB), respiratory syncytial virus (RSV), human metapneumovirus (hMPV) and SARS-CoV-2 was assessed using laboratory-developed RT-PCR assays. The assay for FLUAB, RSV and hMPV is a multiplex assay performed on the BD MAX [2]. The assay for SARS-CoV-2 targets the E gene and utilizes easyMag extraction with amplification and detection on the ABI 7500.

Previously positive NP specimens in viral transport medium were stored at -70C and thawed prior to use. The NP swab was placed in these specimens and allowed to stand for up to 5 minutes at room

temperature. The swab was then placed in two tubes of fresh viral transport medium and stored for 72 hours at room temperature, at 2-8C and at -20C. Aliquots were tested at 0, 24, 48 and 72 hours.

Statistical analysis. Repeated measures analysis of variance was performed to assess changes in cycle threshold values over time for each of the viruses.

RESULTS

Swabs are 15 cm in length with a 1.8 cm head and a 3.5 cm neck. A breakpoint location occurs at 10 cm. The head diameter is 3 mm at the narrow end and 4 mm at the wide end. The neck diameter is 1 mm. Ten swabs were determined to be smooth and free of burs. Nylon fibers did not easily release from the swabs. The head and neck could be bent to 90^{o} without breakage and reverted to original form. The neck could be bent more than 50 times without breakage. The swab was easily broken at the breakpoint. Gram stain of interior cheek specimens collected using the swabs demonstrated the presence of epithelial cells. There was no statistically significant difference in detection of respiratory viruses from swabs stored in viral transport medium for up to 72 hours at room temperature, 2-8 C and at -20 C.

DISCUSSION

The SARS-CoV-2 pandemic has caused an unprecedented demand for specimen collection supplies; chief among these being the nasopharyngeal swab. To address this demand, laboratories have been forced to look for alternatives. 3D printed swabs have been developed. Many prototypes have been determined to be too brittle, stiff, flimsy or rough for use while swabs from several manufacturers have been determined to be acceptable [2, 3]. The Microbrush Test Swab demonstrated physical characteristics similar to commercially available nasopharyngeal flocked swabs. In addition to performing adequately for the detection of SARS-CoV-2, these swabs also have been shown to be acceptable for use for detection of the most common respiratory viruses. There was no evidence of inhibition in any assays tested.

REFERENCES

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