International Journal of Technology 11(5) 888-899 (2020)
Received July 2020 / Revised October 2020 / Accepted October 2020

International Journal of Technology

http://ijtech.eng.ui.ac.id

Setting Acceptance Criteria for a National Flocked Swab for Biological Specimens during the COVID-19 Pandemic

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Abstract. Swab sticks are a means of sampling a person by swabbing the nasopharyngeal pathway. This tool is at a critical point, where domestic availability in Indonesia is lacking because it is purely dependent on foreign supplies during the coronavirus disease 2019 (COVID-19) pandemic. The procurement process takes weeks or even months. Therefore, a collaboration of national companies with different industrial backgrounds and the Research Center for Biomedical Engineering, Universitas Indonesia, addressed this scarcity by developing and producing a national swab stick. Since there was no swab stick manufacturer in Indonesia, the production was arranged in such a way from four different industries, following ISO 13485:2016, Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes'. The companies contributing have strong experience in resin production, plastic processing, flocking technology, and medical packaging. However, it is important to ensure that the quality of the product developed meets the quality of existing products. This manuscript summarizes the quality assurance of the swab stick design, prototype, and production. Here, we propose a series of measurements; namely, geometrical, tensile, peel, surface, flock adsorption, and residue testing. The conclusion shows that the developed swab stick has stiffness around 400 MPa, deflected at 15N, a density of 1.5–2.5 Dtex, water contact angle at 78 degrees, and adsorbs around 25–35μL of liquid water. Moreover, there was no solvent or any toxic substance around the flocked swab during the residue testing. These qualities shall be developed further into a national product with nearly 100% local content in order to increase availability of the national medical device and fight COVID-19 in Indonesia. The product was formally registered under the trade name Sterilized Nasopharynx Swab Stick HS 19.

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doi: 10.14716/ijtech.v11i5.4335

Keywords: COVID-19 pandemic; ISO 13485; National swab stick; Quality assurance; 100% local content

1. Introduction

A nasopharyngeal swab (hereafter referred to as "swab") is a method for collecting clinical trial samples of nasal secretions from the back of the nose and throat (Sheridan, 2020). Samples are then analyzed to determine the presence of organisms or other clinical markers for disease. This diagnostic method is usually used in cases of suspected whooping cough, diphtheria, influenza, and various diseases caused by the coronavirus family, including severe acute respiratory syndrome (SARS), Middle East respiratory syndrome (MERS), and coronavirus disease 2019 -COVID-19 (Pavord and Pavord, 2005; Junkins, 2010; Irving et al., 2012).

Similar in concept to cotton swabs, swab sticks used for nasopharyngeal collecting are small sticks made of short plastic rods which are covered at one end with adsorbent materials such as cotton, polyester, or nylon. Previously, swab sticks were made from nichrome or stainless-steel wire. The swab material used for certain diagnostic applications can vary based on the type of test performed. Several studies have shown that flocked swabs are able to collect greater sample volumes compared to fiber swabs (Gritzfeld et al., 2011).

In general, the structure of a swab stick aims to obtain a specimen from the patient's nasopharynx safely, but also has enough volume to be followed up with subsequent procedures on a polymerase chain reaction machine. There are two major parts. The first is the part that will enter the contours of the nasopharynx, which is not straight; flexibility is needed so that it is comfortable for patients. The stick is commonly produced by the injection-molding method. However, an optimum operating operation and mold design shall be defined to gain the product as required (Chalid et al., 2017; Hasnan et al., 2017; Wang et al., 2019).

The second important part is the flocked swab which consists of nylon material, the function of which is to hold the specimen volume of the nasopharynx without loss when moved; therefore, the capillary structure of the flock is attached to the surface of the swab stick. In order to fulfill this function, there are several challenges; namely, a material and geometric form of the main material flock swab and a flocking process that is able to make the material "stand" and form a "crowd" (flocking) so that the capillary force is formed on the flocked swab. The procedure can be approached in the textile industry and is usually called the electrostatic flocking process. Electrostatic flocking uses an electric charge to direct fibers and form a line that is perpendicular to the surface of the substrate. This technique optimizes the results obtained with longer fibers. In this method, the substrate is pre-coated with an adhesive and then passed through a high-voltage electrostatic field chamber. This method can be improved by the existence of pneumatic techniques to provide good coverage on three-dimensional objects (Walther et al., 2007; Basaran et al., 2012; Nunes et al., 2016).

This paper reports the testing of a flocked swab produced by our consortium that consisted of researchers and industrial partners during the project "Donation of National Flock Swab for Fighting COVID-19". Our partners have strong competency and knowledge in raw material selection, mold design, plastic processing, flocking, packing, and sterilization processes. These companies, all based in Indonesia, are geographically separated and located around the Jakarta Provinces, Tangerang Provinces, and West Java Province. Therefore, a set of acceptance criteria for the product needed to be measured and standardized to assure quality, although communication hurdles might occur. The project

was to realize a rapid design and development of a nasopharynx swab stick using local resources. However, the design and manufacturing processes needed to be integrated and needed to comply with ISO 13485:2016 Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes.

2. Methods

2.1. Manufacturing

There are three main processes in producing the swab sticks: injection mold, flocking, and sterilization and packaging. Figure 1 shows the production line from raw material to packaging. The material used for the swab stick is a polypropylene homopolymer (Trilene HI10HO, Chandra Asri Petrochemical Tbk) in the form of a natural pellet, with the main specifications shown in Table 1. The flock material was 99.9% nylon 66.

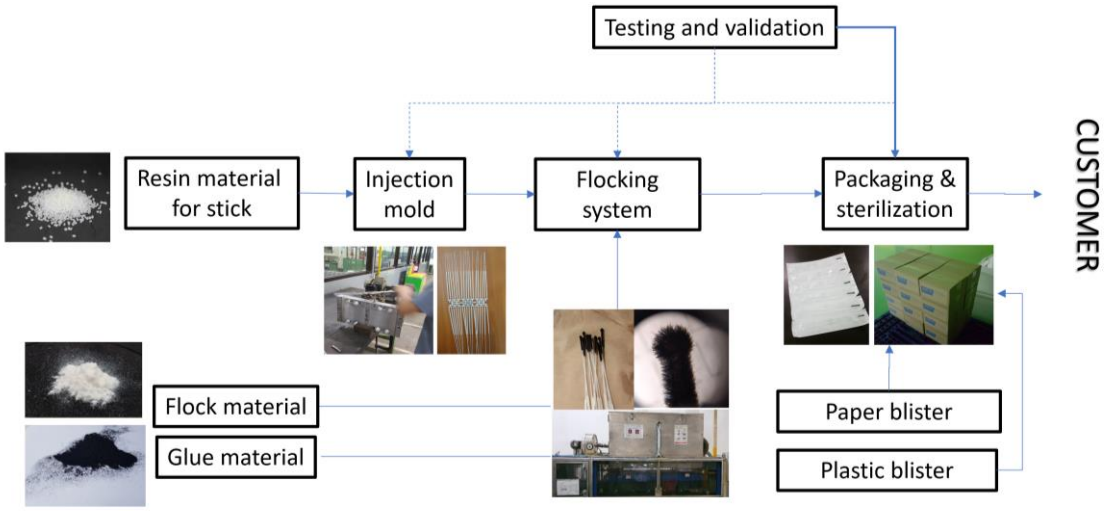

Figure 1 Production line of the national swab stick

The design of the nasopharynx swab stick was designed by the team as depicted in Figure 2. The design was then evaluated thoroughly through product risk-assessment activities that reported together with the review of the swab stick. The mold was manufactured by the workshop at Dynapack Asia Pte Ltd. Later, the polypropylene material was injected by a plastic injection machine (Haitian HTF90W1/J5) which had a clamping force of 90 kN. The temperature setting was 200–240°C to realize the swab stick as designed.

Nylon flock (1.5 dtex/1.25 mm) was used to create clouds of flocks in a closed chamber. A DC electric generator was installed in the flocking chamber. The distance between the fiber source and the grounded substrate was maintained at 100 mm. The flock fibers were charged by corona discharge from a mesh electrode inside the chamber. This charging electrode was maintained at potential levels around 70 kV.

A plasma treatment was also added in the process before the gluing of the nylon flock. The binding process was carried out with a plasma-binding device called Corona SB by BlackHole Lab (Paris, France). The device produced high voltages with high frequency generators, which makes sparks on the surface of the swab stick. The output power of this device can be adjusted from 10,000 to 48,000 volts.

Sterilization was carried out by ethylene oxide gas which was placed inside the vault. The parameters of sterilization were: −0.80 bar (vacuum) pressurized within an exposure time of 3 hours. The environmental conditions were kept at a humidity of 60% and a

temperature of 55°C. The total rinsing cycle was completed three times for every batch of production.

2.2. *Geometrical Measurement*

A Vernier caliper was utilized to measure the diameter and length at several points of the swab stick (Figure 2). The swab stick was divided into multiple sections which consisted of lengths 01–03 and diameters 01–04. Multiple measurements were conducted and the number of the specimen followed the ISO 2859-1:1999 Sampling Procedures for Inspection by Attributes guidelines. An acceptable quality limit (AQL) was defined based on the number of total products in one batch. Once the AQL was determined, a sampling with n = 8 was collected to verify the consistency of the quality.

2.3. *Mechanical Testing*

Specimens of the flocked swab were measured by a universal tensile machine MCT series from AND (Tokyo, Japan) with a maximum capacity of 500N. The procedure followed ASTM (American Society for Testing and Materials) D638 tensile testing protocol. Here, the test speed was set at 10 mm/min and ended until its breakpoint (Fatriansyah et al., 2019; Purwanto and Harprastanti, 2019).

2.4. *Peel Adhesion Testing*

A peel adhesion test following PSTC (Pressure Sensitive Tape Council) 3 guidelines was conducted to confirm the bonding of the flocked materials onto the swab stick surface. Note that a specific adhesive was previously coated during electrostatic flocking to glue the flocking material. Hence, this peel testing removed the remnant of the flocked material from the swab stick. Later, a visual observation was taken using a digital microscope and scanning electron microscope FESEM (Field Emission Scanning Electron Microscope) to view the result of the peel testing. The adhesive tape that was used here was 3M 810 Scotch Magic Tape (Cifriadi et al., 2017).

2.5. *Water Contact Testing of Adhesive and Flocked Material*

The adhesive material was coated onto the swab stick, peeled, and unfolded from the stick. It formed a layer of dried adhesive. A small drop of water was then shed onto the surface and observed under a microscope. Second, the adhesive with the flocked material from the swab stick was peeled and unfolded the same as the previous one. Similarly, a drop of water was also shed onto the surface. The image from the visual inspection was then conducted on both specimens to see the difference (Judawisastra et al., 2018).

2.6. *Adsorption Testing*

A weighing scale with a 0.001 gram significance value was utilized in this experiment. First, an amount of water was dropped onto the scale and weighed. Second, the swab stick was gently pressed onto the weighing scale surface at 180 degrees. The swab stick was kept on the surface for around 10 seconds and rotated at around 1 RPM. Finally, the swab stick was removed, and the weighing scale showed the mass reduction of the water. This value indicated the portion that adsorbed into the swab stick (Suprapto et al., 2020).

2.7. *Residue Testing*

Fourier-transform infrared spectroscopy (FTIR) measurement was conducted to ensure that the finished product was clean and free of toxic residue. The swab stick was immersed and gently stirred in a glass vial for about 1 minute. The vial was then placed in the Nicolet iS50 FTIR Spectrometer from Thermofisher Scientific (Waltham, USA) for spectra recording in the range of 4000-375 cm^{-1}. The second specimen that was used as a control solution was deionized water (Kusrini et al., 2018; Jamilatun et al., 2019).

3. Results and Discussion

3.1. Concept Design and Product Risk Assessment

A structured concept selection process helps to maintain objectivity throughout the concept phase of the development process and guides the product development team through a critical process. The team established two main criteria on which the choice of a product concept would be based:

- The swab stick is easy to bend and follows the contour of the nasopharynx and does not injure the nasopharynx when the tip of the stick reaches the nasopharyngeal wall.
- However, the end of the stick needs to be stiff enough and easy to break.
- The flock on the swab stick is thick enough to be able to take a sufficient number of biological specimens as samples.
- The flock on the swab has perfect adhesion so that it does not come off easily during use and is free from residual hazardous materials.

The above criteria can be reflected into the following properties:

- Swab stick stiffness represented by elastic modulus (Pascal)
- Swab stick bending represented by strength (Pascal)
- Flock adsorption represented by adsorbed water (microliter)
- Flock adhesiveness represented by peeling test
- Toxicity of the residual material represented by infrared spectroscopy.

Later on, a risk assessment involves the identification of risks followed by their evaluation or ranking. It is important to have a template for recording appropriate information about each risk. Table 1 shows the range of information that may need to be recorded. The focus of the risk matrix is the assessment of significant risks and the implementation of suitable risk responses. It is shown that the potential hazards of the swab stick are the selection of its material, its structure, its production processes, and its operation.

Table 1 Risk analysis of swab stick

No.	Hazard identification	Sequence of events	Hazardous conditions	Potential harm
1A	Biological: viruses, bacteria	Transfer product to a hospital	Product is exposed to open air	Patient will be infected
1B	Biological: viruses, bacteria	Cleaning method is not up to standard	The product is still not clean or has residue of hazardous materials	Patient will be infected
2A	Physical: too stiff	The process of taking virus samples in the nasopharynx	The product is too stiff so may injure the patient's nasal passages	Patient will be injured
2B	Physical: too sharp	The process of taking virus samples in the nasopharynx	There is a sharp geometry due to imperfections in the manufacturing process	Patient will be injured
2C	Physical: used products	Use of products that have been used by other people	The product has been exposed to bacteria, viruses, and other contaminants	Patient will be infected
3A	Chemical: there is a remaining manufacturing product grease	There are still manufacturing contaminants	Chemical contamination	Patient will be infected
4A	User: the sampling method is inappropriate	The sampling process in the nasopharynx is not according to standards operation procedures	Sampling is not optimal	Longer sampling process, the patient will be disturbed

The risk architecture, strategy, and protocols shown in Table 2 represent the internal arrangements for communicating on risk issues. The risk strategy should set out the

objectives that risk-management activities in the organization are seeking to achieve. Finally, the risk protocols describe the procedures by which the strategy will be implemented and risks managed. Table 2 shows the risk mitigation and also the risk reduction by means of standard operation procedure (SOP).

Table 2 Risk evaluation of swab stick

No.	Initial risk				Action	Final risk			
	Prob	Severity	Score	Estimation of risk		Prob	Severity	Score	Estimation of risk
1A	2	3	6	Unacceptable risk	1. Perform sterilization according to the procedure 2. Transfer the sterile product according to the procedure 3. Carry out operations according to procedures 4. Sterilize the operating room according to procedure	1	3	3	Investigate further risk reduction
1B	1	3	3	Investigate further risk reduction	1. Write down the sterilization method in the product manual	1	3	3	Investigate further risk reduction
2A	2	2	4	Investigate further risk reduction	1. Choosing materials according to predetermined standards 2. Conduct a material verification process according to the Standard Operation Procedure	1	2	2	Insignificant risk
2B	2	2	4	Investigate further risk reduction	1. Carry out the manufacturing process according to the predetermined standard operation procedure	1	2	2	Insignificant risk
2C	2	3	6	Unacceptable risk	1. Write in the product usage instructions that the product cannot be used repeatedly	1	3	3	Investigate further risk reduction
3A	2	2	4	Investigate further risk reduction	1. Carry out a cleaning process according to standards and SOPs	1	2	2	Insignificant risk

4A	2	2	4	Investigate further risk reduction	1. Carry out the sampling process in accordance with the standards and SOPs	1	2	2	Insignificant risk

3.2. Geometrical Measurement

The swab stick was produced by the injection-molding process and resulted in a tubular shape. Note that the dimension contributes to the structural property of the stick apart from the material itself. Therefore, in order to assure the geometrical shape, we divided into several segments as shown in Figure 2.

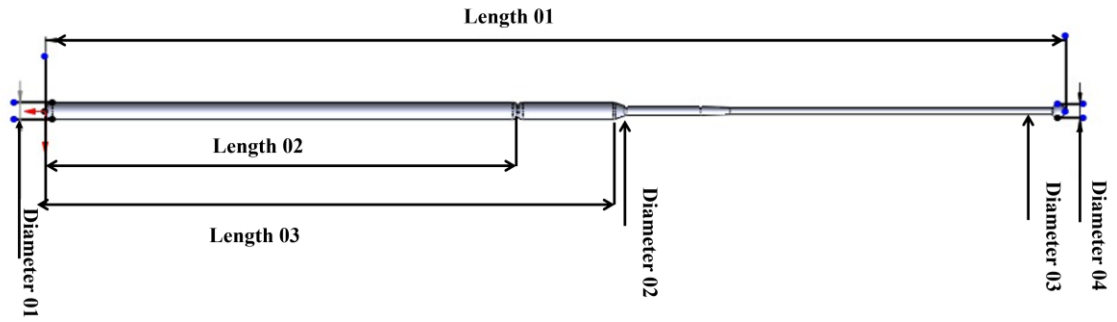

Figure 2 Measurement profile of the swab stick

Figure 3a shows the measurement of the length profiles that consisted of three segments: the total length (length 01), the base until the breaking point (length 03), and from the base up to the end of diameter 01. The measurement shows that the measured value is comparable to the designed/expected profile. The standard deviations were also relatively small between the produced sticks. Figure 3b shows the measurement result of the tubular diameter from the base (01), the end of the base (02), the neck part (03), and the tip of the stick (04). Similarly, it also shows that the measured values confirm that we achieved the expected dimensions.

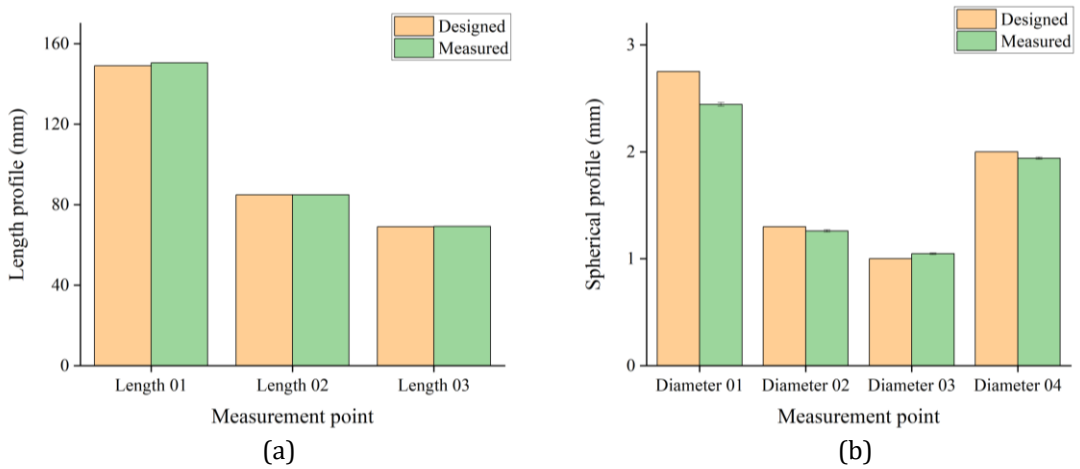

Figure 3 Geometrical measurement of the swab stick profile

Table 3 shows the calculation of difference, the margin between the measured and designed dimension, together with the allowable limit based on the AQL. The calculation also shows that the difference was at a tolerable range of product quality. It can be

concluded that the injection-mold process resulted in the geometrical shape as expected and that it complied with the design quality.

Table 3 Geometrical measurement of swab stick at all segments

No	Stick profile	Δ Difference (mm) (design – measure)	Allowable Δ (mm)
1	Length 01	1.46	±1.50
2	Length 02	0.10	±0.50
3	Length 03	0.30	±0.50
4	Diameter 01	0.32	±0.50
5	Diameter 02	0.04	±0.30
6	Diameter 03	0.05	±0.25
7	Diameter 04	0.06	±0.18

3.3. Mechanical Testing

One of the important features of this nasopharynx swab stick is that it is easy to bend once it has reached the nasopharynx so that it does not hurt the patient. However, a material that bends relatively too easily is also not recommended since it will make it difficult for the paramedics to perform the swab test. Therefore, a perfect combination of the right dimension and suitable material is a key point in order to realize this feature.

The mechanical testing was conducted to obtain mechanical properties such as ultimate tensile strength and modulus elasticity/stiffness in order to gain information about the abovementioned desired quality. The measurement result shown in Figure 4 presents the stress-strain curve. The curve shows that the force was achieved at around 15 N as it simulated the nasopharynx area (Figure 4b). The simulation shows that it was forced by a 15 N force in the y-direction and it deflects as the strain chart shows. Table 4 provides the mechanical properties resulting from tensile testing. It gave elastic modulus at around 409 MPa.

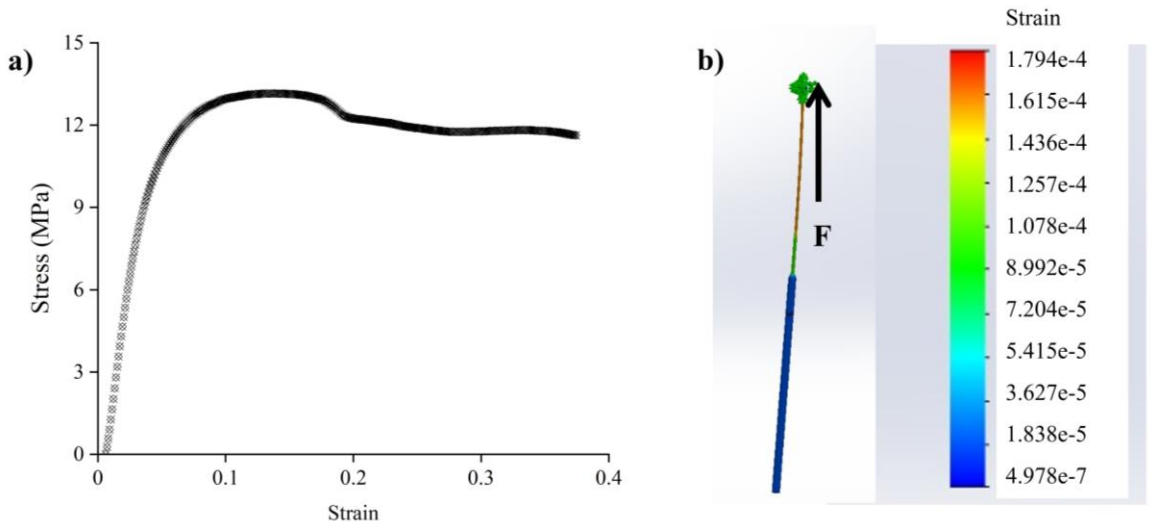

Figure 4 Stress-strain characterization of swab stick

Table 4 Mechanical properties of swab stick

No	Mechanical properties	Measured value
1	Maximum force (N)	14.47±0.61
2	Ultimate tensile strength (MPa)	13.01±0.27
3	Modulus Young (MPa)	409.30±53.84

3.4. Flocking Quality

The testing of the finished flocked material is depicted in Figure 5a. The flocked material firmly covered the surface of the swab stick. Figure 5b confirms that the flock fiber stood up straight on the tip as desired. This observation was needed to determine the density of the fibers in the flocked swab part. Observations were made by visually measuring the flocked fiber attached to the surface of the swab stick. The density test showed that the flock has a density of 1.5–2.5 Dtex, with weight in grams per 100 meters.

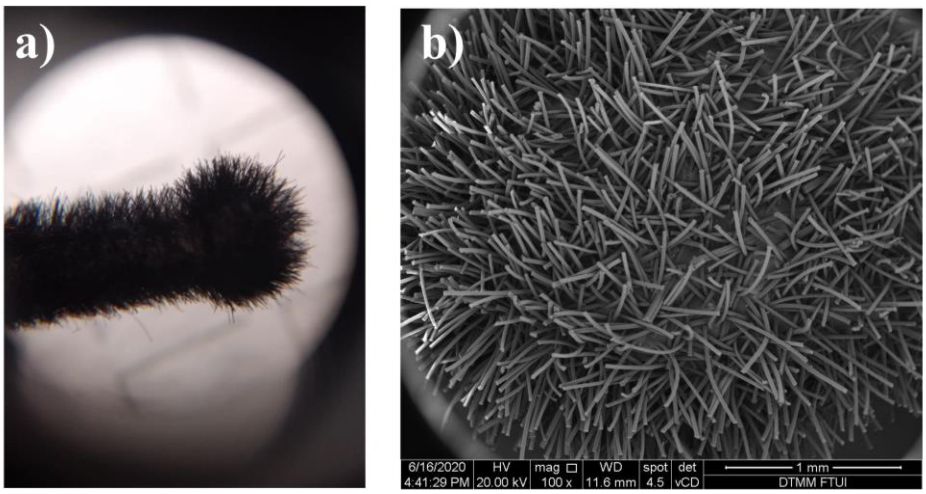

Figure 5 Visual observation of finished flocked material (a) and scanning electron microscope (SEM) image of the tip (b)

Peel testing was carried out in order to determine the bond strength of the flocked nylon material against the stick material. It also allowed us to observe the bond by observing the remaining flock that was captured on the adhesive tape. Later, an adhesive peel test was conducted by peeling the neck of the swab stick using adhesive tape. Figure 6 shows the result of the adhesive peeling test before and after the treatment. Here, it can be seen that the adhesive peel test pulled out some amount of flocked fiber as designated by the holes on the stick body. The low adhesiveness of the microfiber to the glue was caused by the orientation of the fibers that were not perpendicularly attached to the glue and also due to a lack of glue thickness.

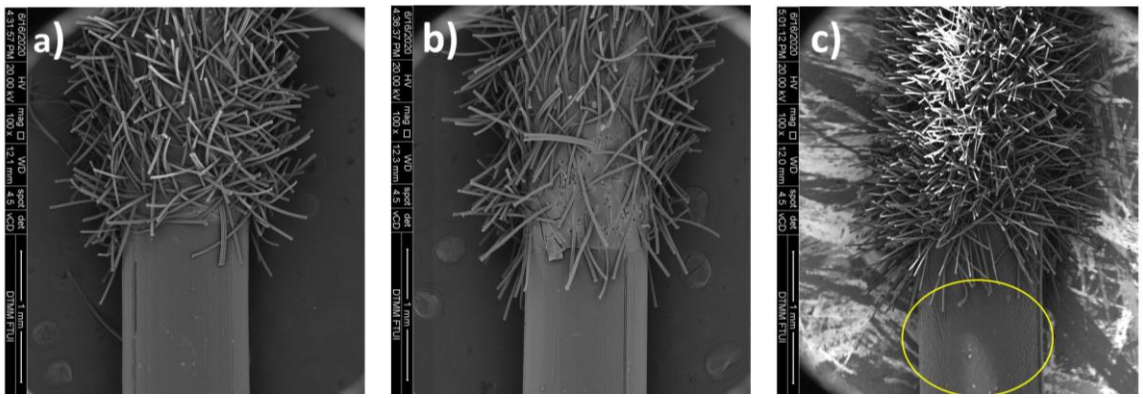

Figure 6 Scanning electron microscope (SEM) observation of swab sticks: (a) before; (b) after the testing adhesive peeling test; and (c) the plasma treated swab stick indicated a corrugated surface

In the second phase of development, a plasma arc was introduced to modify the surface of the swab stick. The plasma arc had both physical and chemical changes of characteristics.

Physically, the surface of the swab stick was corrugated, as depicted in Figure 6c. Chemically, the plasma arc reacted with the polymer, modifying the orientation of the polymer branch. It also indicated, by a specific odor, the existence of ozone during the contact of plasma and the polymer.

3.5. Surface Contact

This test was carried out to determine the behavior of the flocked surface when in contact with a liquid specimen. Two substrates were prepared which were: (i) substrate with an adhesive that was used to glue the flock material to the stick; and (ii) adhesive with flocked material. Figure 7 provides the surface contact measurement that resulted in 120° and 78° for adhesive only and adhesive with flocked material surface, respectively. The hydrophobic surface is indicated by an angle of 90–150°, whereas the hydrophilic surface is indicated by an angle of less than 90°. Thus, it can be concluded that the existence of nylon flock provides a more attractive force to the liquid specimen. This test shows adhesiveness between the glue and the microfiber. Good wetting between glue and fibers will produce a strong bond and prevent the microfiber from loosening and detaching.

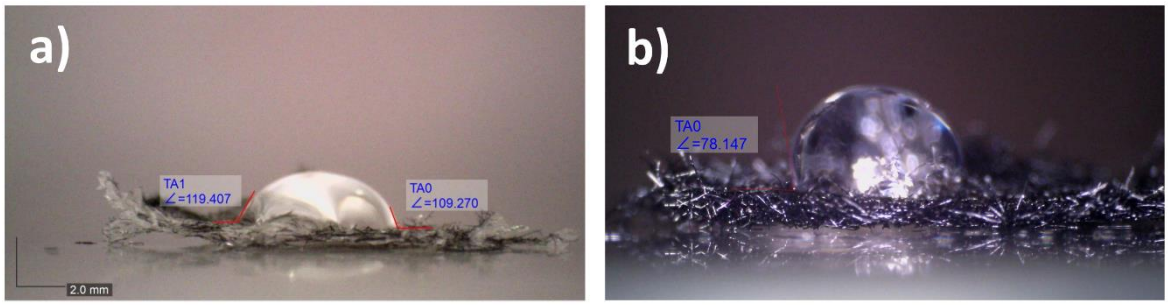

Figure 7 Surface contact measurement of: (a) adhesive; and (b) adhesive with flocked material in contact with deionized water

3.6. Water Adsorption

The flocked swab realized a capillary system formed by microfibers that surrounded the stick. We applied the Archimedes principle to measure the liquid that had adsorbed into the flocked swab. Here, we used deionized water as a simulated material to replicate biological specimens. Supplementary Figure 1 shows liquid water that is adsorbed by two specimens (b–c) compared to its initial state (a). The minus sign indicates the reduction of liquid mass from the initial point (supplementary Figure 1a). Our measurement shows that the adsorbed liquid ranged from 25–35 microliters. A swab stick will be used to obtain infected epithelial tissue in the nasopharynges by applying a swab test. The epithelial tissue dissolves in mucosa then adsorbs into the microfiber. Therefore, analysis of the adsorption capacity will indicate the success of the sampling process of an infected person.

3.7. Residue Testing

FTIR was conducted to detect the presence of contaminants in the swab stick product. Here, the liquid specimen that was previously immersing the swab stick product was compared to deionized water without any treatment as a benchmark. The residue of an organic compound might be attached to the swab stick which came from the manufacturing and handling process. Cleaning a swab stick is necessary to ensure cleanliness from residue. Since the swab stick will be inserted into nasopharynges, contaminants will affect the internal tissue with which it is in contact. Supplementary Figure 2 suggests that there is no other substance that came out from the specimen with the swab stick product. This

indicates that the whole process of injection mold-flocking is free from any unwanted substances.

During the COVID-19 pandemic, not only Indonesia but also other countries such as the United States have deemed producing alternative swabs as a critical measure. The Decker group showed the development of producing 3D printed swab sticks that also function as dacron swabs. However, the parameters that were used were similar, such as water uptake, bending capability/tensile test, and clinical performance (Decker et al., 2020). In a similar vein, Kline and colleagues also showed a simpler way of using dacron swabs, storing them in a viral medium with an accurate reading of polymerase chain reaction for COVID-19 virus detection (Kline et al., 2020).

4. Conclusions

Our fabrication process, which integrates a series of industrial lines, has been proven to produce a functional swab stick with the quality as described above. We were also able to determine a set of protocols to assure the product conformed to the design. It has been shown that the swab stick was developed using designated materials, production processes, and geometries so that they have the right stiffness properties, with a modulus of elasticity around 400 MPa. The flocked swab developed from nylon 66 has hydrophilic properties making it easier to adsorb the biological sampling process. It can adsorb liquid specimens at a range of 25–35 microliters. These qualities are comparable to those commercial swab sticks that are available on the market. Note that our production strategy uses injection molds that practically enable us to produce a higher quantity; i.e., 1 million pieces, rather than the alternative offered by 3D printed products.

Acknowledgements

We acknowledge the contribution of Dynapack Asia Pte Ltd, PT Chandra Asri Petrochemical Tbk, PT Ingress Malindo Ventures, PT Toyota Auto Body-Tokai Extrusion, PT Toyota Motor Manufacturing Indonesia, PT Langgeng Jaya Fiberindo, PT Indachi Prima, PT Sri Tita Medika, PT Cakra Manunggal Pratama, and PT Samudra Montaz. The development was supported by the Direktorat Inovasi & Science Techno Park, Universitas Indonesia.

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