# 510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
# DECISION SUMMARY

## I Background Information:

### A 510(k) Number

K211675

### B Applicant

Ningbo Dasky Life Science Co., Ltd.

### C Proprietary and Established Names

Dasky Disposable Sampling Tube (Model name: VSM02)

### D Regulatory Information

| Product Code(s) | Classification | Regulation Section | Panel |
|---|---|---|---|
| QBD | Class II | 21 CFR 866.2950 - Microbial Nucleic Acid Storage and Stabilization Device | MI - Microbiology |

## II Submission/Device Overview:

### A Purpose for Submission:

To obtain a substantial equivalence determination for the Dasky Disposable Sampling Tube (Model name: VSM02), for the collection, transport and storage of unprocessed samples suspected of containing SARS-CoV-2 virus to the laboratory for downstream testing.

### B Measurand:

Storage and stability of nucleic acids from SARS-CoV-2 virus.

### C Type of Test:

Microbial nucleic acid storage and stabilization device

## III Intended Use/Indications for Use:

### A Intended Use(s):

See Indications for Use below.

### B Indication(s) for Use:

The Dasky Disposable Sampling Tube (Model name: VSM02) is intended for the stabilization, transportation and inactivation of infectious unprocessed nasopharyngeal specimen samples suspected of containing SARS-CoV-2. These devices can be used for collection transport and storage of specimens from the collection site to the laboratory. The specimens collected and stored in a Dasky Disposable Sampling Tube (Model name: VSM02) are suitable for use with compatible laboratory based molecular diagnostic devices.

### C Special Conditions for Use Statement(s):

For prescription use only.

### D Special Instrument Requirements:

None

## IV Device/System Characteristics:

### A Device Description:

The Dasky Disposable Sampling Tube (Model name: VSM02) consists of a plastic transport tube with media which is supplied alone or in a kit with a nasopharyngeal (NP) swab, and an optional biosafety bag. The plastic transport tube contains 3 mL of the stabilization media. The components of the media are intended to inactivate SARS-CoV-2 virus, lyse the cells, disrupt/lyse the lipid membranes and denature proteins for storage of the specimen between 39 ºF and 73 ºF (4 ºC - 23 ºC). The media is sold in the following configurations.

- A plastic screw-cap tube filled with 3 mL of Dasky Disposable Sampling Tube media.
- A plastic screw-cap tube filled with 3 mL of Dasky Disposable Sampling Tube media and a NP nylon flocked swab for sample collection.

### B Principle of Operation:

The Dasky Disposable Sampling Tube (Model name: VSM02) contains nucleic acid preservation media, which contains a high concentration of guanidinium salt and nucleic acid stabilizer. After the collected virus sample is thoroughly mixed with the media, the virus (or other pathogens) will be rapidly inactivated, lysed and the nucleic acid will be released. Nucleic acid stabilizers in the liquid protect the released nucleic acids (RNA) from degradation by RNase. The specimen processed by this collection tube can be used with compatible nucleic acid extraction and amplification platforms.

The media contains the following reagents:

- Tris

- Protease K
- Guanidine hydrochloride
- Dithiothreitol
- Triton X-100
- Distilled water

## V Substantial Equivalence Information:

### A Predicate Device Name(s):
DNA/RNA Shield Collection Tube

### B Predicate 510(k) Number(s):
K202641

### C Comparison with Predicate(s):

| **Device & Predicate Device(s):** | Device: K211675 | Predicate: K202641 |
|---|---|---|
| Device Trade Name | Dasky Disposable Sampling Tube (Model name: VSM02) | DNA/RNA Shield Collection tube |
| **General Device Characteristic Similarities** | | |
| Intended Use/Indications For Use | The Dasky Disposable Sampling Tube (Model name: VSM02) is intended for the stabilization, transportation and inactivation of infectious unprocessed nasopharyngeal specimen samples suspected of containing SARS-CoV-2. These devices can be used for collection transport and storage of specimens from the collection site to the laboratory. The specimens collected and stored in a Dasky Disposable Sampling Tube (Model name: VSM02) are suitable for use with compatible laboratory based molecular diagnostic devices. | The DNA/RNA Shield collection tube is intended for the stabilization and inactivation of upper and lower respiratory human specimens suspected of containing SARS-CoV-2.<br>These devices can be used for collection transport and storage of specimens at ambient temperatures (20-25°C).<br>Specimens collected and stored in a DNA/RNA Shield collection tube are suitable for use with legally marketed molecular diagnostic devices. |
| Microorganism nucleic acids preserved | Same | SARS-CoV-2 |
| Container | Same | Tube, plastic, screw cap vials |
| Medium Volume | 3 mL | 1 mL, 2 mL |
| Special conditions for use | Same | 1. For in vitro diagnostic use only<br>2. For Prescription Use only |
| Sample source | Same | Human respiratory |
| **General Device Characteristic Differences** | | |
| RNA stabilization at refrigeration | 144 hours (4°C) | no refrigeration claims |
| RNA | 48 hours (23°C) | 28 days |

| | | |
|---|---|---|
| stabilization at ambient temperature | | |
| Specimen Type | Nasopharyngeal specimens for SARS-CoV-2. | Lower and Upper Respiratory Specimens for SARS-CoV-2. |
| Analyte | RNA | RNA and DNA |
| Shelf life | 1 year | 2 years |

## VI Standards/Guidance Documents Referenced:

Special controls that are applicable to regulation 21 CFR 866.2950.

## VII Performance Characteristics (if/when applicable):

### A Analytical Performance:

1. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

**Shelf life:** The Shelf-life for the Dasky Disposable Sampling Tube (Model name: VSM02) is 1 year after the date of manufacture. The stability of the Dasky Disposable Sampling Tube (Model name: VSM02) was performed using Realtime stability study on a total of 9 samples (3 Lots). The item appearance inspection, pH detection, RT-PCR test, virus inactivation efficiency detection and Limit of detection are considered as the factor of evaluation.

**Sterilization:** The Dasky Disposable Sampling Tube (Model name: VSM02) with media are not sold as sterile nor are they intended to be sterilized by the user. These vials are single use devices that do not require cleaning by the operator.

2. Detection Limit:

a) LoD

The detection limit of SARS-CoV-2 nucleic acid (RNA) in 3 mL media in the Dasky Disposable Sampling Tube (Model name: VSM02) was determined. The detection limit concentration was verified to ensure that SARS-CoV-2 RNA could be repeatedly recovered from the disposable sample tube at the lowest detection concentration with an accuracy greater than 95%.

LoD testing was conducted by spiking multiple volume of SARS-CoV-2 virus with a titer of $10^5$ Genomic Copy Equivalents (GCE)/mL (determined by real-time qPCR) into clinical NP swab matrix collected from individuals who tested negative for SARS-CoV-2, and then using the NP swab to transfer the virus sample into 3 mL of media in the Dasky Disposable Sampling Tube (Model name: VSM02) to achieve the final concentration of 63 GCE/mL, 70 GCE/mL, $1x10^2$ GCE/mL, $3x10^2$ GCE/mL, $1x10^3$ GCE/mL and $1x10^4$ GCE/mL, for each of the 20 tubes/lot for three lot.

Purified RNA was extracted from 200 µL samples by using MagMAX Viral/Pathogen Nucleic Acid Isolation Kit manufactured by Thermo Scientific. RT-PCR was performed

on the ABI7500 using the EUA-authorized TaqPath COVID-19 Combo kit of Thermo Scientific.

~78% detection (viral targets $C_t$ values are <37) of the SARS-CoV-2 RNA was observed in samples at 63 GCE/mL (16/60 replicates). The detection of the SARS-CoV-2 at all other higher concentrations:$1x10^4$ GCE/mL, $1x10^3$ GCE/mL, $3x10^2$ GCE/mL, $1x10^2$ GCE/mL and 70 GCE/mL resulted in 60/60 replicates. The LoD testing results are summarized in Table 1:

Table 1. LoD testing

| **GCE/mL** | **Total #** | **Positive #** | **Mean $C_t$** | | |
|---|---|---|---|---|---|
| | | | **ORF1ab** | **N gene** | **S gene** |
| $10^4$ | 60 | 60 | 20.94 | 21.08 | 21.04 |
| $10^3$ | 60 | 60 | 24.23 | 23.99 | 24.12 |
| 3x $10^2$ | 60 | 60 | 26.70 | 26.95 | 26.93 |
| $10^2$ | 60 | 60 | 29.95 | 30.04 | 30.29 |
| **70** | **60** | **60** | **32.84** | **32.82** | **33.94** |
| 63 | 60 | 47 | 36.13 | 36.04 | 35.89 |

In summary, the LoD testing at 70 GCE/mL resulted in 60/60 replicates for NP swabs, which meet the pre-defined acceptance criteria for NP swabs.

b) Specimen stability

The specimen stability study was conducted by spiking 4.5 µL of SARS-CoV-2 virus at 1x $10^5$ GCE/mL into the clinical NP swab specimen collected from individuals who tested negative for SARS-CoV-2, then using the NP swab to transfer the virus sample into the Dasky Disposable Sampling Tube (Model name: VSM02) contianing 3 mL media to achieve the final concentration of the samples at 150 GCE/mL (2.1x LoD).

Three Dasky Disposable Sampling Tube (Model name: VSM02) of each lot (Lot 20100732-01, Lot 21060732-02 and Lot 21121032-01) were tested by RT-PCR and served as $T_0$; The measured $C_t$ values for the samples stored at 23℃ for at least 48 hours or at 4℃ for at least144 hours and were defined as $T_{23->48}$ and $T_{4->144}$, respectively. Purified RNA was extracted from 200 µL samples by MagMAX Viral/Pathogen Nucleic Acid Isolation Kit manufactured by Thermo Scientific. RT-PCR was performed on the ABI7500 using the EUA-authorized TaqPath COVID-19 Combo kit of Thermo Scientific. The deviation between $C_t$ measurement value and initial $C_t$ measurement value of different storage time is less than 2. The results for the specimen stability study are summarized in Table 2.

Table 2. Specimen Stability

| Lot No. | Storage condition | Replicate | $C_t$ | | | Interpretation | % Positive |
|---|---|---|---|---|---|---|---|
| | | | ORF1ab | N gene | S gene | | |
| 20100732-01 | $T_0$ | 1 | 28.6 | 28.7 | 28.4 | Positive | 100% |
| | | 2 | 29.7 | 29.6 | 29.2 | Positive | |
| | | 3 | 28.3 | 28.2 | 28.1 | Positive | |

| | | | | | | |
|---|---|---|---|---|---|---|
| | $T_{23->48}$ | 1 | 30.9 | 30.1 | 30.3 | Positive |
| | | 2 | 30.5 | 30.9 | 29.8 | Positive |
| | | 3 | 29.9 | 29.3 | 29.9 | Positive |
| | $T_{4->144}$ | 1 | 29.0 | 29.4 | 29.0 | Positive |
| | | 2 | 30.7 | 30.1 | 29.5 | Positive |
| | | 3 | 29.8 | 30.1 | 30.9 | Positive |
| 21060732-02 | $T_0$ | 1 | 29.1 | 29.2 | 28.8 | Positive |
| | | 2 | 29.0 | 30.5 | 29.8 | Positive |
| | | 3 | 28.3 | 28.7 | 29.6 | Positive |
| | $T_{23->48}$ | 1 | 29.2 | 28.9 | 29.8 | Positive |
| | | 2 | 29.4 | 29.8 | 30.5 | Positive |
| | | 3 | 28.5 | 29.6 | 29.9 | Positive |
| | $T_{4->144}$ | 1 | 29.8 | 29.5 | 29.0 | Positive |
| | | 2 | 29.2 | 29.0 | 29.5 | Positive |
| | | 3 | 30.2 | 30.5 | 30.9 | Positive |
| 21121032-01 | $T_0$ | 1 | 28.1 | 28.9 | 29.7 | Positive |
| | | 2 | 29.8 | 28.7 | 28.3 | Positive |
| | | 3 | 28.1 | 29.5 | 29.8 | Positive |
| | $T_{23->48}$ | 1 | 30.0 | 30.9 | 29.7 | Positive |
| | | 2 | 29.3 | 29.8 | 28.7 | Positive |
| | | 3 | 29.0 | 28.3 | 29.5 | Positive |
| | $T_{4->144}$ | 1 | 29.4 | 29.0 | 29.3 | Positive |
| | | 2 | 29.1 | 29.4 | 29.6 | Positive |
| | | 3 | 29.4 | 29.3 | 29.1 | Positive |

The deviation between the initial $C_t$ measurement value and the $C_t$ measurement value of samples stored at either 23℃ for a minimum of 48 hours or 4℃ for a minimum of 144 hours is less than 2 $C_t$. The results demonstrated acceptable RNA stabilization at 23℃ for 48 hours or 4℃ for 144 hours.

c) Inactivation

Three batches of the Dasky Disposable Sampling Tube (Model name: VSM02) were used for inactivation assessment. In the experimental group, 30 µL SARS-CoV-2 virus at $1x10^5$ GCE/mL was added to clinical NP swab specimen collected from individuals who tested negative for SARS-CoV-2 virus, and then then using the NP swab to transfer the virus sample into the Dasky Disposable Sampling Tube (Model name: VSM02) containing 3 mL of media to achieve $1x10^3$ GCE/mL. In the control group, 30 µL SARS-CoV-2 virus with a titer of $1x10^5$ GCE/mL was added to clinical NP swab specimen collected from individuals who tested negative for SARS-CoV-2, and then then using the NP swab to transfer the virus sample into 3 mL PBS (phosphate buffered saline). The experimental group and the control group were incubated at room temperature for five (5) minutes. After 5 minutes, the samples of the experimental group and the control group were diluted 1:1000 with ultrapure water; 30 µL of diluted samples from the experimental group and control group were used to infect Vero-E6 cells (the cells were grown in a 96-well plates for 24 hours. prior to infection). After 4 days of infection, the morphology of

the cells was observed under an electron microscope to determine the cytological changes. By observing the cell morphology of the infected Vero-E6 cells, it was found that the virus in the control group could infect Vero-E6 cells. For the experimental group, the virus was inactivated and was no longer able to infect Vero-E6 cells after exposure to the media in the Dasky Disposable Sampling Tube (Model name: VSM02) for 5 minutes. The intact morphology of the cells could be observed under the microscope. The results for the specimen stability study were summarized in Table 3.

Table 3. Virus inactivation assessment

| Sample type (SARS-CoV-2 virus at 1x $10^3$ GCE/mL) | Test number | LOT No. | | |
|---|---|---|---|---|
| | | 20100732-01 | 21060732-02 | 21121032-01 |
| | | Inactivation results | | |
| Experimental group | 1# | uninfected | uninfected | uninfected |
| | 2# | uninfected | uninfected | uninfected |
| | 3# | uninfected | uninfected | uninfected |
| Control group | 1# | infected | infected | infected |

In the Inactivation efficiency test, three lots of media in the Dasky Disposable Sampling Tube (Model name: VSM02) were evaluated. For the SARS-CoV-2 virus at the concentration of 1x $10^3$ GCE/mL, it can be 100% inactivated at a minimum of 5 minutes in the Dasky Disposable Sampling Tube (Model name: VSM02).

## VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

## IX Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.