CLINICAL STUDY REPORT SYNOPSIS

Name of Manufacturer: PAMA Manufacturing	Individual Study Table Referring to Part of the Dossier Volume: Page:	*(For National Authority Use Only)*
Name of Device: SWB-0007 (nasopharyngeal swab)		
Name of Active Ingredient: Not applicable to this study		

TITLE OF STUDY:

Clinical Safety and Effectiveness of Novel Canadian Manufactured Nasopharyngeal Swabs for Collection of Samples being Tested for SARS-CoV-2 in a Pandemic Setting

INVESTIGATOR:

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STUDY CENTER(S):

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STUDIED PERIOD:	**PHASE OF DEVELOPMENT:**
Date first Enrollment: 08 February 2021 **Date of Last Enrollment:** 25 February 2021	Not applicable as this was a feasibility study.

PRIMARY OBJECTIVE:

The primary objective of this study was to determine whether the newly designed and manufactured nasopharyngeal swab (NP swabs) (test swabs) were comparable to commercially available flocked swabs (control swabs) with respect to user characteristics, ability to collect a specimen, and test results agreement.

METHODOLOGY:

This feasibility study used a single-arm design, in which patients under investigation (PUIs) were self-controlled. As part of the clinical assessment of COVID-19, PUIs were screened and informed consent signed prior to any study-related swab procedures being performed. PUIs that consented to this study were swabbed according to standard practice and procedural order determined through randomization. PUIs were swabbed with a commercially available flocked swab in one nostril and with the test swab into the opposite nostril for sample specimen collection. The order in which the NP swabs were inserted into the left or right nostril (either test or control swab) was randomized. Molecular RT-PCR testing was performed as per testing protocol.

NUMBER OF PATIENTS ANALYZED:

Eighty-six (86) PUIs were enrolled in this study and randomized according to first swab/first nostril as follows: 21 Control/Left, 22 Control/Right, 21 Test/Left, 21 Test/Right.

ELIGIBILITY:

Criteria for Inclusion:

PUIs were eligible to be included in the study only if <u>all</u> of the following criteria applied:

1. Male or female adult ≥ 18 years of age at the time of informed consent.
2. Inpatient or outpatient presenting to a SARS-CoV-2 testing center for testing.
3. ≥ 2 days since the onset of symptoms (fever, respiratory symptoms, dry cough, etc.).
4. Willing and able to give informed consent for participation in the study.

Criteria for Exclusion:

1. Known to have a bleeding disorder and/or low platelet count (thrombocytopenia of <50,000 platelets/μL to avoid risk of mild bleeding).
2. Taking a systemic anticoagulant.
3. Deviated septum significant enough to prevent insertion of the NP swab into each of the nostrils.

IDENTITY OF INVESTIGATIONAL PRODUCTS:

Table 1. Identity of Test and Control products

Product	Test Product	Control Product
Treatment ID	Batch #1	Batch #1
Product Name	SWB-0007	Norgen iClean Swab® part number CM-96000
Manufacturer	PAMA Manufacturing	Norgen Biotek Corp
Lot No.	#P200835A	#20160060
Manufacture Date	Not Available	23/04/2020
Expiration Date	27/08/2023	22/04/2023
Route of Administration	Nasopharyngeal	Nasopharyngeal

CRITERIA FOR EVALUATION:

The primary endpoints of this study were:

- **Diagnostic RT-PCR test performance agreement**: For each result, the cycle threshold (Ct) value and patient symptomatology was reported (success criteria: ≥ 90% positive % agreement, when a composite control was used).
- **Ability to collect a specimen (RNase P):** For each RT-PCR test result, Ct values for the target SARS-CoV-2 viral gene and housekeeping gene (RNase P) was reported (success criteria: no statistically significant difference between RNase P levels measured from test and control swabs).
- **Usability:** For each PUI, qualitative assessments (i.e. flexibility, fit, ability to navigate to the nasopharynx) of both the test and control swabs was reported, presented and compared in tabular format.

There were no safety endpoints as this was a feasibility study.

STATISTICAL METHODS AND RESULTS:

Analyses were conducted for the NP test swab compared to the NP control swab. Demographic data was summarized using descriptive statistics (Table 2). Descriptive statistics was presented as a number (%) for categorical variables and number, mean ± standard deviation (SD), median.

Table 2. Subject Disposition

	ALL
Characteristic	**N = 86**
Age (years)	
Mean (SD)	37 (12)
Median (IQR)	36 (29, 45)
Range	18, 64
Sex	

Male	42 / 86 (49%)
Female	44 / 86 (51%)
Participant Recruitment	
Inpatient	0 / 86 (0%)
Outpatient	86 / 86 (100%)

Diagnostic RT-PCR Test Performance Agreement

Positive percent agreement, negative percent agreement and associated 95% confidence interval (CI) for positive agreement were calculated to assess diagnostic performance. A calculated positive percent agreement ≥ 90% was considered a success. Positive percent agreement was the percentage of control NP swab positive results in which the test NP swab result was positive. Negative percent agreement was the percentage of control NP swab negative results in which the test NP swab result was negative (Table 3 and Table 4).

Table 3. Test Performance Agreement Results

Test Swab Result	**Control Swab Result n(%)**			
	Positive N = 33	**Negative N= 52**	**Inconclusive N = 1**	**Invalid N = 0**
Positive	31 (94.0%)	0 (0%)	0 (0%)	0 (0%)
Negative	2 (6.1%)	51 (98.0%)	1 (100.0%)	0 (0%)
Inconclusive	0 (0%)	1 (1.9%)	0 (0%)	0 (0%)
Invalid	0 (0%)	0 (0%)	0 (0%)	0 (0%)

Table 4. Test Performance Agreement Pass/Fail Results

# Control Positive Results	33
# Test Positive Results	31
% Agreement	93.90%
95% LB	82.40%

Ability to Collect a Specimen (Ct and RNase P)

The ability to collect a specimen was compared between the test NP swab and control NP swab for all patients that tested positive for SARS-CoV-2 on the control swab using a paired analysis approach performed separately for both the target SARS-CoV-2 viral gene (Table 5) and the housekeeping gene (RNase P) (Table 6). The test and control NP swabs were considered similar in their ability to pick up a sample if the absolute RNase P mean Ct difference was ≤ 2.

Table 5. Summary Ct Values for Control Positive Diagnosis Test

# Total Positive Results	N = 31
Control Swab	23.3 (4.67)
Test Swab	23.4 (4.92)
Difference (C-T)	-0.1 (4.27)
95% CI for Difference	[-1.7, 1.5]

*Values are mean (standard deviation) based on 31 cases with a positive control and test PCR result

Table 6. Summary RNaseP Values for Control Positive Diagnosis Test

# Total Positive Results	N = 33
Control Swab	27.8 (3.64)

Test Swab	29.3 (3.24)
Difference (C-T)	-1.5 (3.00)
95% CI for Difference	[-2.6, -0.4]

*Values are mean (standard deviation) based on 33 cases with a positive control

Usability

The usability analysis compared flexibility, fit, and ability to navigate to the nasopharynx of both the test and control swabs (Table 6 and Table 7).

Table 6. Qualitative Assessment

	All
Assessment	**N = 86**
Comparable Flexibility	
Yes	86 / 86 (100%)
Comparable Fit	
No	1 / 86 (1.2%)
Yes	85 / 86 (99%)
Comparable Nasopharynx Navigation	
No	1 / 86 (1.2%)
Yes	85 / 86 (99%)

Table 7. List of Qualitative Assessment Descriptions

Assessment	**N = 86**
Comparable Flexibility	
NA	86 / 86 (100%)
Comparable Fit	
Control swab has better adjustment	1 / 86 (1.2%)
NA	85 / 86 (99%)
Comparable Nasopharynx Navigation	
NA	85 / 86 (99%)
Patient's nostril has a small size	1 / 86 (1.2%)

All statistical analyses were performed using R version 4.0.2

CONCLUSIONS:

Diagnostic RT-PCR Test Performance Agreement: A calculated positive percent agreement ≥ 90% was considered a success. The actual positive percent agreement was 93.90%. Therefore the test NP swab PASSED.

Ability to Collect a Specimen (RNase P): The test and control NP swabs were considered similar in their ability to pick up a sample if the absolute RNase P mean Ct difference was ≤ 2. The actual absolute mean Ct difference was -0.1 (4.27) and -1.5 (3.0) for the RnaseP. Therefore the test NP swab PASSED.

Usability: There was no major flexibility, fit, or navigation of the nasopharynx issues.

The SWB-0007 nasopharyngeal swab manufactured by PAMA Manufacturing is comparable to commercially available flocked swabs with respect to user characteristics, ability to collect a specimen, and test results agreement.

DATE OF REPORT: 26 March 2021 Final Version 1.0

INVESTIGATOR SIGNATURE PAGE

Clinical Safety and Effectiveness of Novel Canadian Manufactured Nasopharyngeal Swabs for Collection of Samples being Tested for SARS-CoV-2 in a Pandemic Setting

I confirm that I have read this clinical study report synopsis. To the best of my knowledge, it accurately describes the conduct and results of the study in accordance with the appropriate guidelines and all applicable federal government codes, acts and regulations, GCP requirements and ICH guidance on Good Clinical Practice.

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Signature  Date 26th March 2021