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CLINICAL PROGRAM UPDATE: TWO KEY STUDIES CONFIRM RHINOSWAB SUPERIOR PERFORMANCE

TOPLINE

- **Nasal Swab Yield study (n=394) confirms Rhinoswab captures statistically significant larger sample than standard of care nasal swab**
- **Elution Efficiency study confirms Rhinoswab delivers superior elution efficiency when compared to standard of care nasal swab.**

May 13, 2021: Melbourne, Australia.
Rhinomed Limited (ASX:RNO; OTCQB:RHNMF) a leader in wearable nasal and respiratory technology is pleased to report an important update on its Rhinoswab™ clinical program.

In December 2020 the company established that the Rhinoswab was comparable to existing standard of care nasal swabs in detecting the SARS-CoV-2 virus in RT-PCR testing. This study was undertaken at the VIDRL (Peter Doherty Institute).

Since December the company has further refined the swab technology by improving the nylon flock used on the swab. Two studies have now been completed to assess the performance of the Rhinoswab against the current commercially available standard of care nasal swab (Copan eSwab™).

Both studies have now confirmed that the Rhinoswab outperforms the standard of care nasal swab (Copan eSwab™) in two critical key performance factors: capture (yield) and elution efficiency.

Rhinomed's new Rhinoswab has recently been approved for sale in the Australian market and is listed on the ARTG and in the US with the FDA. The Rhinoswab standardises the collection process and makes nasal sampling easy and comfortable for users. With production underway in Melbourne, Australia the company is seeking to scale up in order to meet demand. More information on the Rhinoswab is available at https://www.rhinomed.global/about-rhino-med/sample-collection/

NASAL SWAB YIELD STUDY

The objective of the Nasal Swab Yield Study was to compare the mean absorption/sample capture performance of the Rhinoswab against the commercially available standard of care nasal swab (Copan eSwab™) at various insertion time points.

Methodology

A randomised trial was conducted where 394 samples were collected from participants over a six week period. Participants were swabbed twice a day with a minimum of five hours between each sample collection. Participants were randomly assigned a nasal swab. Each swab was weighed prior to use and then weighed again post use using a calibrated Sartorius analytical scale.

- Participants were instructed to insert the standard of care nasal swab (Copan eSwab™) according to the manufacturer's Instructions for Use (15 seconds, each nostril).
- Participants were asked to insert the Rhinoswab according to the Rhinoswab Instructions for Use. Participants were randomly assigned one of three different time periods for insertion - 15 seconds, 60 seconds and 120 seconds.

Results

The results of the study are displayed below.

Swab	Insertion time period	Mean (g)	95% CI range	
Standard of Care (Copan eSwab™)	15 secs each nostril	0.0278	0.0231	0.0324
Rhinoswab	15 secs	0.0408	0.0341	0.0475
Rhinoswab	60 secs	0.0437	0.0369	0.0506
Rhinoswab	120 secs	0.0496	0.0417	0.0575

Conclusion

All Rhinoswabs captured a mean sample larger than the standard of care (Copan eSwab™) across all insertion time periods - 15 seconds, 60 seconds and 120 seconds.

	Standard of Care (Copan eSwab)	Rhinoswab	Performance improvement
15 seconds insertion each nostril	0.0278g		
15 seconds insertion		0.0408g	1.47 times greater than standard of care swab
60 seconds insertion		0.0438g	1.57 times greater than standard of care swab
120 seconds insertion		0.0496g	1.78 times greater than standard of care swab

This study provides statistically powered evidence that the Rhinoswab, in addition to its comfort, ease of use and standardised sample collection procedure, captures a statistically larger sample from the nose than standard of care nasal swab (Copan eSwab™).

EVALUATION OF RHINOSWAB ELUTION EFFICIENCY

Independent laboratory, Gnomix (Adelaide, Australia) was engaged to compare the elution efficiency of the Rhinoswab™ compared to the standard of care nasal swab (Copan eSwab™).

Methodology

An aliquot of gamma-irradiated (inactivated) SARS-CoV-2 virus (strain VIC/01/202) was received from the Victorian Infectious Diseases Reference Laboratory (VIDRL) with a nominal CT value of 18 (assay dependent). The SARS-CoV-2 virus was diluted 1/200 in a stock solution of donated saliva to represent a high virus burden sample and 1/2000 in to represent a low virus burden sample.

Two protocols were followed.

1. To reflect the standard of care, the high and low virus burden samples were applied as 4 x 5µl spots (20µl) onto 10 Rhinoswabs™ and 5 standard of care nasal swab (Copan eSwab™).
2. To evaluate the inherently greater potential capture area of the Rhinoswab™ in comparison to the standard of care nasal swab (Copan eSwab™) 4 x 8µl spots (32µl) were applied onto 10 Rhinoswabs™.

In both instances each swab was then placed into a 5ml tube containing 1ml of Saline, vortexed vigorously for 30 seconds and left to elute for 1 hour at room temperature. Standard curve samples were prepared by spiking 32µl, 20µl, 15µl, 10µl and 5µl of the respective high and low virus burden samples into a 5ml tube containing 1ml of Saline, vortexed vigorously for 30 seconds and left to sit for 1 hour at room temperature.

Assay

Following elution, 140µl of eluate was extracted using the QIAamp Viral RNA Mini Kit (QIAGEN) according to the manufacturer's instructions. The QuantiNova IC RNA was included in all samples as an extraction control. Reverse transcription and qPCR were performed using the QuantiNova Pathogen +IC Kit (QIAGEN) in combination with the SARS-CoV-2 N1+N2 assay kit (QIAGEN) according to the manufacturer's instructions. A 6µl volume of input viral RNA was used in the QuantiNova Pathogen Assay and thermal cycling was performed on a Rotorgene Q qPCR instrument using the conditions in the QuantiNova Pathogen +IC Kit handbook. The QuantiNova IC RNA, extraction negative control and PCR negative control were included on each run.

Results:

Standard load

1. **20µl at High Virus burden**

   Sample loading of 20µl of the high virus burden sample yielded an average of 16.34µl recovery (82%) for the Rhinoswab™ and an average of 14.5µl (73%) for the comparable standard of care nasal swab (Copan eSwab™). This suggests a superior elution efficiency for the Rhinoswab™ when comparing identical initial loadings of the high virus burden sample.

	High Virus Burden 20 µl (1ml Elution) Average Ct	Average µl recovered
Rhinoswab™	25.45 (+/- 0.24)	16.34 µl (82%)
Standard of Care nasal swab (Copan eSwab™)	25.75 (+- 0.43)	14.50 µl (73%)

20µl at Low Virus burden

Sample loading of 20µl of the low virus burden sample yielded an average of 21.8µl recovery (~100% taking into account experimental deviation) for the Rhinoswab™ and an average of 14.5µl (73%) for the comparable standard of care nasal swab (Copan eSwab™). This suggests superior elution efficiency for the Rhinoswab™ when comparing identical initial loadings of the low virus burden sample.

	Low Virus Burden 20 µl (1ml Elution) Average Ct	Average µl recovered
Rhinoswab™	29.15 (±0.24)	21.80 µl (~100%)
Standard of Care nasal swab (Copan eSwab™)	30.39 (±1.03)	17.33µl (87%)

2. **Greater load potential**

32µl at High Virus burden

A sample loading of 32µl of the high virus burden on the Rhinoswab™ was also tested to evaluate the inherently greater potential capture area of the Rhinoswab™ in comparison to the standard of care nasal swab (Copan eSwab™). This yielded an average of 21.0µl recovery (66%) for the Rhinoswab™. This indicates that it is possible to recover more virus from the extra loading capacity, although there appears to be slightly diminished overall efficiency.

	High Virus Burden 32 µl (1ml Elution) Average Ct	Average µl recovered
Rhinoswab™	24.94 (±0.17)	21 µl (66%)

32µl at Low Virus burden

A sample loading of 32µl of the low virus burden on the Rhinoswab™ was also tested to evaluate the inherently greater potential capture area of the Rhinoswab™ in comparison to the Standard of Care nasal swab (Copan eSwab™). This yielded an average of 28.7µl recovery (90%) for the Rhinoswab™. This indicates that it is possible to recover more virus from the extra loading capacity, although there appears to be slightly diminished overall efficiency.

	Low Virus Burden 32 µl (1ml Elution) Average Ct	Average µl recovered
Rhinoswab™	28.5 (±0.49)	28.7 µl (90%)

Conclusion

Under the conditions tested and with the materials supplied, the Rhinoswab™ demonstrated not only a comparable but also a superior elution efficiency to the commercially available Standard of Care nasal swab (Copan eSwab™).

This report has been authorised for release to the market by the Board.

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Rhinomed Global (https://www.rhinomed.global) is an Australian-based medical technology company with a patented nasal technology platform whose first products are used by consumers in the global sleep, respiration, and nasal congestion markets. These products, sold at major US retailers, support the development, acceptance, and adoption of a pipeline of future wearable, sensor, diagnostic, and drug delivery opportunities. The company has recently secured FDA class 1 registration for its Rhinoswab, a dual nostril swab designed to collect nasal specimens for diagnostic testing for respiratory diseases, particularly COVID-19.

Since its formation six years ago, Rhinomed has built the necessary foundation to accelerate its already increasing revenue growth. The company trades on the **ASX:RNO** and the **OTCQB:RHNMF**