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RHINOSWAB DETECTS SARS-CoV-2 IN DOHERTY INSTITUTE RT-PCR STUDY

- **Study undertaken at the Victorian Infectious Disease Laboratory (VIDRL), part of The Peter Doherty Institute for Infection and Immunity (The Doherty) met its key end point of establishing that the Rhinomed swab is comparable to standard of care nasal swabs.**
- **Study established 100% category detection of SARS-CoV-2 for the Rhinomed swab (Rhinoswab).**
- **No difference in the mean Ct value for detection of SARS-CoV-2 at both low and high virus burdens.**
- **Rhinoswab is comparable to standard of care swab in its ability to diagnose SARS-CoV-2 with RT-PCR.**

December 14, 2020 Melbourne, Australia.
Rhinomed Limited (ASX:RNO OTCQB:RHNMF), a leader in nasal airway and respiratory technology, is pleased to report positive data from its lab-based spiking study of Rhinomed's new Rhinoswab conducted at the Victorian Infectious Diseases Reference Laboratory (VIDRL), part of The Peter Doherty Institute for Infection and Immunity (The Doherty) in Melbourne.

The study's objective was to demonstrate efficacy in detecting the SARS-CoV-2 virus at both low and high viral loads.

The study assessed how well the Rhinoswab performed in transferring a viral load for testing when compared to commercial comparators. It considered the amount of virus the swab was subjected to, as well as how well the swab could elute the acquired viral load for adequate testing by a PCR device.

The eluted volume from the Rhinoswab was found to be comparable to the commercially available Copan eSwab when artificially dipped into a neat saliva solution spiked with inactivated SARS-CoV-2, at both high and low virus burdens. The relative maximal volume recovered was also comparable between the devices.

The results showed that there were no statistical differences between the mean Ct values at the two viral concentrations obtained from both swabs when fully immersed in a viral solution, and that both swabs reported 100% accurate diagnosis of SARS-CoV-2. This indicates that the Rhinoswab is comparable to the comparator (the Copan ESwab) in terms of its ability to diagnose Covid-19 with a PCR from full saturation.

Rhinomed CEO Michael Johnson commented, "We are delighted to have worked with VIDRL, the Doherty and Dr Julian Druce, Dr Mike Catton and their team to have confirmed that the Rhinoswab can detect SARS-CoV-2 using lab-based RT-PCR."

"This is a critical step in demonstrating that the Rhinoswab has a role to play in responding to the need for an easy to deploy, self-administered and effective sampling methodology."

"We are now reaching out to the many health systems, Covid Test developers and pathology groups for whom a comfortable, self-administered and effective swab will enable mass, high frequency testing. This response will be an important part of ensuring we can respond quickly and effectively to future Covid outbreaks."

Rhinomed is continuing its R&D program to optimise the swab and understand its utility with clinical sample collection. Further work is also seeking to assess its suitability across a range of other upper respiratory diseases including influenza.

The Study

The Doherty assessed the in vitro virus capture and recovery of virus signal of the Rhinomed dual-nostril swab device compared to the commercially available Copan eSwab using mock respiratory samples spiked with gamma-irradiated SARS-CoV-2 at two viral concentrations (low and high virus burdens) . The Rhinoswab and Copan eSwab were artificially dipped into both the high and low virus burden spiked saliva solutions and eluted into 1mL of saline following maximal saturation.

The results showed that both the Rhinoswab device and Copan eSwab performed equivalently following the artificial dipping into the SARS-CoV-2 solution and then eluted in 1mL saline. All negative Rhinoswab devices that were dipped into neat saliva gave negative results by RT-PCR as expected.

The Doherty concluded that the eluted volume from the Rhinoswab device was comparable to the commercially available Swab when artificially dipped into a neat saliva solution spiked with inactivated SARS-CoV-2, at both high and low virus burdens.

The average Ct values from the in-house RT-PCR targeting Helicase are shown in the table below.

	Low virus Burden, 1mL elution CT Average	**High virus Burden, 1mL elution CT Average**
Rhinoswab by Rhinomed	29.5	26.4
Copan eswab	29.4	26.0

In a second experiment a high virus burden solution was applied as 4 x 5µL (VT=20µL) onto both the Rhinoswab (n=10) and Copan eSwab (n=5) and eluted into 1mL, 2mL or 3mL saline. The results of this experiment showed that when 20µL of the same neat saliva high virus burden solution was applied directly to each device as 4 x 5µL amounts, the Copan eSwab eluted more efficiently across all elution volumes in saline. Better recovery from the Rhinoswab device was observed in the larger elution volumes, with the 3mL volume yielding the best recovery.

Both swabs showed 100% detection of the virus at all media volumes when tested using rt-PCR.

1mL elution	Mean Ct (+/- SD)
Rhinoswab 20µL at Ct=26,	30.8 (+/- 0.61)
E-Swab 20µL at Ct=26,	28.2 (+/- 0.06)

2 mL Elution	Mean Ct (+/- SD)
Rhinoswab 20µL at Ct=26,	30.6 (+/- 0.42)
E-Swab 20µL at Ct=26,	28.5 (+/- 0.43)

3 mL Elution	Mean Ct (+/- SD)
Rhinoswab 20µL at Ct=26,	30.3 (+/- 0.26)
E-Swab 20µL at Ct=26,	28.8 (+/- 0.13)

Conclusions

The eluted volume from the Rhinoswab device was comparable to the commercially available Copan eSwab when artificially dipped into a neat saliva solution spiked with inactivated SARS-CoV-2, at both high and low virus burdens. The relative maximal volume recovered was also comparable between the devices.

The results showed that there were no statistical differences between the mean Ct values at the two viral concentrations obtained from both swabs when fully immersed in a viral solution, and that both swabs reported 100% accurate diagnosis of SARS-CoV-2. This indicates that the Rhinomed nasal swab is comparable and on par to the competitor, Copan ESwab in terms of ability to diagnose Covid-19 with a PCR from full saturation.

This announcement has been authorised for release by the Board.

Media Enquiries
Michael Johnson, CEO & Director
+61 (03) 8416 0900
mjohnson@rhinomed.global
Follow us on **Twitter** @rhinomedceo and @theturbinecom

Rudi Michelson, Monsoon Communications
+61 (0)411 402 737
rudim@monsoon.com.au

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**