

The following questions and answers have been signed off by Ministry of Health

30 June 2021

Questions and answers on Rako Science's COVID-19 PCR saliva test

Is the Rako Science saliva test a PCR test?

Yes. It is a Real Time Quantitative Polymerase Chain Reaction (RT-qPCR) assay using the Thermo Fisher COVID-19 TaqPath Assay.

How did Rako Science validate its saliva test?

Rako Science obtained 101 saliva samples from the University of Illinois paired with contemporaneously collected nasopharyngeal samples of which 28 were positive. A further five saliva samples were paired with contemporaneously collected mid-turbinate nasal samples. These paired samples were independently processed at Victoria University of Wellington and IGENZ in Auckland.

What is the accuracy of the Rako Science saliva test in comparison with nasopharyngeal tests?

Rako Science's validation study found a limit of detection of < 1 viral copy per microlitre saliva and a 98.0% accuracy (concordance) with nasopharyngeal samples. The failure of both the NP and saliva qPCR test to detect one positive sample each is likely due to differences in the virus replication at different sites during infection. Independent scientist, Associate Professor Janet Pitman from Victoria University of Wellington has concluded the Rako Science saliva test is at least as accurate as nasopharyngeal tests.

What is the sensitivity of the Rako Science saliva test in comparison with nasopharyngeal tests?

Rako Science's saliva test sensitivity is 96.6%.

What is the specificity of the Rako Science saliva test in comparison with nasopharyngeal tests?

Rako Science's saliva test specificity is 98.6%.

What is the limit of detection of the Rako Science saliva test?

Rako Science's validation study based on 480 spiked samples found a limit of detection of <1 viral particles per microliter.

Does the Rako Science saliva test use an RNA extraction step?

No. Rako Science's protocol makes the RNA available for the PCR process without the need for extraction. This ensures extraction kits are available for NP tests during community outbreaks.

Does the Rako Science "pool" saliva samples?

No. Each sample is processed individually.

Does the Rako Science saliva test have issues with sample viscosity?

No. The Rako protocol circumvents issues with saliva viscosity.

How quickly are Rako Science' saliva tests processed and reported?

Results are available on the same day if samples are collected in the morning. Samples collected in the afternoon are reported by 12pm the following day.

Is the Rako Science saliva test an “in-house” developed test?

No. The Rako Science saliva test was developed by the University of Illinois and it has FDA Emergency Use Authorisation. The Rako Science saliva test uses the multiplex ThermoFisher Scientific COVID-19 TaqPath Assay which targets three SARS-CoV-2 genes. Thermo Fisher scientists are continuously assessing the effectiveness of its assay against global genomic databases of SARS-CoV-2 variants. The UIUC protocol has received a “Right of Reference” (ROR) from ThermoFisher Scientific.

Ends

The following questions and answers have NOT been signed off by Ministry of Health but are rhetorical questions and answers provided to counter misinformation about Rako Science

27 November 2021

Addendum to agreed Questions and Answers to counter misinformation about Rako Science

Ministry officials are advising that “Saliva and rapid antigen tests were of questionable accuracy, and needed to be confirmed by a nasal test” Is that True?

No – that is not true. Some saliva and some antigen tests may be of questionable accuracy. Not all tests are the same. Rako Science saliva test has been diagnostically validated using two independent New Zealand laboratories to have 98.0% accuracy (concordance) with nasopharyngeal swabs. It was accredited by IANZ against the ISO 15189 standard in February 2021 before the round of accreditations in April 2021 where an IANZ spokesperson is quoted in media reports:

An IANZ spokesman said it would normally assess things like Covid-19 tests against a fixed set of international standards, however these standards had been modified by the Ministry of Health’s clinical advisory teams.

Source: Leaked study shows Ministry of Health struggling with saliva testing as it seeks legal power to take over Covid-19 testing | Stuff.co.nz

There is no publicly accessible knowledge of the accuracy, the assessors or the standards applied to saliva tests accredited by IANZ in April 2021 or subsequently. If Ministry of Health advice is that accredited saliva tests have questionable accuracy, then this advice does not apply to the Rako Science saliva test which was accredited by IANZ before the Ministry of Health clinical advisory teams applied modified standards.

Information leaked by Ministry officials are advising that “Rako Science turned down a contract for testing unvaccinated teachers because we are at capacity” Is that True?

No – that is not true. Rako Science has the capacity to run 10,000 tests per day and there is plenty of additional capacity. The Ministry of Health procurement team made it clear in discussions that Rako Science was not in negotiations for a contract. They also advised that our discussions would remain

confidential. In the end the discussions were terminated because Rako Science believed that the quality of the testing solution proposed by Ministry of Health would be reputationally damaging to both the Ministry and Rako Science.

Information leaked by Ministry officials are advising that “Rako Science turnaround time is too long for samples taken out of the Auckland region” Is that True?

No – that is not true. The 98% of samples processed through Rako Science are resulted in November 2021 were within 24 hours. Rako Science turnaround times are published monthly [here](#).