

## COVID-19 sampling options

With the emerging COVID-19 situation, OraSure and its wholly-owned subsidiary DNA Genotek have received many questions surrounding the viability of using our medical devices to enable COVID-19 sampling. The following document is intended to provide a brief overview of products that may be viable for use in these applications. Please note that at this time we do not have any completed validations for this specific use. This information is intended as a guideline for your reference. Please contact your sales representative if you would like kits for assessment purposes.

We understand that the current standard of care for collecting COVID-19 samples is via a nasopharyngeal swab or oropharyngeal swab, however we believe oral samples collected by spitting into a tube or using a sponge to be a suitable alternative<sup>1</sup>. We can provide a recent publication showing that the coronavirus can be successfully detected in saliva.

### Nucleic acid (RNA and DNA) collection and stabilization

DNA Genotek offers devices that include a liquid that is suitable for nucleic acid stabilization including RNA. DNA Genotek products are ideal for use in both at-home or clinic collected samples and include either a liquid saliva or a sponge based form factor.

While we have not had the opportunity to test COVID-19 directly with our kits, we know that our stabilization solution has a very broad spectrum microbiome activity spanning from bacteria to viruses. Attached are two whitepapers (WP) describing some viral RNA work with this stabilization liquid<sup>2,3</sup>. Additionally, DNA Genotek chemistries are compatible with standard bleach decontamination protocols, unlike many other nucleic acid stabilization chemistries which are guanidine based and incompatible with bleach.

OM-505 saliva collection	OR-100 sponge oral collection
<p>1 mL direct spit kit collecting both microbial and viral DNA and RNA.</p> <p>Alternatively, a back of throat 2 mL gargle can be captured using this kit.</p> 	<p>This kit will collect less sample volume than the saliva kit but could be used for both oral or potentially shallow nasal collections.</p> 

Both collection kits rely on the same stabilization liquid integrated within the kit and will stabilize RNA in the sample for weeks at ambient temperature.

We currently believe that the chemistry in these kits would be efficient at rendering the sample in the kit non-infective.

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## Antigen/antibody collection and stabilization

### The OraSure® oral specimen collection device

Enables the collection of an oral fluid sample. This is not appropriate for nucleic acid testing. This will only preserve antibodies and antigens.



OraSure offers an oral specimen collection device that may also be used in support of testing for COVID-19.

Given the emerging COVID-19 pandemic, we have had an increase in the number of requests surrounding the efficacy of using this product for COVID-19 screening. We have not tested it for this application and do not have data specific to COVID-19. Our OraSure collection device includes chlorhexidine which is known to be effective at disrupting cells and enveloped viruses. While COVID-19 is an enveloped virus we do not have specific data demonstrating chlorhexidine or our chemistry with this virus. As always, we would recommend that you follow safe sample management practices for samples you suspect may be infectious.

Please let us know if you have any further questions or would like to test either of these products for COVID-19 use.

### References

- <sup>1</sup> Clinical Infectious Diseases, *Consistent Detection of 2019 Novel Coronavirus in Saliva*. Kelvin Kai-Wang To, et al, Feb 2020.
- <sup>2</sup> DNA Genotek, *OMNIgene®•ORAL (OM-505) stabilizes RNA from human viruses at room temperature for several weeks*. PD-WP-00024, June 2015.
- <sup>3</sup> DNA Genotek, *Compatibility of saliva collected using OMNIgene®•ORAL (OM-505) with the Abbott m2000rt RealTime System for the detection of viral RNA*. PD-WP-00025, March 2015.
- <sup>4</sup> DNA Genotek, *Inactivation of SARS-CoV-2 in samples collected using Oragene®, ORAcollect® and OMNIgene® products from DNA Genotek*. PD-WP-00025, March 2015

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Some OraSure Technologies, Inc and DNA Genotek products may not be available in all geographic regions, contact your sales representative for details.

