IGeneX Nasal Swab Home Collection Kit for SARS-CoV-2 Detection

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BACKGROUND

Accurate diagnostic testing is critical to reduce transmission and contain outbreaks of COVID-19[1]. Self-administered in-home sample collection enables individuals who are symptomatic or have had a possible exposure event to begin quarantine and obtain testing, precluding the need for in person contact with healthcare care providers, further increasing safety and saving PPE. Increased convince and safety increase the likelihood of an individual getting tested. We evaluated the IGeneX NASAL Swab Home Collection Kit for use with ChromaCode's HDPCR™ SARS-CoV-2 Assay, an FDA Emergency Use Authorized test intended for the qualitative detection of nucleic acid from SARS-CoV-2 in human upper respiratory specimens collected by a healthcare professional. We have submitted the validation data to the FDA for Emergency Use Authorization. The IGeneX NASAL Swab Home Collection Kit contains collection materials and illustrated instructions to guide self-collection of an anterior nasal swab and shipment to the IGeneX CLIA laboratory.

METHODS

HDPCR™ SARS-CoV-2 Assay: The HDPCR SARS-CoV-2 Assay uses TaqMan® probe chemistry and proprietary analysis to allow qRT-PCR multiplexing within a single-well. The product includes the same N1 and N2 oligonucleotide primer and probe sequences for the detection of the SARS-CoV-2 viral RNA and the human RNase P gene used in the CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel for Emergency Use Only.

Human Usability Study: 30 control participants (ages 18-66) collected nasal swabs using IGeneX Nasal Swab Home Collection Kit V and sent the samples to IGeneX by FEDEX. The samples were processed per ChromaCode's HDPCR SARS-COV-2 Assay protocol and RNA was extracted using the MagMax Viral/Pathogen kit. The extracted RNA was run on the QuantStudio 12k Flex (ThermoFisher) using the HDPCR SARS-CoV-2 kit.

Stability Study: Nasal swabs in Viral transport medium (VTM) were collected from 35 human controls. All the samples were tested for SARS-COV-2 by Real-time RT-PCR and confirmed negative for SARS-COV-2. Briefly, three high positive nasopharyngeal swab samples in VTM buffer were mixed and log diluted to determine the limit of detection. Once the limit of detection was determined, the high positive pooled sample was diluted to 2X LOD with negative pooled human control Nasal Swab VTM buffer. 30 tubes with 3ml sample/tube were prepared. Nasal swabs were placed in each of the tube. Samples were held at 40℃ for 12 hours, then 32℃ for 24, 48 and 52 hours, respectively. Samples were tested at time 0, 12 hours, 36 hours, 56 hours and 60 hours post incubation. Samples were allowed to equilibrate to room temperature for 2 hours before testing. RNA was extracted from these samples using the ThermoFisher MagMax Viral/Pathogen kit and run on the QuantStudio 12k Flex using the and HDPCR SARS-COV-2 kit.

HUMAN USABILITY STUDY RESULTS

To determine usability, a cohort of 30 lay individuals with a diverse range of ages and educational backgrounds were sent the collection kit. Individuals self-collected, packaged and shipped the nasal swabs to the IGeneX CLIA laboratory for testing for SARS-COV-2 using ChromaCode's HDPCR™ SARS-CoV-2 Assay (Figure 1). Results are summarized in Table 1 below.

Figure 1. HDPCR SARS-CoV-2 Assay, SARS-CoV-2 detected

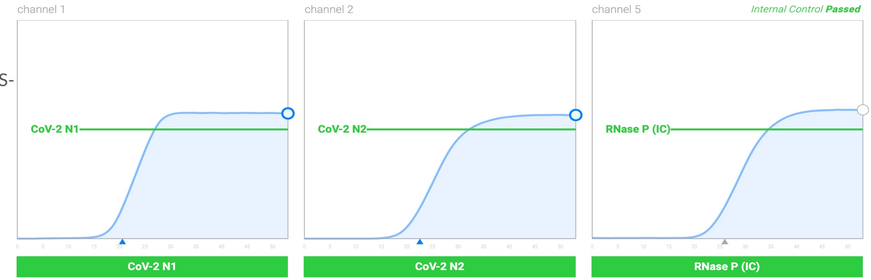

Table 1. Human Usability Study Results Summary

Samples Tested	Sample Type (nasopharyngeal Swab)	RNase P (Pos)	SARS-CoV-2 RT-PCR (Neg)	SARS-CoV-2 RT-PCR (Ind)
30	Negative	30/30	30/30	0/30

STABILITY STUDY RESULTS

The acceptance criteria laid out for the study was a 95% agreement or greater for positives samples The results including average Ct Values for each time point are summarized in the table below. Based on this data, the samples are stable up to 12 hours at 40℃, followed by 52 hours at 32℃. All three time points met the acceptability criteria and supported sample shipping stability, using a drop box, with over-night or 48-hour shipping.

Table 2. Stability Study Results Summary

Swab	Time	N	Positive (%)	Internal Control Ct (human RNase P)	Target 1 Ct	Target 2 Ct
2xLoD swab VTM	0h	5	5 (100%)	23.1	30.02	31.8
VTM	0h	1	0	22.9	Neg	Neg
2xLoD swab VTM	12h	20	20 (100%)	24.75	33.08	34.78
VTM	12h	1	0	22.9	Neg	Neg
2xLoD swab VTM	36h	20	19 (95%)	24.82	32.78	34.4
VTM	36h	1	0	23.1	Neg	Neg
2xLoD swab VTM	60h	20	20 (100%)	23.79	32.14	33.72
2xLoD swab VTM	64h	20	20 (100%)	25.53	32.34	33.96
VTM	64h	1	0	23.9	Neg	Neg

CONCLUSION

The IGeneX NASAL Swab Home Collection kit, pending FDA review of submitted validation data, paired with the HDPCR SARS- CoV-2 Assay enables in-home self-collection and transport to provide convenient, robust and sensitive SARS-CoV-2 testing.

[1]Weissleder, R., Lee, H., Ko, J. & Pittet, M. J. COVID-19 diagnostics in context. Sci. Transl Med. 12, eabc1931 (2020). DOI: 10.1126/scitranslmed.abc1931