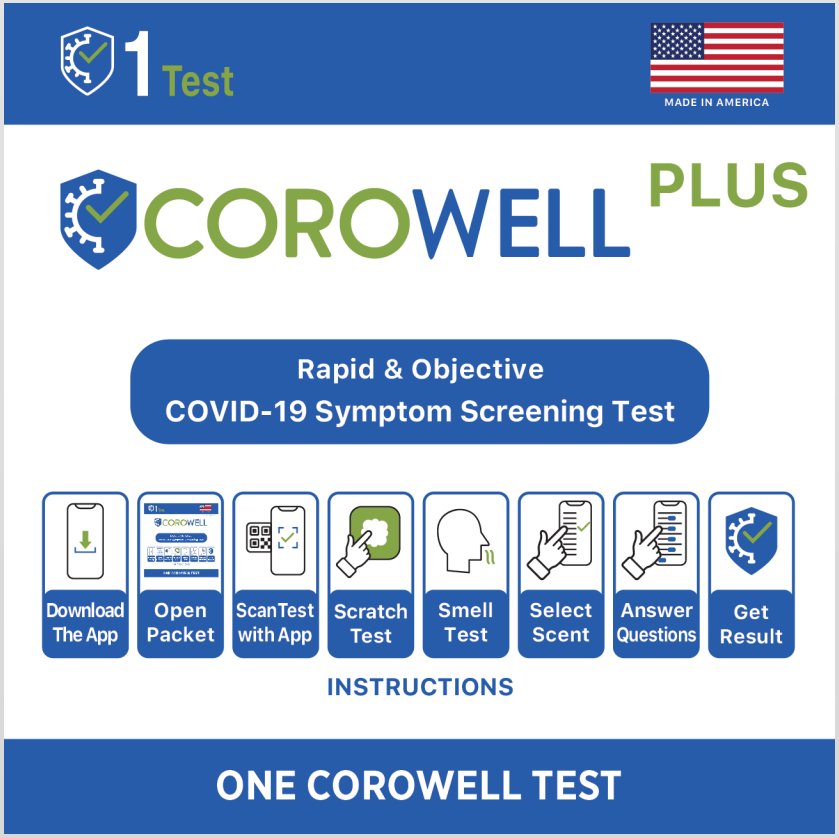
COVID-19 Symptom Screening Test

Digital Therapeutic Platform for easy and fast COVID-19 detection

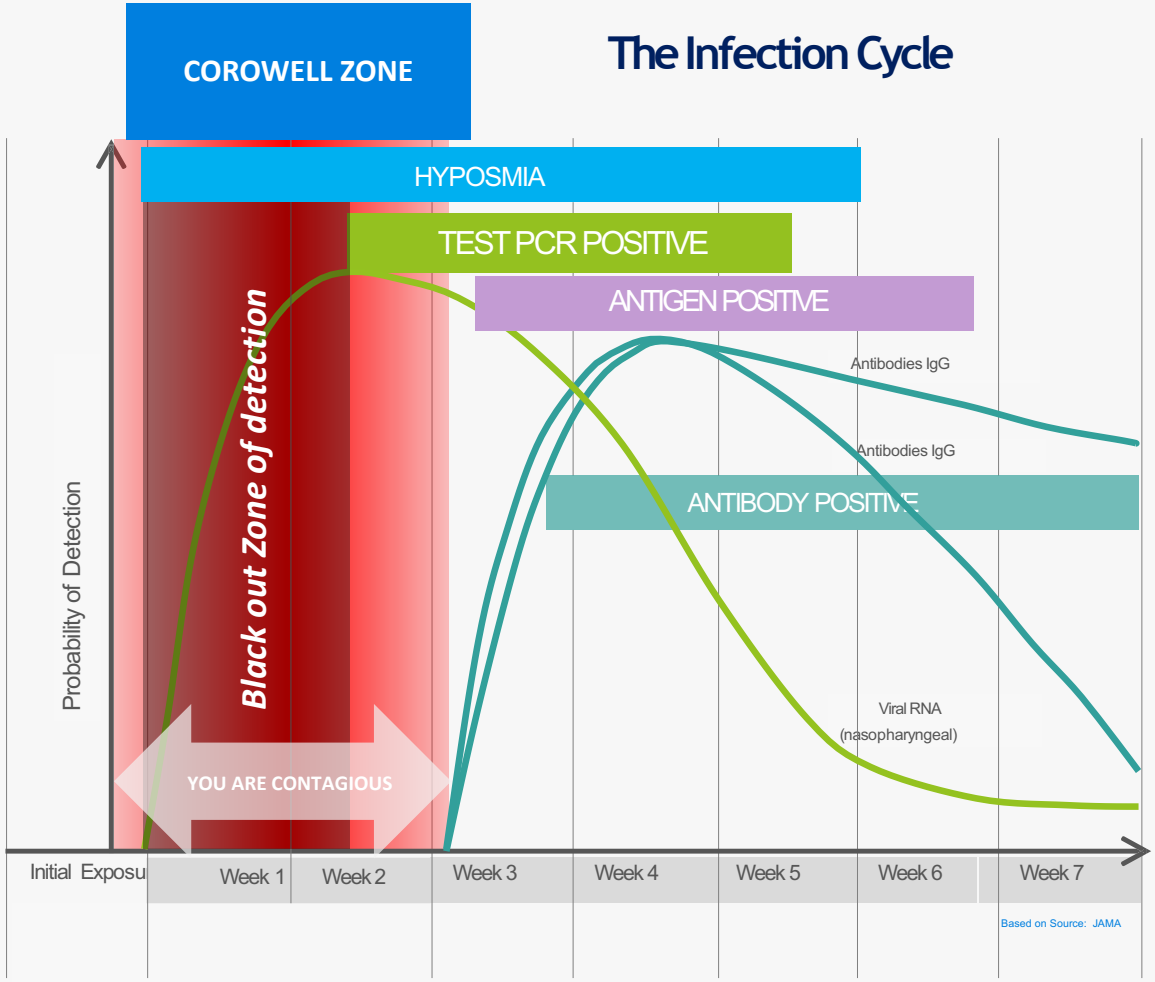


Corowell BV
Johannes Geradtsweg 76
1222PX Hilversum
The Netherlands

COROWELL
IF YOU CAN'T SMELL, YOU ARE NOT WELL!

Corowell versus other tests on the market today

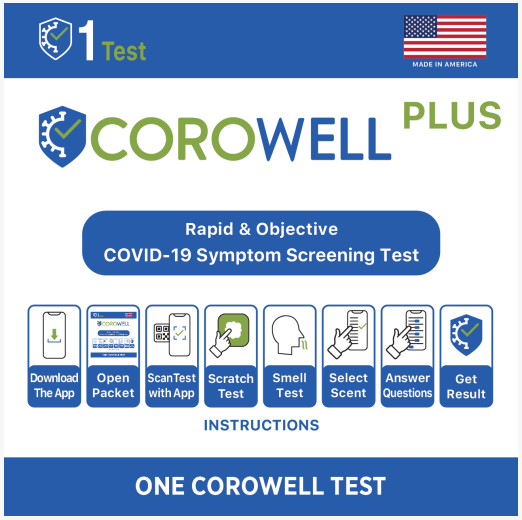
We are a non-invasive screening test that can find those infected as early as day 2 of infection



Corowell BV
Johannes Geradtsweg 76
1222PX Hilversum
The Netherlands

COROWELL
IF YOU CAN'T SMELL, YOU ARE NOT WELL!

Break infection chains immediately



With an innovative 1-minute COVID 19 symptom screening test that anyone can do, anywhere

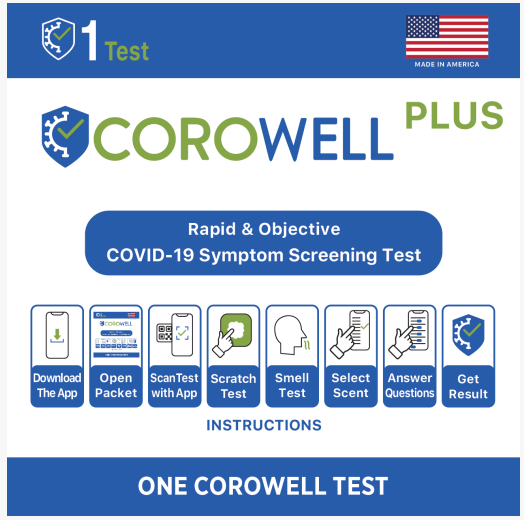
Accuracy validated at 96% versus PCR

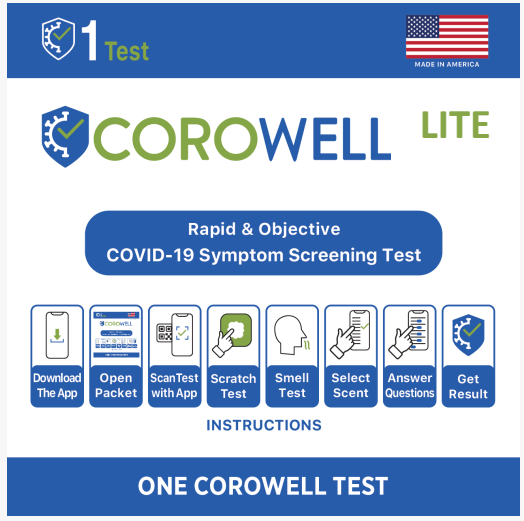
Corowell BV
Johannes Geradtsweg 76
1222PX Hilversum
The Netherlands

COROWELL
IF YOU CAN'T SMELL, YOU ARE NOT WELL!

We are COROWELL

- FDA registered digital Therapeutic platform that uses machine learning to identify those in the first 2 days of infection including an olfactometer and 2 apps
- 96% accuracy versus PCR validated in multiple large clinical trials with over 30,000 users
- Product is produced in the US with capacity for over 100Mio per month
- Our disposable element which is the only physical element of the test has an expiration date of 10 years
- Identify hot spots infection data for every test made in the whole state regardless of at home or in the lab in REAL TIME collated in an easy-to-use local dashboard





Corowell BV
Johannes Geradtsweg 76
1222PX Hilversum
The Netherlands

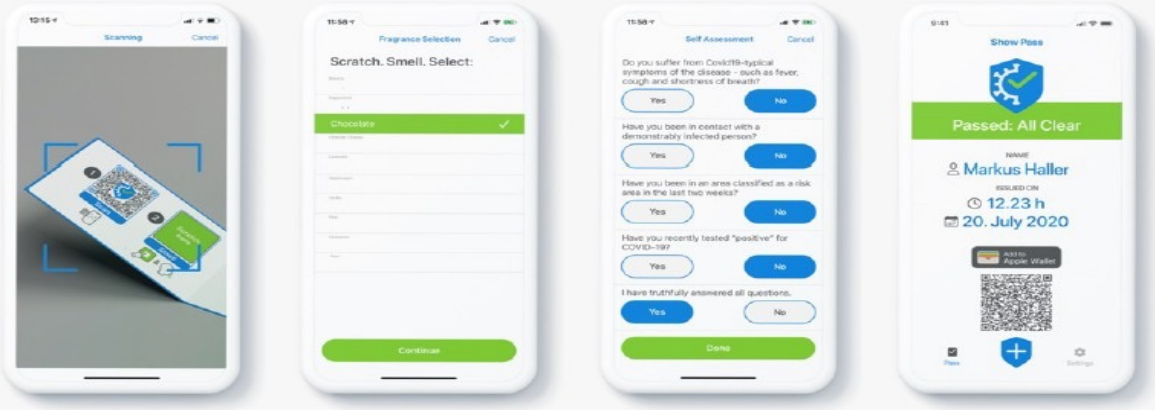
COROWELL
IF YOU CAN'T SMELL, YOU ARE NOT WELL!

We are a Digital Therapeutic platform that uses machine learning multi-variable-algorithms and two components to identify those that are suspected of infection - an objective measurement feature using a disposable element as an olfactometer, and a subjective questionnaire based on the WHO/CDC official triage process - both integrated into an easy-to-use app.

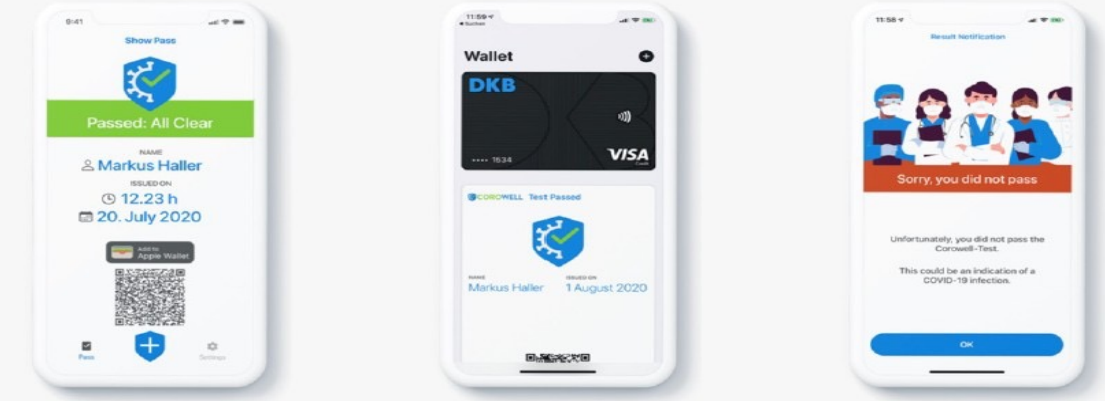
Corowell BV
Johannes Geradtsweg 76
1222PX Hilversum
The Netherlands

COROWELL
IF YOU CAN'T SMELL, YOU ARE NOT WELL!

Corowell Screening App



Corowell Pass



Pass displayed in Corowell app

Pass added to Apple or Google Wallet

Test failed: No Pass issued

Corowell BV
Johannes Geradtsweg 76
1222PX Hilversum
The Netherlands

COROWELL
IF YOU CAN'T SMELL, YOU ARE NOT WELL!

Accuracy of 96% versus PCR – validated in multiple large clinical trials

COROWELL clears ~960 of 1000 people from the suspicion of infection in 60 sec.

Corowell BV
Johannes Geradtsweg 76
1222PX Hilversum
The Netherlands

* Wells PM, Doores KJ, Couvreur S et al.,. J Infect 2020

COROWELL
IF YOU CAN'T SMELL, YOU ARE NOT WELL!

The remaining ~ 40 of the 1000 people COROWELL filtered as suspected of infection

ONLY these 40 will be then tested with a PCR, if needed

Corowell BV
Johannes Geradtsweg 76
1222PX Hilversum
The Netherlands

COROWELL
IF YOU CAN'T SMELL, YOU ARE NOT WELL!

Rigorous Clinical Data in over 5 clinical trials with over 30,000 users

COROWELL the IDEAL screening tool
Very high sensitivity in asymptomatic people

Results from our 3 pivotal registrational trials in comparison with PCR

	RT-PCR Positive	RT-PCR Negative	Total
Corowell "FAIL" = "SUSPECTED" POSITIVE	9	18	27
Corowell "PASS" = "NOT SUSPECTED" NEGATIVE	1	437	438
Total	10	455	465
Sensitivity	90.00%		
Specificity	96.04%		

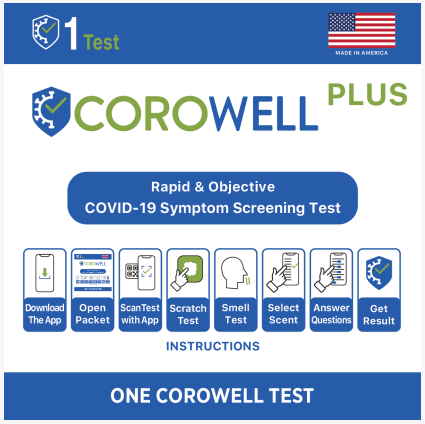
EXTRAORDINARY results considering that we do not take any biological samples form the body and that our results are available in 60 sec.

COROWELL B.V.
Johannes Geradtsweg 76
1222PX Hilversum
The Netherlands

Rigorous Clinical Data

Parameters Important for Clinical Use:

- ✓ Sensitivity of 90% and specificity of 96% versus PCR
- ✓ Capable of Early Detection as early as 2 days after infection long before any other symptom has appeared
- ✓ Features Hyposmia / Anosmia test plus Symptom Questionnaire
- ✓ Filters for “infection-suspects”
- ✓ Fast & Easy - Anywhere, Anytime, by Anyone
- ✓ Registered with FDA, CE, at BfArM and Health Canada and 31 additional countries with 10 more soon
- ✓ Has been used globally in many countries



Around 30,000 users tested in 5 clinical trials

e.g. in 2 clinical trials where **415** subjects were tested with both Corowell test and PCR at the same time in the asymptotic early group – only one false negative and one false positive

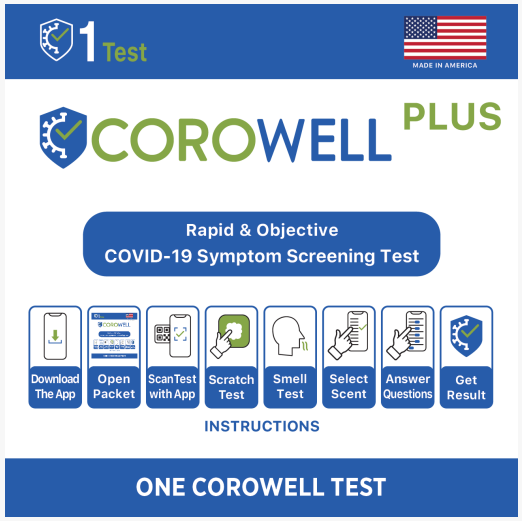
Sensitivity of 90% and specificity of 96% – antigen testing is at 44% sensitivity in this population*.

Corowell is effective at early detection of COVID 19 symptoms as a screening tool and people suspected of infection the earliest than any other test on the market today

COROWELL B.V.
Johannes Geradtsweg 76
1222PX Hilversum
The Netherlands

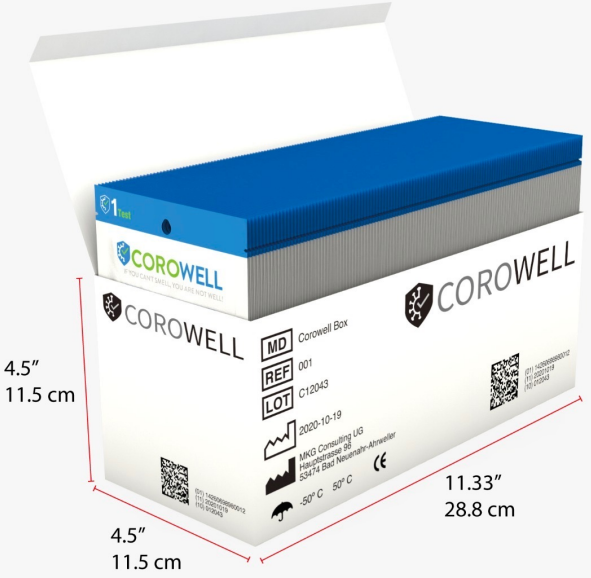
*https://www.sciencedirect.com/science/article/pii/S1201971221005658

Available in multiple pack sizes to suit your application



Single test for quick individual tests at home or on-the-go.

Various pack sizes

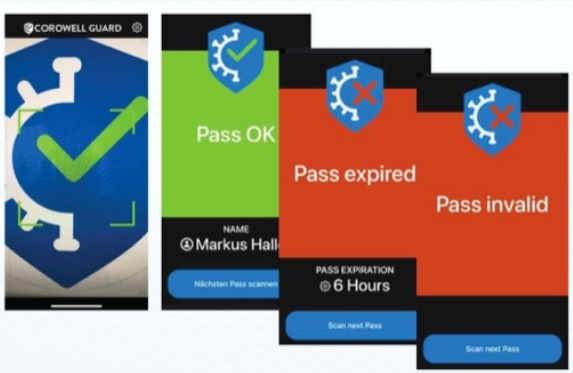


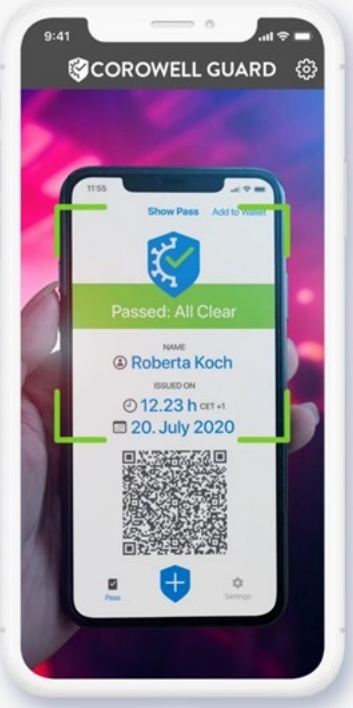
125pc packs for larger screenings such as sports arenas, restaurants, etc.

Corowell BV
Johannes Geradtsweg 76
1222PX Hilversum
The Netherlands

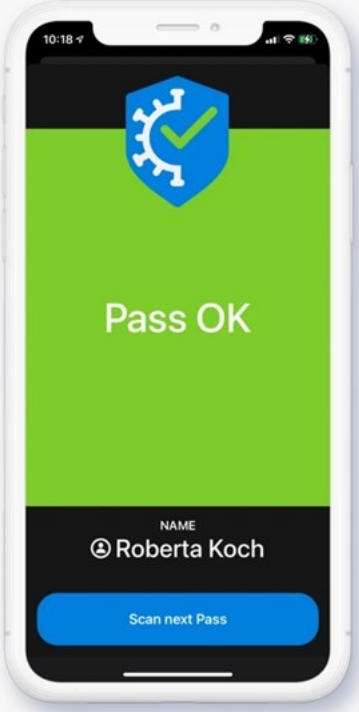
COROWELL
IF YOU CAN'T SMELL, YOU ARE NOT WELL!

Verify authenticity of smell test results at venues with Corowell Guard

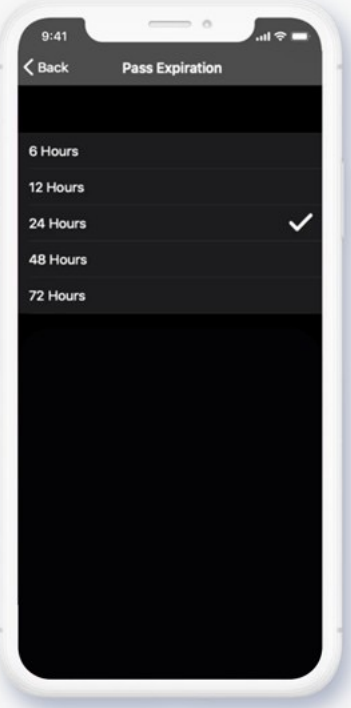




Confirm the validity of Corowell Passes



Quickly check your client's Pass



Set your own Corowell Pass expiration time

Corowell BV
Johannes Geradtsweg 76
1222PX Hilversum
The Netherlands

COROWELL
IF YOU CAN'T SMELL, YOU ARE NOT WELL!

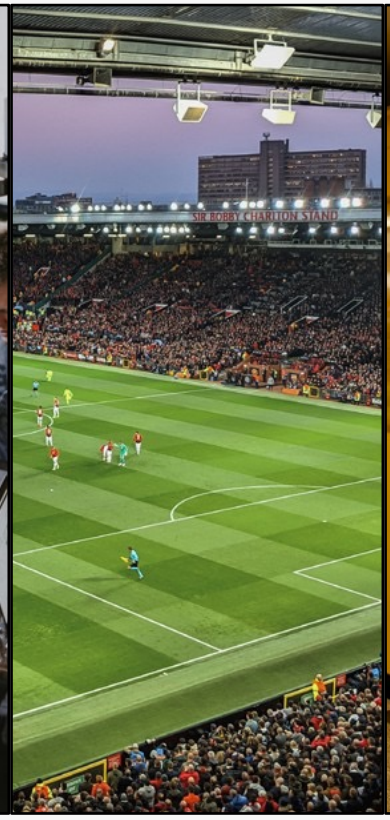
Applications

Restaurants

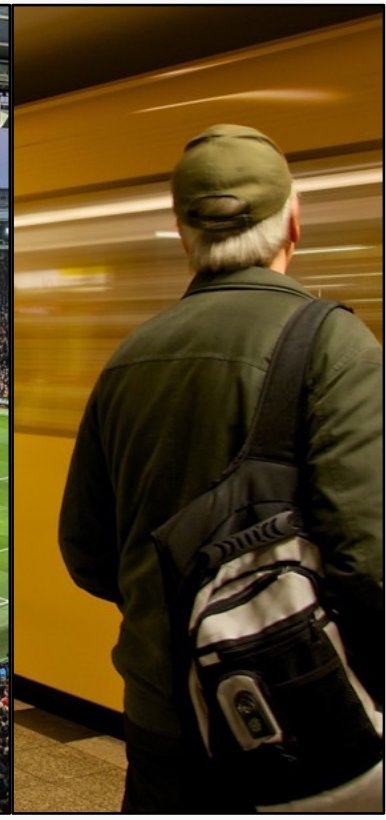
Schools &
Universities

Cruises &
Tours

Workplace
& Buildings



Stadiums &
Festivals

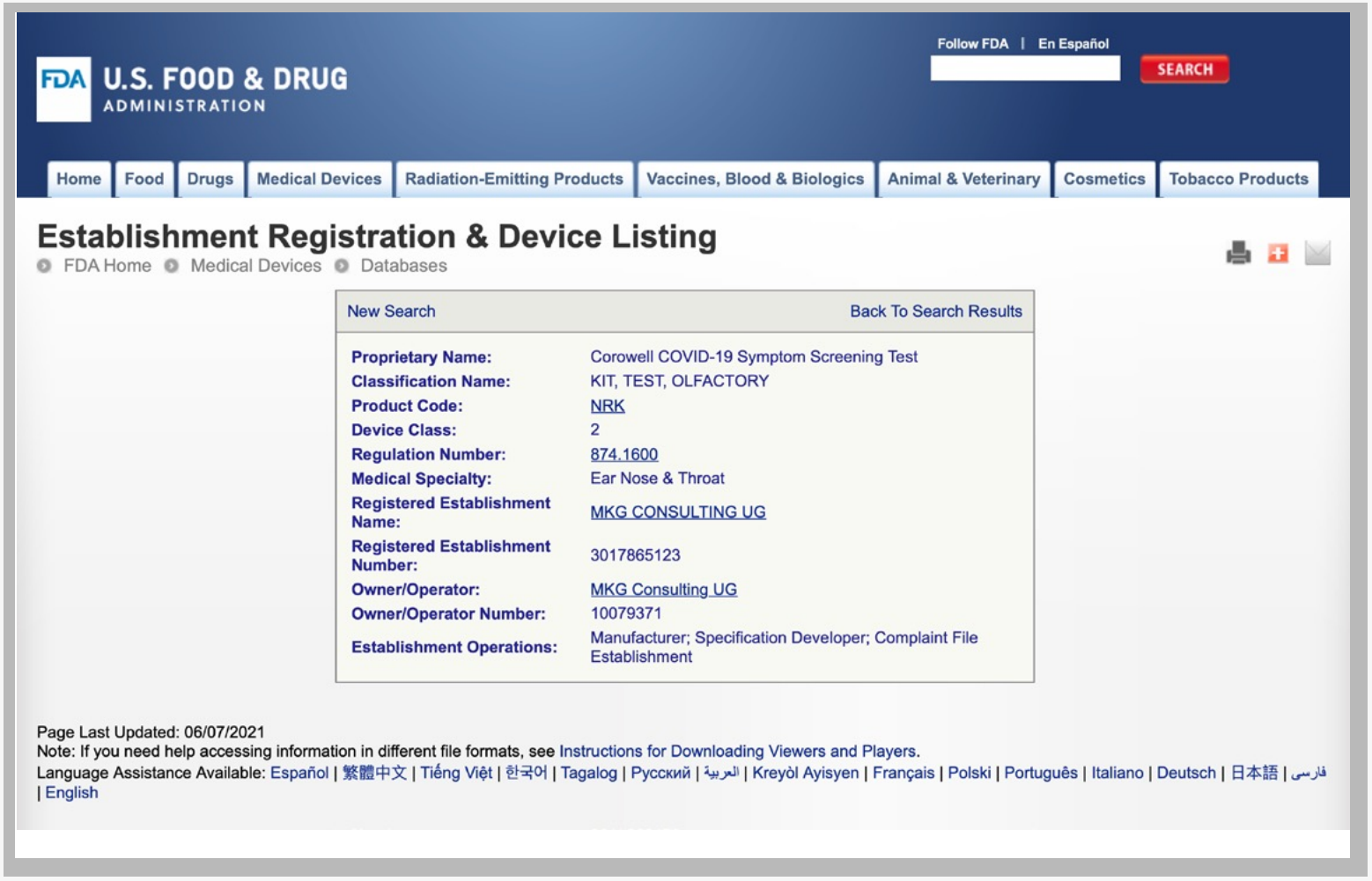


Bus, Train and
Plane Terminals

Corowell BV
Johannes Geradtsweg 76
1222PX Hilversum
The Netherlands

COROWELL
IF YOU CAN'T SMELL, YOU ARE NOT WELL!

Certifications



U.S. FOOD & DRUG ADMINISTRATION

Follow FDA | En Español

SEARCH

Home | Food | Drugs | Medical Devices | Radiation-Emitting Products | Vaccines, Blood & Biologics | Animal & Veterinary | Cosmetics | Tobacco Products

Establishment Registration & Device Listing

FDA Home › Medical Devices › Databases

New Search | Back To Search Results

Proprietary Name:	Corowell COVID-19 Symptom Screening Test
Classification Name:	KIT, TEST, OLFACTORY
Product Code:	NRK
Device Class:	2
Regulation Number:	874.1600
Medical Specialty:	Ear Nose & Throat
Registered Establishment Name:	MKG CONSULTING UG
Registered Establishment Number:	3017865123
Owner/Operator:	MKG Consulting UG
Owner/Operator Number:	10079371
Establishment Operations:	Manufacturer; Specification Developer; Complaint File Establishment

Page Last Updated: 06/07/2021

Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

Language Assistance Available: Español | 繁體中文 | Tiếng Việt | 한국어 | Tagalog | Русский | العربية | Kreyòl Ayisyen | Français | Polski | Português | Italiano | Deutsch | 日本語 | فارسی | English

Corowell BV
Johannes Geradtsweg 76
1222PX Hilversum
The Netherlands

Certifications

CERTIFICATE OF REGISTRATION – US FDA

PRODUCT NAME: Corowell COVID-19 Symptom Screening Test

FDA LISTING NO.: D428183

MANUFACTURER: MKG Consulting UG
OWNER No.: 10079371

ADDRESS: Hauptstraße 96
53474 Bad Neuenahr-Ahrweiler
Germany

ISSUE DATE: December 3rd 2020

REGISTERED DEVICES:

MANUFACTURER REF	DEVICE	REGISTRATION NUMBER
426069898000EU	Corowell COVID-19 Symptom Screening Test	3017865123

MKG Consulting UG hereby confirms that the above-mentioned manufacturer has registered and listed the Corowell COVID-19 Symptom Screening Test as medical device, CLASS II (exempt) as per the U.S. Code of Federal Regulation Title 21 Part 807 – *Establishment Registration and Device Listing for Manufacturers and initial Importers of Devices.*

The Corowell COVID-19 Symptom Screening Test was specifically NOT registered under the FDA Emergency Use Authorization (EUA) process, but the manufacturer listed the Device via the standard medical device registration process.

Director Quality & Regulatory Affairs

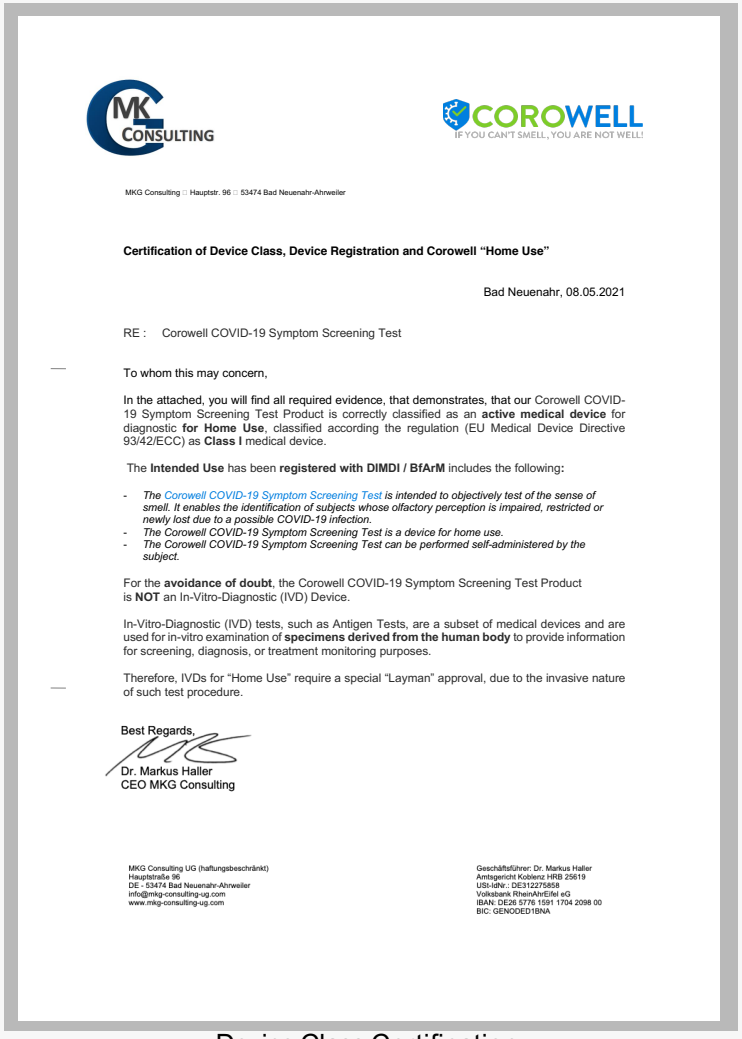
Alexander Wegener

MKG-Consulting · MKG · VAT DE312275858 · HRB 25619 · Medical Devices

Attachments:
1) FDA Notification of New Device Establishment 03-Dec-2020
2) GUDID Device Indentifier (DI) Record Details
3) FDA Device Registration & Listing

Certificate ID: CW21-0010_C00

Device Registration



MKG Consulting □ Hauptstr. 96 □ 53474 Bad Neuenahr-Ahrweiler

Certification of Device Class, Device Registration and Corowell "Home Use"

Bad Neuenahr, 08.05.2021

RE : Corowell COVID-19 Symptom Screening Test

To whom this may concern,

In the attached, you will find all required evidence, that demonstrates, that our Corowell COVID-19 Symptom Screening Test Product is correctly classified as an **active medical device** for diagnostic **for Home Use**, classified according the regulation (EU Medical Device Directive 93/42/ECC) as **Class I** medical device.

The **Intended Use** has been **registered with DIMDI / BfArM** includes the following:

- *The Corowell COVID-19 Symptom Screening Test is intended to objectively test of the sense of smell. It enables the identification of subjects whose olfactory perception is impaired, restricted or newly lost due to a possible COVID-19 infection.*
- *The Corowell COVID-19 Symptom Screening Test is a device for home use.*
- *The Corowell COVID-19 Symptom Screening Test can be performed self-administered by the subject.*

For the **avoidance of doubt**, the Corowell COVID-19 Symptom Screening Test Product is **NOT** an In-Vitro-Diagnostic (IVD) Device.

In-Vitro-Diagnostic (IVD) tests, such as Antigen Tests, are a subset of medical devices and are used for in-vitro examination of **specimens derived from the human body** to provide information for screening, diagnosis, or treatment monitoring purposes.

Therefore, IVDs for "Home Use" require a special "Layman" approval, due to the invasive nature of such test procedure.

Best Regards,

Dr. Markus Haller
CEO MKG Consulting

MKG Consulting UG (haftungsbeschränkt)
Hauptstraße 96
DE - 53474 Bad Neuenahr-Ahrweiler
info@mkg-consulting-ug.com
www.mkg-consulting-ug.com

Geschäftsführer: Dr. Markus Haller
Amtsgericht Koblenz HRB 25619
USt-IdNr.: DE312275858
Volksbank RheinAhrEifel eG
IBAN: DE26 5776 1591 1704 2098 00
BIC: GENODED1BNA

Device Class Certification

Certifications

CERTIFICATE OF REGISTRATION

MANUFACTURER: **MKG Consulting UG**

ADDRESS: **Hauptstrasse 96**
53474 Bad Neuenahr-Ahrweiler
Germany

ISSUE DATE: **December 3rd 2020**

REGISTERED DEVICES:

MANUFACTURER REF	DEVICE	REGISTRATION NUMBER
426069898000EU	Corowell COVID-19 Symptom Screening Test	3017865123

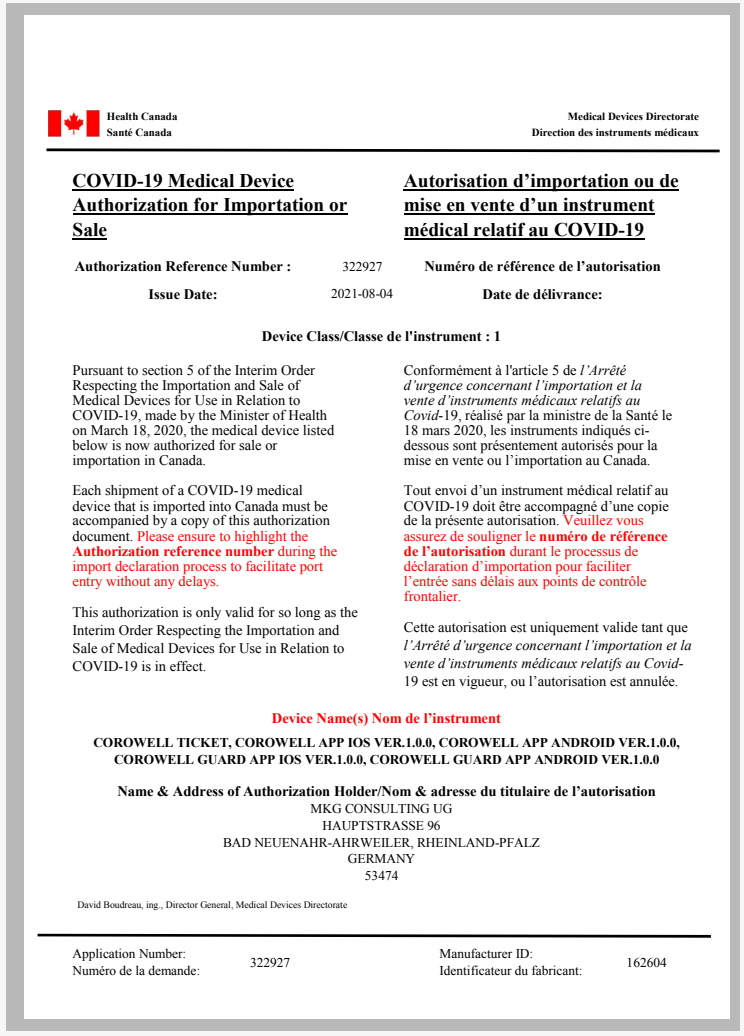
MKG Consulting UG hereby confirms that the above-mentioned manufacturer has registered and listed the above-mentioned medical devices as per in the U.S. Code of Federal Regulation Title 21 Part 807 – *Establishment Registration and Device Listing for Manufacturers and initial Importers of Devices*.

Director Quality & Regulatory Affairs

Alexander Wegener

Certificate ID: CW21-0010_C00

Device Registration EU



Health Canada
Santé Canada

Medical Devices Directorate
Direction des instruments médicaux

COVID-19 Medical Device Authorization for Importation or Sale

Autorisation d'importation ou de mise en vente d'un instrument médical relatif au COVID-19

Authorization Reference Number : 322927 **Numéro de référence de l'autorisation**

Issue Date: 2021-08-04 **Date de délivrance:**

Device Class/Classe de l'instrument : 1

Pursuant to section 5 of the Interim Order Respecting the Importation and Sale of Medical Devices for Use in Relation to COVID-19, made by the Minister of Health on March 18, 2020, the medical device listed below is now authorized for sale or importation in Canada.

Each shipment of a COVID-19 medical device that is imported into Canada must be accompanied by a copy of this authorization document. Please ensure to highlight the **Authorization reference number** during the import declaration process to facilitate port entry without any delays.

This authorization is only valid for so long as the Interim Order Respecting the Importation and Sale of Medical Devices for Use in Relation to COVID-19 is in effect.

Conformément à l'article 5 de *l'Arrêté d'urgence concernant l'importation et la vente d'instruments médicaux relatifs au Covid*-19, réalisé par la ministre de la Santé le 18 mars 2020, les instruments indiqués ci-dessous sont présentement autorisés pour la mise en vente ou l'importation au Canada.

Tout envoi d'un instrument médical relatif au COVID-19 doit être accompagné d'une copie de la présente autorisation. Veuillez vous assurez de souligner le **numéro de référence de l'autorisation** durant le processus de déclaration d'importation pour faciliter l'entrée sans délais aux points de contrôle frontalier.

Cette autorisation est uniquement valide tant que *l'Arrêté d'urgence concernant l'importation et la vente d'instruments médicaux relatifs au Covid*-19 est en vigueur, ou l'autorisation est annulée.

Device Name(s) Nom de l'instrument

COROWELL TICKET, COROWELL APP IOS VER.1.0.0, COROWELL APP ANDROID VER.1.0.0, COROWELL GUARD APP IOS VER.1.0.0, COROWELL GUARD APP ANDROID VER.1.0.0

Name & Address of Authorization Holder/Nom & adresse du titulaire de l'autorisation
MKG CONSULTING UG
HAUPTSTRASSE 96
BAD NEUENAHR-AHRWEILER, RHEINLAND-PFALZ
GERMANY
53474

David Boudreau, ing., Director General, Medical Devices Directorate

Application Number: / Numéro de la demande: 322927

Manufacturer ID: / Identificateur du fabricant: 162604

Device Registration Canada

COROWELL B.V.
Johannes Geradtsweg 76
1222PX Hilversum
The Netherlands

Identification of infection hot spots in real time

Our databases keep track of every QR-Code for COROWELL testing

…. ***IDENTIFY*** and detect infection "hot spots" in real time with precision.

Enables localized, highly granular pandemic control measures.

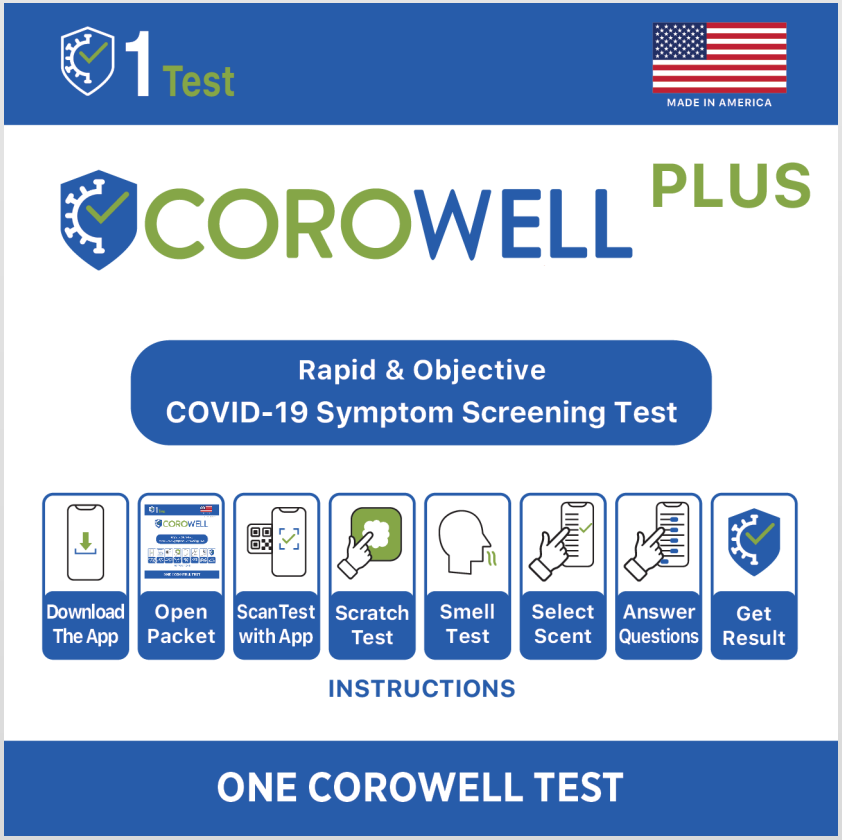
All data is HIPAA compliant.

Corowell BV
Johannes Geradtsweg 76
1222PX Hilversum
The Netherlands

COROWELL
IF YOU CAN'T SMELL, YOU ARE NOT WELL!

Contact Us

For COVID-19 Symptom Screening Test



Corowell BV
Johannes Geradtsweg 76
1222PX Hilversum
The Netherlands

COROWELL
IF YOU CAN'T SMELL, YOU ARE NOT WELL!