highly sensitive & specific testing in just

30min

for Covid-19

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Fluoremetric

SARS-CoV-2

Time Line of Coronavirus

2019.12

The outbreak of disease started

Dec. 2019 the first case reported in China.

2020.03

Declaration of Pandemic

World Health Organization (WHO) declared the COVID-19 as **a pandemic on 11 March 2020**

2020.04

Global Travel Ban

Global travel ban in response to the COVID-19 pandemic by April 2020

2020.07

By the end of July 2020

- Over 17 million confirmed cases
- Close to 700 thousand deaths
- The epidemic spread all over the world

Travel bans eased gradually to opened the borders.
But there is still risk of the next waves of COVID-19 pandemic.

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What Is The Coronavirus ?

- Diagnostic testing is the only efficient way to know the spread of the SARS-CoV-2.
  - The median incubation time is estimated to be 5.1 days with symptoms expected to be present within 12 days of infection.
- **WHO defined molecular diagnostics as the gold standard for COVID-19 testing.**

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Options for Response

In order to monitor and minimize the risk of COVID-19 incidence the following options for response are suggested.

- **Monitoring framework** to rapidly detect increased transmission
- **Testing strategy**
- Contact tracing
- Non-pharmaceutical interventions to prevent a large upsurge
- Risk communication

https://www.ecdc.europa.eu/en/covid-19-pandemic

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Testing Strategies

- Comprehensive testing of all people with COVID-19-compatible symptoms.
- Testing of persons displaying symptoms compatible with COVID-19 as part of syndrome-based surveillance systems.
- Systematic random or comprehensive testing of high-risk populations or settings, irrespective of symptoms (e.g. healthcare workers).
- Testing of close contacts
- Random testing of the general population, irrespective of symptoms (point prevalence studies).
- Testing of serological markers (sero-epidemiological studies).

https://www.ecdc.europa.eu/en/covid-19-pandemic

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Travel-Related Measures to Reduce Spread

- Comprehensive testing of all people with COVID-19-compatible symptoms.
- Screening of travelers prior to or at entry at destination
  - Health questionnaires
  - Temperature screening
  - **Immunity certificate**
- **Requirement for recent negative RT-PCR test**
  - Testing before travel
  - Testing at destination
- Management of travelers with symptoms and contact tracing
- Provision of information to travelers regarding advice on travel and accessing of services

https://www.ecdc.europa.eu/en/covid-19-pandemic

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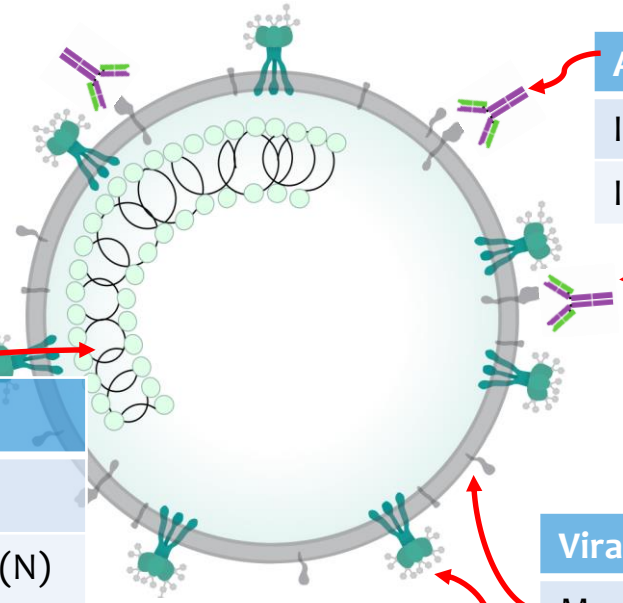
Covid-19 Testing



Antibodies

- IgG
- IgM

RNA Gennome

- ORF1ab
- Nucleocapside gene (N)
- RdRP
- E Gene

Viral Antigens

- Membrane proteins
- Spike glycoprotein

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Covid-19 Testing

Viral gene (nucleic acid) detection is the key method for diagnosing Covid-19

Direct Method

Indirect Method

Virus Isolation	Viral Gene Detection	Antigen Detection	Serology IgM	Serology IgG

Availability

Sensitivity

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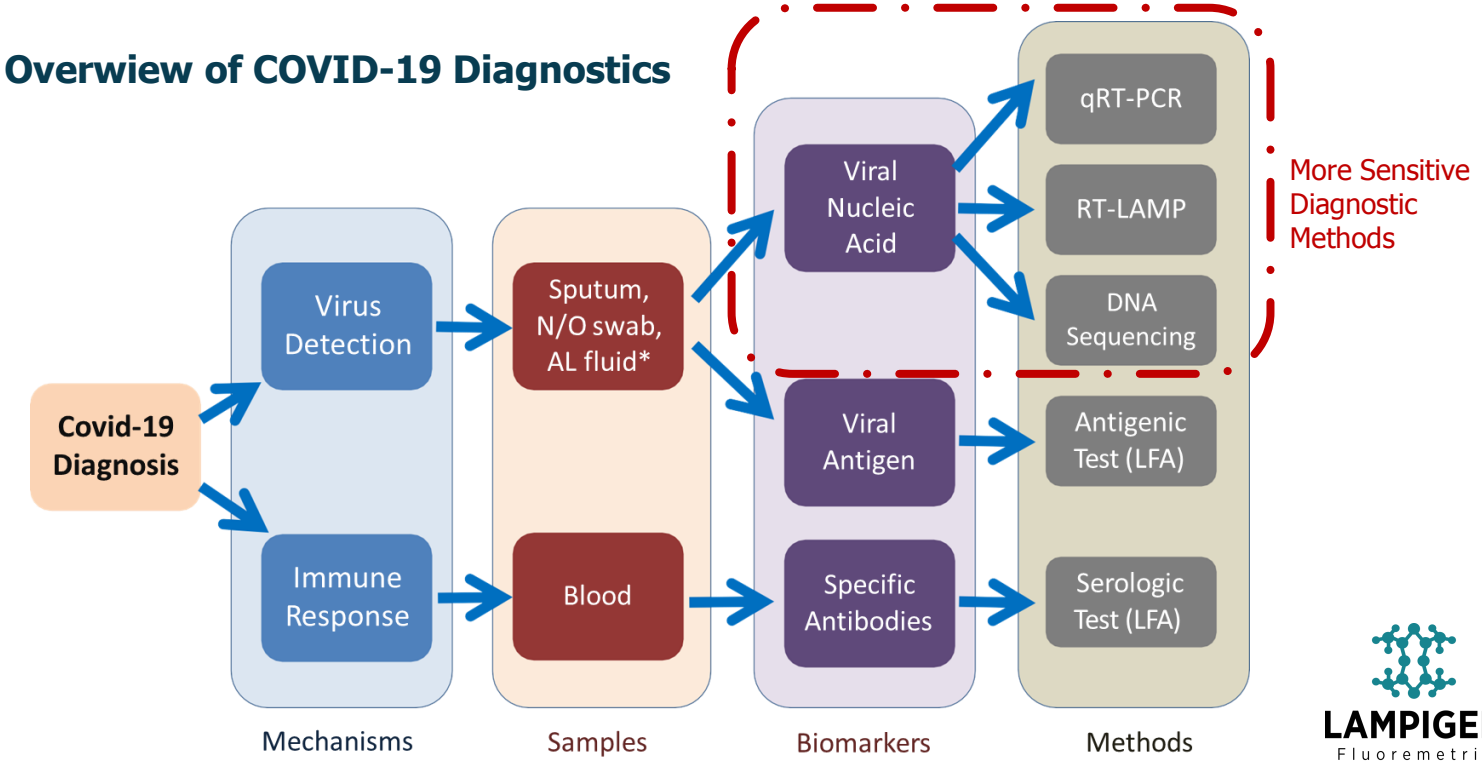
Covid-19 Testing



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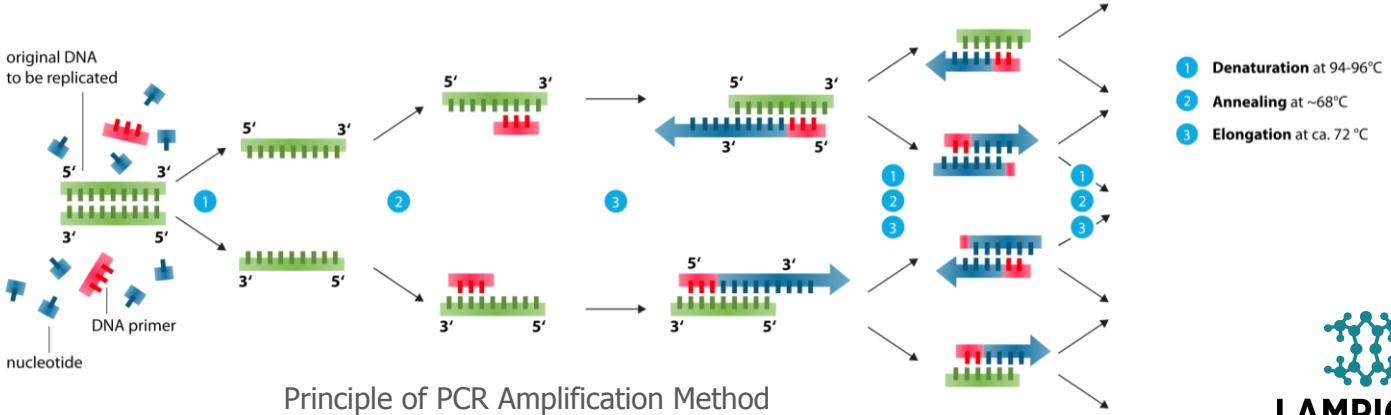
Covid-19 Detection Methods

Molecular Diagnostics for Infection - PCR

PCR (polymerase chain reaction) is a standard method for molecular diagnostics since 1990.

It requires specific expensive items of equipment and highly trained analysts and upwards of 4–8 h to process.



Principle of PCR Amplification Method

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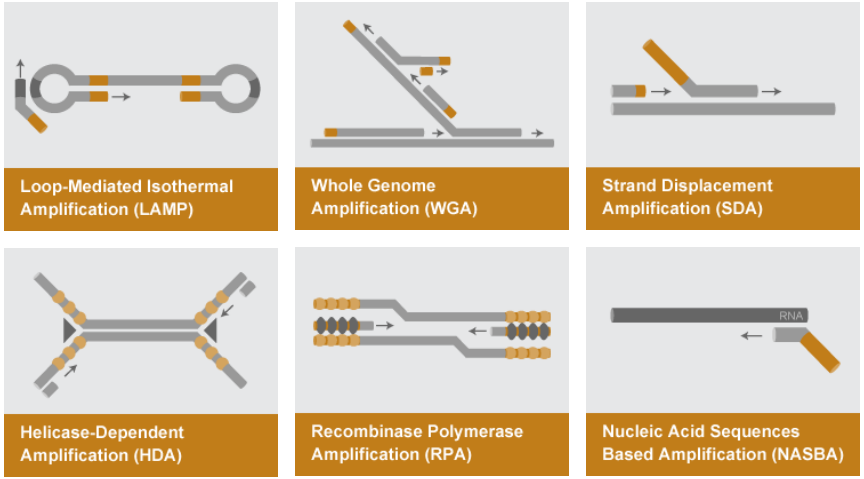
Covid-19 Detection Methods

Molecular Diagnostics for Infection – Isothermal Amplification

Isothermal amplification method is led to save time in diagnosis.

Five to six different types of isothermal amplification methods have been created. Among them **LAMP (loop mediated isothermal amplification)** is one of the widely experienced one.

Isothermal Amplification Methods



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Comparison of Detection Methods

LAMP has important advantages over PCR

Table 1

Comparison between PCR and LAMP based methods of viral RNA detection. Table adapted from Nguyen *et al* (2020).

PCR	LAMP
Bulky and cumbersome	Smaller, simpler, portable.
Specialised thermal cyclers required	Only a heat block is required *
4–8 h until result	1 h until result
Requires skilled technicians	Requires no specific skill
Requires an additional reverse transcription step	Can be performed directly on RNA
Unstable reactions prone to inhibitors requiring purification steps	Stable and inhibitors tolerated, and thus purification steps not required
Detects DNA	Detects DNA and RNA
Tested on patient samples	Less tested on patient samples

LAMP is highly

SENSITIVE, SPECIFIC and RAPID

method to detect SARS-CoV-2

* Heat block is not required in Fluoremetric method

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ALL IN ONE

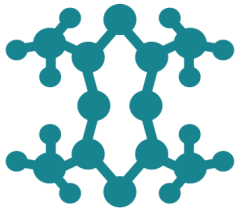
Has swabs, VTM as well as positive and negative controls in the kit

EASY TO USE

Simple to process, esay to interpret.

RAPID

Gives positive result only in 30 minutes



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ACCURATE

Detects 2 different genes* It is not a subjective test (not depends on a personal evaluation)

SENSITIVE

Presence of small amount of viruses are enough to detect

PORTABLE

Its device can be moved at any PoC points

FLEXIBLE

Any number of samples from 1 to 47 can be tested in one run

* N gene and ORF1ab gene

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LAMPIGEN Fluorometric / SARS-CoV-2

LAMPIGEN Fluorometric

- LAMPIGEN is a vitro **Point of Care** diagnostic test for **SARS-CoV-2** virus based on Reverse Transcription Loop-mediated isothermal Amplification **(RT-LAMP)** technology with the fluorometric detection method.
- LAMPIGEN is associated with fluorometric RT-LAMP devices (Genie® II, III and HT)

LAMPIGEN
Fluorometric
SARS-CoV-2

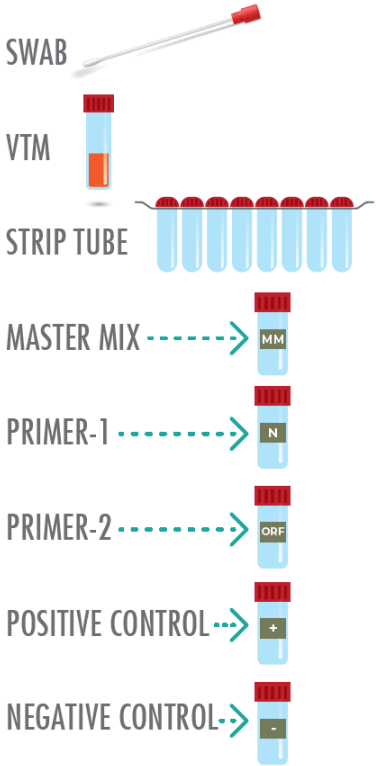
LAMPIGEN Components

LAMPIGEN Components

LAMPIGEN supplies all necessary components in its kit box

Including;

- Oro/nasopharyngeal swabs &
- Virus transport medium (VTM) units.



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SARS-CoV-2

LAMPIGEN Components

LAMPIGEN Fluorometric SARS-CoV2 RT-LAMP Kit Components *

Components Stored at -15°C to -25°C

Components	Number of vials	Reactions per vial
RT-LAMP Mastermix	10	100
Primer Mix-1 (N gene)	2	250
Primer Mix-2 (ORF1ab gene)	2	250
Positive Control	1	20
Negative Control	1	20

Components Stored at Room temperature

Components	Number of sets	Numbers per set	Total units
Tube-Strip	128	8	1024
Virus Transport Medium (VTM)			500
Oro/Nasopharyngeal swabs			500

* 500 tests/kit

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SARS-CoV-2

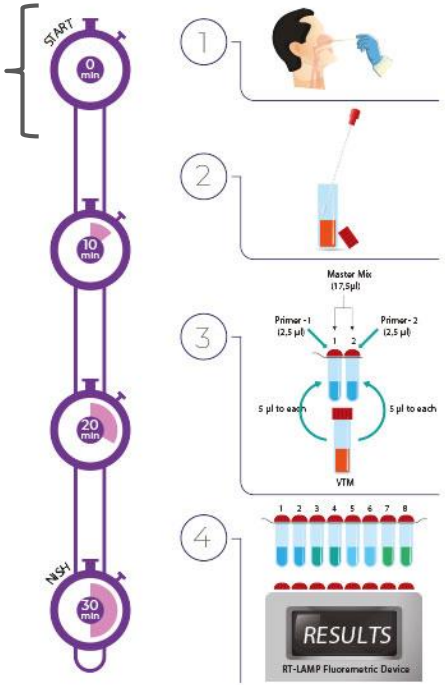
Test Process – Step 1

Sample Collection

Swab should be inserted first into one nostril of the patient up to 2.5 cm (1 inch) from the edge of the nostril.

It must be rolled 5 times along the mucosa inside the nostril to ensure that both mucus and cells are collected.

Then using the same swab process should be repeated for the other nostril to ensure that an adequate sample is collected from both nasal cavities.



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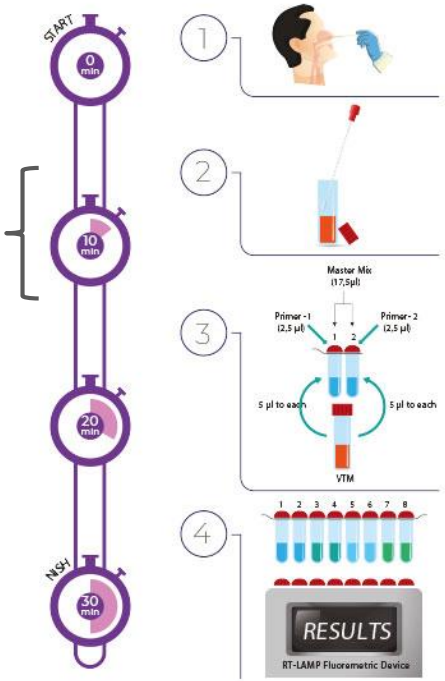
Test Process – Step 2

VTM

Then swab is placed in VTM.

The tail of the swab is broken and the body is left into the VTM.

Both **swabs** and **VTM** are present in the **KIT Box**



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Test Process – Step 3

Preparation of Testing Samples

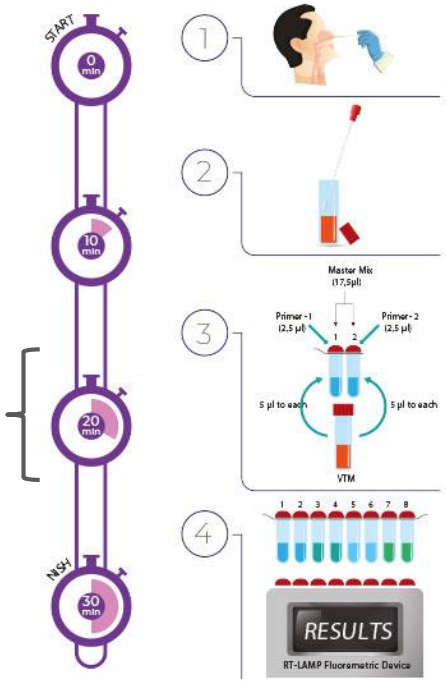
Since two genes will be tested samples should be duplicated into two tubes.

First; put 17,5 µl of **Mastermix** into two adjacent tubes.

Then add 2,5 µl of **Primer-1** into the first tube and 2,5 µl of **Primer-2** into the second tube.

A fresh reaction mix should be prepared before each batch of samples is tested.

Samples should be tested in duplicate: wells 1&2; wells 3&4; wells 5&6; wells 7&8. Duplicates must be set up in the configuration shown in the figure. One pair of controls should be placed in each run.



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Test Process – Step 4

Test Results

The Fluorometric LAMPIGEN Kit is only applicable with specified instrument.

The Genie® HT device detects amplified product in real-time by using fluorescence detection. It automatically run an anneal curve at the end of amplification, where the reaction is heated to 98°C and slowly cooled. This acts as a secondary confirmatory check - ensuring LAMP amplicons are specific to SARS-CoV-2. The test result is interpreted and reported automatically

Processes up to 12 strips-of-8 tubes simultaneously. Maximum 47 samples in a single run; but it can run even for one patient

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SARS-CoV-2

Sensitive and Accurate Detection

PERFORMANCE

FAST AND ACCURATE TESTING FOR COVID -19

Detection Sensitivity	3 - 5 copies / µl
Genes Detected	N gene & ORF1ab gene
Detection Method	Fluorometric

LAMPIGEN detects **2 genes**
with **Fluorometric Method**
which is sensitive enough for only **3 to 5 copies in µl**

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Sensitive and Accurate Detection

Highly Specific to SARS-CoV2

Tested Respiratory Pathogens		
Legionella pneumophila	Human Coronavirus HKU1	Human Parainfluenza 3
Haemophilus influenzae	Influenza A virus (Flu A)	Human Parainfluenza 4
Streptococcus pneumoniae	Influenza B virus (Flu B)	Human bocavirus
Bordetella parapertussis	Influenza A/H1	Respiratory syncytial virus
Human Coronavirus NL63	Influenza A/H3	Human adenovirus
Human Coronavirus 229E	Human Parainfluenza 1	Enterovirus
Human Coronavirus OC43	Human Parainfluenza 2	Parechovirus

All the above pathogens were tested with **LAMPIGEN** to check for cross reactions and resulted as **NEGATIVE**.

No cross reaction was observed with any of the possible pathogenic microorganisms during development tests.

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High Sensitivity & High Specificity

LAMPIGEN has high sensitivity & high specificity

Overall Diagnostic Sensitivity [1]	100 %
Overall Diagnostic Specificity [2]	97 %

1- 100% (samples with <CT25) (Concordance with RT-qPCR to detect positives)
2- Samples were tested in singles using the qRT-PCR. For the statistics, it was assumed that the qRT-PCR results were correct. Cycle threshold (CT) is the number of cycles required for the fluorescent signal to cross a defined threshold for the comparator qRT-PCR. (Concordance with RT-qPCR to detect negatives)

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SARS-CoV-2


LAMPIGEN RT LAMP PCRCOVID-19 Kit
Qualitative detection of SARS-CoV-2 RNA
CE
LOT
IVD
20012001
01.05.2021
REF
100 tests
D2001-100
-25°C to -15°C
PHARMALINE
SAĞLIK HİZMETLERİ TİCARET A.Ş.
T. +90 216 346 86 66 (pbx) F. +90 216 346 50 07
Atatürk Caddesi, Atatürk Cadde Konutları No:43
A-Blok Daire:6 Sahrayicedid Mh. Kadıköy-İstanbul
www.pharmaline.com.tr
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LAMPIGEN
SARS-CoV-2

europetesting

Product Testing & Analysis and Laboratory Services

Hygiene Tested Quality

CE

ATTESTATION OF COMPLIANCE
UYGUNLUK ONAYI

Üretici / Manufacturer
PHARMALINE SAĞLIK HİZMETLERİ TİCARET A.Ş
Adres / Adress
SAHRAYICEDİT MAH. ATATÜRK CAD. NO: 43 / 6 KADIKÖY / İSTANBUL / TÜRKİYE
Telefon / Phone
+90 216 346 86 66
E-mail / Web
info@pharmaline.com.tr / www.pharmaline.com.tr

Beyan / Declaration

Teslim edilen versiyonumuzda aşağıda tanımlanan ürünün 98/79/EEC Vücut Dışında Kullanılan (In vitro) Tıbbi Tanı Cihazları Yönetmeliği tasarım ve tipine göre tarafımızca dolaşıma sokulan uygun temel güvenlik ve sağlık şartlarına uygun olduğunu beyan ederiz. Ürünün değiştirilmesi durumunda, tarafımızdan üzerinde anlaşmaya varılamayan bu beyan geçerliliğini kaybedecektir.

That the following described product in our delivered version complies with appropriate basic safety and health requirements of 98/79/EEC In Vitro Diagnostic Medical Devices Directive on its design and type, as brought into circulation by us, In case of alteration of the product, not agreed upon by us, this declaration will lose its validity.

Ürün İsmi- Product Name
LAMPIGEN COVID-19 RT-LAMP PCR KIT
LAMPIGEN VIRAL TRANSPORT MEDIUM KIT

COVIDIGEN COVID-19 QRT PCR KIT
COVIDIGEN VIRAL TRANSPORT MEDIUM KIT

Modeller / Models
LAMPIGEN LAMPPH2020-500, PH2021VTM
COVIDIGEN PH2020-100, PH2020-500, PH2020VTM
Ürünün Markası / Product Brand
LAMPIGEN / COVIDIGEN
Direktif ve Yönetmelikler / *Directives And Regulations*
98/79/EEC Vücut Dışında Kullanılan (In vitro) Tıbbi Tanı Cihazları Yönetmeliği
98/79/EEC In Vitro Diagnostic Medical Devices Directive

Harmonize Standartlar/ *Harmonised Standards*:
TS EN ISO 9001:2015, TS EN ISO 13485:2016

CERTIFICATE NUMBER: PC-EU-2020-11339

Sertifika Bitiş Tarihi / Certificate Expiration *Date*: 28.07.2021

Accredited System Certification Approval

Seal and Date	Certification Manager
28.07.2020	MRUDULA BABAU

Europetesting Product Testing & Analysis And Laboratory Services
Plot No 20,Sector 41,Rail Vihar,Next Seawoods Grand Central Station(W), Off Palm Beach Road, Navi Mumbai-400706 India
www.europetesting.com info@europetesting.com

CERTIFICATE / ZERTIFIKAT / СВИДЕТЕЛЬСТВО / СЕРТИФИКАТ / CERTIFICATO TO / CERTIFIKÁ

PHARMALINE
SAĞLIK HİZMETLERİ TİCARET A.Ş.

AB-UYGUNLUK BEYANI
EC-DECLARATION OF CONFORMITY

ÜRETİCİ/ MANUFACTURER: PHARMALİNE SAĞLIK HİZMETLERİ TİCARET A.Ş.

ÜRETİCİNİN ADRESİ/ADDRESS OF MANUFACTURER:

ATATÜRK CADDESİ, ATATÜRK CADDESİ KONUTLARI NO:43 A BLOK DAİRE:6
SAHRAYICEDİT MAHALLESİ -KADIKOY -İSTANBUL-TÜRKİYE

ÜRÜN TANIMI/ PRODUCT DESCRIPTION:

Lampigen COVID-19 Rt-LAMP PCR Kit (Catalog No: LAMPPH2020-500)

Lampigen COVID 19 Rt- LAMP PCR Kit (Katalog No: LAMPPH2020-500)

ÜRÜN TİPİ/ PRODUCT TYPE:

98/79/AT VÜCUT DIŞINDA KULLANILAN (İN VİTRO) TIBBİ TANI CİHAZLARI YÖNETMELİĞİ EK III ÜRÜNÜ

98/79/EC IN VITRO DIAGNOSTIC MEDICAL DEVICES DIRECTIVE ANNEX III PRODUCT

UYGUNLUK DEĞERLENDİRME PROSEDÜRÜ/ CONFORMITY ASSESSMENT PROCEDURE:

AŞAĞIDA LİSTELENEN CE İŞARETLİ TIBBİ CIHAZLARIN, VÜCUT DIŞINDA KULLANILAN TIBBİ CIHAZLARLA ILGILI KONSEY DİREKTİFİ 98/79/EC'NİN EK III'Ü UYARINCA GEREKLİ TEKNİK BELGELERE UYGUN OLDUĞUNU BEYAN EDERİZ.

WE HEREBY DECLARE THAT THE DISTRIBUTED CE MARKED MEDICAL DEVICES LISTED BELOW CONFORM TO THE REQUIRED TECHNICAL DOCUMENTATION, IN ACCORDANCE WITH ANNEX III OF THE COUNCIL DIRECTIVE 98/79/EC, CONCERNING IN VITRO DIAGNOSTIC MEDICAL DEVICES.

ÜRÜN SINIFI/ PRODUCT CLASSIFICATION:

GENEL IVD CİHAZLAR / IVD DİĞER
BU YÖNETMELİĞE UYGUNLUK İLE İLGİLİ AÇIKLAMALAR VE BİLGİLER ÜRÜN TEKNİK DOSYASINDA BELİRTİLMİŞTİR.

CLASSIFIED AS GENERAL/OTHER IVD DEVICES
THE JUSTIFICATION FOR COMPLIANCE WITH THIS DIRECTIVE IS GIVEN ON THE PRODUCT TECHNICAL FILE.

YETKİLİ İMZA / AUTHORISED SIGNATURE: **TARİH /** DATE: 06.08.2020

Melih TÜRKOĞLU

Pharmaline Saglik Hizmetleri Ticaret A.S.
Atatürk Caddesi, Atatürk Caddesi Konutlari
No: 43 A Blok Daire 6 Sahrayicedit-Kadiköy
34734 Istanbul, Turkey
Phone: +90 216 346 86 66
E-Mail: info@pharmaline.com.tr
http://www.pharmaline.com.tr/

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USD IBAN:
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SWIFT: TCZBTR2A

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Bu Belge ile

Pharmaline Sağlık Hizmetleri Tic. A.Ş.

Sahrayıcedit Mh. Atatürk Cd. Atatürk Konutları
A Blok Apt. No:43/6 Kadıköy/İSTANBUL
TÜRKİYE

Firmasının

GMP - Good Manufacturing Practice
İyi Üretim Uygulamaları

şartlarına uygun bir Sistemine aşağıda belirtilen kapsam dahilinde sahip olduğunu onaylar

Laboratuvar Malzemeleri, Medikal Ürünleri Ve Ekipmanlarının Üretimi Ve Satışı

Kategori/Alt Kategori	: ---
Belge No	: U-0044
Belge İlk Yayın Tarihi	: 27 Temmuz 2020
Karar Tarihi	: 27 Temmuz 2020
Belge Yayın Tarihi	: 27 Temmuz 2020
Geçerlilik Tarihi	: 26 Temmuz 2021

Bu belge, firmanın UKS'nin Belgelendirme Kurallarına uyması ve yılda en az 1 kez yapılacak gözetim denetimlerinde başarılı olması halinde ilk belgelendirme kararı veya yeniden belgelendirme kararı olan karar tarihini ifade eden tarihinden itibaren 3 yıl süreyle geçerlidir.
FR.73/Yayın Tarihi 01.03.2013/Rev. Tarihi 02.11.2015/Rev. No:03

Genel Müdür

www.uksbelgelendirme.com.tr
Belgenin geçerlilik durumu http://www.uksbelgelendirme.com.tr adresinden kontrol edilebilir.

UKS Uluslararası Kalite Sistemleri Ve Belgelendirme Ltd. Şti
Ataköy Mah. Dicle Cad. No:35 Esenyalı / İSTANBUL
Telefon: +90 216 330 45 77 Pbx Faks: +90 216 330 67 47
info@uksbelgelendirme.com.tr

UKS ULUSLARARASI KALİTE SİSTEMLERİ VE BELGELENDİRME LTD. ŞTİ.

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Sahrayıcedit Mh. Atatürk Cd. Atatürk Konutları
A Blok Apt. No:43/6 Kadıköy/İSTANBUL
TÜRKİYE

Firmasının

ISO 13485:2016

şartlarına uygun bir Medikal Tıbbi Cihazlar Kalite Yönetim Sistemine aşağıda belirtilen kapsam dahilinde sahip olduğunu onaylar

Laboratuvar Malzemeleri, Medikal Ürünleri Ve Ekipmanlarının Üretimi Ve Satışı

Kategori/Alt Kategori	: ---
Belge No	:MDQ-0096
Belge İlk Yayın Tarihi	:27 Temmuz 2020
Karar Tarihi	:27 Temmuz 2020
Belge Yayın Tarihi	:27 Temmuz 2020
Geçerlilik Tarihi	:26 Temmuz 2021

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FR.73/Yayın Tarihi 01.03.2013/ Rev. Tarihi 14.03.2019/Rev. No:04

CAS ACCREDITED
CAS-MS-0011

Genel Müdür

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UKS Uluslararası Kalite Sistemleri Ve Belgelendirme Ltd. Şti
Ataköy Mah. Dicle Cad. No:35 Esenyalı / İSTANBUL
Telefon: +90 216 330 45 77 Pbx Faks: +90 216 330 67 47
info@uksbelgelendirme.com.tr

Contacts

Pharmaline Sağlık Hizmetleri Ticaret A.Ş.

For More Information

Please do not hesitate to contact our experts and visit our web sites for detailed information.
Our experts would be greatful to inform you about our test kits.

Pharmaline Sağlık Hizmetleri Ticaret A.Ş.
Atatürk Caddesi, Atatürk Cadde Konutları, No:43 A Blok Daire:6 Sahrayıcedid Mahallesi
Kadıköy Istanbul-Türkiye

WEB Sites
www.lampigen.com
www.lampigen.com.tr
www.pharmaline.com.tr

E-mail adress
info@lampigen.com
info@lampigen.com.tr
info@pharmaline.com.tr

Phone
+90 216 346 86 66