CORONEX-COVID 19 Ver 2.0.

Multiplex RT-qPCR Detection Kit [1000 rxn]-
Ref:DS-CSC19-M1000

DESCRIPTION

CORONEX-COVID 19 (Ver 2.0) qPCR kit provides detection in a single tube, including two independent genes of 2019 Sars-CoV2 and an internal control which targets the human RNAseP (RNP) gene to assess specimen quality and reaction efficiency. Specific primers and probes were designed for the detection of conserved region of 2019 nCoV's 'Orf1ab' and 'N' gene, respectively, avoiding nonspecific interference of SARS2003 and BatSARS-like virus strains. Internal control (RNAseP gene) provides a nucleic acid extraction procedural control and a secondary negative control.

PRODUCT CONTENTS

Components	Ingredient	Cap number	Amount
CORONEX-Covid19 DS Mix E	RT-qPCR Master mix	**1**	10X1250 µl
CORONEX-Covid19 DS PP1	Orf1ab, N and RNP gene primer probe mix	**2**	5X 500 µl
CORONEX-Covid19 DS PTC*	Positive control for Orf1ab, N and RNP genes	**3**	200 µl
No-Template Control (NTC)	No-Template Control	**4**	200 µl

Setup no 1 and 2 contents are prepared more than 10%.

* The "CORONEX-Covid19 DS PTC" contained in the kit is a synthetic DNA prepared to be used as the positive control. It contains the target regions of all genes (Orf1ab, N and RNP) that are amplified with the primer-probe sets included within the kit. It is not isolated from the virus; it does not have the entire virus genome and has no infectious properties.

STORAGE AND SHELF LIFE

All reagents should be stored at -25 °C to -15 °C with protection from light. The reagents are stable for 14 months when stored at the recommended condition. The expiration date will not change if the kit is opened and stored at the recommended condition. The expiration date will not change if the kit is transported with ice-packs for 4 days and/or treated with 6 freeze-thaw cycles.

INSTRUMENTS

Real time PCR instrument with FAM and HEX channels, such as Magnetic Induction Cycler BMS Mic qPCR, Qiagen Rotor-Gene Q, Biorad CFX96, Montania 4896 Real-Time PCR and LightCycler 480 (Roche).

SAMPLING

Suitable specimen type: upper respiratory specimen (including nasal swabs, nasopharyngeal swabs/aspirates/washes and sputum) and lower respiratory specimen (including respiratory aspirates, bronchial washes and bronchoalveolar lavage fluids).

PROTOCOL

1. Specimen Preparation

The samples should be extracted according to the manufacturer's procotol of viral RNA extraction kits. The extracted RNA can be directly used as nucleic acid template for the reaction.

2. Reagent Preparation

Thaw the required reagents, mix by shaking, and centrifuge briefly before use. Prepare the mixture in a RNase-free centrifuge tube as follows [1]:

NOTE: All work should be carried out on ice/cold plate.

Components	Cap number	Volume (µl Per Reaction)
CORONEX-Covid19 DS Mix E	**1**	12.5 µl
CORONEX-Covid19 DS PP1	**2**	2.5 µl
Total Volume	-	15 µl

[1] **Calculate the number of reaction tubes (sample number + positive control + negative control). It is recommended to set both negative and positive controls for each test.**

Mix the above mixture thoroughly, and make aliquots of 15 µl into different PCR reaction tubes.

3. Template Addition

Add 5 µl of extracted RNA from specimen to different PCR reaction tubes which contained 15 µl of PCR mix. The total volume is 20 µl. Cap the reaction tubes tightly, centrifuge them at low speed.

CORONEX-COVID 19 Ver 2.0.

4. qRT-PCR Amplification

Put the reaction tubes on a PCR instrument, setup and run the following cycling protocol:

Step	Temperature	Time	Cycles
Reverse Transcription	48 °C	20 min	1
Pre-denaturation	95 °C	2 min	1
PCR Cycles	95 °C	5 sec	35
	60 °C (Read)	10 sec	

Settings of detection fluorescence: Orf1ab and N genes FAM) and RNP (HEX). Please set the internal reference parameter of fluorescence of the instrument to "None". For example: for ABI series instruments, please set "Passive Reference" to "None".

5. Data Analysis

For Biorad real time PCR instruments;

FAM and HEX:

Threshold should be set to: auto threshold

Analysis Profile for BMS MIC instrument;

Set analysis parameters as follows;

FAM and HEX:

Method: Dynamic

Ignore Cycles Before :5

Exclusion: Extensive,

Fluorescence Cut Off Level: %15 should be on.

Analysis Profile for RotorGeneQ instrument;

When starting a run, make sure Green and Yellow channels are on the channel setup list. Select Gain Optimization and check box 'Perform Optimization Before 1st Acquisition' for both green and yellow channels.

FAM and HEX:

Select dynamic tube.

Ignore first 10 cycles.

Outlier Removal should be set to '5%'.

Eliminate cycles before should be set to:0

Threshold should be set to: 0.03

INTERPRETING PATIENTS' TEST RESULTS

If the criteria of QUALITY CONTROL is met, analysis the data of sample as follows:

- Please follow sigmoidal curves in wells which you observe Ct values.
- The cut-off value in the FAM channel should be evaluated according to the table below#.

In Peltier Block Devices (Biorad CFX, Montania etc)	≤ 35
In Rotor System devices (Qiagen Rotorgene, BMS Mic etc)	≤ 33

#In CDC statements and internationally published literature, it has been reported that passive virus residues can be detected in advanced cycles (1-7).

- If the Ct value of HEX channel is ≤ 33, analyze the results according to the following table:

Orf1ab and N Gene (FAM)	RNP Gene (HEX)	Interpretation
+	+	The patient is SARS-CoV-2 positive.
-	+	The patient is SARS-CoV-2 negative.
-	-	The result is uncertain. The test should be repeated.***1**
+	-	The result is uncertain. The test should be repeated.***1**

*1. If the results remain same, repeat the specimen collection/RNA extraction and perform the test again. It is kindly recommended to repeat specimen collection after two days.

References

1. Jefferson T., Spencer E., Brassey J., Heneghan C. Viral cultures for COVID-19 infectivity assessment. medRxiv, 2020, doi: https://doi.org/10.1101/2020.08.04.20167932
2. Bullard J, Durst K, Funk D, Strong JE, Alexander D, Garnett L et al. Predicting Infectious SARS-CoV-2 From Diagnostic Samples. Clinical Infectious Diseases, 2020, doi: 10.1093/cid/ciaa638.
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4. Yu F, Yan L, Wang N, Yang S, Wang L, Tang Y, Gao G, Wang S, Ma C, Xie R, Wang F, Tan C, Zhu L, Guo Y, Zhang F. Quantitative Detection and Viral Load Analysis of SARS-CoV-2 in Infected Patients, Clinical Infectious Diseases, 2020; 71(15): 793–798, https://doi.org/10.1093/cid/ciaa345
5. Mina M (Harvard T.H. Chan School of Public Health). Your Coronavirus Test Is Positive. Maybe It Shouldn't Be. The New York Times,2020. https://www.nyt"mes.com/2020/08/29/health/coronav"rus-test"ng.html
6. U.S.A. Centers for Disease Control and Prevention (CDC) report: Duration of Isolation and Precautions for Adults with COVID-19. 2020. https://www.cdc.gov/coronav"rus/2019-ncov/hcp/durat"on-"solat"on.html
7. Drew RJ, O'Donnell S, LeBlanc D, McMahon M, Natin D. The importance of cycle threshold values in interpreting molecular tests for SARS-CoV-2 [published online ahead of print, 2020 Jul 10]. Diagn Microbiol Infect Dis. 2020;98(3):115130. doi:10.1016/j.diagmicrobio.2020.115130

Contact Us:

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DS CORONEX
COVID-19 QPCR
TEST KİT


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Sağlık Teknolojileri A.Ş.
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Galip Erdem Cad. 611. Sok. No: 9
DS CORONEX
COVID-19 QPCR
TEST KİT


DS CORONEX
CORONEX COVID-19 QPCR TEST KİT
100 Rxn
Declaration of Conformity
IVD
-15°C
-25°C
2020-08
2021-11
DS BİO ve NANO TEKNOLOJİLERİ
ÜRÜN TAKİP DOĞRULAMA
İÇ ve DIŞ TİCARET ANONİM ŞTİ.
İşçi Blokları Mah. Muhsin Yazıcıoğlu Cad.
No:45/7 Çankaya/ANKARA


DS CORONEX
COVID-19 QPCR
TEST KİT
DS CORONEX
CORONEX COVID-19 QPCR TEST KİT
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ÜRÜN TAKİP DOĞRULAMA
İÇ ve DIŞ TİCARET ANONİM STI.

CE

Uygunluk Beyannamesi

In vitro tanısal medikal cihaz (test kiti) ile ilişkili EC Yönergesi 98/79/EC'ye dayanarak, bahsedilen test-kitinin tasarımı ve yapılış tipi bakımından, yukarıda bahsedilen EC yönergesinin şartlarını yerine getirdiğini belirtiriz.

Eğer cihaz (test kiti) aşağıda imzası olanların rızası olmadan değiştirilirse, bu belge geçersiz sayılacaktır.

Ürünün Tanımı	: CORONEX-Covid19 Test Kiti
İlgili EC Yönergesi	: In Vitro Tanı Yönergesi (IVDD) 98/79/EC (Annex III)
Sınıflandırma	: IVD Diğer
Uyumlaştırılmış Standartlar	: ISO/IEC 17025:2005, IVDD 98/79/EC (Annex III), OIE Yönergesi
Üretici	:DS Bio ve Nanoteknoloji Ürün Takip ve Doğrulama İç ve Dış Tic. A.Ş. İşçi Blokları Mah. Muhsin Yazıcıoğlu Cad. 45/7 Ankara 06530 Türkiye

Yetkili Temsilci : Dinçer ŞEN

Tarih: 10.04.2020

İmza

DS BİO ve NANO TEKNOLOJİ ÜRÜN TAKIP
DOĞRULAMA İÇ ve DIŞ TİCARET ANONİM ŞTİ.
İşçi Blokları Mah. Muhsin Yazıcıoğlu Cad.No:45 / 7
Lavida City 6. Kat Çankaya /ANKARA
Başkent VD: 271 079 5479

DS CORONEX

COVID-19 QPCR

TEST KİT

DS CORONEX

CORONEX COVID-19 QPCR TEST KİT

100 Rxn

1

2

3

4

Tıbbi Cihaz Bilgileri

Tibbi Cihaz Detayları | Ürün Geçmişi | Piyasaya Arz Bilgisi | Takip Konfigürasyonu | Ürün Titubb Geçmişi | SUT Kodları

Tanımlayıcı Bilgiler

Ürün Tanımı:	**CORONEX - YOK - COVID-19 QPCR TEST KİTİ 100 RXN**
Birincil Ürün Numarası:	8682723153038 (GS1)
Firma:	2667269173754 - GENSUTEK SAĞLIK TEKNOLOJİLERİ ANONİM ŞİRKETİ (Üretici/İthalatçı/Bayi/İhracatçı)
Marka:	CORONEX
Ürün Adı:	COVID-19 QPCR TEST KİTİ 100 RXN
Ürün Künyesi:	Ürün Künyesi.pdf
Orijinal Etiket Türkçe mi?:	Hayır
Türkçe Etiket:	Türkçe Etiket.pdf
Orijinal Etiket:	100rxn.etiket.pdf
Versiyon/Model:	YOK
Referans/Katalog No:	YOK
İçerikteki Ürün Sayısı:	100
Ürün Açıklaması:	Hastalardan nazofaringeal aspirat/lavaj, bronkoalveoler lavaj, nazofaringeal sürüntü, orofaringeal sürüntü örneklerinden RNA izolasyonu sonrası virüsü taşıyıp taşımadıkları tespit edilir.
Aynı Barkodlu Ürünler:	Aynı Barkodlu Ürünler

Durum Bilgileri

Durum:	Kayıtlı
Tekil Ürün Durumu:	Tekil ürün hiç dahil edilmemiş.
Son İşlem:	Kontrolü Tamamla
Ürün Tipi:	Tıbbi Cihaz
Veri Kaynağı:	Firma
İncelenmeye Alındığı Tarih:	05/10/2020
Güncellenme Tarihi:	06/10/2020
ÜTS Başlangıç Tarihi:	21/04/2020
Durum Tarihi:	21/04/2020

Sınıflandırma Bilgileri

Sınıf:	IVD Diğer
GMDN:	64756 - SARS-CoV-2 immünoglobulin G (IgG) / IgM antikor IVD, kit, immünokromatografik test (ICT), hızlı
Branş Türü Kodu:	1225-KİT

İthal/İmal Bilgileri

İthal/İmal Bilgisi:	İmal
Menşei Ülke:	Türkiye

Ürün Belgeleri

Belge No	Belge Türü	Orjinal Doküman	Türkçe Doküman
9173754-UB1	Uygunluk Beyanı	UB.ORJ.pdf	UB.TR.pdf

1 - 15 | Sayfa başına 15 kayıt

Ürün Görselleri

Görselleri Göster

Ürün Görsel Dosyası
100 rxn iç.pdf

Özellikler

MRG Güvenlik Bilgisi:	Bilgi Bulunmuyor	Kalibrasyona tabi mi?:	Hayır
Lateks içeriyor mu?:	Hayır	Bakıma tabi mi?:	Hayır
Ftalat/DEHP içeriyor mu?:	Hayır	Steril paketlendi mi?:	Hayır
Ürün iyonize radyasyon içerir mi?:	Hayır	Kullanım Öncesinde Sterilizasyon Gerekli mi?:	Hayır
Ürün nanomateryal içeriyor mu?:	Hayır	Tıbbi Cihaz Satış, Reklam ve Tanıtım Yönetmeliği Ek-3 Kapsamında mı?:	Hayır
Vücuda implante edilebilir mi?:	Hayır	Sağlık Marketinde Satılacak mı?:	Hayır
Tek kullanımlık mı?:	Hayır	Başka Bir Tıbbi Cihazın Bileşeni, Aksesuarı, Yedek Parçası mı?:	Hayır
Ürünün sınırlı kullanım sayısı var mı?:	Evet		
Sınırlı Kullanım Sayısı:	100		
SUT Eşleşme Durumu:	Eşleşme Yok		
Raf ömrü var mı?:	Evet		
Raf Ömrü:	15 Ay		

Saklama Koşulu Bilgileri

Saklama Koşulu Gerektiriyor mu?: Evet

Saklama Koşulu Tipi	Min	Max	Birim
Saklama/Depolama Ortamı Sıcaklığı	-25	-15	Derece Santigrat

CE

Declaration of Conformity

In accordance with EC Directing 98/79/EC relating to in vitro diagnostic medical device(test kit). We herewith declare that the under-mentioned test kit, in view of its design and type of constraction, meets the requirements of the above EC Directive.

If device(test kit) is modified without the agreement of the under-signed, this declaration becomes invalid.

Description of Device	: CORONEX-Covid19 Test Kit
Relevant EC Directive	: In Vitro Diagnostic Directive (IVDD) 98/79/EC (Annex III)
Classification	: IVD Other
Harmonized Standarts	:ISO/IEC 17025:2005, IVDD 98/79/EC (Annex III), OIE Guideline
Manufacturer	: DS Bio and Nanotechnology Product Tracing and Tracking Co Isci blokları Mah. Muhsin Yazicioglu Cad. 45/7 Ankara 06530 Turkey

Authorized Representative :Dinçer SEN

Date: 10.04.2020

Signature

DS BİO ve NANO TEKNOLOJİ ÜRÜN TAKIP
DOĞRULAMA İÇ ve DIŞ TİCARET ANONİM ŞTİ.
İşçi Blokları Mah. Muhsin Yazıcıoğlu Cad.No:45 / 7
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ÜRÜNÜN TANIMI

DS Nano ve Biyoteknoloji laboratuvarlarında geliştirilen Coronex COVID19, 2019-nCoV koronavirüs 19 (COVID 19) hastalığına yolaçan yeni tip Koronavirüs'ü hastaların nazofaringeal aspirat / lavaj, bronkoalveoler lavaj, nazofaringeal sürüntü, orofaringeal sürüntü örneklerinden, RNA nükleik asitini cDNA e çeviren,eş zamanlı qPCR ile tespit eden test kitidir.

ÜRÜN AKSESUARLARI

Coronex COVID 19 kiti 7 parçadan oluşmaktadır.

- CORONEX-Covid19 DS Mix-E(polymeraz enzimi),
- CORONEX-Covid19 DS FP1 (yalnızca 2019-nCoV virüsünün ORF3A bölgesine özgü forward primer),
- CORONEX-Covid19 DS RP1 (yalnızca 2019-nCoV virüsünün ORF3A bölgesine özgü reverse primer),
- CORONEX-Covid19 DS P1 (yalnızca 2019-nCoV virüsünün ORF3A bölgesine özgü prob),
- CORONEX-Covid19 DS PCT1 (0,000001 ng virüsün ORF 3a bölgesine özgü sentetik, enfekte etmeyen kontrol cDNA, pozitif kontrol olarak kullanılır),
- C1 (RNA nükleik asitini cDNA e çeviren reverse transcriptaz enzimi),
- C2 (RNA nükleik asitinin yıkılmasını engelleyen RNAaz inhibitörü)

ÜRÜNÜN KULLANIM AMACI

DS Nano ve Biyoteknoloji laboratuvarlarında geliştirilen Coronex COVID19 kit hastaların nazofaringeal aspirat / lavaj, bronkoalveoler lavaj, nazofaringeal sürüntü, orofaringeal sürüntü örneklerinden RNA izolasyonu sonrası virüsü taşıyıp,taşımadıkları tespit edilir, hızlı tanı amacı vardır.

Real-time PCR cihazı ile ile kit içerisinde bulunan negatif ve pozitif örnekler baz alınarak elde edilen Cq değeri vermektedir. Cq değeri 38 nin altında olan örnekler pozitif olarak değerlendirilmektedir. Cq değer 38-42 arası çıkan örneklerin tekrarlanması, 42 Cq değerindeki örnekler negatif olarak değerlendirilmektedir.

Certificate

This is to Certify that

DS Ürün Takip Doğrulama İç ve Dış Ticaret A.Ş.

İŞCI BLOKLARı MAHALLESI MUHSIN YAZICIOĞLU CADDESI NO: 45/7
ÇUKURAMBAR / ÇANKAYA / ANKARA-TURKEY.

has been found in Compliance with requirements of

Environmental Management System

ISO 14001:2015

for the following scope:

**NÜKLETID ÜRETIM, OLIGO ÜRETIMI, DNA-RNA ÜRETIMI,
DNA-RNA DIZAYNı, BIOENFORMATIK,
YAZıLıM İŞLETME, YAZıLıM GELIŞTIRME.**

(Scope in English: Nucleotide Production, Oligo Production, DNA-RNA Production, DNA-RNA Design, Bioenformatics, Software Business, Software Development.)

Certificate No. : **EMS/08134/0918**

Original Certificate Date : **24 - September - 2018**

Issue Date : **24 - September - 2018**

Expiry Date : **23 - September - 2021**

To check this certificate status visit:
"http://uasl.uk.com/certifiedorganization.html"

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Quality Control Certification

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India Office: 2nd Floor, Aman Market,
Narela Mandi, Delhi - 110 040, India

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ÇUKURAMBAR / ÇANKAYA / ANKARA-TURKEY.

is in Compliance with

Testing and Calibration of Laboratories

ISO/IEC 17025:2017

for the following scope:

NÜKLETID ÜRETIM, OLIGO ÜRETIMI, DNA-RNA ÜRETIMI,
DNA-RNA DIZAYNı, BIOENFORMATIK,
YAZıLıM İŞLETME, YAZıLıM GELIŞTIRME.

(Scope in English: Nucleotide Production, Oligo Production, DNA-RNA Production, DNA-RNA Design, Bioenformatics, Software Business, Software Development.)

Certificate No. : **TCL/08086/0918**

Original Certificate Date : **24 - September - 2018**

Issue Date : **24 - September - 2018**

Expiry Date : **23 - September - 2021**

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Cornwall, UK

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APPLICATION PROTOCOL Program the qPCR devices as follows and add the reagents to the qPCR tubes in the order specified below, close the tubes, place them ino the qPCR device and start the run.					
Reaction setup			**qPCR Program**		
Component	**Add order**	**Reaction**	**Cycle Number**	**Temperature**	**Duration**
CORONEX-Covid19 DS Mix-E	1	5 µL	1	45 °C	10 min.
CORONEX-Covid19 DS FP1	2	0.2 µL	1	95 °C	2 min.
CORONEX-Covid19 DS RP1	3	0.2 µL	40	95 °C	5 sec.
CORONEX-Covid19 DS P1	4	0.2 µL		60 °C	20 sec.
CORONEX-Covid19 DS C1	7	0.1 µL			
CORONEX-Covid19 DS C2	8	0.2 µL			
CORONEX-Covid19 DS PCT1 (positive control)	6	1 µL			
Template		3.5 µL			
TOTAL REACTION VOLUME		**10µL**		FAM	

WARNING: Interpretation of Results: 1) Examine the shape of the amplification curves obtained in the FAM channels and record non-sigmoidal curves as negative. 2) Calculate the number of threshold cycles (Cq). 3)Record the result as negative if 38≤Cq and as positive If Cq<38

Intended Use and Test Principle: Kit is used for testing 2019-nCoV causing Coronavirus Disease 2019 (COVID-19). The kit is applied to nucleic acid isolates from nasopharyngeal aspirate/lavage, bronchoalveolar lavage, nasopharyngeal swab, oropharyngeal swab and sputum samples. Rapid diagnosis with the kit is achieved both conventional PCR (cPCR) and real-time PCR (qPCR) targeting 2019-nCoV ORF (open reading frame) viral translational region. This region-specific oligonucleotide primer and prob sets gives positive results only with 2019-nCoV. In the 2019-nCoV routine PCR screening, **CORONEX-COVID 19** test kit, primer and prob set is applied; if the result is 2019-nCoV ORF (open reading frame) viral translational region positive, the patient result can be interpreted as infection positive. If the result is negative, patient result can be interpreted as disease free.

Analytical Specification: Kit is validated Bio-Rad CFX384 and Biomolecular Systems MIC qPCR machine. The kit's testing limit (LOD) is the lowest viral copy that can be tested with 99% probability.

Warnings: Master stock reagents should be kept on the cold block during cPCR and qPCR set up. If possible, all PCR set up should be performed on the cold block.
Kit components should be mixed by gently shaking before use. The micropipettes used for pipetting cPCR and qPCR mixes, positive control and patient samples should be separated.

Kit content (Shelf Life: 12 monts) Storage: -20 °C; Transport: +2-8 °C, 200 rxn.		
Intended Use/Content/Target	**Quantity**	**Consumption per reaction**
CORONEX-Covid19 DS Mix-E	1 X 1000 µL	5 µL
CORONEX-Covid19 DS FP1	1 X 80 µL	0.4 µL
CORONEX-Covid19 DS RP1	1 X 80 µL	0.4 µL
CORONEX-Covid19 DS P1	1 X 80 µL	0.4 µL
CORONEX-Covid19 DS C1	1 X 20 µL	0.1 µL
CORONEX-Covid19 DS C2	1 X 40 µL	0.2 µL
CORONEX-Covid19 DS PCT1 (positive control)	1 X 10 µL	1 µL

Certificate

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DS Ürün Takip Doğrulama İç ve Dış Ticaret A.Ş.

İŞCI BLOKLARı MAHALLESI MUHSIN YAZICIOĞLU CADDESI NO: 45/7
ÇUKURAMBAR / ÇANKAYA / ANKARA-TURKEY.

is in Compliance with

Auditing Management Systems

ISO 19011:2018

for the following scope:

NÜKLETID ÜRETIM, OLIGO ÜRETIMI, DNA-RNA ÜRETIMI,
DNA-RNA DIZAYNı, BIOENFORMATIK,
YAZıLıM İŞLETME, YAZıLıM GELIŞTIRME.

(Scope in English: Nucleotide Production, Oligo Production, DNA-RNA Production, DNA-RNA Design, Bioenformatics, Software Business, Software Development.)

Certificate No.	: **AMS/08136/0918**
Original Certificate Date	: **24 - September - 2018**
Issue Date	: **24 - September - 2018**
Expiry Date	: **23 - September - 2021**

To check this certificate status visit:
"http://qccertification.com/Client.aspx"

Authorised Signature

For **Quality Control Certification**

Head Office: 2nd Floor, Aman Market,
Narela Mandi, Delhi - 110 040, India

UK Office: 1929, Chynoweth House,
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Cornwall, UK

Quality Control Certification accredited by UASL, UK
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Certificate

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İŞCI BLOKLARı MAHALLESI MUHSIN YAZICIOĞLU CADDESI NO: 45/7
ÇUKURAMBAR / ÇANKAYA / ANKARA-TURKEY.

is in Compliance with

Medical Laboratories
Requirements for Quality and Competence

ISO 15189:2012

for the following scope:

NÜKLETID ÜRETIM, OLIGO ÜRETIMI, DNA-RNA ÜRETIMI,
DNA-RNA DIZAYNı, BIOENFORMATIK,
YAZıLıM İŞLETME, YAZıLıM GELIŞTIRME.

(Scope in English: Nucleotide Production, Oligo Production, DNA-RNA Production, DNA-RNA Design, Bioenformatics, Software Business, Software Development.)

Certificate No. : **MLRQC/08087/0918**

Original Certificate Date : **24 - September - 2018**

Issue Date : **24 - September - 2018**

Expiry Date : **23 - September - 2021**

To check this certificate status visit:
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For **Quality Control Certification**

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Certificate

This is to Certify that

DS Ürün Takip Doğrulama İç ve Dış Ticaret A.Ş.

İŞCI BLOKLARı MAHALLESI MUHSIN YAZICIOĞLU CADDESI NO: 45/7
ÇUKURAMBAR / ÇANKAYA / ANKARA-TURKEY.

is in Compliance with

Risk Management

ISO 31000:2018

for the following scope:

NÜKLETID ÜRETIM, OLIGO ÜRETIMI, DNA-RNA ÜRETIMI,
DNA-RNA DIZAYNı, BIOENFORMATIK,
YAZıLıM İŞLETME, YAZıLıM GELIŞTIRME.

(Scope in English: Nucleotide Production, Oligo Production, DNA-RNA Production, DNA-RNA Design, Bioenformatics, Software Business, Software Development.)

Certificate No. : **RM/08121/0918**

Original Certificate Date : **24 - September - 2018**

Issue Date : **24 - September - 2018**

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