



Spesera

Health Products, Imp. & Exp. Trade Ltd.



TC Sağlık Bakanlığı
İSTANBUL
SAĞLIK
MÜDÜRLÜĞÜ

T.C.
İSTANBUL VALİLİĞİ
İL SAĞLIK MÜDÜRLÜĞÜ

Belge No **34/TCISM/4335 - 0**
Tarih **01/07/2020**

TIBBİ CİHAZ SATIŞ MERKEZİ YETKİ BELGESİ

MERKEZİN

Adı **ŞPESERA SAĞLIK ÜRÜNLERİ İÇ VE DIŞ TİC. LTD. ŞTİ.**
Adresi **Göztepe Mh. Batışehir Cd. No:2/3/1B12 BAĞCILAR / İSTANBUL**

İŞLETME SAHİBİ/SAHİPLERİ

Adı ve Soyadı **:Spesera Sağlık Ürünleri İç ve Dış Ticaret Limited Şirketi**

SORUMLU MÜDÜRÜN

Mernis No **:54046040384**
Adı ve Soyadı **:Gülcen ASSAF**
Doğum Yeri ve Tarihi **:ŞARKIKARAAĞAÇ / 14.06.1972**
Sorumlu Müdür Yeterlilik Belge Tarihi ve Numarası: **25.02.2020 / SM24227**

Yukarıda adı ve adresi belirtilen tıbbi cihaz satış merkezinin sorumlu müdür **Gülcen ASSAF** sorumluluğunda faaliyet göstermesi uygun görülmüştür.

Bu Belge 15/05/2014 tarih ve 29001 sayılı Resmî Gazete de yayımlanan "Tıbbi Cihaz Satış,Reklam ve Tanıtım Yönetmeliği" hükümlerine göre düzenlenmiştir.

e-imzalıdır

Uz. Dr. Hasan Basri VELİOĞLU
Vali a.
Başkan



Bu belge 5070 sayılı elektronik imza kanunu göre güvenli elektronik imza ile imzalanmıştır.

"Evetim elektronik imza suretine <http://e-belge.saglik.gov.tr/adresinden> 4446954445-4173-8860-550621e1265 kodu ile doğrulabilirsiniz."

T.C.
BAĞCILAR BELEDİYE BAŞKANLIĞI
Ruhsat ve Denetim Müdürlüğü

İŞYERİ AÇMA VE ÇALIŞMA RUHSATI

Kayıt ve Dosya No : 72019
Ruhsat Sayısı : 2005542
Ruhsat Tarihi : 19/02/2020

İŞYERİNİN

Adı veya Ünvanı : SPESERA SAĞLIK ÜRÜNLERİ İÇ VE DIŞ TİCARET
LIMITED ŞİRKETİ
Ana Faaliyet Konusu : SAĞLIK ÜRÜNLERİ DEPOLAMASI VE TOPTAN SATIŞI
Tali Faaliyet Konusu : Ambalajlama ve Paketleme
Adresi : GÖZTEPE Mah., BATIŞEHİR Cad., No : 2 /3/1B12
Bağcılar / İSTANBUL
Bulunduğu Yer : Pafta: F21C17C2D Ada: 1562 Parsel: 11
Kullanım Alanı : 308 m²
Türü / Sınıfı : Gayrisihhi Müessese / 2-9.13
Motor Gücü : 4 hp
Çalışma Saatleri : 08:00 - 20:00 (6301 sayılı Öğle Dinlenme Kanunu hükümleri uygulanacaktır)

Bu belge 10.08.2005 tarihi 25902 sayılı resmi gazetede yayımlanan 2005/9207 sayılı İşyeri Açma ve Çalışma Ruhsatlarına ilişkin yönetmeliğe istinaden (sökülen kabinli vinci kullanmamak kayıt ve şartı ile) hazırlanmıştır.





T.C. SANAYİ VE TEKNOLOJİ BAKANLIĞI
SANAYİ GENEL MÜDÜRLÜĞÜ

SANAYİ SİCİL BELGESİ

e-belge

Belge Tarihi : 15/03/2021	Belge No : 785157	Veriliş Sebebi : İlk Kayıt	
İşyeri İşletme Ünvanı : SPESERA SAĞLIK ÜRÜNLERİ İÇ VE DIŞ TİCARET LİMİTED ŞİRKETİ			
İşyeri Adresi : GÖZTEPE MAHALLESİ BATIŞEHİR CADDE DİŞ KAPI NO: 2 /3 İÇ KAPI NO: 1B12. BAĞCILAR/İSTANBUL			
Vize Tarihi :	Vize Dönemi Bitiş Tarihi :	Vergi/TC No : 7810414636	
Üretim Konusu			
TAŞIMA BESİYERİ (NÜKLEİK ASİT (DNA, RNA) EKSTRAKTE EDİCİ VE KORUYUCU TAŞIMA SIVISI) (315 L)(TAŞIMA BESİYERİ (NÜKLEİK ASİT (DNA, RNA) EKSTRAKTE EDİCİ VE KORUYUCU TASIMA SIVISI) (315 L)),			
Yukarıda hüviyeti yazılı işletme 24.04.1957 tarih ve 6948 sayılı Kanunun ikinci maddesi gereğince tescil edilmiş olup 2941 sayılı Seferberlik ve Savaş Hali Kanunu hükümleri gereğince Türk Silahlı Kuvvetlerine tahsis edildiği takdirde bu tahsisi taahhüt etmiş sayılır.			Belge Basım Tarihi : 01/12/2021
Bu belge düzenleniş tarihi itibarıyla belge iptali gerçekleştirilmediği sürece geçerli olup iki yılda bir vize ettirilmek zorundadır.		Sanayi Sicil Belgesi	1/1. sayfasıdır.
İş bu e-belge İSTANBUL Sanayi ve Teknoloji İl Müdürlüğü tarafından düzenlenmiş olup belge geçerliliği doğrulamak için yukarıdaki QRCode veya aşağıdaki link kullanılmalıdır. https://sanayisicil.sanayi.gov.tr/App_Pages/CommonPages/QRCodeIsletmeBilgileriGoruntuleme.aspx?ID=KchqQCSh2LK2czaLdUgB3w%3d%3d			

İ S T A N B U L

T İ C A R E T O D A S I

FAALİYET BELGESİ

(SİCİL KAYIT SURETİ)

TARİH: 24/08/2021

SİCİL NO : 614120-0

MERSİS: 0781-0414-6360-0011

FİRMA : SPESERA SAĞLIK ÜRÜNLERİ İÇ VE DIŞ TİCARET LİMİTED ŞİRKETİ

ADRES : GÖZTEPE MAH.BATIŞEHİR CAD. NO:2/3/1B12 BAĞCILAR

MEŞGALE:

1-Tıpta , cerrahide ,dişçilikte ve veterinerlikte kullanılan her türlü teşhis ve tedaviye yönelik tıbbi hammadde, yarı mamul, mamul ,araç gereç ve işletme malzemelerinin imalatını ,alımını, satımını, ithalatını ve ihracatını yapmak. 2-Biyoteknoloji ürünleri,yaşam bilimleri, tıp, veterinerlik, biyoloji, halk sağlığı ve genetik bilimlerin bütün alanlarında, tarım, gıda, ilaç, kimya ve savunma sanayilerinde , hastane, tahlil kalite ve araştırma laboratuvarı ve eczanelerde tanı, hijyen, araştırma, geliştirme, tahlil, üretim ve sair her türlü amaçla kullanılan kimyevi ve biyolojik esaslı her türlü ham madde, mamul madde, ilaç, kültür, besiyeri, katkı maddesi, preparat ve sair ürünleri aynı amaçlarla kullanılan her türlü tıbbi ve laboratuvar analiz, test, araç ve gereç, tahlil kiti, sarf malzemesi, alet, makine, cihaz, bilgisayar programı ve sistemlerini `` Vücut dışında kullanılan tıbbi tanı ürünleri yönetmeliği `` uyarınca araştırmak ve geliştirmek, üretmek, imal etmek, alımını, satımını, ithalatını ve ihracatını yapmak. 3-Her türlü medikal malzemenin alımını ,satımını, ithalatını ve ihracatını yapmak. 4-Her türlü hastane, dispanser, özel muayenehane, poliklinik, laboratuvar ve bu yerlerde kullanılan bilmum tıbbi alet ve edevat makine ve cihazlarla, bunların yedek parça , aksesuarlarını ve her türlü işletme malzemelerinin ,alımını, satımını, ithalatını ve ihracatını yapmak. 5-Özel hastane kurmak ve bu hastane bünyesinde olmak üzere dispanser, özel muayenehane, özel poliklinik, laboratuvar işletmeciliği yapmak, kiralamak ve kiraya vermek. 6-Yurtdışında ve yurtdışında konusu ile ilgili seminerler düzenlemek, ilmi, eğitsel ve lisansla ilgili kitap, broşür ,dergi çıkarmak veya bu yönde çalışan firmalarla işbirliği yapmak. 7-Sağlık sektöründe kullanılan makine araç gereç ve cihazların, her türlü ilaç ve sarf malzemelerinin tanıtılması, depolanması, dağıtım işlemlerini yapmak, yaptırmak, promosyon organizasyonlarını düzenlemek. 8-Tıp alanında kullanılan bilmum kimyevi maddelerin alım satımını yapmak. Güzellik müstehzarları itriyat ve kozmetik ürünleri saç cilt ve vücut bakımı mamulleri ve benzerlerinin imalatını ,alımını, satımını, ithalatını ve ihracatını yapmak. 9-Tıp alanında teshise yönelik mikrobiyoloji, biokimya ve patoloji kimyevi müstehzarları , kitleri ve sarf

malzemelerinin imalatını , alımını, satımını, ithalatını ve ihracatını yapmak. 10-Şirket yukarıda sayılan maddelerle ilgili olarak imalat, ithalat, ihracat ,dahili ticaret, mümessillik, müşavirlik, distribitörlük ve acentalık yapabilir. Ayrıca bu maksat ve gayesinin tahakkuku için yukarıda belirtilen işletme mevzuu çerçevesinde kalmak üzere bütün hakları iktisap ve borçları ilzam edebilir. 11-Şirket iştiغال mevzuuna dahil kurulmuş veya kurulacak şirketlere hissedar olabilir. Yerli veya yabancı hükmü ve yabancı şahıslarla birlikte yeni şirketler kurabilir. Sürekli veya süreksiz her türden ortaklık tesis edebilir. 14-Konusu ile ilgili kamu ve özel ihalelere iştirak edebilir. Taahhüt işlerini deruhde edebilir. 15-Şirket iktisadi maksat ve mevzuunun gerektirdiği bİlcümle ticari, sinai, hukuki, mali ve idari işleri yapabilir. Patent, marka, know-how, ve sair sinai mülkiyet haklarını iktisap edebilir. Gerektiğinde üçüncü şahısların istifadesine tahsis edebilir. Şirket amacını gerçekleştirmek için her türlü gayrimenkul ve her türlü vasıta alabilir, satabilir, kiralar, kiraya verir, bunlar üzerinde ayni ve şahsi her türlü hakları tesis edebilir, ipotek alabilir, ipotek verebilir ve ipotekleri fek edebilir. Şirket gayrimenkulleri üzerinde irtifak, intifa, sükna, gayrimenkul, mükellefiyeti, kat irtifakı, kat mülkiyeti tesis edebilir. Her türlü gayrimenkullerle ilgili olarak tapu daireleri nezdinde cins tashihi, ifraz, tevhit, taksim, parselasyon ile ilgili her nevi muamele ve tasarrufları gerçekleştirebilir. Şirket amacına uygun olarak , ilgili mevzuat çerçevesinde kalmak kaydıyla internet ortamında elektronik ticaret yapabilir.

DERECESİ : 02

SERMAYE : *****150.000,00 TL' dir.

İŞE BAŞLAMA TARİHİ : 30/1/2007

MESLEK GR. : 8 İLAÇ VE TIBBİ CİHAZ

NACE KODU :

46.46.01 Cerrahi, tıbbi ve ortopedik alet ve cihazların toptan ticareti
NACE Rev.02

47.74.01 Belirli bir mala tahsis edilmiş mağazalarda tıbbi ve ortopedik ürünlerin perakende ticareti (gözlük hariç diğer medikal ürünler dahil) NACE Rev.02

BU BELGE ODA KAYDI FAAL OLAN YUKARIDA ÜNVANI YAZILI ÜYENİN TALEBİ
ÜZERİNE VERİLMİŞTİR. ÜZERİNDE TAHRİFAT YAPILAN BELGELER GEÇERSİZDİR.

Bu belge 60 (altmış) gün süreyle geçerlidir.

5070 Sayılı Elektronik İmza Kanununa göre Güvenli Elektronik İmza ile
imzalanmıştır. Elektronik olarak imzalanan belgeye aşağıdaki URL
adresinden ulaşılabilir.



e-imza
Genel Sekreter y.
ÜYE SİCİL MÜDÜRLÜĞÜ

İSTANBUL
TİCARET
ODASI
— 1882 —

REGISTRATION NOTIFICATION

Ref. No.: MU-EAR-22101

Date: 09/03/2022

This is to certify that, according to the Council Directive 98/79/EC, MedUnion S.L performed all notification duties and responsibilities as the European Authorized Representatives (EC REP) of:

Manufacturer: Spesera Health Products. Imp & Exp. Trade, Ltd
Address: Goztepe mah. Batisehir cad. No:2/3 Bagcilar/ISTANBUL

The Manufacturer has provided MedUnion S.L. with all the appropriate declarations according to the 98/79/EC Directive-article 10 requirements including the EC Declaration of Conformity confirming that his In-Vitro Diagnostics medical devices, as stipulated in the Annex I, are fulfilling the applicable requirements of the European Council Directive 98/79/EC

The notification of the In-Vitro Diagnostic medical devices in the Annex I has been completed by MedUnion S.L on the **09/03/2022** with Registratation number **RPS/602/2022** in Spanish Medicines and Medical Products Agency.

Conformity Assessment Route: Medical device directive: Council Directive 98/79/EC concerning in vitro diagnostic medical devices (IVDD 98/79/EC).

In-Vitro Diagnostic medical devices: Please see ANNEX I-List of devices (1 page, 22 devices)



Ms Shu Chuan Kuo, Managing Director
MedUnion S.L.

ANNEX I- List of Devices

Ref. No.: MU-EAR-22101

Nº	Product Name	Class
1	COVID-19 Antigen Rapid Test	Other
2	COVID-19 Antigen/InfluenzaA+B Ag Combo rapid test	Other
3	COVID-19 IgG/IgM Rapid test kit	Other
4	Malaria pf/pv One Step Rapid Test	Other
5	Malaria pf/pan One Step Rapid Test	Other
6	fFN Rapid Test	Other
7	D-Dimer Rapid Test Device	Other
8	Influenza A/B Ag Rapid Test	Other
9	Troponin I Rapid Test	Other
10	Typhoid AntigenRapid Test	Other
11	Adenovirus Ag Rapid Test	Other
12	Rotavirus Rapid Test	Other
13	Strep A Rapid Test	Other
14	FOB Rapid Test	Other
15	Mycobacterium Tuberculosis Antibody Rapid Test	Other
16	One Step COC Rapid Test	Other
17	One Step Multi-Drug Test Dip Card	Other
18	H.Pylori Antigen Rapid Test	Other
19	H.Pylori Antibody Rapid Test	Other
20	Syphilis Rapid test	Other
21	Pregnancy one step Rapid test	Other
22	Urine multi strip test	Other

Sertifika



SPESESA SAĞLIK ÜRÜNLERİ İÇ VE DIŞ TİC. LTD. ŞTİ.

Göztepe Mah. Batışehir Cad. No: 2/3 No: 1B12 Bağcılar /İstanbul

BELLA yukarıda adı geçen kuruluşun Kalite Yönetim Sisteminin aşağıdaki kapsamda uygunluğunu değerlendirmiş olup onaylamaktadır.

ISO 9001:2015

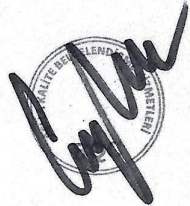
Kapsam

Mikrobiyolojik Ürünlerin Ambalajlanması, Tıbbi Laboratuvar Malzemelerinin Hazırlanması, Alımı, Satımı, İthalatı Ve İhracatı

EA KODU: 29



Sertifika No : 19-217-1115
Sertifika İlk Yayın Tarihi : 26.03.2019
Yeniden Basım Tarihi : 21.03.2022/03
Sertifika Bitiş Tarihi : 25.03.2025



Bu belge 21.03.2022 – 25.03.2023 tarihleri arasında geçerlidir



TÜRKAK BDS NO
YS-A685-SD37



Kalite Yönetim Sistemi
TS EN ISO/IEC 17021
AB-0110-YS

Bu sertifika kuruluşun değerlendirme şartlarına uyması ve yılda en az bir kere yapılacak gözetime denetiminin başarılı geçmesi halinde 3 yıl boyunca geçerlidir. Bu sertifikanın mülkiyeti Bella Kalite Belgelendirme Hiz. Ltd. Şti'ne aittir ve istenildiğinde iadesi zorunludur. Sertifikanın geçerlilik durumu Türkak Belge Doğrulama Sisteminin sertifikansız üzerinde bulunan QR kodunuza kontrol edilebilir.
Bella Kalite Belgelendirme Hiz. Ltd. Şti. Cevizli Mah. Zuhdi Cad. No:44 B Blok D:56 Rütim İstanbul Konutları Maltepe/İSTANBUL
Tel: 0 216 518 33 08 Fax: 0 216 518 40 74 www.bqcet.co.uk - info@bqcet.co.uk

FR.12/03.02.2021/04

Sertifika



SPESERA SAĞLIK ÜRÜNLERİ İÇ VE DIŞ TİC. LTD. ŞTİ.

Göztepe Mah. Batışehir Cad. Numara:2/3 No:1B 12 Bağcılar /İstanbul

BELLA yukarıda adı geçen kuruluşun Gıda, Yem ve Su Mikrobiyolojisi-Kültür Ortamının Hazırlama, Üretim, Muhafaza ve Performans Deneyi Sisteminin aşağıdaki kapsamda uygunluğunu değerlendirmiş olup onaylamaktadır.

ISO 11133:2014

Moleküler Biyoloji, Mikrobiyoloji, Biyoteknoloji Alanlarında Kullanılan
Cihaz, Sarf ve Kimyasal Maddelerin İmalatı, İthalatı, İhracatı ve
Pazarlaması



Sertifika No	: 19-19005
Sertifika İlk Yayın Tarihi	: 18.03.2019
Yeniden Basım Tarihi	: 18.03.2022-03
Sertifika Bitiş Tarihi	: 18.03.2023
Geçerlilik Periyodu	: 1 YIL



Bu sertifika kuruluşun değerlendirme şartlarına uyması ve yılda en az bir kere yapılacak gösterim denetiminin başarılı geçmesi halinde 3 yıl boyunca geçerlidir. Bu sertifikanın mülkiyeti Bella Kalite Belgelendirme Hiz. Ltd. Şti'ne aittir ve istenildiğinde iadesi zorunludur. Sertifikanın geçerlilik durumu Türkak Belge Doğrulama Sisteminin sertifikamız üzerinde bulunan QR koduna göre kontrol edilebilir.
Bella Kalite Belgelendirme Hiz. Ltd. Şti. Cevizli Mah. Zuhat Cad. No:44 B Blok D:56 Ritim İstanbul Komutları Maltepe/İSTANBUL
Tel: 0 216 518 33 08 Fax: 0 216 518 40 74 www.bqcert.co.uk - info@bqcert.co.uk

FR.12/03.02.2021/04

Sertifika



SPESERA SAĞLIK ÜRÜNLERİ İÇ VE DIŞ TİC. LTD. ŞTİ.

Göztepe Mah. Batışehir Cad. Numara:2/3 No:1B 12 Bağcılar /İstanbul

BELLA yukarıda adı geçen kuruluşun Tıbbi Cihazlar Yönetim Sisteminin aşağıdaki kapsamda uygunluğunu değerlendirmiş olup onaylamaktadır.

ISO 13485:2016

Moleküler Biyoloji, Mikrobiyoloji, Biyoteknoloji Alanlarında Kullanılan
Cihaz, Sarf ve Kimyasal Maddelerin İmalatı, İthalatı, İhracatı ve
Pazarlaması



Sertifika No	: 19-19006
Sertifika İlk Yayın Tarihi	: 18.03.2019
Yeniden Basım Tarihi	: 18.03.2022-03
Sertifika Bitiş Tarihi	: 18.03.2023
Geçerlilik Periyodu	: 1 YIL



Bu sertifika kuruluşun değerlendirme şartlarına uyması ve yılda en az bir kere yapılacak gözetim denetiminin başarılı geçmesi halinde 3 yıl boyunca geçerlidir. Bu sertifikanın mülkiyeti Bella Kalite Belgelendirme Hiz. Ltd. Şti'ne aittir ve istenildiğinde iade edilebilir. Sertifikanın geçerlilik durumu Türkak Belge Doğrulama Sisteminden sertifikanız üzerinde bulunan QR kodunuzla kontrol edilebilir.
Bella Kalite Belgelendirme Hiz. Ltd. Şti, Cevizli Mah. Zuhdi Cad. No:44 B Blok D:56 Ritim İstanbul Konutları Maltepe/İSTANBUL
Tel: 0 216 518 33 98 Fax: 0 216 518 40 74 www.bqcrt.co.uk info@bqcrt.co.uk

FR.12/03.02.2021/04

Certificate



SPESERA SAĞLIK ÜRÜNLERİ İÇ VE DIŞ TİC. LTD. ŞTİ.

Göztepe Mah. Batışehir Cad. No: 2/3 No: 1B12 Bağcılar /İstanbul

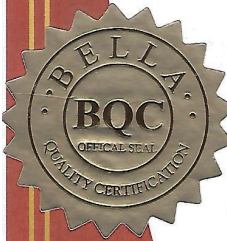
BELLA Certification certify that the Quality Management Systems of the above organization has been audited and found to be in accordance with the requirements of the management system standards detailed below Standard

ISO 9001:2015

Scope of Certification

Packaging of Mikrobiological Products, Preparation of Medical Laboratory Materials,
Reception, Sale, Import and Export

EA CODE: 29



Certificate No : 19-217-1115
Certification Cycle Start Date : 26.03.2019
Reissue Date : 21.03.2022/03
Certificate Expire Date : 25.03.2025



Validity Date of Current Certification Period: 21.03.2022 – 25.03.2023



TÜRKAK BDS NO
YS-A685-5D57



This certificate is valid for above address(es) and scope upon compliance with Bella procedure(s), instruction(s) and the above mentioned standard and successful completion of regular surveillance audits. The validity of this certificate can be checked through on www.bqcert.co.uk webpage.
Bella Kalite Belgelendirme Hiz. Ltd. Şti. Cevizli Mah. Zuhul Cad. No:44 B Blok D:56
Ritim İstanbul Konutları Maltepe/İSTANBUL - Tel: 0 216 518 33 08 Fax: 0 216 518 40 74 www.bqcert.co.uk - info@bqcert.co.uk

FR.12/03.02.2021/04

Certificate



SPESESA SAĞLIK ÜRÜNLERİ İÇ VE DIŞ TİC. LTD. ŞTİ.

Göztepe Mah. Batışehir Cad. Numara:2/3 No:1B 12 Bağcılar /İstanbul

BELLA has evaluated and approved the suitability of the Microbiology of Food, Animal Feed and Water Preparation, Production, Storage and Performance Testing of Culter Media Management Systems within the scope of the following.

ISO 11133:2014

Production, Import, Marketing and Export of Devices and Chemicals
Equipments That Used in the Fields of Molecular Biology,
Microbiology and Biotechnology



Certificate No : 19-19005
Certification Cycle Start Date : 18.03.2019
Reissue Date : 18.03.2022/03
Certificate Expire Date : 18.03.2023
Validity Date : 1 Year



This certificate is valid for above address(es) and scope upon compliance with Bella procedure(s), instruction(s) and the above mentioned standard and successful completion of regular surveillance audits. The validity of this certificate can be checked through on www.bqcert.co.uk webpage.
Bella Kalite Belgelendirme Hiz. Ltd. Şti. Cevizli Mah. Zuhai Cad. No:44 B Blok D:56
Ritim Istanbul Konutları Maltepe/İSTANBUL - Tel: 0 216 518 33 08 Fax:0 216 518 40 74 www.bqcert.co.uk - info@bqcert.co.uk

FR.12/03.02.2021/04

Certificate



SPESERA SAĞLIK ÜRÜNLERİ İÇ VE DIŞ TİC. LTD. ŞTİ.

Göztepe Mah. Batişehir Cad. Numara:2/3 No:1B 12 Bağcılar /İstanbul

BELLA has evaluated and approved the compliance of the Medical Devices
Management Systems within the scope of the following

ISO 13485:2016

Production, Import, Marketing and Export of Devices and Chemicals
Equipments That Used in the Fields of Molecular Biology,
Microbiology and Biotechnology



Certificate No : 19-19006
Certification Cycle Start Date : 18.03.2019
Reissue Date : 18.03.2022/03
Certificate Expire Date : 18.03.2023
Validity Date : 1 Year



This certificate is valid for above address(es) and scope upon compliance with Bella procedure(s), instruction(s)
and the above mentioned standard and successful completion of regular surveillance audits. The validity of this certificate
can be checked through on www.bqcert.co.uk webpage.
Bella Kalite Belgelendirme Hiz. Ltd. Şti. Cevizli Mah. Zuhul Cad. No:44 B Blok D:56
Ritim İstanbul Konutları Maltepe/İSTANBUL - Tel: 0 216 518 33 08 Fax:0 216 518 40 74 www.bqcert.co.uk - info@bqcert.co.uk

FR.12/03.02.2021/04



**THE REPUBLIC OF TURKEY
MINISTRY OF HEALTH
TURKISH MEDICINES AND MEDICAL DEVICES AGENCY**

Certificate No: 163897

Date of Issue : 17 September 2021

CERTIFICATE OF FREE SALE

To whom it may concern,

It is hereby certified that the products detailed in the attached schedule, which are manufactured by "SPESERA SAĞLIK ÜRÜNLERİ İÇ VE DIŞ TİC. LTD. ŞTİ." (Göztepe Mh. Batışehir Cd. No:2/3/1b12 BAĞCILAR İSTANBUL), have been affixed with the CE mark in accordance with Medical Device Directives of the European Union (EU) and are freely sold in Turkey.

This certificate is issued to be given to the relevant competent authorities of "Bulgaria" and is valid for 36 months from the date of issue.

Yours sincerely,


Ömer Faruk KURU
Head of Medical Devices
Registration and Coordination Department

This certificate consists of 4 page/s and 22 products. The products listed in the attached schedule are registered from the date of issuance of this certificate and information about the current status of these products is accessible through

<https://utsuygulama.saglik.gov.tr/UTS/vatandas#/vatTibbiCihazListele>.



PRODUCT SCHEDULE

#	Barkod	Brand	Label Name	Reference No / Version / Model	GMDN Code
1	8681176311002	SPESERA	COVID-19 IgG/IgM Rapid Test Cassette	SP-225	64756
2	8681176311019	SPESERA	sNAT Transfer Tube	SP-227	58697
3	8681176311026	SPESERA	SPESERA COVID - 19 Antigen Rapid Test Cassette	SP-226	64787
4	8681176311125	SPESERA	Influenza A+B Rapid Test Cassette	SP-222	49119
5	8681176311156	SPESERA	H.PYLORI ANTIGEN Rapid Test Cassette	SP-207	30825
6	8681176311354	SPESERA	FOB Rapid Test Cassette	SP-304	54532
7	8681176311385	SPESERA	HAV IgG/IgM Rapid Test Cassette	SP-215	48270
8	8681176311064	SPESERA	TROPONIN I Rapid Test Cassette	SP-306	46989
9	8681176311095	SPESERA	CHLAMYDIA Rapid Test Cassette	SP-109	50759
10	8681176311101	SPESERA	CK-MB Rapid Test Cassette	SP-307	52995



11	8681176311088	SPESERA	BETA HCG (PREGNANCY) Rapid Test Cassette	SP-103	33819
12	8681176311132	SPESERA	Beta HCG DIPSTICK	SP-101	33819
13	8681176311149	SPESERA	Urine Strip 10T	SP-309	54514
14	8681176311187	SPESERA	SYPHILIS Rapid Test Cassette	SP-219	51788
15	8681176311194	SPESERA	GIARDIA LAMBLIA Rapid Test Cassette	SP-205	52249
16	8681176311248	SPESERA	H.PYLORI ANTIBODY Rapid Test Cassette	SP-206	62029
17	8681176311231	SPESERA	STREP A HIZLI TEST	SP-220	51707
18	8681176311224	SPESERA	DENGUE IgG/IgM Rapid Test Cassette	SP-208	63238
19	8681176311200	SPESERA	TYPHOID Rapid Test Cassette	SP-211	51560
20	8681176311347	SPESERA	TUBERCULOSIS (TB) Rapid Test Cassette	SP-223	51172
21	8681176311279	SPESERA	ADENOVİRÜS Rapid Test Cassette	SP-201	49856



Date of Issue : 17 September 2021

22	8681176311170	SPESERA	ROTAVİRÜS- ADENOVİRÜS Rapid Test Cassette	SP-204	48235
----	---------------	---------	--	--------	-------

End of product schedule.





Live, work, travel in the EU

COVID-19 In Vitro Diagnostic Devices and Test Methods Database

[Home](#) > [COVID-19 In Vitro Diagnostic Medical Devices](#) >

COVID-19 In Vitro Diagnostic Medical Device - detail

COVID-19 In Vitro Diagnostic Medical Device - detail

Covid-19 Antigen Rapid Test Cassette

Manufactured by SPESERA SAĞLIK ÜRÜNLERİ İÇ VE DIŞ LTD. ŞTİ.,
Turkey - www.spesera.com.tr

Device identification number	2246
CE Marking	Yes
HSC common list	No
Format	Near POC / POC
Physical Support	Cassette
Target type	Antigen
Specimen	Nasal swab, Nasopharyngeal swab, Throat swab

Cross-reactivity (pathogens tested)	Alpha Coronavirus 229E (HCoV-229E), Alpha Coronavirus NL63 (HCoV-NL63), Beta Coronavirus HKU1 (HCoV-HKU1), Beta Coronavirus OC43 (HCoV-OC43)
Commercial Status	Commercialised
Last Update	2022-03-14 09:42:40 CET
Comments	Covid-19 Antigen Rapid Test Cassette

Assay Type	Immuno-Antigen
Reader Required	No
Subcategory	Extraction kit
Method	Immunochromatography
Measurement	Qualitative
Time	15 minutes
Subclass	Multiple
LOD	580 TCID50/ml
Positive control	$100 \times TP / (TP + FP) = 100 \times 238 / 242 = 98.34\%$
Negative control	$100 \times TN / (FN + TN) = 100 \times 530 / 538 = 98.51\%$
Analytical Sensitivity	93.76 %
Analitical Specificity	97.5 %
Clinical Sensitivity	96.89 %
Clinical Specificity	99.1 %
Notes	Ares(2021)3875860

The database contains publicly available In Vitro Diagnostic Medical Devices for COVID-19 and it is being updated periodically. Please note that additional performance



Sağlık Ürünleri İç ve Dış Tic. Ltd. Şti.

Test listesi

KATALOG NO

ÜRÜNLER

AMBALAJ

KROMOJENİK BESİYERLERİ

SP-4000	CHROMagar CANDIDA	10 x 90 mm
SP-4001	CHROMagar ORIENTATION	10 x 90 mm
SP-4002	CHROMagar S.AUREUS	10 x 90 mm
SP-4003	CHROMagar MRSA	10 x 90 mm
SP-4004	CHROMagar VRE	10 x 90 mm
SP-4005	CHROMagar PSEUDOMONAS8	10 x 90 mm
SP-4006	CHROMagar SALMONELLA	10 x 90 mm
SP-4007	CHROMagar SALMONELLA PLUS	10 x 90 mm
SP-4008	CHROMagar E.COLI	10 x 90 mm
SP-4009	CHROMOGENIC UTI	10 x 90 mm
SP-4010	CHROMOGENIC ECC (E.COLI/COLIFORM)	10 x 90 mm
SP-4011	CHROMOGENIC 0157	10 x 90 mm
SP-4012	CHROMOGENIC TBX	10 x 90 mm
SP-4013	CHROMOGENIC SALMONELLA	10 x 90 mm

PETRİDE BESİYERLER (90MM)

SP-1000	ALOA AGAR	10 x 90 mm
SP-1001	BAIRD PARKER AGAR (BPA)	10 x 90 mm
SP-1002	BAIRD PARKER AGAR (BPA) w/RPF SUPPLEMENT	10 x 90 mm
SP-1003	BACILLUS CEREUS (MYP) AGAR	10 x 90 mm
SP-1004	BILE ESCULIN AGAR	10 x 90 mm
SP-1005	BILE ESCULIN AZIDE (ENTEROCOCCOSEL) AGAR	10 x 90 mm
SP-1006	BRILLIANT GREEN AGAR (BGA)	10 x 90 mm
SP-1007	BRAIN HEART INFUSION AGAR	10 x 90 mm
SP-1008	CAMPYOBACTER BLOOD AGAR	10 x 90 mm
SP-1009	CAMPYOBACTER BLOOD-FREE AGAR (MCCDA BOLTON)	10 x 90 mm
SP-1010	CAMPYOBACTER SELECTIVE AGAR (SKIRROW)	10 x 90 mm
SP-1011	CETRIMIDE AGAR	10 x 90 mm
SP-1012	ÇİKOLATAMSI AGAR	10 x 90 mm
SP-1013	ÇİKOLATAMSI AGAR w/BIOVITEX +VX FACTOR	10 x 90 mm
SP-1014	DG-18 AGAR	10 x 90 mm
SP-1015	DRBC AGAR	10 x 90 mm
SP-1016	DNAse AGAR	10 x 90 mm
SP-1017	EMB AGAR	10 x 90 mm
SP-1018	ENDO AGAR	10 x 90 mm
SP-1019	ENTEROCOCCOSEL w/ VANCOMYSIN AGAR	10 x 90 mm
SP-1020	HEKTOEN ENTERIC AGAR	10 x 90 mm
SP-1021	5% KOYUN KANLI AGAR	10 x 90 mm
SP-1022	5% KOYUN KANLI MUELLER HINTON AGAR	10 x 90 mm
SP-1023	KING B MEDIUM	10 x 90 mm
SP-1024	LEGIONELLA BCYE AGAR w/L-CYSTEINE	10 x 90 mm
SP-1025	LEGIONELLA GVPC SELECTIVE AGAR	10 x 90 mm
SP-1026	LEGIONELLA BMPA SELECTIVE AGAR	10 x 90 mm
SP-1027	LEGIONELLA MWY SELECTIVE AGAR	10 x 90 mm
SP-1028	LISTERIA OXFORD AGAR	10 x 120 mm
SP-1029	LISTERIA PALCAM AGAR	10 x 150 mm
SP-1030	LT 100 AGAR	10 x 90 mm
SP-1031	m-LES ENDO AGAR	10 x 90 mm
SP-1032	MACCONKEY AGAR	10 x 90 mm
SP-1033	MACCONKEY AGAR w/SORBITOL	10 x 90 mm
SP-1034	MANNITOL SALT AGAR	10 x 90 mm
SP-1035	MUELLER HINTON AGAR	10 x 90 mm
SP-1036	MUELLER HINTON AGAR 120 MM	10 x 90 mm
SP-1038	NUTRIENT AGAR	10 x 90 mm
SP-1039	PLATE COUNT AGAR (PCA)	10 x 90 mm
SP-1040	PLATE COUNT AGAR (PCA) w/SKIM MILK	10 x 90 mm
SP-1041	POTATO DEXTROSE AGAR (PDA)	10 x 90 mm
SP-1042	PSEUDOMONAS CN AGAR	10 x 90 mm
SP-1043	R2A AGAR	10 x 90 mm
SP-1044	SABOURAUD DEXTROSE AGAR (SDA)	10 x 90 mm
SP-1045	SABOURAUD DEXTROSE AGAR (SDA) w/CHLORAMPHENICOL	10 x 90 mm
SP-1046	SABOURAUD DEXTROSE AGAR (SDA) w/CAF +CYC	10 x 90 mm
SP-1048	SCHAEGLER AGAR	10 x 90 mm
SP-1049	SLANETZ BARTLEY AGAR (SBA)	10 x 90 mm
SP-1050	SALMONELLA SHIGELLA (SS) AGAR	10 x 90 mm
SP-1052	THAYER MARTIN AGAR	10 x 90 mm
SP-1053	TRYPTIC SOY AGAR (TSA)	10 x 90 mm
SP-1054	TRYPTIC SOY AGAR (TSA) w/ NEUTRALISANT	10 x 90 mm
SP-1055	TSC AGAR	10 x 90 mm
SP-1056	XLD AGAR	10 x 90 mm
SP-1058	VIOLET RED BILE (VRB) AGAR	10 x 90 mm
SP-1059	VIOLET RED BILE DEXTROSE (VRBD) AGAR	10 x 90 mm
SP-1060	VRE AGAR	10 x 90 mm
SP-1061	YEAST EXTRACT AGAR	10 x 90 mm

PETRİDE BESİYERLER (BÖLMELİ)

SP-2000	EMB / ÇİKOLATAMSI AGAR	10 x 90 mm
SP-2003	5% KOYUN KANLI / EMB AGAR	10 x 90 mm
SP-2004	5% KOYUN KANLI / ÇİKOLATAMSI AGAR	10 x 90 mm
SP-2005	5% KOYUN KANLI / UTI AGAR	10 x 90 mm

Test listesi

KATALOG NO

ÜRÜNLER

AMBALAJ

PETRİDE BESİYERLER (60 MM)

SP-6001	BILE ESCULIN AZIDE (ENTEROCOCCOSEL) AGAR	10 × 60 mm
SP-6002	CHROMOGENIC COLIFORM (CCA) AGAR	10 × 60 mm
SP-6004	DG 18 AGAR	10 × 60 mm
SP-6005	DRBC AGAR RODAK	10 × 60 mm
SP-6006	LACTOSE TTC TERGITOL AGAR	10 × 60 mm
SP-6007	LEGIONELLA BCYE AGAR w/L-CYSTEINE	10 × 60 mm
SP-6008	LEGIONELLA GVPC SELECTIVE AGAR	10 × 60 mm
SP-6009	m-CP AGAR	10 × 60 mm
SP-6010	m-FC AGAR	10 × 60 mm
SP-6011	m-LES ENDO AGAR	10 × 60 mm
SP-6012	PLATE COUNT AGAR (PCA) RODAK	10 × 60 mm
SP-6013	PLATE COUNT AGAR (PCA) w / NEUTRALISANT RODAK	10 × 60 mm
SP-6014	PSEUDOMONAS CN AGAR	10 × 60 mm
SP-6015	SABOURAUD DEXTROSE AGAR w / NEUTRALISANT RODAK	10 × 60 mm
SP-6016	SABOURAUD DEXTROSE AGAR RODAK	10 × 60 mm
SP-6017	SLANETZ BARTLEY AGAR (SBA)	10 × 60 mm
SP-6018	TRYPTIC SOY AGAR w / NEUTRALISANT RODAK	10 × 60 mm
SP-6019	TRYPTIC SOY AGAR RODAK	10 × 60 mm

TÜP VE ŞİŞEDE BESİYERLERİ

SP-3000	ACETAMIDE BROTH	25 × 9 mL
SP-3001	AKJ BROTH	25 × 9 mL
SP-3002	ALKALINE PEPTONE WATER	25 × 9 mL
SP-3003	BILE ESCULIN AGAR	25 × 6 mL
SP-3004	BRAIN HEART INFUSION BROTH	25 × 5 mL
SP-3005	EC BROTH	25 × 9 mL
SP-3006	GLUKOZ BUYYON	25 × 9 mL
SP-3007	GN BROTH	25 × 5 mL
SP-3008	INDOL BROTH	25 × 5 mL
SP-3009	KLIGLER IRON AGAR	25 × 6 mL
SP-3010	LAURYL SULFATE TRYPTOSE BROTH w/MUG+DURHAM TÜP	25 × 9 mL
SP-3011	LETHEEN BROTH	25 × 10 MI
SP-3012	LISTERIA FRASER BROTH	25 × 10 mL
SP-3013	LISTERIA FRASER BROTH	10 × 225 mL
SP-3014	LISTERIA FRASER HALF BROTH	10 × 90 mL
SP-3015	LISTERIA FRASER HALF BROTH	10 × 225 mL
SP-3016	LOWENSTEIN JENSEN MEDIUM	25 × 6 mL
SP-3017	LT 100 BROTH	25 × 9 mL
SP-3018	LT 100 BROTH	10 × 90 mL
SP-3019	LYSINE IRON (LIA) AGAR	25 × 6 mL
SP-3020	MAC CONKEY BROTH	10 × 100 mL
SP-3021	MAXIMUM RECOVERY DILUENT	25 × 9 mL
SP-3022	MAXIMUM RECOVERY DILUENT	10 × 90 mL
SP-3023	MOTILITY INDOL ORNITHIN (MIO) MEDIUM	25 × 5 mL
SP-3024	MOTILITY TEST MEDIUM	25 × 5 mL
SP-3025	MKTTn BROTH	25 × 10 mL
SP-3026	MR VP (CLARK LUBS) MEDIUM	25 × 5 mL
SP-3027	mTSB BROTH	25 × 9 mL
SP-3028	mTSB BROTH	10 × 90 mL
SP-3029	mTSB BROTH	10 × 225 mL
SP-3030	MUELLER HINTON BROTH	25 × 5 mL
SP-3031	MUELLER HINTON BROTH w/AT KANLI 2,5 %	25 × 5 mL
SP-3032	6,5 % NaCl BROTH	25 × 5 mL
SP-3033	NUTRIENT BROTH	25 × 5 mL
SP-3033	PEPTONE (TRYPTONE) WATER	25 × 9 mL
SP-3034	PEPTONE (TRYPTONE) WATER	10 × 90 mL
SP-3035	PEPTONE (TRYPTONE) WATER	10 × 225 mL
SP-3036	BUFFERED PEPTONE WATER	25 × 9 mL
SP-3037	BUFFERED PEPTONE WATER	10 × 90 mL
SP-3038	BUFFERED PEPTONE WATER	10 × 225 mL
SP-3039	PHENYLALANINE AGAR	25 × 6 mL
SP-3040	RAPPAPORT VASSILIADIS SOY (RVS) BROTH	25 × 9 mL
SP-3041	RAPPAPORT VASSILIADIS SOY (RVS) BROTH	10 × 90mL
SP-3042	SABOURAUD DEXTROSE (SDA) AGAR w/ CAF	25 × 6 mL
SP-3043	SABOURAUD DEXTROSE BROTH	25 × 5 mL
SP-3044	SELENITE F BROTH	25 × 5 mL
SP-3045	SIMMON'S CITRATE AGAR	25 × 6 mL
SP-3046	SIM MEDIUM	25 × 5 mL
SP-3047	THIOGLYCOLLATE MEDIUM	25 × 5 mL
SP-3048	THIOGLYCOLLATE MEDIUM	10 × 90 mL
SP-3049	THIOGLYCOLLATE MEDIUM w/ TWEEN 80	10 × 90 mL
SP-3050	TRYPTIC SOY BROTH (TSB)	25 × 5 mL
SP-3051	TRYPTIC SOY BROTH (TSB)	10 × 90 mL
SP-3052	TSC AGAR	25 × 18 mL
SP-3053	TRIPLE SUGAR IRON (TSI) AGAR	25 × 6 mL
SP-3054	UREA AGAR	25 × 6 mL
SP-3055	YEAST EXTRACT AGAR	25 × 7 mL
SP-3056	YEAST EXTRACT AGAR	25 × 18 mL

DİĞER ÜRÜNLER

SP-5000	KAN KÜLTÜR ŞİŞESİ (YETİŞKİN)	10 ad / kt
SP-5001	KAN KÜLTÜR ŞİŞESİ (PEDIATRİK)	10 ad / kt
SP-5002	BONCUKLU SAKLAMA BESİYERİ	100 × 1 mL



Sağlık Ürünleri İç ve Dış Tic. Ltd. Şti.

Rapid Test listesi

WOMEN'S HEALTH

SP-101	Pregnancy (hCG) Rapid Test Dipstick	Urine	Dipstick	50 T	CE
SP-102	Pregnancy (hCG) Rapid Test Cassette	Urine	Cassette	50T	CE
SP-103	Pregnancy (hCG) Rapid Test Cassette	S/P/U	Cassette	50T	CE
SP-104	TOXO IgG/IgM Rapid Test Cassette	S / P	Cassette	40T	ISO
SP-105	Rubella IgG/IgM Rapid Test Cassette	S / P	Cassette	40T	ISO
SP-106	CMV IgG/IgM Rapid Test Cassette	S / P	Cassette	40T	ISO
SP-107	HSV 1/2 IgG/IgM Rapid Test Cassette	WB/S/P	Cassette	40T	CE
SP-108	ToRCH IgG/IgM Combo Rapid Test Cassette	S / P	Cassette	25 T	ISO
SP-109	Chlamydia Rapid Test Cassette	Swab / Urine	Cassette	20 T	ISO

INFECTIOUS DISEASE

SP-201	Adenovirus Rapid Test Cassette	Feces	Cassette	25 T	CE
SP-202	Rotavirus Rapid Test Cassette	Feces	Cassette	25 T	CE
SP-203	Norovirus Rapid Test Cassette	Feces	Cassette	25 T	CE
SP-204	Rotavirus and Adenovirus Combo Rapid Test Cassette	Feces	Cassette	25 T	CE
SP-205	Giardia Lamblia Rapid Test Cassette	Feces	Cassette	10T	CE
SP-206	H. pylori Antibody Rapid Test Cassette	S / P	Cassette	25 T	CE
SP-207	H. pylori Antigen Rapid Test Cassette	Feces	Cassette	25 T	CE
SP-208	Dengue IgG/IgM Rapid Test Cassette	WB/S/P	Cassette	25 T	CE
SP-209	Dengue NS1 Rapid Test Cassette	WB/S/P	Cassette	25 T	CE
SP-210	Dengue IgG/IgM And NS1 Combo Rapid Test Cassette	WB/S/P	Cassette	25 T	CE
SP-211	Typhoid Rapid Test Cassette	WB/S/P	Cassette	25 T	CE
SP-212	Malaria Pf./ Pan Rapid Test Cassette	WB	Cassette	25 T	CE
SP-213	Malaria Pf./P.v. Rapid Test Cassette	WB	Cassette	25 T	CE
SP-214	HAV IgM Rapid Test Cassette	S / P	Cassette	25 T	CE
SP-215	HAV IgG/IgM Combo Rapid Test Cassette	S / P	Cassette	25 T	CE
SP-216	HBsAg Rapid Test Cassette	S / P	Cassette	25 T	ISO
SP-217	HCV Rapid Test Cassette	S / P	Cassette	25 T	ISO
SP-218	HIV 1.2 Rapid Test Cassette	WB/S/P	Cassette	25 T	ISO
SP-219	Syphilis Rapid Test Cassette	S / P	Cassette	25 T	CE
SP-220	Strep A Rapid Test Cassette (Control Line in Red)	Throat Swab	Cassette	20 T	CE
SP-221	MONO Rapid Test Cassette	WB/S/P	Cassette	25 T	CE
SP-222	Influenza A+B Rapid Test Cassette	Swab / Nasal Aspirate	Cassette	20 T	CE
SP-223	Tuberculosis (TB) Rapid Test Cassette	WB/S/P	Cassette	25 T	CE
SP-224	HBsAb Rapid Test Cassette	S / P	Cassette	40 T	ISO
SP-225	COVID-19 IgG/IgM Rapid Test Cassette	WB/S/P	Cassette	25 T	CE
SP-226	COVID-19 Antigen Rapid Test Cassette	Swab / Nasal Aspirate	Cassette	25 T	CE
SP-227	SNAT Transfer Tube	Swab	Tube	25 T	CE
SP-228	Influenza A+B/COVID-19 AG Combo Rapid Test	Swab / Nasal Aspirate	Cassette	25 T	CE
SP-229	Clostridium Difficile Toksin A+B Rapid Test	Feces	Cassette	25 T	CE
SP-230	Antibody Neutralizing Rapid Test Cassette	WB/S/P	Cassette	25 T	CE
SP-231	COVID-19 Antigen(Oral fluid) Rapid Test Cassette	Oral fluid	Cassette	25 T	CE

DRUGS OF ABUSE / TUMOR & CARDIAC

SP-301	Multi-drug 6drugs Test Cassette	Urine	Cassette	25 T	CE
SP-302	MULTI-drug 10drugs Test Cassette	Urine	Cassette	25T	CE
SP-303	Multi-drug 12 drugs Test Cassette	Urine	Cassette	25 T	CE
SP-304	FOB Rapid Test Cassette	Feces	Cassette	25 T	CE
SP-305	PSA Rapid Test Cassette	WB/S/P	Cassette	25 T	ISO
SP-306	CTNI Rapid Test Cassette	WB/S/P	Cassette	25 T	CE
SP-307	CK-MB Rapid Test Cassette	WB/S/P	Cassette	10T/25T	CE
SP-308	Vitamin D Rapid Test Cassette	Urine	Cassette	10 T	CE
SP-309	Urinalysis Reagent Dipsticks - 10 parameters	Urine	Dipstick	100 T	CE
SP-310	D-Dimer Rapid Test Cassette	WB/S/P	Cassette	25 T	CE

SPESERA PCR KIT

SP-400	Spesera Sars CoV-2 Real Time PCR Diagnosis Kit	KIT	KIT	100 T	CE
--------	--	-----	-----	-------	----

Spesera

Sağlık Ürünleri İç ve Dış Tic. Ltd. Şti.



INFECTIOUS DISEASES TESTS

SPESERA SAĞLIK ÜRÜNLERİ İÇ VE DIŞ TİC. LTD. ŞTİ.
Göztepe mah. Batışehir cad. No:2/3 İç Kapı No: 1B12 Bağcılar/İSTANBUL
www.spesera.com.tr Tel: +90 535 049 92 66



Health Products, Imp. & Exp. Trade Ltd.

PRODUCT LIST

SP201	Adenovirus Rapid Test Cassette	Feces	Cassette	25 T	CE
SP-202	Rotavirus Rapid Test Cassette	Feces	Cassette	25 T	CE
SP-203	Norovirus Rapid Test Cassette	Feces	Cassette	25 T	CE
SP-204	Rotavirus and Adenovirus Combo Rapid Test Cassette	Feces	Cassette	25 T	CE
SP-205	Giardia Lamblia Rapid Test Cassette	Feces	Cassette	10T	CE
SP-206	H. pylori Antibody Rapid Test Cassette	S / P	Cassette	25 T	CE
SP-207	H. pylori Antigen Rapid Test Cassette	Feces	Cassette	25 T	CE
SP-208	Dengue IgG/IgM Rapid Test Cassette	WB/S/P	Cassette	25 T	CE
SP-209	Dengue NS1 Rapid Test Cassette	WB/S/P	Cassette	25 T	CE
SP-210	Dengue IgG/IgM And NS1 Combo Rapid Test Cassette	WB/S/P	Cassette	25 T	CE
SP-211	Typhoid Rapid Test Cassette	WB/S/P	Cassette	25 T	CE
SP-212	Malaria P.f./ Pan Rapid Test Cassette	WB	Cassette	25 T	CE
SP-213	Malaria P.f./P.v. Rapid Test Cassette	WB	Cassette	25 T	CE
SP-214	HAV IgM Rapid Test Cassette	S / P	Cassette	25 T	CE
SP-215	HAV IgG/IgM Combo Rapid Test Cassette	S / P	Cassette	25 T	CE
SP-216	HBsAg Rapid Test Cassette	S / P	Cassette	25 T	ISO
SP-217	HCV Rapid Test Cassette	S / P	Cassette	25 T	ISO
SP-218	HIV 1.2 Rapid Test Cassette	WB/S/P	Cassette	25 T	ISO
SP-219	Syphilis Rapid Test Cassette	S / P	Cassette	25 T	CE
SP-220	Strep A Rapid Test Cassette (Control Line in Red)	Throat Swab	Cassette	20 T	CE
SP-221	MONO Rapid Test Cassette	WB/S/P	Cassette	25 T	CE
SP222	Influenza A+B Rapid Test Cassette	Swab / Nasal Aspirate	Cassette	20 T	CE
SP-223	Tuberculosis (TB) Rapid Test Cassette	WB/S/P	Cassette	25 T	CE

TEST PROCEDURE



Spesera

Sağlık Ürünleri İç ve Dış Tic. Ltd. Şti.



TUMOR MARKERS



CARDIAC MARKERS

DRUGS OF ABUSE



URINALYSIS REAGENT STRIPS





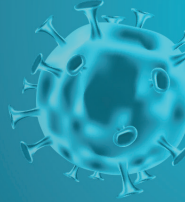
Health Products, Imp. & Exp. Trade Ltd.

Drugs of Abuse/Tumor & Cardiac Markers /Other PRODUCT LIST

Cat. No.	Product Description	Specimen	Format	Kit Size	Status
SP-301	Multi-drug 6drugs Test Cassette	Urine	Cassette	25 T	CE
SP-302	Multi-drug 10drugs Test Cassette	Urine	Cassette	25T	CE
SP-303	Multi-drug 12 drugs Test Cassette	Urine	Cassette	25 T	CE
SP-304	FOB Rapid Test Cassette	Feces	Cassette	25 T	CE
SP-305	PSA Rapid Test Cassette	WB/S/P	Cassette	25 T	ISO
SP-306	cTnI Rapid Test Cassette	WB/S/P	Cassette	25 T	CE
SP-307	CK-MB Rapid Test Cassette	WB/S/P	Cassette	10 T/25 T	CE
SP-308	Vitamin D Rapid Test Cassette	WB	Cassette	10 T	CE
SP-309	Urinalysis Reagent Dipsticks - 10 parameters	Urine	Dipstick	100 T	CE



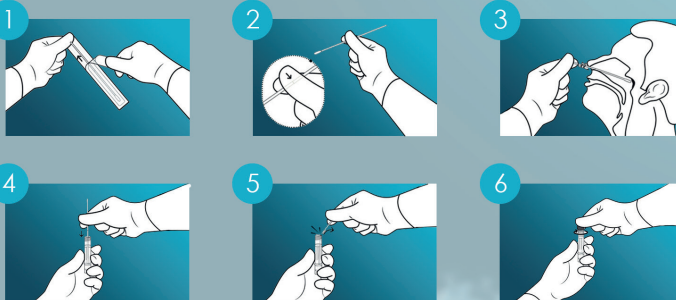
sNAT TRANSFER TUBE FOR COVID-19



TRANSFER TUBE FOR COVID-19

Nasopharyngeal Swab + transfer Tube

NUCLISWAB* is a sampling and transport system used for collection and transport of viruses and cells from clinical samples or from environment, for isolation of nucleic acids that will be used in nucleic acid amplification tests.



Spesera
Health Products, Imp. & Exp. Trade Ltd.



www.spesera.com.tr



+90 553 755 25 02

Tıbbi Cihaz Bilgileri

Tanımlayıcı Bilgiler

Ürün Tanımı:	SPESERA - YOK - sNAT Transfer Tube
Birincil Ürün Numarası:	8681176311019 (GS1)
Firma:	2667269041913 - SPESERA SAĞLIK ÜRÜNLERİ İÇ VE DIŞ TİC. LTD. ŞTİ. (Üretici/İthalatçı/Bayı/İhracatçı)
Marka:	SPESERA
Ürün Adı:	sNAT Transfer Tube
Ürün Künyesi:	Ürün Künyesi.pdf
Orjinal Etiket:	sNAT Transfer Tube.jpg
Versiyon/Model:	YOK
Referans/Katalog No:	SP-227
İçerikteki Ürün Sayısı:	1
Ürün Açıklaması:	

Sınıflandırma Bilgileri

Sınıf:	IVD Diğer
GMDN:	58697 - Viral transport aracı IVD
Branş Türü Kodu:	49267-REAKTİF

Ürün Görselleri

Ürün Görsel Dosyası	↑↓
sNAT Ürün Görsel.jpg	
	↓

Özellikler

MRG Güvenlik Bilgisi:	Bilgi Bulunmuyor
Lateks içeriyor mu?:	Hayır
Ftalat/DEHP içeriyor mu?:	Hayır
Ürün iyonize radyasyon içerir mi?:	Hayır
Ürün nanomateriyal içeriyor mu?:	Hayır
Vücuda implante edilebilir mi?:	Hayır
Tek kullanımlık mı?:	Evet
Ürünün sınırlı kullanım sayısı var mı?:	Evet
Sınırlı Kullanım Sayısı:	1

Durum Bilgileri

Durum:	Kayıtlı
Tekil Ürün Durumu:	Tekil ürün hiç dahil edilmemiş.
Ürün Tipi:	Tıbbi Cihaz
Güncellenme Tarihi:	03/12/2020
ÜTS Başlangıç Tarihi:	25/11/2020
Durum Tarihi:	03/12/2020
Konfigürasyon Türü:	Tekil Takip Kapsamında

İthal/İmal Bilgileri

İthal/İmal Bilgisi:	İmal
Menşei Ülke:	Türkiye
Yerli Malı Belgesi Var mı?	Hayır

Raf ömrü var mı?:	Evet
Raf Ömrü:	24 Ay
Kalibrasyona tabi mi?:	Hayır
Bakıma tabi mi?:	Hayır
Steril paketleni mi?:	Hayır
Paketlemede kullanılan sterilizasyon yöntemi belli mi?:	
Kullanım Öncesinde Sterilizasyon Gerekli mi?:	Hayır
Tıbbi Cihaz Satış, Reklam ve Tanıtım Yönetmeliği Ek-3 Kapsamında mı?:	Hayır
Başka Bir Tıbbi Cihazın Bileşeni, Aksesuarı, Yedek Parçası mı?:	Hayır

Saklama Koşulu Bilgileri

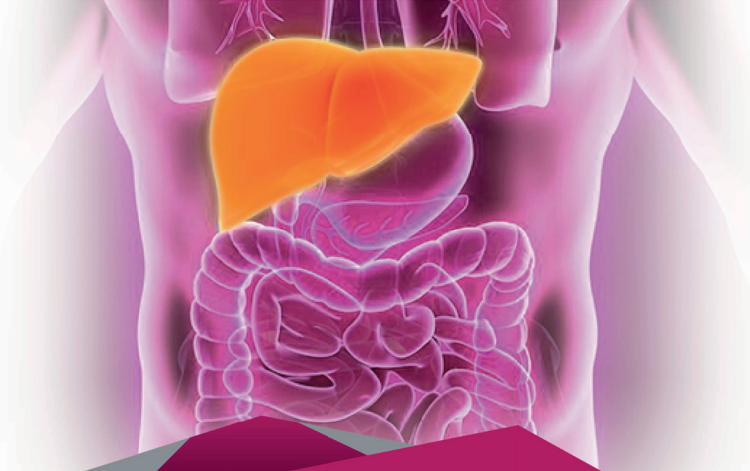
Saklama Koşulu Gerekliyor mu?:	Evet				
Saklama Koşulu Tipi	↑↓	Min ↑↓	Max ↑↓	Birim	↑↓
Saklama/Depolama Ortamı Sıcaklığı		2	30	Derece Santigrat	
					↓

Spesera

Sağlık Ürünleri İç ve Dış Tic. Ltd. Şti.



INFECTIOUS DISEASES TESTS



SPESENA SAĞLIK ÜRÜNLERİ İÇ VE DIŞ TİC. LTD. ŞTİ.

Göztepe mah. Batışehir cad. No:2/3 İç Kapı No: 1B12 Bağcılar/İSTANBUL

www.spesera.com.tr

Tel: +90 535 049 92 66

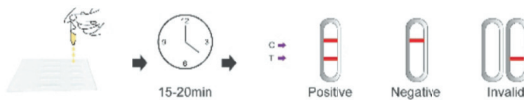


Health Products, Imp. & Exp. Trade Ltd.

PRODUCT LIST

SP-201	Adenovirus Rapid Test Cassette	Feces	Cassette	25 T	CE
SP-202	Rotavirus Rapid Test Cassette	Feces	Cassette	25 T	CE
SP-203	Norovirus Rapid Test Cassette	Feces	Cassette	25 T	CE
SP-204	Rotavirus and Adenovirus Combo Rapid Test Cassette	Feces	Cassette	25 T	CE
SP-205	Giardia Lamblia Rapid Test Cassette	Feces	Cassette	10T	CE
SP-206	H. pylori Antibody Rapid Test Cassette	S / P	Cassette	25 T	CE
SP-207	H. pylori Antigen Rapid Test Cassette	Feces	Cassette	25 T	CE
SP-208	Dengue IgG/IgM Rapid Test Cassette	WB/S/P	Cassette	25 T	CE
SP-209	Dengue NS1 Rapid Test Cassette	WB/S/P	Cassette	25 T	CE
SP-210	Dengue IgG/IgM And NS1 Combo Rapid Test Cassette	WB/S/P	Cassette	25 T	CE
SP-211	Typhoid Rapid Test Cassette	WB/S/P	Cassette	25 T	CE
SP-212	Malaria P.f./ Pan Rapid Test Cassette	WB	Cassette	25 T	CE
SP-213	Malaria P.f./P.v. Rapid Test Cassette	WB	Cassette	25 T	CE
SP-214	HAV IgM Rapid Test Cassette	S / P	Cassette	25 T	CE
SP-215	HAV IgG/IgM Combo Rapid Test Cassette	S / P	Cassette	25 T	CE
SP-216	HBsAg Rapid Test Cassette	S / P	Cassette	25 T	ISO
SP-217	HCV Rapid Test Cassette	S / P	Cassette	25 T	ISO
SP-218	HIV 1.2 Rapid Test Cassette	WB/S/P	Cassette	25 T	ISO
SP-219	Syphilis Rapid Test Cassette	S / P	Cassette	25 T	CE
SP-220	Strep A Rapid Test Cassette (Control Line in Red)	Throat Swab	Cassette	20 T	CE
SP-221	MONO Rapid Test Cassette	WB/S/P	Cassette	25 T	CE
SP-222	Influenza A+B Rapid Test Cassette	Swab / Nasal Aspirate	Cassette	20 T	CE
SP-223	Tuberculosis (TB) Rapid Test Cassette	WB/S/P	Cassette	25 T	CE
SP-224	HBsAb Rapid Test Cassette	S / P	Cassette	40 T	ISO
SP-225	COVID-19 IgG/IgM Rapid Test Cassette	WB/S/P	Cassette	25 T	CE
SP-226	COVID-19 Antigen Rapid Test Cassette	Swab / Nasal Aspirate	Cassette	25 T	CE
SP-227	SNAT Transfer Tube	Swab	Tube	25 T	CE
SP-228	Influenza A+B/COVID-19 AG Combo Rapid Test	Swab / Nasal Aspirate	Cassette	25 T	CE
SP-229	Clostridium Difficile Toksin A+B Rapid Test	Feces	Cassette	25 T	CE
SP-230	Antibody Neutralizing Rapid Test Cassette	WB/S/P	Cassette	25 T	CE
SP-231	COVID-19 Antigen(Oral fluid) Rapid Test Cassette	Oral fluid	Cassette	25 T	CE

TEST PROCEDURE





Saęlık Ürünleri İ ve Dış Tic. Ltd. Şti.

COVID-19 IgG/IgM Rapid Test

COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) is a solid phase immunochromatographic assay for the rapid, qualitative and differential detection of IgG and IgM antibodies to 2019 Novel Coronavirus in human whole blood, serum or plasma.



SPESERA SAęLIK ÜRÜNLERİ
İ VE DİŞ TİC. LTD. ŞTİ.
Göztepe mah. Batışehir cad. No:2/3
İ Kapi No: 1B12 Bağcılar/STANBUL

Tel: 00905350499266
www.spesera.com.tr

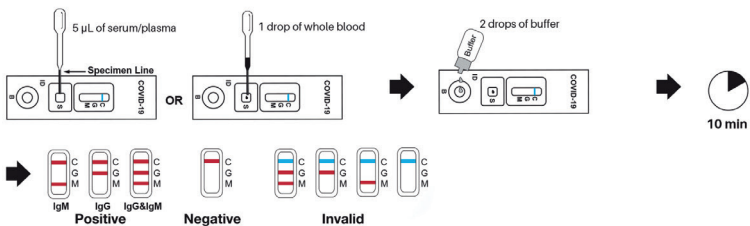
Key Facts of COVID-19

- The 2019 new coronavirus pneumonia (NCP), or “COVID-19”, was discovered for the 2019 Wuhan Viral Pneumonia case in China and was named by World Health Organization on January 12, 2020.
- For confirmed coronavirus disease 2019 (COVID-19) cases, reported illnesses have ranged from mild symptoms to severe illness and death. Symptoms can include:
 - Fever
 - Cough
 - Shortness of breath
- The virus is thought to spread mainly from person-to-person.
 - Between people who are in close contact with one another (within about 6 feet).
 - Via respiratory droplets produced when an infected person coughs or sneezes.
 - These droplets can land in the mouths or noses of people who are nearby or possibly be inhaled into the lungs.

Features & Benefits

- Fast results as soon as 2-10 minutes.
- Facilitates patient treatment decisions quickly.
- Simple, time-saving procedure.
- Little specimens, only 5 µL of serum/plasma or 10 µL of whole blood specimens.
- All necessary reagents provided & no equipment needed.
- High sensitivity and specificity.

Test Procedure & Interpretation



Ordering Information

Product Description	Specimen	Catalog No.	Format	Kit Size
COVID-19 IgG/IgM Rapid Test	Whole Blood/Serum/Plasma	GCCOV-402a	Cassette	25 Tests/Kit

Tıbbi Cihaz Bilgileri

Tanımlayıcı Bilgiler

Ürün Tanımı:	SPESERA - yok - COVID-19 IgG/IgM Hızlı Tanı Kiti
Birincil Ürün Numarası:	8681176311002 (GS1)
Firma:	2667269041913 - SPESERA SAĞLIK ÜRÜNLERİ İÇ VE DIŞ TİC. LTD. ŞTİ. (Üretici/İthalatçı/Bayı/İhracatçı)
Marka:	SPESERA
Ürün Adı:	COVID-19 IgG/IgM Hızlı Tanı Kiti
Ürün Künyesi:	Ürün Künyesi.pdf
Orjinal Etiket:	Etiket Covid.jpg
Versiyon/Model:	yok
Referans/Katalog No:	SP-225
İçerikteki Ürün Sayısı:	1
Ürün Açıklaması:	

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

Özellikler

MRG Güvenlik Bilgisi:	Bilgi Bulunmuyor
Lateks içeriyor mu?:	Hayır
Ftalat/DEHP içeriyor mu?:	Hayır
Ürün iyonize radyasyon içerir mi?:	Hayır
Ürün nanomateryal içeriyor mu?:	Hayır
Vücuda implante edilebilir mi?:	Hayır
Tek kullanımlık mi?:	Evet
Ürünün sınırlı kullanım sayısı var mı?:	Evet
Sınırlı Kullanım Sayısı:	1

Durum Bilgileri

Durum:	Kayıtlı
Tekil Ürün Durumu:	Tekil ürün hiç dahil edilmemiş.
Ürün Tipi:	Tıbbi Cihaz
Güncellenme Tarihi:	10/11/2020
ÜTS Başlangıç Tarihi:	10/11/2020
Durum Tarihi:	10/11/2020
Konfigürasyon Türü:	Tekil Takip Kapsamında

İthal/İmal Bilgileri

İthal/İmal Bilgisi:	İmal
Menşei Ülke:	Türkiye
Yerli Mali Belgesi Var mı?	Hayır

Saklama Koşulu Bilgileri

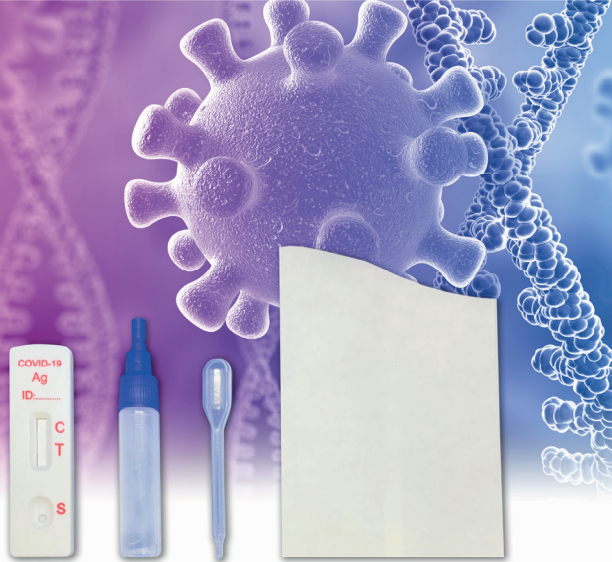
Saklama Koşulu Gerektiriyor mu?:	Evet						
Saklama Koşulu Tipi	↑↓	Min	↑↓	Max	↑↓	Birim	↑↓
Saklama/Depolama Ortamı Sıcaklığı		2		30		Derece Santigrat	
							



Spesera

Sağlık Ürünleri İç ve Dış Tic. Ltd. Şti.

COVID-19 ANTIGEN RAPID TEST KIT (ORAL FLUID)



SPESERA SAĞLIK ÜRÜNLERİ | İÇ VE DIŞ TİC. LTD. ŞTİ.
Göztepe mah. Batışehir cad. No:2/3 | İç Kapi No: 1B12 Bağcılar/İSTANBUL
www.spesera.com.tr | Tel: +90 535 049 92 66



Health Products, Imp. & Exp. Trade Ltd.

COVID-19 ANTIGEN RAPID TEST KIT (ORAL FLUID)

Detection kit for SARS-CoV-2 antigen in sputum or Posterior oropharyngeal saliva from human

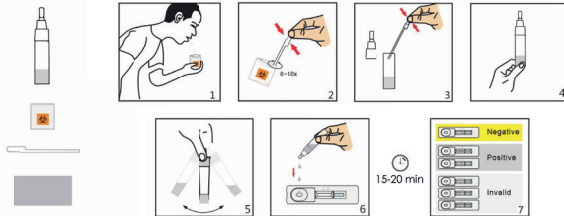
INTENDED USE

COVID-19 Antigen Rapid Test Kit is an immunochromatographic assay kit for the qualitative detection of SARS-CoV -2 antigen in sputum and Posterior oropharyngeal saliva from human.

TEST PROCEDURE

Please read the instructions carefully and allow the test device and specimens to equilibrate to temperature (15°C-30°C) prior to testing. Before performing the test, please read the instructions carefully and allow the test device and sample to reach the indoor temperature (15°C-30°C)

1. Saliva and sputum specimens from the back of the oropharynx: Use soap and water mixed with alcohol to clean the hands. The best time for specimen collection: after getting up, before brushing your teeth, eating or drinking.
2. Take out the saliva sampling bag, make a "Kua Kua" sound from the deep throat, clear the saliva from the deep throat, and then spit the saliva (about 2ml) into the bag. Do not have any saliva contamination on the surface of the sampling bag.
3. Use the dropper provided to stir the sputum sample 8-10 times, then aspirate the sputum sample and add it to the extraction tube.
4. Take out the extraction tube containing the extraction buffer then mix the extraction buffer and specimen well.
5. Take out the test device from the packaging box and place it on a flat table.
6. Add 4 drops of the mixed solution to the sample hole of the test card.
7. Read the result at 15 minutes. If you haven't read it for 20 minutes or more, the result is invalid and it is recommended to repeat the test..

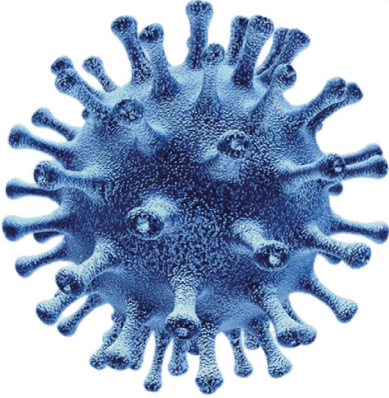


SPESERA SAĞLIK ÜRÜNLERİ İÇ VE DIŞ TİC. LTD. ŞTİ.

Göztepe mah. Batışhir cad. No:2/3 İç Kapı No: 1B12 Bağcılar/İSTANBUL

www.spesera.com.tr

Tel: +90 535 049 92 66



Spesera

Sağlık Ürünleri İç ve Dış Tic. Ltd. Şti.

Göztepe mah. Batışehir cad. No:2/3
İç Kapı No: 1B12 Bağcılar/İSTANBUL
Tel: 00905350499266
www.spesera.com.tr

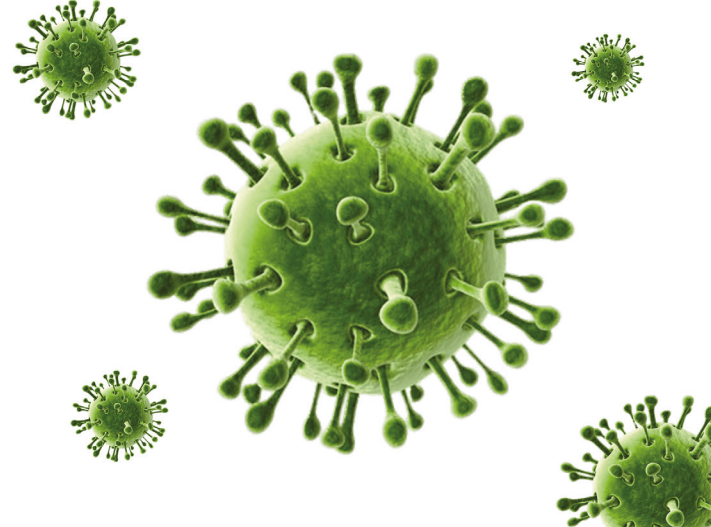
Revision Date: 2020-08-18
B21967-01



Spesera

Health prouducts, Imp. & Exp. Trade Ltd.

Influenza & COVID-19 Ag Combo Rapid Test Cassette (Swab)



INTENDED USE

The Influenza & COVID-19 Ag Combo Rapid Test Cassette (Swab) is an in vitro immunochromatographic assay for the qualitative and differential detection of nucleocapsid protein antigen from influenza A (including the subtype H1N1), influenza B and/or SARS-CoV-2 in nasopharyngeal (NP) swab specimens. It is intended to aid in the rapid diagnosis of influenza A, influenza B and/or SARS-CoV-2 infections. This test provides only a preliminary test result. Therefore, any reactive specimen with the Influenza & COVID-19 Ag Combo Rapid Test Cassette (Swab) must be confirmed with alternative testing method(s) and clinical findings.

SUMMARY AND EXPLANATION

Influenza is an acute and highly contagious viral infection of the respiratory tract. The causative agents of the disease are immunologically diverse, single-strand RNA virus known as influenza viruses. There are three types of influenza viruses: A, B and C. Type A viruses are the most prevalent and are associated with most serious epidemics, while Type B infection is generally milder. Type C virus have never been associated with a large epidemic of human disease. Both type A and B viruses can circulate simultaneously, but usually one type is dominant during a given season and particular epidemic area. The disease is easily transmitted through coughing and sneezing of aerosolized droplets containing live virus. Influenza outbreaks normally occur each year during fall and winter seasons.

The novel coronaviruses belong to the β genus. COVID-19 is an acute respiratory infectious disease. Entire human population is susceptible. Currently, the patients infected by the novel coronavirus are the main source of infection; asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main manifestations include fever, fatigue, dry cough, and loss of taste and smell. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases. This test is for detection of SARS-CoV-2 nucleocapsid protein antigen. Antigen is generally detectable in upper respiratory specimens during the acute phase of infection. Rapid diagnosis of SARS-CoV-2 infection will help healthcare professionals to treat patients and control the disease more efficiently and effectively.

PRINCIPLE OF THE TEST

The Flu A&B Antigen Rapid Test is an immunochromatographic membrane assay that uses highly sensitive monoclonal antibodies to detect influenza type A and B nucleoprotein antigens in nasopharyngeal swab samples. The test strip is composed of the following parts: namely sample pad, reagent pad, reaction membrane, and absorbing pad. The reagent pad contains the colloidal-gold conjugated with the monoclonal antibodies against Influenza virus A and B; the reaction membrane contains the secondary antibodies either for virus A or for B. The whole strip is fixed inside a plastic device. When the sample is added into the sample well, conjugates dried in the reagent pad are dissolved and migrate along with the sample. If influenza A presents in the sample, a complex formed between the anti-influenza A conjugate and the virus will be captured by the specific anti-influenza A monoclonal antibodies coated on the A region (A). If the sample contains influenza B, a complex formed between the anti-influenza B conjugate and the virus will be captured by the specific anti-influenza B monoclonal antibodies coated on the B region (B). Results appear at 10 minutes in the form of a red line that develops on the membrane. To serve as a procedural control, a red line will always appear in the control region (C) indicating that proper volume of sample has been added and membrane wicking has occurred.

The COVID-19 Antigen Rapid Test Cassette is an immunochromatographic membrane assay that uses highly sensitive monoclonal antibodies to detect nucleocapsid protein from SARS-CoV-2 in nasopharyngeal (NP) swab. The test strip is composed of the following parts: namely sample pad, reagent pad, reaction membrane, and absorbing pad. The reagent pad contains the colloidal-gold conjugated with the monoclonal antibodies against the nucleocapsid protein of SARS-CoV-2; the reaction membrane contains the secondary antibodies for nucleocapsid protein of SARS-CoV-2. The whole strip is fixed inside a plastic device. When the sample is added into the sample well, conjugates dried in the reagent pad are dissolved and migrate along with the sample. If SARS-CoV-2 antigen presents in the sample, a complex formed between the anti-SARS-2 conjugate and the virus will be captured by the specific anti-SARS-2 monoclonal antibodies coated on the test line region (T). Absence of the T line suggests a negative result. To serve as a procedural control, a red line will always appear in the control line region (C) indicating that proper volume of sample has been added

and membrane wicking has occurred.

MATERIALS PROVIDED

1. 20 Test cassettes
2. 20 Sterile swabs
3. 20 Extraction tubes and 20 dropper tips
4. 1 Workstation
5. 2 Buffers
6. 1 Package insert

MATERIALS REQUIRED BUT NOT PROVIDED

- 1.Clock,timer or stopwatch

WARNINGS AND PRECAUTIONS

- 1.For in vitro diagnostic use only.
- 2.The test device should remain in the sealed pouch until use.
- 3.Do not use kit past its expiration date.
- 4.Swabs, tubes and test devices are for single use only.
- 5.The extraction buffer contains a solution with a preservative (0.09% sodium azide). If solution comes in contact with the skin or eyes, flush with ample volumes of water.
- 6.Solutions that contain sodium azide may react explosively with lead or copper plumbing. Use large quantities of water to flush discarded solutions down a sink.
- 7.Do not interchange or mix components from different kit lots.
- 8.When collecting a nasopharyngeal swab sample, use the Nasopharyngeal Swab supplied in the kit.
- 9.Wear appropriate personal protection equipment and gloves when running each test and handling patient specimens. Change gloves between handling of specimens suspected of COVID-19.
- 10.Specimens must be processed as indicated in the SPECIMEN COLLECTION and SAMPLE PREPARATION

PROCEDURE sections of this Product Insert. Failure to follow the instructions for

use can result in inaccurate results.

- 11.To obtain accurate results, do not use visually bloody or overly viscous samples.
- 12.Proper laboratory safety techniques should be followed at all times when working with SARS-CoV-2 patient samples. Patient swabs, used Test Strips and used extraction buffer vials may be potentially infectious. Proper handling and disposal methods should be established by the laboratory in accordance with local regulatory requirements.
- 13.Humidity and temperature can adversely affect results.
- 14.Used testing materials should be discarded in accordance with local regulations.

STORAGE AND STABILITY

1. The kit can be stored at room temperature or refrigerated (2-30°C).
2. Do not freeze any of the test kit components.
3. Do not use test device and reagents after expiration date.
4. Test devices that have been outside of the sealed pouch for more than 1 hour should be discarded.

SPECIMEN COLLECTION

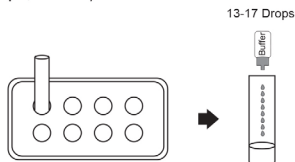
Use the nasopharyngeal swab supplied in the kit.

- 1.Carefully insert the swab into the nostril of the patient, reaching the surface of posterior nasopharynx. that presents the most secretion under visual inspection.
- 2.Swab over the surface of the posterior nasopharynx. Rotate the swab several times.
- 3.Withdraw the swab from the nasal cavity.

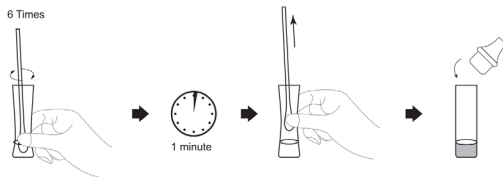


SAMPLE PREPARATION PROCEDURE

1. Insert the test extraction tube into the paper stand in this product. Make sure that the tube is standing firm and reaches the bottom of the stand.
2. Add the sample extraction buffer to the extraction tube until it reaches the lower mark (about 13-17 drops, 0.5 mL).



3. Insert the swab into the extraction tube which contains 0.5 ml of the extraction buffer.
4. Roll the swab at least 6 times while pressing the head against the bottom and side of the extraction tube.
5. Leave the swab in the extraction tube for 1 minute.
6. Squeeze the tube several times with fingers from outside of the tube to immerse the swab. Remove the swab. The extracted solution will be used as test sample.



SPECIMEN TRANSPORT AND STORAGE

Do not return the nasopharyngeal swab to the original paper packaging.

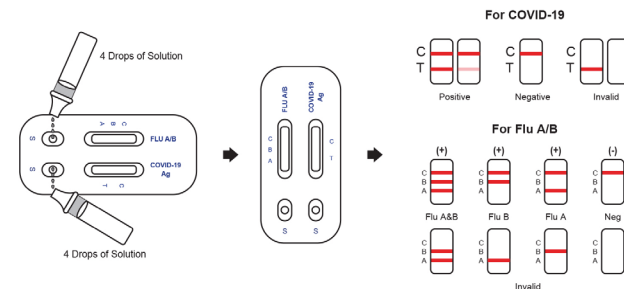
For best performance, direct nasopharyngeal swabs should be tested as soon as possible after collection. If immediate testing is not possible, and to maintain best performance and avoid possible contamination, it is highly recommended the nasopharyngeal swab is placed in a clean, unused plastic tube labeled with patient information, preserving sample integrity, and capped tightly at room temperature

(15-30°C) for up to 1 hour prior to testing. Ensure the swab fits securely within the tube and the cap is tightly closed. If greater than 1 hour delay occurs, dispose of sample. A new sample must be collected for testing.

TEST PROCEDURE

Allow the test device, test sample and buffer to equilibrate to room temperature (15-30°C) prior to testing.

1. Remove test device from the sealed pouch just prior to the testing and lay flat on work bench.
2. Insert a nozzle with filter into the sample extraction tube tightly.
3. Reverse the sample extraction tube, and add 4 drops (about 100 µl) of test sample by squeezing the extracted solution tube into the each sample well (S).
4. Wait for the colored band(s) to appear. The result should be read in 15 minutes. Do not interpret the result after 20 minutes.



INTERPRETATION OF RESULTS

For Flu A&B Antigen Rapid Test

1. POSITIVE:

1.1 Flu A Positive:

The presence of two lines as control line (C) and A test line within the result window indicates a positive result for Influenza A viral antigen.

1.2 Flu B Positive:

The presence of two lines as control line (C) and B test line within the result window indicates a positive result for Influenza B viral antigen.

1.3 Flu A+B Positive:

The presence of three lines as control line (C), A test line and B test line within the result window indicates a positive result for Influenza A and Influenza B viral antigen.

2. NEGATIVE:

The presence of only control band (C) within the result window indicates a negative result.

3. INVALID:

If the control band (C) is not visible within the result window after performing the test, the result is considered invalid. Some causes of invalid results are because of not following the directions correctly or the test may have deteriorated beyond the expiration date. It is recommended that the specimen be re-tested using a new test.

For COVID-19 Antigen Rapid Test

1. POSITIVE:

The presence of two lines as control line (C) and test line (T) within the result window indicates a positive result.

2. NEGATIVE:

The presence of only control line (C) within the result window indicates a negative result.

3. INVALID:

If the control line (C) is not visible within the result window after performing the test, the result is considered invalid. Some causes of invalid results are because of not following the directions correctly or the test may have deteriorated beyond the expiration date. It is recommended that the specimen be re-tested using a new test.

NOTE:

1.The intensity of color in the test line region (T) may vary depending on the concentration of analyses present in the specimen. Therefore, any shade of color in the test line region (T) should be considered positive. Please note that this is a qualitative test only, and cannot determine the concentration of analytes in the specimen.

2.Insufficient specimen volume, incorrect operating procedure or expired tests are

the most likely reasons for control band failure.

QUALITY CONTROL

A procedural control is included in the test. A red line appearing in the control line region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique. Control standards are not supplied with this test. However, it is recommended that positive and negative controls are sourced from a local competent authority and tested as a good laboratory practice, to confirm the test procedure and verify the test performance.

LIMITATIONS

1. The Influenza & COVID-19 Ag Combo Rapid Test Cassette (Swab) is for professional in vitro diagnostic use, and should only be used for the qualitative detection of influenza A ,B and/or SARS-CoV-2 in nasopharyngeal (NP) swab specimens.

2. The etiology of respiratory infection caused by microorganisms other than influenza A , B or SARS-CoV-2 will not be established with this test.

3. The Influenza & COVID-19 Ag Combo Rapid Test Cassette (Swab) is capable of detecting both viable and non-viable influenza and SARS-CoV-2 particles. The performance of the Influenza & COVID-19 Ag Combo Rapid Test Cassette (Swab) depends on antigen load and may not correlate with cell culture performed on the same specimen.

4. If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at anytime rule out the presence of influenza A A , B or SARS-CoV-2 viral antigens in specimen, as they may be present below the minimum detection level of the test. As with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.

5.Inadequate or inappropriate specimen collection, storage, and transport may yield false negative test result.

6. Failure to follow the Test Procedure may adversely affect test performance and/or invalidate the test result.

7. Although this test has been shown to detect cultured avian influenza viruses, including avian influenza A subtype H5N1 virus, the performance characteristics of

this test with specimens from humans infected with H5N1 or other avian influenza viruses are unknown.

8. Performance characteristics for influenza A were established when influenza A/H3 and A/H1 were the predominant influenza A viruses in circulation. When other influenza A viruses are emerging, performance characteristics may vary.

9. Positive and negative predictive values are highly dependent on prevalence. False positive test results are more likely during periods of low influenza activity when prevalence is moderate to low. Positive test results do not rule out co-infections with other pathogens.

10. For COVID-19 Antigen Rapid Test, positive test results do not differentiate between SARS-CoV and SARS-CoV-2. Negative results should be treated as presumptive and confirmed with an FDA authorized molecular assay, if necessary, for clinical management, including infection control.

PERFORMANCE CHARACTERISTICS

For FluA&B Antigen Rapid Test:

1. Analytical Sensitivity

The minimum detection limit is 1.5×10^4 TCID₅₀ /test for the Influenza A virus antigen and is 1.5×10^5 TCID₅₀ /test for the Influenza B virus antigen.

2. Analytical Reactivity

The influenza A strain listed tested positive in the Influenza A & B Ag Rapid Test. Although the specific influenza strains causing infection in human can vary, all contain the conserved nucleoproteins targeted by Influenza A&B Ag Rapid Test.

Strains	Sources	Subtypes	Concentration
Flu A/Hubei/PR8/2001	Human	H1N1	1.8×10^4 TCID ₅₀ /test
Flu A/New Kaledonia/20/99	Human	H1N1	1.8×10^4 TCID ₅₀ /test
Flu A/Yamagata/32/89	Human	H1N1	1.8×10^4 TCID ₅₀ /test
Flu A/Beijing/262/95	Human	H1N1	1.8×10^4 TCID ₅₀ /test
Flu A/Singapore/1/57	Human	H2N2	3.0×10^4 TCID ₅₀ /test
Flu A/Hubei/3/2005	Human	H3N2	3.0×10^4 TCID ₅₀ /test
Flu A/Akita/1/94	Human	H3N2	3.0×10^4 TCID ₅₀ /test
Flu A/Kita Kyusyu/159/93	Human	H3N2	3.0×10^4 TCID ₅₀ /test
Flu A/Iowa/15/30	Swine	H1N1	3.0×10^4 TCID ₅₀ /test
Flu A/Hongkong/168/93	Swine	H1N1	3.0×10^4 TCID ₅₀ /test
Flu A/Anhui/24/2004	Swine	H5N1	6.0×10^4 TCID ₅₀ /test
Flu A/Hubei/134/2000	Swine	H9N2	6.0×10^4 TCID ₅₀ /test
Flu A/Hubei/251/2001	Swine	H9N2	6.0×10^5 TCID ₅₀ /test

Flu A/Yuyao/1/2006	Chicken	H5N1	6.0×10^4 TCID ₅₀ /test
Flu A/Yuyao/2/2006	Chicken	H5N1	6.0×10^4 TCID ₅₀ /test
Flu A/Jiangsu/2/2004	Chicken	H5N1	6.0×10^4 TCID ₅₀ /test
Flu A/Hubei/216/83	Duck	H7N8	3.0×10^5 TCID ₅₀ /test
Flu A/Hubei/118/2003	Duck	H9N2	1.5×10^5 TCID ₅₀ /test
Flu A/Hubei/155/2003	Duck	H9N2	6.0×10^5 TCID ₅₀ /test
Flu A/Hubei/137/1982	Duck	H10N4	3.0×10^4 TCID ₅₀ /test
Flu A/Egypt/3/97	Duck	H5N3	6.0×10^4 TCID ₅₀ /test
Flu A/Henan/1/2004	Tree sparrow	H5N1	6.0×10^5 TCID ₅₀ /test
Flu A/Henan/2/2004	Tree sparrow	H5N1	3.0×10^5 TCID ₅₀ /test
Flu A/Henan/4/2004	Tree sparrow	H5N1	6.0×10^5 TCID ₅₀ /test
Flu A/Wisconsin/66	Turkey	H9N2	6.0×10^4 TCID ₅₀ /test
Flu A/England/1/63	Turkey	H7N3	6.0×10^4 TCID ₅₀ /test
Flu A/Singapore/1/57	Bird	H5N1	6.0×10^4 TCID ₅₀ /test
Flu A/Hunan/71/2004	Bird	H5N1	6.0×10^4 TCID ₅₀ /test
Flu A/S. hanxi/50/2006	Bird	H5N1	6.0×10^4 TCID ₅₀ /test
Flu A/S. hanxi/42/2006	Bird	H5N1	6.0×10^4 TCID ₅₀ /test
Flu A/Fujian/320/2004	Bird	H5N1	3.0×10^5 TCID ₅₀ /test

Influenza A&B Ag Rapid Test can detect all nine influenza B strains.

3. Clinical Study Data Summary

The Influenza A&B Ag Rapid Test performance vs. Cell Culture

Kind of samples	Type	Sensitivity(%)	Specificity(%)	Accuracy(%)
Nasal Swab	A	92.6 (25/27)	96.4 (81/84)	95.5 (106/111)
	B	90.0 (27/30)	95.8 (91/95)	94.4 (118/125)
Throat Swab	A	83.3 (20/24)	95.2 (59/62)	91.9 (79/86)
	B	82.6 (19/23)	91.8 (67/73)	89.6 (86/96)
Nasal Aspirate	A	88.9 (48/54)	93.3 (125/134)	92.0 (173/188)
	B	91.2 (52/57)	95.4 (98/103)	93.8 (150/160)
Nasal discharge/ Nasal mucus	A	80.7 (46/57)	94.9 (93/98)	89.7 (139/155)
	B	89.6 (62/69)	94.6 (87/92)	92.5 (149/161)

4. Analytical Specificity And Cross-reactivity

The Influenza A&B Ag Rapid Test was evaluated with a total of 30 bacterial and viral isolates. Bacterial isolates were evaluated at a concentration between 10^7 and 10^9 org/mL. Viral isolates were evaluated at a concentration of at least 10^4 - 10^8 TCID₅₀/mL. Adenovirus 18 and Parainfluenza virus 3 were tested at 10^2 TCID₅₀/mL. None of the organisms or viruses listed below gave a positive result in the Influenza A&B Ag Rapid Test.

Bacterial Panel:

Acinetobacter calcoaceticus	Bacteroides fragilis
Neisseria gonorrhoeae	Neisseria meningitidis
Pseudomonas aeruginosa	Staphylococcus aureus
Streptococcus pneumoniae	Streptococcus sanguis
Proteus vulgaris	Streptococcus sp. Gp. B
Streptococcus sp. Gp. C	Streptococcus sp. Gp. G
Mycobacterium tuberculosis	Mycoplasma orale

Viral Panel:

Human Adenovirus B	Human Rhinovirus 2
Human Adenovirus C	Human Rhinovirus 14
Adenovirus type 10	Human Rhinovirus 16
Adenovirus type 18	Measles
Human Coronavirus OC43	Mumps
Human Coxsackievirus A9	Sendai virus
Coxsackievirus B5	Parainfluenza virus 2
Human herpesvirus 2	Parainfluenza virus 3

5. Interfering Substances

Whole blood, and several over-the-counter (OTC) products and common chemicals were evaluated and did not interfere with the Influenza A&B Ag Rapid Test at the levels tested: whole blood (2%); three OTC mouthwashes (25%); three OTC throat drops (25%); three OTC nasal sprays (10%); 4-Acetamidophenol (10mg/mL); Acetylsalicylic Acid (20mg/mL); Chlorpheniramine (5mg/mL); Dextromethorphan (10mg/mL); Diphenhydramine (5 mg/mL); Ephedrine (20mg/mL); Guaiacol glyceryl ether (20mg/mL); Oxymetazoline (10mg/mL); Phenylephrine (100 mg/mL); and Phenylpropanolamine (20mg/mL).

For COVID-19 Antigen Rapid Test:

1. Clinical Sensitivity, Specificity and Accuracy

The COVID-19 Antigen Rapid Test Cassette (Swab) has been evaluated with specimens obtained from patients. A commercialized molecular assay was used as the reference method. The results show that the COVID-19 Antigen Rapid Test Cassette (Swab) has a high overall relative accuracy.

Table 1: The COVID-19 Antigen Rapid Test vs PCR

COVID-19 Rapid Test Cassette	Method	PCR		Total Results
	Results	Positive	Negative	
	Positive	39	0	39
	Negative	6	116	122
	Total Results	45	116	161

Relative Sensitivity: 86.7% (95%CI*: 73.2%-95.0%)

*Confidence Intervals

Relative Specificity: 100% (95%CI*: 96.9%-100%)

Accuracy: 96.3% (95%CI*: 92.1%-98.6%)

INDEX OF SYMBOLS

	Consult instructions for use		Tests per kit		Authorized Representative
	For <i>in vitro</i> diagnostic use only		Use by		Do not reuse
	Store between 2-30°C		Lot Number		Catalog#

Göztepe mah. Batışehir cad. No:2/3
İç Kapı No: 1B12 Bağcılar/İSTANBUL
Tel: 00905350499266
www.spesera.com.tr



Sağlık Ürünleri İç ve Dış Tic. Ltd. Şti.

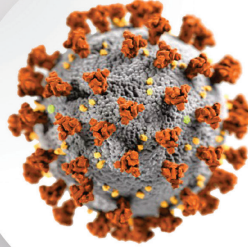


Coronavirus Ag Rapid Test

► COVID-19 Overview

The novel coronaviruses belong to the β genus. COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, patients infected by the novel coronavirus are the main source of infection; asymptomatic infected people can also be an infectious source. The main symptoms include fever, fatigue, loss of smell and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases.

SARS viral antigen is generally detectable in upper respiratory specimens during the acute phase of infection. The Coronavirus Ag Rapid Test is a rapid screening tool to detect the presence of SARS viral antigen in the form of a visually interpreted result within minutes.



Product Information

The Coronavirus Ag Rapid Test Cassette (Swab) is an in vitro immunochromatographic assay for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 in nasopharyngeal (NP) swab specimens directly or after the swabs has been added to viral transport media from individuals who are suspected of COVID-19 by their healthcare provider. It is intended to aid in the rapid screening of SARS-CoV-2 infections. The Coronavirus Ag Rapid Test Cassette (Swab) does not differentiate between SARS-CoV and SARS-CoV-2.

Specification

Information	InDetail
Time to result	15 minutes
Storage	2-30°C
Shelf life	24 months
Specimen type	Nasopharyngeal swab



Contents

- 25 Test cassettes • 25 Sterile swabs
- 25 Extraction tubes and nozzle
- Workstation • 2 Buffers • Package insert

Test Procedure & Interpretation

Specimen collection

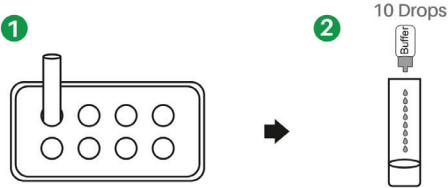
Use the nasopharyngeal swab supplied in the kit.

1. Carefully insert the swab into the nostril of the patient, reaching the surface of posterior nasopharynx. that presents the most secretion under visual inspection.
2. Swab over the surface of the posterior nasopharynx. Rotate the swab several times.
3. Withdraw the swab from the nasal cavity.

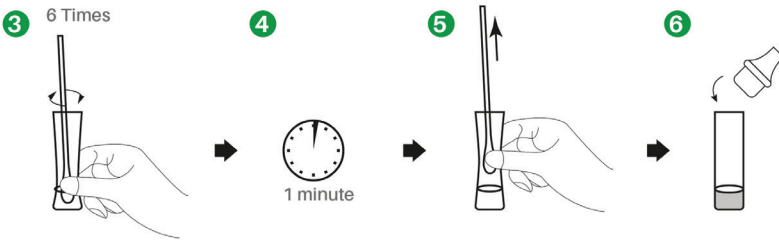


Sample preparation

1. Insert the test extraction tube into the workstation in this product. Make sure that the tube is standing firm and reaches the bottom of the workstation.
2. Add 300 µL (about 10 drops) of the extraction buffer into the extraction tube.



3. Insert the swab into the extraction tube which contains 300 µL of the extraction buffer. Roll the swab at least 6 times while pressing the head against the bottom and side of the extraction tube.
4. Leave the swab in the extraction tube for 1 minute.
5. Squeeze the tube several times with fingers from outside of the tube to immerse the swab. Remove the swab. The extracted solution will be used as test sample.
6. Push the nozzle which contains a filter onto the extraction tube. Ensure the nozzle has a tight fit.



Test procedure & interpretation of results



Benefits

- Rapid testing for SARS vial antigen within 15 minutes
- Facilitates patient treatment decisions quickly
- Simple, time-saving procedure
- No instrumentation required
- High sensitivity and specificity

Ordering Information

Product Description	Specimen	Catalog No.	Format	Kit Size	Carton Size	Carton Volume	Gross Weight
Coronavirus Antigen Rapid Test	Nasopharyngeal Swab	SP226	Cassette	25 Tests/Kit	30 Kits/ Carton	690*410*455 mm	17.2 kg

√ CE Marked

Tıbbi Cihaz Bilgileri

Tıbbi Cihaz Detayları	Ürün Geçmiş	Piyasaya Arz Bilgisi	Takip Konfigürasyonu	Ürün Tıbbut Geçmiş	SUT Kodları
-----------------------	-------------	----------------------	----------------------	--------------------	-------------

Tanımlayıcı Bilgiler

Ürün Tanımı:	SPESERA - YOK - SPESERA COVID -19 ANTİJEN TESTİ
Birincil Ürün Numarası:	8681176311026 (GS1)
Firma:	2667269041913 - SPESERA SAĞLIK ÜRÜNLERİ İÇ VE DIŞ TIC. LTD. ŞTİ. (İretici/İthalatçı/Bayi/İhracatçı)
Marka:	SPESERA
Ürün Adı:	SPESERA COVID -19 ANTİJEN TESTİ
Ürün Künyesi:	Ürün Künyesi.pdf
Orijinal Etiket Türkçe mi?:	Evet
Orijinal Etiket:	spesera etiket.pdf
Versiyon/Model:	YOK
Referans/Katalog No:	SP-226
İçerikteki Ürün Sayısı:	1
Ürün Açıklaması:	SPESERA COVID -19 ANTİJEN TESTİ
Aynı Barkodlu Ürünler:	Aynı Barkodlu Ürünler

Sınıflandırma Bilgileri

Sınıf:	IVD Diğer
GMDN:	64787 - SARS-CoV-2 antijen IVD, kit, immunokromatografik test (ICT), hızlı
Branş Türü Kodu:	1225-KİT

Durum Bilgileri

Durum:	Kayıtlı
Tekil Ürün Durumu:	Tekil ürün hiç dahil edilmemiş.
Ürün Tipi:	Tıbbi Cihaz
Veri Kaynağı:	Firma
İncelenmeye Alındığı Tarih:	24/03/2021
Güncellenme Tarihi:	26/03/2021
ÜTS Değişiklik Tarihi:	11/12/2020
Durum Tarihi:	26/03/2021

İthal/İmal Bilgileri

İthal/İmal Bilgisi:	İmal
Menşei Ülke:	Türkiye

Ürün Belgeleri

Belge No	Belge Türü	Orijinal Doküman	Türkçe Doküman
9041913-UB5	Uygunluk Beyanı	Spesera-ub.pdf	
1	1 - 15	Sayfa başına 15 kayıt	

Ürün Görselleri

Görselleri Göster

Ürün Görsel Dosyası
spesera 1.pdf
spesera 1 (2).pdf
spesera 4.pdf
spesera 2.pdf

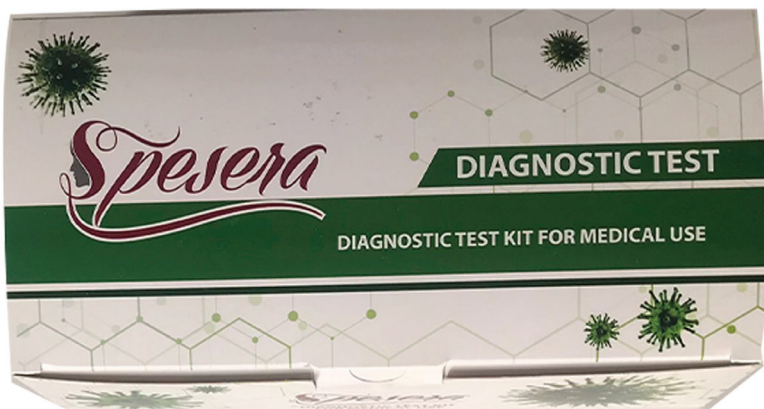
Özellikler

MRG Güvenlik Bilgisi:	Bilgi Bulunmuyor	Kalibrasyona tabi mi?:	Hayır
Latex içeriyor mu?:	Hayır	Bakıma tabi mi?:	Hayır
Fltalat/DEHP içeriyor mu?:	Hayır	Steril paketlenildi mi?:	Hayır
Ürün iyonize radyasyon içerir mi?:	Hayır	Kullanım Öncesinde Sterilizasyon Gerekliliği 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?:	Evet	Başka Bir Tıbbi Cihazın Bileşeni, Aksesuarı, Yedek Parçası mı?:	Hayır
Ürünün sınırlı kullanımı sayısı var mı?:	Evet		
Sınırlı Kullanım Sayısı:	1		
Ekstra Bilgi Linki:	http://www.spesera.com/tr		
SUT Eşleşme Durumu:	Eşleşme Yok		
Raf ömrü var mı?:	Evet		
Raf Ömrü:	24 Ay		

Saklama Koşulu Bilgileri

Saklama Koşulu Gerekliyor mu? **Evet**

Saklama Koşulu Tipi	Min	Max	Birim
Saklama/Depolama Ortamı Sıcaklığı	2	30	Derece Santigrat





Sağlık Ürünleri İç ve Dış Tic. Ltd. Şti.



COVID 19 ANTIGEN TEST



Sağlık Ürünleri İç ve Dış Tic. Ltd. Şti.

SPESERA SAĞLIK ÜRÜNLERİ
İÇ VE DIŞ TİC. LTD. ŞTİ.
Göztepe mah. Batışehir cad. No:3/2
İç Kapı No: 1B12 Bağcılar/İSTANBUL
Tel: 00905537552502
www.spesera.com.tr

Revision Date: 2020-07-21

For Rapid Detection of SARS-CoV-2