COVID-19

www.redcell.com.tr

REDCELL BIOTECHNOLOGY

Is an active innovation and research company that takes part in the medical scope since 2018. We aim to pioneer the field all around the world.

As RedCell Biotechnology team, with more than 30 years of experience both in research and in the field, we design our products with future in mind.

As RedCell Biotechnology, we strictly follow related qualifications in the manufacturing processes, and always consider the scientific efficiency and newest developments to offer the best products to our customers.

All of our products are fully and clearly documented and authorized by the related agencies on the international field. We are producing the right products with the right policies.

The COVID-19 pandemic has repeatedly shown the importance of efficient diagnosis in controlling the outbreak. Thus, here we aim to provide the healthcare workers and the patients with the best tools today can have, for a better tomorrow.

REDCELL

rNAT-VTM

rNAT Viral Transfer Medium offers an easy solution to both the transfer of the sample to the laboratory and the preparation of the sample for testing.

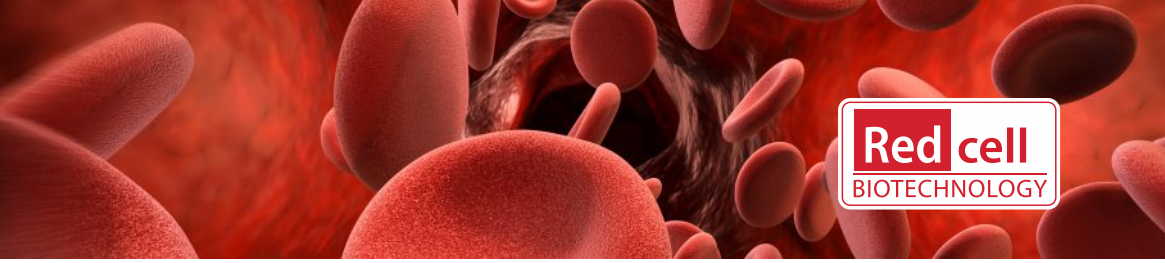
A rNAT tube contains extractive and preservative solution. While breaking apart the structural part of the viral pathogen, it preserves the fragile RNA for testing and allows direct transition from sampling to testing.

REDCELL

COVID-19 PCR Reagents

Redcell Direct SARS-CoV-2 RT-qPCR Kit is a multiplex nucleic acid detection test. It offers an easy and flexible method for COVID-19 testing. The kit detects 2 different regions of the SARS-CoV-2 viral nucleic acid through amplification.

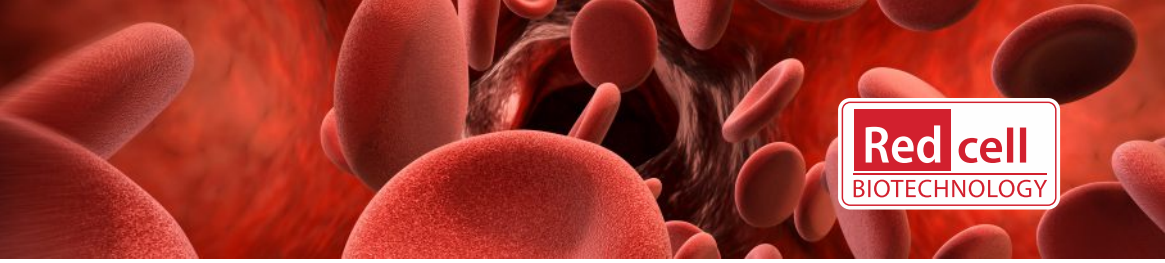
An internal control sequence is also included. The reagents are adaptable to every environment and device while offering a high sensitivity result. Reagent are also compatible with commonly found reagents to enable a more flexible use.



REDCELL

COVID-19 Rapid Antigen Test

Redcell Covid-19 Rapid Antigen Test is a lateral flow immunoassay for rapid diagnosis of COVID-19. Results are given under 10 minutes with sensitivity of >95%. The kit is designed for application in all environments and all instruments required for test is included in the package.

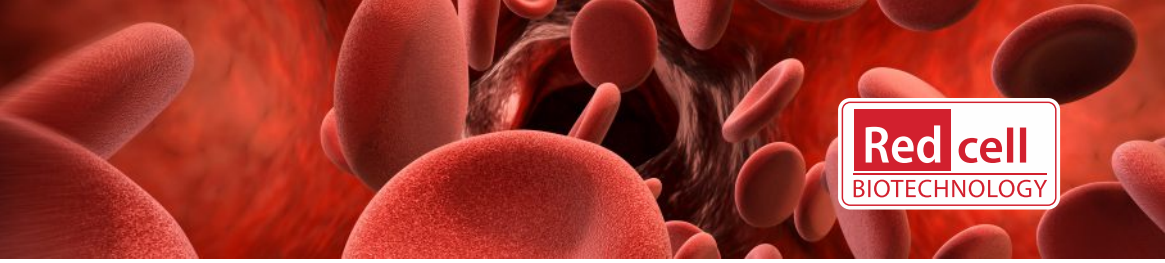


REDCELL

COVID-19 Neutralizing Antibody Screen

Redcell Covid-19 Neutralizing Antibody Screen is an Competitive Enzyme Linked Immunoassay to determine patient immunity against COVID-19. Test determines the percent neutralization of SARS-CoV-2 viral antigens by antibodies.

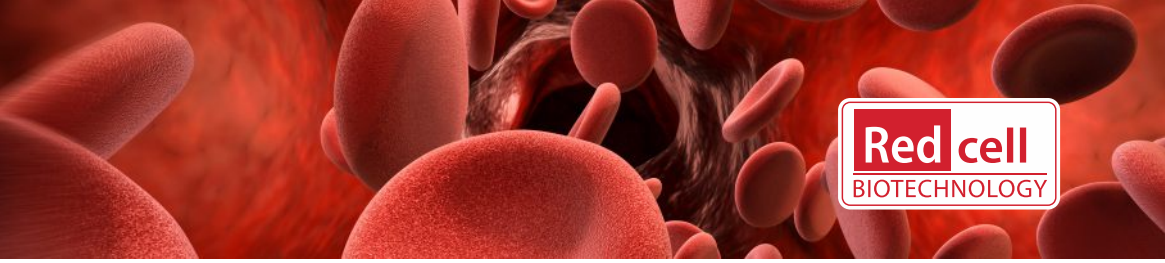
Different versions of the kit is available for variants:
Wild type, Alpha variant, Delta variant, Omicron variant
All variant screen (Wild+Alpha+Delta+Omicron)



REDCELL Flocked SWAB

Specimen collection device with tufts of polyester material attached to the end of a plastic shaft; used to collect specimens of bacterial and viral pathogens properly.

Highly hydrophylic and easy to dilute in viral transfer medium.



REDCELL

VTM

Redcell Viral Transfer Medium enables the collection and transfer of viral samples while keeping the virion structure intact. Isolation, extraction or culture procedures then can be applied in the laboratory.

CERTIFICATE

EC Certificate No. 1434-IVDD-075/2020
EC Design-examination

Directive 98/79/EC concerning
***in vitro* diagnostic medical devices**

Polish Centre for Testing and Certification certifies
that manufactured by:

RED CELL BİYOTEKNOLOJİ A.Ş.

Serifali Mah. Beyit Sok. No: 66 D3
Umraniye, Istanbul, TURKEY

in vitro diagnostic medical devices,
List A

List of devices covered by this certificate is given in the Annex no. 1

in terms of design documentation, comply with requirements of Annex IV (Section 4) to Directive 98/79/EC (as amended) implemented into Polish law, as evidenced by the audit conducted by the PCBC

Validity of the Certificate: from 27.02.2020 to 27.05.2024

The date of issue of the Certificate: 27.02.2020

CE 1434

Application No: 227/2019
Module

mgr Anna Wyroba
Vice-President

Polish Centre for Testing and Certification

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ybm BELGELENDİRME

SERTİFİKA
CERTIFICATE

REDCELL BİYOTEKNOLOJİ A.Ş.

ŞERİFALİ MAH. BEYİT SOK. NO:66/4
ÜMRANİYE/İSTANBUL

BRUCELLA JEL VE MİKROAGLUTİNASYON TESTLERİ, KAN GRUPLAMA SİSTEMLERİ, YENİDOĞAN TARAMA TESTLERİ, ELISA TABANLI TESTLER (KOLORİMETRİK, LUMİNESANS, FLORESANS), PCR TABANLI TESTLER, İMMUNOKROMATOGRAFİK TANI TESTLERİ (HIZLI TANI TESTLERİ, LFIA), VİRAL TRANSPORT BESİYERLERİ, KALİTE KONTROL TESTLERİ ÜRETİMİ

PRODUCTION OF BRUCELLA GEL AND MICROAGLUTINATION TESTS, BLOOD GROUPING SYSTEMS, NEONATAL SCREENING TESTS, ELISA BASED TESTS (COLORIMETRIC, LUMINESCENCE, FLUORESCENCE), PCR BASED TESTS, IMMUNOCHROMATOGRAPHIC DIAGNOSTICS TESTS (RAPID TESTS,LFIA), VIRAL TRANSPORT MEDIUM, QUALITY CONTROL TESTS

kapsamında
with a scope of

ISO 13485:2016

has established that is in compliance with the Medical Devices Quality Management System Standard

Sertifika No: MDD1023
İlk Yayın Tarihi: 25.06.2019
Sertifika Yayın Tarihi / Rev No: 03.06.2020/01
Sertifika Geçerlilik Tarihi: 24.06.2021
Yeniden Belgelendirme Tarihi: 24.06.2022

CB–MDQMS–1605

GENEL MÜDÜR

RED CELL BİYOTEKNOLOJİ A.Ş.

EC Declaration of Conformity

issued in accordance with EC directive 98/79/EC relating to Medical Devices

Manufacturer: REDCELL BİYOTEKNOLOJİ A.Ş.
Adress: ŞERİFALİ MAHALLESİ BEYİT SOKAK NO:66/4 ÜMRANİYE/İSTANBUL
Product name: REDCELL COVID 19 REAL TIME PCR SYSTEMS AND ACCESSORİES
Product models:

Direct RT-qPCR SARS-CoV-2
rNAT Nucleic Acid Extraction Reagent
rNAT Transfer Tube and Flocked SWAB

Product description: COVID 19 REAL TIME PCR TESTS PRODUCTION
Applied directives: The Directive 98/79/EC on medical devices, conformity assessment according to Annex III
Classification: IVD Others
Applied harmonised standards: EN ISO 14971:2012, EN ISO 15223-1 : 2016, EN ISO 13485:2016, BS EN 13612:2002/AC:2002, BS EN ISO 23640:2015, ISO 18113-1:2009, ISO 18113-2:2009,

The company REDCELL here with declares that the above-mentioned product meets all applicable provisions of the Directive 98/79/EC. The products are safe under prescribed and reasonably foreseeable conditions of storage and use.
The company has implemented measures assuring that all products of the above mentioned type are safe and fulfill essential requirements of the 98/79/EC Directive.
The company has instituted and keeps up to date a systematic procedure to review experience gained from devices in the post-production phase and to implement appropriate means for any necessary corrective actions.
The company undertakes to notify the Competent Authority on any malfunction or deterioration in the product characteristics, performance or inadequacy in the instruction for use which might lead to death or serious damage of patient's health as well as on technical or medical reason leading to systematic recall of the product by manufacturer.
If the device is modified without the agreement of the undersigned, this declaration becomes invalid in relation to the modified product.

Date of issue: 25th, May, 2020 Dr. Erdal ATAC General Manager
On Behalf of Company Co.

Şerifali Mah. Beyit Sok. No: 66 / 4 Ümraniye İstanbul Tel: +90 216 449 49 27 info@redcell.com.tr

F.54 Yayın Tarihi:12.04.2019 Rev.No:00 Revizyon Tarihi: 12.04.2019

RED CELL BİYOTEKNOLOJİ A.Ş.

EC Declaration of Conformity

issued in accordance with EC directive 98/79/EC relating to Medical Devices

Manufacturer: REDCELL BİYOTEKNOLOJİ A.Ş.
Adress: ŞERİFALİ MAHALLESİ BEYİT SOKAK NO:66/4 ÜMRANİYE/İSTANBUL
Product name: REDCELL COVID 19 ANTIBODY TEST KITS
Product models:

COVID-19 IgG-IgM Antibody Test Kit

Product description: COVID 19 Antibody TEST PRODUCTION
Applied directives: The Directive 98/79/EC on medical devices, conformity assessment according to Annex III
Classification: IVD Others
Applied harmonised standards: EN ISO 14971:2012, EN ISO 15223-1 : 2016, EN ISO 13485:2016, BS EN 13612:2002/AC:2002, BS EN ISO 23640:2015, ISO 18113-1:2009, ISO 18113-2:2009,

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Date of issue: 25th, May, 2020

Dr. Erdal ATAC, President
On Behalf of Company Co.

Şerifali Mah. Beyit Sok. No: 66 / 4 Ümraniye İstanbul Tel: +90 216 449 49 27 info@redcell.com.tr

F.54 Yayın Tarihi:12.04.2019 Rev.No:00 Revizyon Tarihi: 12.04.2019

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