"We are working to offer better quality products to the heroes of the pandemic"

www.remedimedical.com

Remedi Laboratuvar Ürünleri Ltd.

is an active innovation company that taking part in medical scope since 2018 and aiming to have an important role in the field not only in the country but also all around the world.

The managing partners of the company are two medical doctors and a chemist who have been working in the field for more than 30 years and having a great experience on research, development and innovation. The staff of the company are also having a great experience in the field.

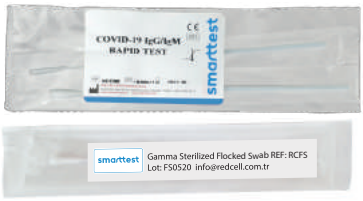
Remedi Laboratuvar Ürünleri Ltd.. always follows the qualifications at the manufacturing while considers scientific efficiency and developments to offer the best and recent opportunities to the customers.

Remedi Laboratuvar Ürünleri Ltd. is committed to obtain "CE" documents for all products which is indispensable at the national level and determines the quality of the product, to improve competitiveness and to open soon in the World while producing the right product with the right policies.

Remedi is manufacturing following reagent with CE mark;

- Remedi Blood Grouping System and Brucella Gel Test.
- Newborn screening tests(TSH / PKU / Biotinidase / IRT),
- RAPID Diagnostic Tests with LFIA (Lateral Flow Immun Assay)
- PCR Reagents
- Viral Transfer Medium and SWAB
- DNA and RNA extraction solutions
- Quality Control Materials

Flocked SWAB



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

VTM

Viral Transfer Medium
viral transfer medium is for transfering the collected specimen from the sample collection field to laboratory. VTM provides safe transfer of the specimen to laboratory.

rNAT-VTM

rNAT Viral Transfer Medium is not only for transfering collected specimen but also extracting RNA. rNAT-VTM is "READY to TEST" and doesnt need any extraction phase before PCR. This spesification maket he testing procedure at least 120 minutes faster comparing with the other conventional system which needs extraction before PCR testing. With rNAT-VTM you do not need to invest for an extraction instrument.

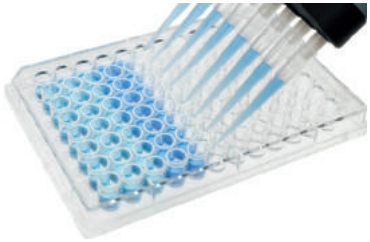
COVID-19 PCR REAGENTS

COVID-19 PCR Reagents three types of boxes including
100, 250 and 1000 tests. In the boxes there are also RNA extraction solution called rNAT which allow the user apply the specimen directly to the PCR instrument bypassing the extraction phase. You may either use rNAT extraction solution with any types of VTM or rNAT-VTM without rNAT extraction solution.

COVID-19 RAPID ANTIBODY TEST

RAPID ANTIBODY TEST allows you to diagnosis whether the patient synthesis IgG and IgM antibody against to COVID-19 VIRUS by using LFIA(Lateral Flow Immun Assay) method.

COVID-19 ELISA TEST



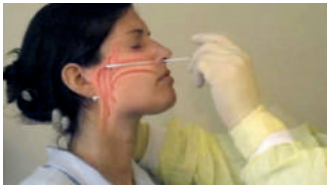
COVID-19 ELISA TEST allows you to diagnosis whether the patient synthesis IgG and IgM antibody against to COVID-19 VIRUS by using ELISA(eEnzym Linked Immun Assay) method.

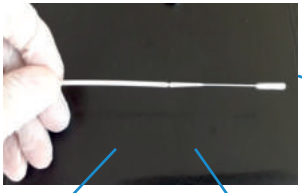
ALTERNATIVE 1

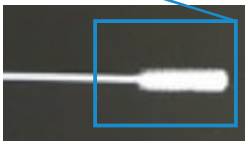
ALTERNATIVE 2

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

STEP 1 - NASOPHARENGEAL SWAB APLICATION







STEP 2 - TRANSFERING SPECIMEN TO THE VIRAL TRANSFER MEDIUM

SMARTTEST VTM
or any other VTM

SMARTTEST rNAT VTM
"READY to TEST"

ALTERNATIVE 1	ALTERNATIVE 2
STEP 3 - TRANSFERING SAMPLE TO A LABORATORY	
A) SMARTTEST VTM It should be transfered to a laboratory in appropriate conditions like other viral transfer medium.	**B) SMARTTEST rNAT VTM** It should be transfered to a laboratory in appropriate conditions. Virus in the specimen is inactivated therefore there is no more contagious disease risc for health care Professional. Inactivation of the virus is not destroy the RNA structure in transfer medium.
STEP 4 - EXTRACTING PHASE AFTER SPECIMEN ARRIVE TO A LABORATORY	
A) SMARTTEST VTM All specimen should be apply RNA extraction after arrive to a laboratory. Extraction phase lasts approximately 120 minutes depending on the instrument.	**B) SMARTTEST rNAT VTM** SMARTTEST rNAT-VTM is "READY to TEST". Therefore it doesnt need an additional extraction phase. Hence the testing time is 120 minutes less than other competitor PCR tests.
If any PCR Reagent will be used for testing Extraction should be applied if any other PCR reagents applied except SMARTTEST PCR test	**If SMARTTEST PCR Reagent** will be used for testing SMARTTEST PCR Reagent includes rNAT extraction solution. This solution allow laboratories apply the specimen direct to PCR testing without any extraction phase.
STEP 5 - PCR TESTING BY USING ANY PCR INSTRUMENT	

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.

VTM

Viral transfer medium is for transfering the collected specimen from the sample collection field to laboratories. VTM provides safe transfer of the specimen to laboratories.

rNAT-VTM

rNAT Viral Transfer Medium is not only for transfering collected specimen but also extracting RNA. rNAT-VTM is “READY to TEST” and doesnt need any extraction phase before PCR. This spesification makes the testing procedure at least 120 minutes faster than the other conventional systems which needs extraction before PCR testing. With SMARTTEST rNAT-VTM if you are establishing your laboratory now and investing the instruments for pandemic do not need to invest for an extraction instrument.

COVID-19 PCR REAGENTS

COVID-19 PCR Reagents three types of boxes including 100, 250 and 1000 tests. In the boxes there are also RNA extraction solution called rNAT which allows the user apply the specimen directly to the PCR instrument bypassing the extraction phase. You may either use REDCELL rNAT extraction solution with any types of VTM orrNAT-VTM without rNAT extraction solution.

COVID-19 RAPID ANTIBODY TEST

RAPID ANTIBODY TEST allows you to diagnosis whether the patient synthesis IgG and IgM antibody against to COVID-19 VIRUS by using LFIA(Lateral Flow Immun Assay) method. Rapid Test's sensitivity and spesfitiy is 99% and 96% respectively.

COVID-19 ELISA TEST

COVID-19 ELISA TEST allows you to diagnosis whether the patient synthesis IgG and IgM antibody against to COVID-19 VIRUS by using ELISA(eEnzym Linked Immun Assay) method.

ybm BELGELENDİRME

SERTİFİKA
CERTIFICATE

A PLUS DİAGNOSTİCS LABORATUVAR SAN. VE TİC. A.Ş.

AHMET YESEVİ MAH. KEREM SK. NO:9 /1- 18 PENDİK / İSTANBUL

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

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

kapsamında
with a scope of

ISO 13485:2016

Tıbbi Cihazlar Kalite Yönetim Sistemine uygun bir sistem kurmuştur.
has established that is in compliance with the Medical Devices Quality Management System Standard.

Sertifika No / *Certificate No* : MDD1039
İlk Yayın Tarihi / *Initial Date* : 17.07.2020
Sertifika Yayın Tarihi / Rev No / *Date of This Certificate / Rev No* : 17.07.2020/00
Sertifika Geçerlilik Tarihi / *Certificate Expiry Date* : 16.07.2021
Yeniden Belgelendirme Tarihi / *Date of Re-Certification* : 16.07.2023

TÜRKAK UAF
CB-MDQMS-1005

Genel Müdür / *General Manager*

Yönetim Belgelendirme Merkezi Test ve Gözetim Hizmetleri Ltd. Şti.

APLUS DIAGNOSTICS

APLUS DIAGNOSTICS A.Ş.

EC Declaration of Conformity

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

Manufacturer	: APLUS DIAGNOSTICS LABORATUVAR SANAYI VE TICARET A.Ş.
Adress	: ŞERİFALİ MAHALLESİ BEYİT SOKAK NO:66/2 ÜMRANİYE/İSTANBUL
Product name	: SMARTTEST COVID 19 IgG / IgM Rapid Antibody Test
Product models	: SMARTTEST IgG/ IgM RAPID ANTIBODY TEST
Product description	: SMARTTEST IgG/ IgM RAPID ANTIBODY TEST TESTS PRODUCTION
Applied directives	: The Directive 98/79/EC on medical devices, conformity assessment according to Annex III
Classification	: IVD Others

Applied harmonized 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 APLUS 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, September, 2020

Dr. Mujdat AYTEKIN General Manager

On Behalf of Company Co.

APLUS DIAGNOSTICS LABORATUVAR SANAYI VE TICARET A.Ş.
Şerifali Mah. Beyit Sok. No: 66 K2 Ümraniye / İSTANBUL

APLUS DIAGNOSTICS LABORATUVAR SANAYI VE TICARET A.Ş.
ŞERİFALİ MAHALLESİ BEYİT SOKAK NO:66/2 ÜMRANİYE/İSTANBUL - 0-216-550-38-38
www.smarttest.com.tr info@smarttest.com.tr

NAC

NATIONAL ACCREDITATION CENTER

ACCREDITATION CERTIFICATE

TO BE ACTIVE AS PROFICIENCY TESTING,

APLUS DIAGNOSTICS LABORATUVAR SANAYİ VE TİCARET A.Ş.

As a result of the audit conducted by the National Accreditation Center (NAC), it is accredited in the annexes to the EN ISO/IEC 17043:2010 Conformity assessment - General requirements for proficiency testing

Accreditation Number : NAC-003-PT
Accreditation Date : 06.01.2020

This certificate is valid until 06.01.2021, if the above mentioned name and address continue to comply with the relevant standards, international and regional rules in addition to the written organization's EN ISO/IEC 17043:2010
Conformity assessment - General requirements for proficiency testing

This certificate is given by NAC. The certificate becomes invalid in case of suspension and cancellation of accreditation. For current accreditation information, visit NAC on info@nationalaccreditationcenter.org .

GENERAL SECRETARY

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

Certificate No: 105393

Date of Issue : 3 November 2020

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 "A PLUS DİAGNOSTİCS LABORATUVAR SAN. VE TİC. A.Ş." (*Şerifali Mh. Beyit Sk. No:66/2 ÜMRANİYE 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 other countries and is valid for 36 months from the date of issue.

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.

Yours sincerely,

Asım HOCAOĞLU, Ph.D.
Head of Medical Devices
Registration and Coordination Department

Address: Sögütözü Mahallesi, 2176. Sokak No:5 06520 Çankaya/ANKARA
Phone: +90 312 218 30 00 Fax: +90 312 218 34 60 https://www.titck.gov.tr

Date of Issue : 3 November 2020

PRODUCT SCHEDULE

#	Barcode	Brand	Label Name	Reference No / Version / Model	GMDN Code
1	8682974422013	SMART TEST	SMARTTEST COVID 19 IgG / IgM Rapid Antibody Test	STRCOVAB	64756

End of product schedule.

Asım HOCAOĞLU, Ph.D.
Head of Medical Devices
Registration and Coordination Department