



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

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## **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.

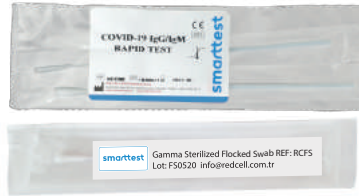
**Remedi Laboratuvar Ürünleri Ltd..** always follows the qualifications at the manufacturing while considers scientific efficiency and developments to offer the best and recent opportunities to the customers.

**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 transferring 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 transferring collected specimen but also extracting RNA. rNAT-VTM is "READY to TEST" and doesn't need any extraction phase before PCR. This specification makes the testing procedure at least 120 minutes faster compared 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(Enzym Linked Immun Assay) method.

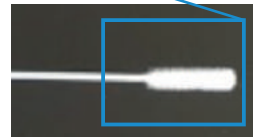
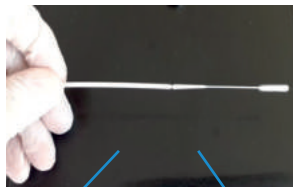
## ALTERNATIVE 1



## 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 transferred to a laboratory in appropriate conditions like other viral transfer medium.

#### B) SMARTTEST rNAT VTM

It should be transferred to a laboratory in appropriate conditions. Virus in the specimen is inactivated therefore there is no more contagious disease risk 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 doesn't 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

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Viral transfer medium is for transferring 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 transferring collected specimen but also extracting RNA. rNAT-VTM is “READY to TEST” and doesn't need any extraction phase before PCR. This specification 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

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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 or rNAT-VTM without rNAT extraction solution.



## COVID-19 RAPID ANTIBODY TEST

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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 spesfity is 99% and 96% respectively.



## COVID-19 ELISA TEST

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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.





## A PLUS DIAGNOSTICS LABORATUVAR SAN. VE TİC. A.Ş.

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

BRUCELLA JELE VE MICROAGGLUTINATION TESTLERİ, KAN GRUPLAMA SİSTEMLERİ,  
YENİDOĞAN TARAMA TESTLERİ, ELİSA TESTLERİ (KOLORMETİK, LÜMİNESANS,  
FLORESANS), PCR TABANLI TESTLERİ, İMMUNOHİSTOKİMYA/İMMÜNOFENOTİP (HİSTO) TANI  
TESTLERİ, URİNA, VİRAL TRANSPORT BEŞİTİLERİ, KALİTE KONTROL TESTLERİ ÜRETİMİ

BRUCELLA JELE AND MICROAGGLUTINATION TESTS, BLOOD GROUPING SYSTEMS, NEONATAL  
SCREENING TESTS, ELISA TESTS (COLORIMETRIC, LUMINESCENCE, FLUORESCENCE), PCR  
BASED TESTS, IMMUNOHISTOCHEMISTRY/IMMUNOPHENOTYPING (HISTO) DIAGNOSIS TESTS,  
URINA, VIRAL TRANSPORT MEDIAN, PRODUCTION OF QUALITY CONTROL TESTS

İspat edilmiştir  
with a scope of

ISO 13485:2016

TÜRKİYE Çiğdem Kalite Yönetim Sistemleri için ulusal Normatif,  
Not established that it is in compliance with the Medical Device Quality Management System Standard.

Sertifika No : NDD/1939  
Çekim Tarihi : 17.07.2020  
İk. Yayımlı Tarihi : 17.07.2020

Sertifika Yayımlı Tarihi / Revizyon : 17.07.2020/00  
İk. Yayımlı Tarihi : 17.07.2020  
Sertifika Geçerlilik Tarihi : 16.07.2021  
Sertifika İnceleme Tarihi : 16.07.2023  
Tasdik Belgeleendirme Tarihi : 16.07.2023  
Date of the Certification



Dr. Mehmet  
BENLİ MURAT  
Genel Müdür  
Genel Müdür

Dr. Mehmet  
BENLİ MURAT  
Genel Müdür  
Genel Müdür

Nüfus Belgeleendirme Hizmeti Test ve Ölçüm Hizmeti (NAC, 95,  
100, 105, 110, 115, 120, 125, 130, 135, 140, 145, 150, 155, 160,  
165, 170, 175, 180, 185, 190, 195, 200, 205, 210, 215, 220, 225, 230, 235, 240, 245, 250, 255, 260, 265, 270, 275, 280, 285, 290, 295, 300, 305, 310, 315, 320, 325, 330, 335, 340, 345, 350, 355, 360, 365, 370, 375, 380, 385, 390, 395, 400, 405, 410, 415, 420, 425, 430, 435, 440, 445, 450, 455, 460, 465, 470, 475, 480, 485, 490, 495, 500, 505, 510, 515, 520, 525, 530, 535, 540, 545, 550, 555, 560, 565, 570, 575, 580, 585, 590, 595, 600, 605, 610, 615, 620, 625, 630, 635, 640, 645, 650, 655, 660, 665, 670, 675, 680, 685, 690, 695, 700, 705, 710, 715, 720, 725, 730, 735, 740, 745, 750, 755, 760, 765, 770, 775, 780, 785, 790, 795, 800, 805, 810, 815, 820, 825, 830, 835, 840, 845, 850, 855, 860, 865, 870, 875, 880, 885, 890, 895, 900, 905, 910, 915, 920, 925, 930, 935, 940, 945, 950, 955, 960, 965, 970, 975, 980, 985, 990, 995, 1000, 1005, 1010, 1015, 1020, 1025, 1030, 1035, 1040, 1045, 1050, 1055, 1060, 1065, 1070, 1075, 1080, 1085, 1090, 1095, 1100, 1105, 1110, 1115, 1120, 1125, 1130, 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**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 DIAGNOSTICS 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

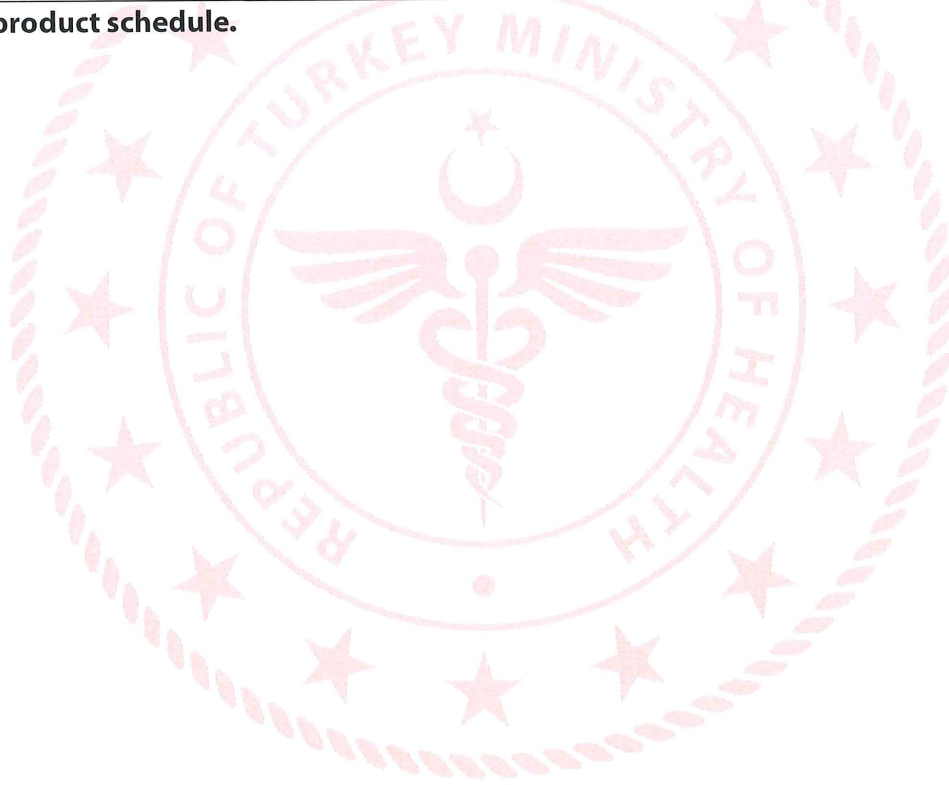


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**PRODUCT SCHEDULE**

#	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