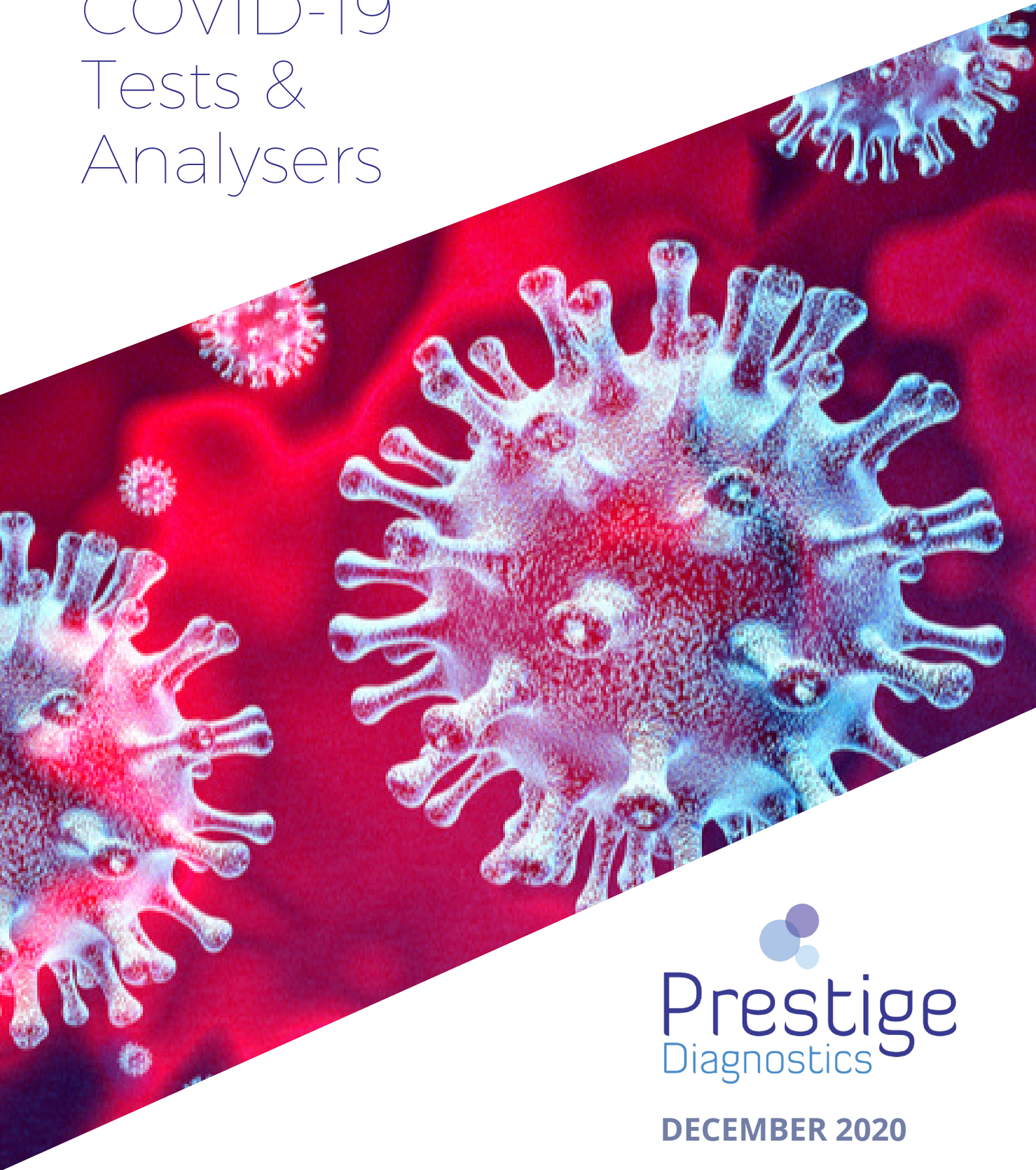


COVID-19 Tests & Analysers




Prestige
Diagnostics

DECEMBER 2020

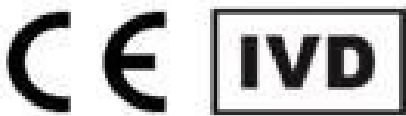
ANTIBODY RAPID TESTS | LYOPHILISED PCR KITS | ELISA ASSAYS
UNIVERSAL & NASAL SWABS WITH CONTAINERS
RNA / DNA MAGNETIC BEAD EXTRACTION KITS | ANALYSERS

Prestige Diagnostics UK is a primary manufacturer of IVD Reagents based in The United Kingdom in the field of Blood Grouping, Coagulation, Clinical Chemistry, Quality Controls & Calibrators, Febrile Antigens, Latex Serology, Syphilis, ELISA Assays, Rapid Tests and Urine Strips.

As an ISO13485 accredited business, we take all forms of quality assurance very seriously. We supply leading distributors across Europe, South East Asia, South America and the majority of Africa.

Our existing partners appreciate our reputation for supplying consistently high-quality, certified products manufactured here in the United Kingdom. Improvement being the key to any successful business, Prestige Diagnostics constantly strives to be innovative in it's approach to the products and services it provides.

ISO 13485:2016



With the recent COVID-19 Global Pandemic, Prestige Diagnostics were determined to put into action a managed strategy to ramp-up production of their popular Specimen Swab kits, Rapid Tests, ELISA Assays and PCR Kits. Prestige Diagnostics are working closely with their network of specialised global distributors to plan their COVID-19 test requirements.

SARS-CoV-2

Coronaviruses are a large family of viruses that cause disease ranging from common cold symptoms to more severe pneumonia. They are enveloped, single strand RNA viruses. Coronaviruses are zoonotic, they can be transmitted from animals to humans. Existing examples include the Middle East Respiratory Virus (MER-CoV) and Severe Acute Respiratory Syndrome (SARS-CoV).

Reports of a novel coronavirus began in the Wuhan district of China in December 2019 and in January 2020 the World Health Organisation designated the new strain 2019-nCoV, later SARS-CoV2. Symptoms include high temperature, cough and breathing difficulties. In immunocompromised individuals symptoms can be more severe leading to pneumonia, severe acute respiratory syndrome or death.



COVID-19 Antibody Rapid Test

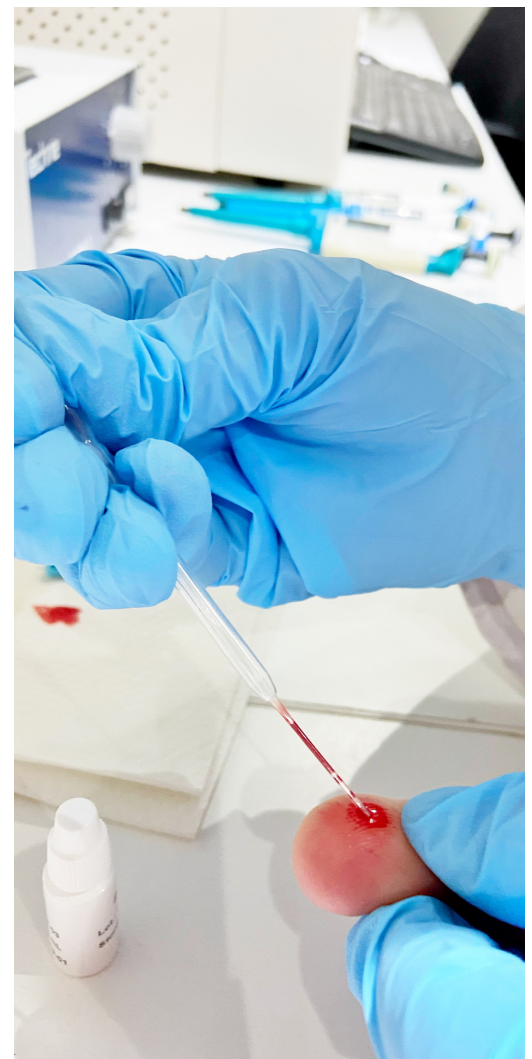
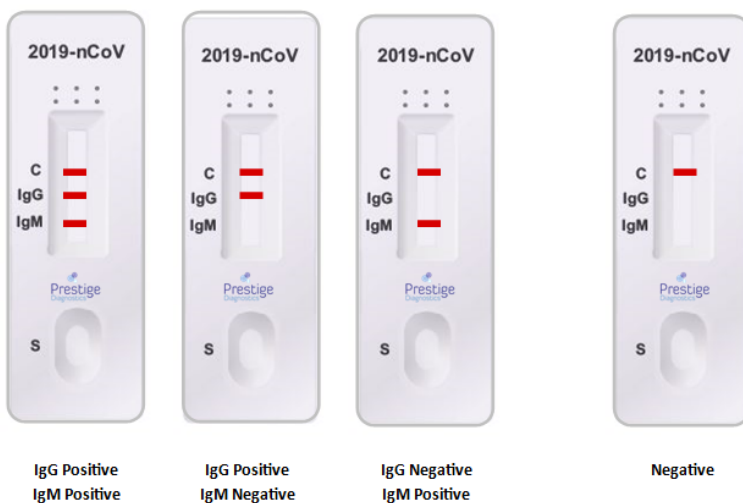
Whole blood (including finger prick) serum and plasma sample
Easy to use - no analyser required
Store at room temperature or refrigerator

Rapid test for the qualitative detection of antibodies (IgG and IgM) against SARS-CoV-2 in whole blood, plasma or serum.



Product Features :

- Ideal for Point-of-Care testing
- Visual results available in just 10-15 minutes
- 20 complete tests in one kit
- 96% accuracy - British-made reliability



RADCOV1 - Antibody Rapid Test - 20x Test Kit

RADCOV2 - Antibody Rapid Test with lancet and Alcohol Swab - 20x Test Kit

RADCOV2-02T - Antibody Rapid Test with lancet and Alcohol Swab - 2x Test Kit (x 5)

For more information visit our website: www.prestigediagnostics.co.uk/coronavirus

NEW

COVID-19 Antigen Rapid Test

Our COVID-19 Antigen rapid test detects nucleocapsid (N) protein fragment of SARS-CoV-2, which makes the test highly specific and for detecting the presence of the virus.

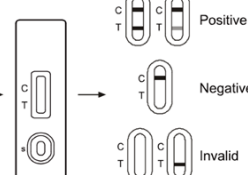
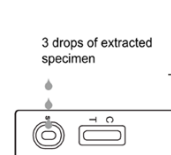
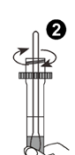
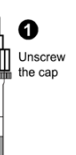
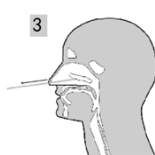
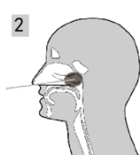
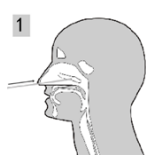
Direct Antigen detection from the site of the infection helps in the early diagnosis of COVID-19 as it plays an important role for virus detection in the early stages of the disease. SARS-CoV-2 antigens are generally detectable in upper respiratory specimens during the acute phase of infection.

Product Features :

- **High accuracy : 98% (Results compared with RT-PCR).**
- **Fast results- i.e. 15 minutes.**
- **Easy visual interpretation.**
- **Simple operation. No equipment required.**



Analytes	Sensitivity	Specificity	Accuracy
COVID-19	96.4%	99.2%	98.0%



RADCOV4 - 2019-nCoV Antigen Rapid Test with Sample Swab and Specimen Container - 20x Test Kit.

NEW

COVID-19 and Influenza A&B Antigen Rapid Test

Detect COVID-19, Flu A & Flu B Infections on one device.

Our 2019-nCoV and Influenza A+B Antigen dual rapid test is a chromatographic immunoassay for the qualitative detection of SARS-CoV-2, Influenza A and Influenza B virus antigens present in nasal swab specimens.

It can be used as an aid in the diagnosis of patients displaying symptoms typical of COVID-19, the Flu and the common cold to differentiate between the source of the infection, in conjunction with clinical presentation and the results of other laboratory tests. Differentiating between SARS-CoV-2 and Influenza A and B may assist in more effectively targeting the correct treatment for the patient.



Analytes	Sensitivity	Specificity	Accuracy
COVID-19	96.4%	99.2%	98.0%
Flu A	95.0%	99.1%	98.4%
Flu B	92.9%	99.1%	98.1%

The test has been evaluated with patient specimens with RT-PCR used as the reference method.

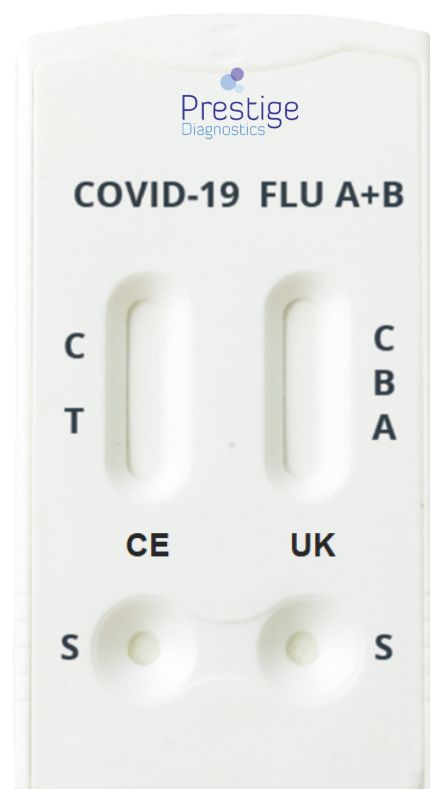
Product Features :

- Screening COVID-19, Influenza A+B on one device.
- High Accuracy.
- Fast results- i.e. 15 minutes.
- Easy visual interpretation.
- Simple operation. No equipment required.

RADCOV5 - 2019-nCoV & FLU A&B Antigen Device

with Sample Swab and Specimen Container - 20x Test Kit.

For more information visit our website: www.prestigediagnostics.co.uk/coronavirus



COVID-19 ELISA Assays

Prestige Diagnostics COVID-19 ELISA Assays are enzyme linked immunosorbent assays for the qualitative detection of total or individual antibodies to SARS-CoV2 in human serum and plasma. They are intended for screening of patients suspected of infection with coronavirus disease 2019.

Product Summary :

- Sandwich ELISA Assays
- Highly specific and sensitive
- Easy to perform thanks to fast and simple procedures
- Equipment relatively inexpensive and available from Prestige Diagnostics
- Up to 90 samples analysed simultaneously
- Small sample volume required (100 µL)
- Colorimetric results easy to analyse



Name	Cat. Number	Clinical Specificity	Clinical Sensitivity
IgM Antibody ELISA	EIACVM1	95.2%	97.1%
IgG Antibody ELISA	EIACVG1	96.7%	98.3%
Total Antibody ELISA	EIACOV1	97.8%	98.9%

EIACVM1 - IgM Antibody ELISA Assay - 96x Test Kit

EIACVG1 - IgG Antibody ELISA Assay - 96x Test Kit

EIACOV1 - Total Antibody ELISA Assay - 96x Test Kit



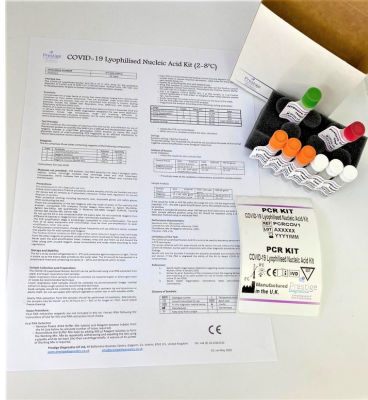
Real-time (PCR) Polymerase Chain Reaction Line



Cat. No. SSCCOV1 or SSCCOV2
**Single-use Specimen
Container and Swab**



Cat. No. PCREXT1
DNA/RNA Extraction Kit



Cat. No. PCRCOV1
COVID-19 - Lyophilised Nucleic Acid Kit



Cat. No. MX-48
**MagXtractor
Automatic Nucleic
Acid Extractor**



Cat. No. PCR-6000
**PCR Nucleic Acid
Detection Analyser**



COVID-19 Single-use Specimen Container and Swab

**Prestige Diagnostics offer not one but two swab and container options;
a universal swab with a 3 mm break-point
and a nasal swab with a 8 mm break-point**

Product Features :

- Choice of swab sampling, oropharyngeal or nasopharyngeal
- Inactivates virus - a specially formulated storage buffer completely inactivates the virus.
- Full preservation of nucleic acid - virus RNA stable for up to 24 hours at 2-8°C.
- Safe and Secure - One-step sampling and preservation to reduce personnel exposure especially for medical workers



SSCCOV1 - Universal Swab Specification

- Swab break-point - 3 cm
- Shaft material - ABS Rod
- Length of swab - 15.4 cm
- Tip size - 23 mm x 7 mm
- Tip material - nylon, flocked
- Sterility - Yes, sterility by ethylene oxide
- Packaging - 20 cm x 3.5 cm - one side plastic cellophane one side paper



SSCCOV2 - Nasal Swab Specification

- Swab break-point - 8 cm
- Shaft material - ABS Rod
- Length of swab - 15 cm
- Tip size - 23 mm x 3 mm
- Tip material - nylon, flocked
- Sterility - Yes, sterility by ethylene oxide
- Packaging - 20 cm x 4 cm - one side plastic cellophane one side paper



SSCCOV1 - Single Use Specimen Container and Universal Swab (3cm break-point) - 50x Text Kit

SSCCOV2 - Single Use Specimen Container and Nasal Swab (8cm break-point) - 50x Test Kit

For more information visit our website: www.prestigediagnostics.co.uk/coronavirus

COVID-19 DNA / RNA Magnetic Extraction Kit

Prestige Diagnostics COVID-19 DNA/RNA Extraction Kit comprises reagents which together are used to isolate and purify DNA or RNA from biological specimens and cultured cells. The resulting purified DNA or RNA is suitable for subsequent applications such as real time PCR.

Product Summary :



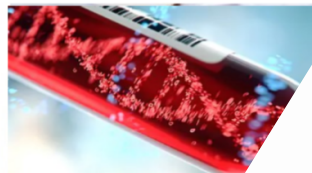
- Ready-to-use reagents prefilled in a 96 deep well plate
- Just add samples
- Processes 16 samples simultaneously on one plate
- Designed for fully automated systems



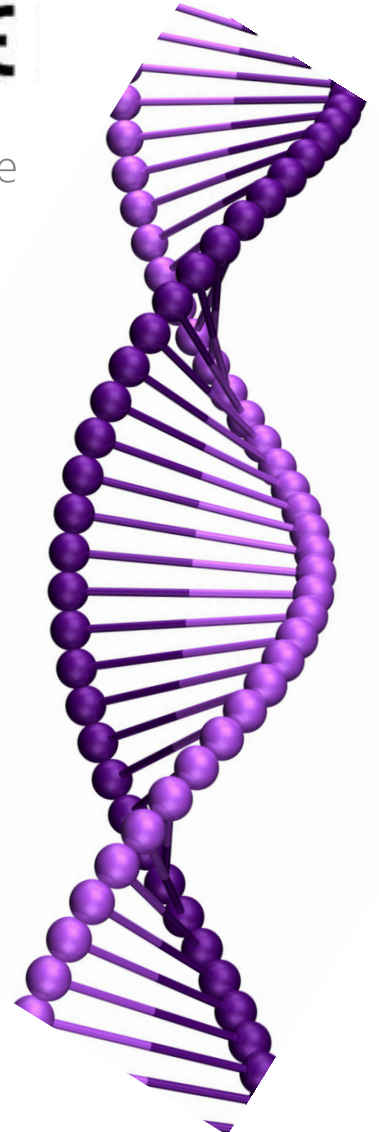
Secretion Swab



Alveolar Lavage Fluid



Serum



PCREXT1 - DNA / RNA Magnetic Bead Extraction Kit - 64x Test Kit (4x16T)

MagXtractor MX-48 Automatic Nucleic Acid Extractor

The MagXtractor MX48 automatic nucleic acid extraction system is based on the principle that nucleic acid binds to magnetic beads which in turn are attracted to and held by the magnetic rod rack, which moves the magnetic beads to different reagent tanks.

It can be used to extract nucleic acid from various samples. It can process up to 32 samples at the same time by adding samples to a 96 deep well plate. Compared with the traditional manual operation, the nucleic acid extraction process is simpler and automatic.

Magnetic bead extraction

The MagXtractor MX48 automatic nucleic acid extraction system uses the universal magnetic bead method to extract nucleic acid, which has the advantages of complete automation, fast extraction speed, stable results, exquisite design and simple operation.

High Performance

- High yield, good repeatability of results
- High throughput, up to 32 samples, time saving
- Controlled heating block ensures the best reaction temperature in the purification process
- Programmable for up to 15 experimental methods
- Various samples: swabs, blood, faeces, sputum,
- Size: 668mm (L) x 583mm (W) x 582mm (H)

Ease of Convenience

- Fully controllable from mobile device or tablet using customised App. • 3.5 inch LCD Display Screen
- No deviation and errors which can occur with manual methods • No special training • Customise temperature and programs • Short operation time
- Open platform for different extraction methods
- Compact and table top size



MagXtractor MX-48 - Automatic Nucleic Acid Extractor

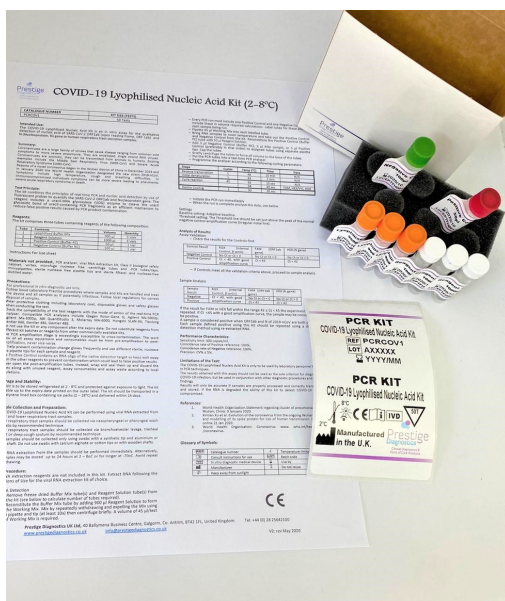
For more information visit our website: www.prestigediagnosics.co.uk/coronavirus

COVID-19 PCR Lyophilised Kit

Prestige Diagnostic's COVID-19 Lyophilised Nucleic Acid Kit is designed for the qualitative detection of nucleic acid of SARS-CoV-2 ORF1ab (open reading frame) and N (Nucleoprotein) gene in human respiratory tract secretion samples

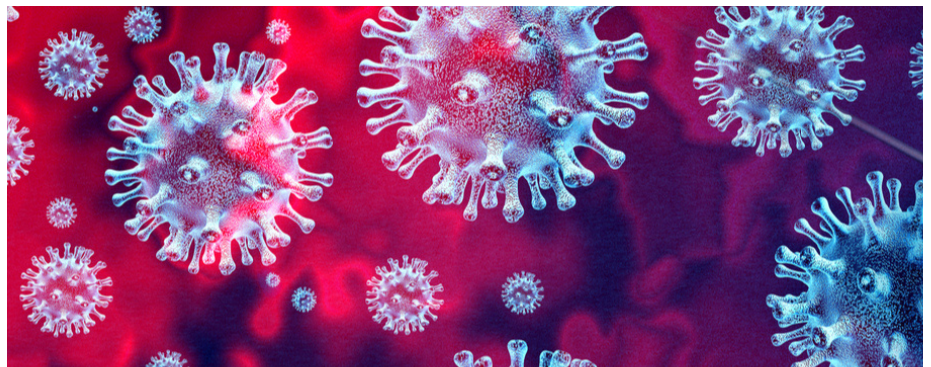
Product Summary :

- Lyophilised format of the PCR buffer offers longer shelf-life
- Open system suitable for use on a range of analysers
- Two target genes for increased specificity
- A rapid cycling program detects nucleic acid of SARS-CoV2 providing excellent turnaround of results
- Sensitivity is 500 copies / ml.



ROX	FAM	CY5
ORF1ab	N gene	Internal Control

***Sensitivity is 500 copies / mL**



PCRCOV1 - PCR Lyophilised Kit Options - 50T, 500T and 1,000T

PCR-6000

PCR Nucleic Acid Detection Analyser

Polymerase chain reaction is a technique used to amplify DNA / RNA samples before they can be studied in detail. This method is widely used in Clinical Diagnostics, Genetic Testing and Forensics.

Real Time PCR is considered by many as the 'gold standard' method of microbial detection and quantification. This is a sensitive and rapid method capable of detecting an enormous variety of bacteria, viruses and fungal infections. The PCR-6000 is a high-tech, compact tabletop PCR analyser ideal for many different applications.

The analyser is equipped with 5 detection channels and is capable of simultaneously detecting 96 wells.

Performance & Parameter

- Simultaneous optical analysis via 5 channels
- Simultaneous detection of 96 wells
- Temperature range 0 - 100°C
- Temperature ramp rate 0.1 - 6.1°C/Sec (approx.)
- Repeatability CV<0.5%

Technical Specifications

- Large (10.4 inch) touch screen for easy programming
- Up to 1,000 test results can be stored on the machine
- Analyser can be used as a stand-alone machine or controlled with a PC
- 2x USB interface (Store results on USB stick or connect directly to PC)
- Compact in Size: 475mm (L) x 355mm (W) x 484mm (H)



The PCR-6000 is designed to work with 0.2ml clear, flat cap PCR tubes. Individual tubes, strips of 8 or 12 and 96 well plates can be used.



Channel	Dyes
1	FAM, SYBR Green I
2	VIC, HEX, TET, JOE
3	ROX, Texas Red
4	CY5
5	Alexa Fluor 680
FRET Probe can also be programmed	

PCR6000 - Real-time Fluorescence Quantitative PCR Analyser

For more information visit our website: www.prestigediagnostics.co.uk/coronavirus



Prestige Diagnostics U.K. Limited

www.prestigediagnosics.co.uk/coronavirus

Ballymena Business Centre
Galgorm, County Antrim,
United Kingdom, BT42 1FL
Tel: +44 (0) 28 2564 2100

Prestige Diagnostics U.K. Ltd. Version 3. December 2020

