

EDELVITAL™

TURN KEY SOLUTION

**Advanced Gold Standard
in microfluidics testing**



Introducing the most accurate turn key solution for PCR detection Assay for SARS- CoV-2, including the Delta and Omicron variants. In addition extract free Plasmodium Nucleic acid detection for Malaria.



EDELVITAL™

Welcome to EDELVITAL™, an Austrian solution provider of in vitro medical devices and Point of Care (POCD) diagnostics. As a result of continuous development in microfluidic platforms and assay formats; there has been a tremendous advancement in this specific field of medical care.

Point-of-care testing (POCT) and qPCR Assays are essential for the rapid detection of analytes of the patient, which facilitates better disease diagnosis, monitoring, and management. It enables quick medical decisions, as diseases can be diagnosed at a very early stage, leading to improved health outcomes and enabling the early start of treatment.

EDELVITAL™ has grown to become a trusted brand in this fast moving market, by providing a wide range of point-of-care (POC) and qPCR or real time assays. Using our portable and easy to use instruments, we critically shorten the time-to-treatment, for individuals suffering anything from the SARS-CoV 2 virus to Malaria . We now look forward to contributing to the eventual full integration, of our devices, into established clinical practice.



edelvital.com

DIST

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Advantages

- ✓ **Speed:** real-time fluorogenic quantitative PCR detection technology is used to enable multiplexing of 16 samples in a 35 minute period, detecting 500 samples a day using a single instrument.
- ✓ **Reliability:** one can rely on a sensitivity level of detection producing up to 500 copies/ml.
- ✓ **Portability:** the instrument is portable (2.6 kg) with a small desktop footprint. The reagents are lyophilised which means that they can be handled at room temperature without incident.
- ✓ **Simplicity:** the simple one-step process means that after adding the sample into the tube it then only has to be placed into the instrument to be amplified.
- ✓ **Cost-effective utilisation:** in addition to the SARS-CoV 2 the instrument can differentiate this virus and the Influenza A and B viruses. It can also be used to detect CT, NG, HCV etc. and is currently being used in Africa for detecting the Plasmodium Malariae agent causing Malaria.
- ✓ **Variant accuracy:** the instrument has the unique ability to identify the different genotypes of the SARS-CoV 2 virus such as Omnicron, including double variants such as Omnicorn/Delta.
- ✓ **Extract-free:** For the first time, blood samples (Plasmodium) require no separation of DNA using DNA extractor machines prior to testing, saving hugely on costs and speed of diagnosis.
- ✓ **Assurance:** All branded products are supported by the manufacturer with a guaranteed compatibility when used with their Assay kits.
- ✓ **Applications:** given it's size and portability, the instrument can be safely used in pharmacies, airports, health institutes even offices without problems.

Work Flow

SARS COV-2

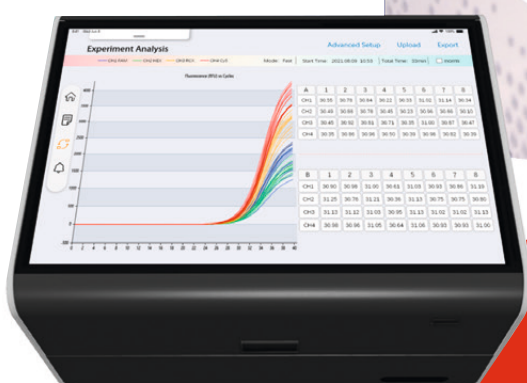


Figure 6 : Interface for instrument operation and analysis

Information for Placing an Order

1. Information for Reagent

Item No.	Product Description	Specification	Validity
ED-HX-302D-2	Fast SARS-CoV-2, Delta Variant Detection Kit (Fluorescent RT-PCR)	48T/Kit	12 Months
ED-HX-402D-2	Fast SARS-CoV-2, Delta & Omicron Variant Detection Kit (Fluorescent RT-PCR)	48T/Kit	12 Months

2. Information for Instrument

Item No.	Product Description	Details
ED1084	EDELVITAL™ qPCR	8 wells, 4 channels, no touch screen
ED4044	EDELVITAL™ qPCR	4 wells, 4 channels, 10-inch touch screen
ED4084	EDELVITAL™ qPCR	8 wells, 4 channels, 10-inch touch screen
ED4164	EDELVITAL™ qPCR	16 wells, 4 channels, 10-inch touch screen

Fast Detection Kit for SARS-CoV-2, Delta & Omicron Variants (Fluorogenic qPCR)

✔ Advanced freeze-drying technology

✔ 4-color fluorogenic detection in the same tube



Target: (SARS-CoV-2) RdRp genes and N genes, Delta variant and Omicron variant.

Sample: Human nasopharyngeal swabs, oropharyngeal swabs.

Detection methods: Real-time qPCR

Specification: 48T /Kit

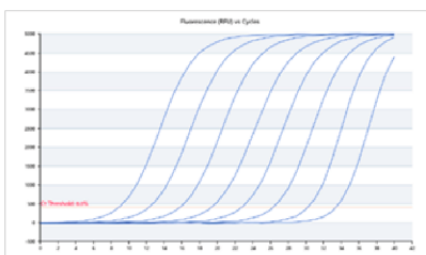
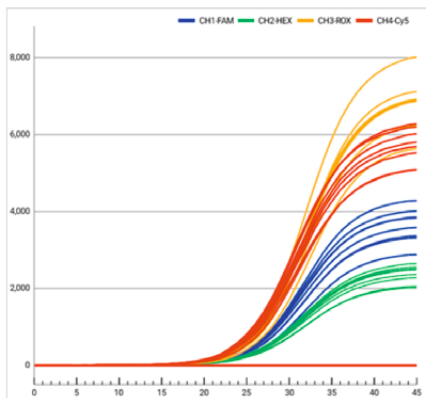
Transport temperature: room temperature

1. Advantages of a real-time PCR detection method

Gold standard for viral nucleic acid detection

Reduced period of detection window and improved rate of positive detection

High specificity and sensitivity to prevent errors and effectively control the spread of the epidemic



2. Product advantages

1. The products are produced by a freeze-drying process, so they can be handled at room temperature saving significant costs in cold chain transportation.

2. Speed: It takes only 35 minutes for the Edelvital one-step rapid detection method to detect 16 samples at one time.

3. Multiplexing: 4-plex detection to simultaneously detect and genotype the virus in the same qPCR tube: SARS-CoV-2, Delta, or Omicron.

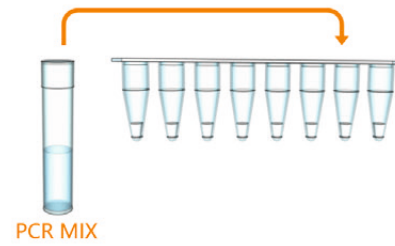
Channel	Fluorogenic Dye	Target Gene
1	FAM	(SARS-CoV-2) RdRp genes and N genes
2	VIC	Internal control gene
3	ROX	Delta variant
4	CyS	Omicron variant

4. Quality control: the list are equipped with a positive reference a negative reference and an internal quality control mechanism to monitor whether the instrument and reagent are operating properly.

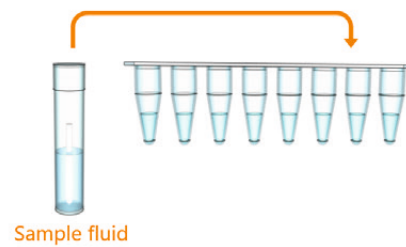
5. Convenience: nucleic acid purification and extraction steps are not required for the virus sample preservation fluid, which is directly added into 8 tubes of freeze-dried reagent for virus nucleic acid detection.

Work Flow

- ✓ qPCR lyophilization reagent redissolution.

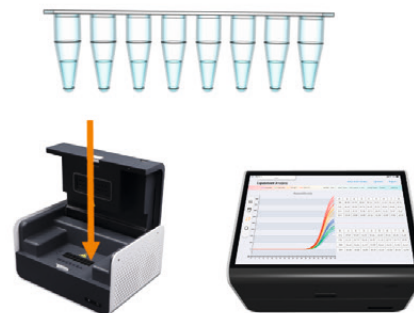


- ✓ Sample Fluid is added to the qPCR tube.



- ✓ qPCR instrument detection, printed reporting.

Experiment time
30-40 minutes



4. Content

Content	Quantity	Function
Sample Preservation Fluid	48 Tubes	Preserve the samples
Enzyme Freeze-dried Powder	8 Strip Tubesx6	
SARS-CoV-2 Positive Control (PC)	1 Tubex S00μL	Real-Time PCR
SARS-CoV-2 Negative Control (NC)	1 Tubex S00μL	
SARS-CoV-2 Reaction Fluid(PCR MIX)	1 Tubex S00μL	

EDELVITAL™ qPCR Series

1. No Moving Parts, Smaller, Faster, More Stable

Proprietary Core Technology Ultra-low-light CMOS Image Sensor (CIS) Chip

The Edelvital product utilises a proprietary in house “Ultra-low-light CMOS image sensor (CIS) chip, which has the advantages of a ultra-high sensitivity combined with a larger dynamic range of detection, while still keeping a low level of operational sound.

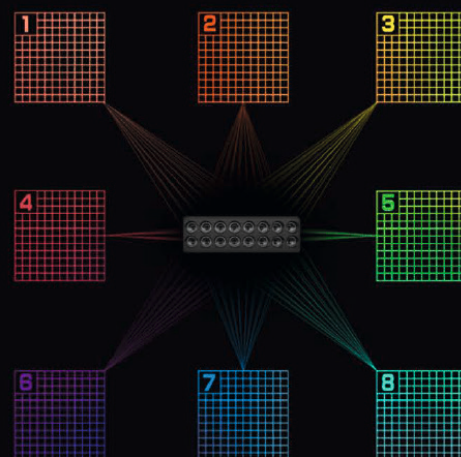
The high sensitivity fluorogenic detection can be achieved without the need for refrigeration allowing for single copy detection.

The instrument’s ability to take pictures simultaneously of all 576 pixels on a single chip means a higher data consistency in comparison to photoelectric sensors.

Advantages of the Edelvital multi-channel fixed optical splitting and filtering image system

1. No moving scanner allowing for stable reliability.
2. No moving parts inside of the instrument, maintenance free operation.
3. Long-term use without the need for constant laborious and expensive calibrations.
4. Chip imaging system for instantaneous, simultaneous and faster collection of fluorescence from all wells.
5. One chip per fluorescence channel, without a time interval between wells, allowing for good uniformity.
6. Utilizing long-life LED’s, the free-form surface concentrating system increases the excitation light intensity by 200% resulting in a high level of cost effectiveness.
7. No reference fluorogenic dye calibration required.
8. Multiplexing for up to 64 indexes for a single detection. Customisable for 6-8 fluorescence channels, with up to 96-128 indexes for a single detection.

Compact real-time fluorogenic PCR instrument for 4-plex virus nucleic acid assay in 25 min.



EDELVITAL™ qPCR Series

2. Solid State Design, More Stable, Faster, More Portable

Precise Temperature Control ---- Unique temperature control software algorithm coordinates the management of the temperature control system

(1) Unique structural design.

The overall dimension of the instrument is only 247x188x133 mm (2.6kg). Easy to transport, especially suitable for small space biosafety cabinet, laboratory, bed-side detection and other scenarios

(2) Unique temperature control technology.

Based on the analysis of a large number of experimental data, the temperature control software algorithm has been upgraded to a more intelligent one to coordinate and control both the semiconductor heating & cooling block (Peltier) and the auxiliary heating & cooling system, therefore not only ensuring the accuracy and consistency of temperature control, but also effectively improving the average ramp rate.

Heating Rate: 8.5°C/s Cooling Rate: 6°C/s



3. User-friendly software

Proprietary software --- easy to operate

- 1 Intuitive software interface
- 2 Fast setup
- 3 Easy to call templates
- 4 Detailed data analysis and review
- 5 Data export function in multiple formats and report export function
- 6 Supports WIFI networking function, online data transmission, remote technical support
- 7 Supports customized connection to third-party data platforms
- 8 Supports customization service: closed software system can be customized according to user requirements

4. Wide Detection Range

Used for the detection of various respiratory pathogens, such as: influenza A virus, influenza B virus, H3N2 influenza virus, respiratory syncytial virus, Plasmodium nucleic acid, Yellow fever (Flavivirus febricis), enterovirus, boca virus, mycoplasma pneumoniae, chlamydia pneumoniae, and other respiratory pathogens.

Product parameters

System Performance Parameters			
# of wells	4 wells	8 wells	16 wells
# of channels	2-ch 4-ch	2-ch 4-ch	2-ch 4-ch
Applicable Consumables	0.2ml eight-link tube or 0.2ml single tube		
Testing Time	A routine nucleic acid assay can be completed in 25 minutes		
Multiplexing	Up to 4-plex fluorescence detection without channel cross interference correction (6 to 8 channels can be customized)		
Reaction System	10-60ul		
Sensitivity	Single copy gene detectable		
Screen Display	Uses a large 10 inch user friendly touch screen		
Networking	Supports WIFI networking, online report printing		
Certification	CE Certification, FDA Registration & Device Listing		

Temperature Control System Parameters	
Temp Control Technology	Incorporated is a high level MARLOW semiconductor chip. Increasing the cycle times to one million, the unique software algorithm coordinates and manages the semiconductor heating, auxiliary heating and cooling systems. This ensures accuracy of temperature control while also increasing the rate at which the
Heating Rate	8.5°C/s (MAX)
Cooling Rate	6.0°C/s (MAX)
Temp Uniformity	± 0.15°C
Temp Accuracy	± 0.1°C

Product parameters

Optical System Parameters	
Optical Core Technology	Multi-channel fixed light splitting and filtering imaging system. longterm use does not require expensive and cumbersome periodic calibration maintenance, and high reliability. One chip per channel, no moving scanner, maintenance free.
Excitation Light Source	Long life maintenance-free LED. The free-form surface concentrating system has the excitation light intensity increased by 200%, and no calibration is required, cost effective.
Excitation wavelength	460nm-670nm
Emission wavelength	510nm-720nm
Detector	Ultra-Low-Light CMOS Image Sensor (CIS) Chips. Chip technology with core independent intellectual property rights. It has the advantages of ultra-high sensitivity, large dynamic detection, low noise and no refrigeration mechanism. One chip takes 16 wells of fluorogram at one time, no time difference between wells, good homogeneity.
Fluorescent Dyes	Channel 1 : FAM, SYBR Green I ; Channel 2: HEX, VIC JOE, TET; Channel 3: ROX; Channel 4: CVS;

Other Technical Parameters	
Report Function	Yes, data exportable in various formats (PDF, CSV, JSON, JPG, Excel)
Communication Interface	Import and export data from/to flash disk or by WIFI. WIFI function optional, remote technical support available, cross-region services extendable.
Language	English and on request
Measurements	247*188*133mm (2.6kg) The instrument is small in size and has no moving parts inside, which saves transportation costs and space, and is suitable for a wide range of scenarios.
Application Scenarios	Hospital, emergency and fever clinics, community health institutions, on-site emergency quarantine, customs and airport ports, food import and export quarantine.
Mobility	The qPCR system in its entirety, is capable of working in the field powered by external batteries.