



FILTER TECHNOLOGY

FLAME DELTA VARIANTS

REFLEX REAGENT KIT

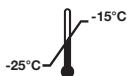
INSTRUCTIONS FOR USE



FLM0003



**GVS SPA, Via Roma 50
Zola Predosa, 40069, Italy**



Store at $-20^{\circ}\text{C} \pm 5^{\circ}\text{C}$



Rev. 00-27/07/2021

About us

The GVS Group is one of the world's leading manufacturers of filters and components for applications in the Healthcare, Life Sciences, Automotive, Appliance, Safety, and Commercial & Industrial Filtration.

The Group's clear strategy towards internationalization, has led to the opening of 12 production facilities located in Italy, UK, Brazil, the United States, China and Romania, as well as offices in Russia, Turkey, Argentina, Japan, Korea. GVS currently have a workforce of over 2,700 people globally.

For 40 years, GVS has focused on innovation in its products range and production processes, constantly improving its development capacity to provide the best service and support for its clients.

We offer a full range of branded products through a global network of dealers and distributors. We also make available all these capabilities on an OEM basis by working closely with companies around the world to provide state of the art materials solutions and/or turn-key final product solutions used in critical applications for the pharmaceutical, medical device, diagnostic, food & beverage and environmental monitoring markets.

PRODUCT NAME

Flame Delta Variant Reflex Reagent Kit

Packing Specifications

48 Tests/Box.

Intended Usage

The addendum kit is used to detect the presence of the Delta variant for screening. It is designed to integrate the FLAME Covid-19 Variants qPCR Master kit.

Kit components

Component name	Specifications	Quantity	Main components
Delta Reagent	875µL	1 Tube	Specific probes for Delta variant
Positive control	400µL	1 Tube	Pseudovirus containing target fragment and internal standard fragment
Instructions Manual	-	1 copy	-

Storage Conditions & Validity

1. The kit should be stored frozen at $-20^{\circ}\pm 5^{\circ}$ and protected from light; the expiration date is 12 months; the production date and expiration date are shown in the outer packaging box.
2. Avoid repeated freezing and thawing of the kit and the number of freezing and thawing shall not exceed 7 times.
3. After opening, the bottles should be stored at $-20^{\circ}\pm 5^{\circ}$ and protected from light. The number of bottles opening times should not exceed 7 times, which will not affect the use within the validity period.

Applicable Instruments

1. This kit has been validated on ABI7500 quantitative fluorescence PCR instrument.
2. For other models not listed, relevant experiments have not been performed or completed for this kit. If users need to use this type of instrument platform to carry out the detection of this reagent, please contact our Technical Department at lifesciences.it@gvs.com for relevant support. NB: The other devices can include quantitative fluorescence PCR platforms with FAM, VIC, ROX and Cy5 channels.

Sample Requirements

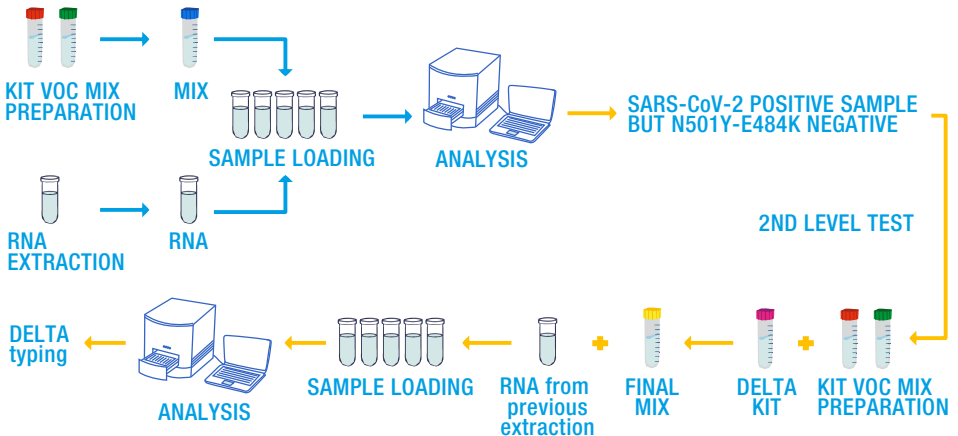
1. Nasopharyngeal swabs, oropharyngeal swabs and other methods are used to obtain samples, and it is recommended to use commercial virus sampling kits for sample collection devices. The specific operation method is as follows:
 - i) Nasopharyngeal swabs: Nasopharyngeal swab: The operator gently rotates the sterile swab to the left and right at the angle parallel to the upper jaw and inserts it from one nostril to the nasal palate in the nasal passage. Generally, the swab stays when there is resistance to the insertion. Rotate slowly to exit after 2-3s.
 - ii) Place the nasopharyngeal swab or oropharyngeal swab into the centrifuge tube containing the preservation solution for later use.
2. Alveolar lavage fluid sample: Use a sterile syringe to extract the sample and place it in a centrifuge tube for examination.
3. Cross-contamination between samples should be avoided.
4. Samples should be tested in time after collection, or stored at $-20^{\circ}\pm 5^{\circ}$ for testing, and kept below -70° for long-term storage.

Testing Method

Once the **positivity** of the sample for SARS-CoV-2 has been defined with the FLAME Covid-19 Variants qPCR Master kit and the **negativity** of mutation of genes N501Y and / or E484K, proceed with the preparation of the Reaction solution of the FLAME Covid-19 Variants qPCR Master kit (as previously carried out) to which add 2.5 µl of Flame Delta Reflex reagent, obtaining a volume of 22.5 µl of the final Delta reaction solution mix. In each well of the plate for PCR to load, add 22.5 µl final Delta reaction solution mix and 5ul of extracted RNA to be tested. Proceed in the same way for the positive control and the negative control : add 22.5 µl of final Delta reaction solution mix and 5 µl of **Positive Control after extraction**; add 22.5 µl of final Delta reaction solution mix and 5 µl of **Negative Control** (from the FLAME Covid-19 Variants qPCR Master kit) **after extraction**.

Controls must be prepared in the number of 1 (1 positive and 1 negative) for each PCR run, regardless of the number of samples tested.

Set the program suggested by datasheet of FLAME Covid-19 Variants qPCR Master kit on the thermal cycler and proceed with reading the amplification curves. Positivity to the delta variant will be detected by the presence of an amplification curve in the ROX channel (Texas Red fluorophore).



Note: The Flame Delta Variant Reflex Reagent Kit is an addendum for RUO. The possibility of using this kit for tracking the presence of the Delta variant in the population (and not for diagnostic report for medical intervention purposes) is permitted in accordance with the current European directive on IVD (IVDD) and with the next European regulation (IVDR).

“In general terms research-use-only (RUO) products are outside the scope of Directive 98/79/EC on in vitro diagnostic medical devices because they are placed on the market without an intended medical purpose. RUO tests could be used e.g., for studying the distribution of antibodies in the population”.....

Ref: COVID-19 TESTS. Q&A on in vitro diagnostic medical device conformity assessment and performance in the context of COVID-19. Guidance by the European Commission HEALTH AND FOOD SAFETY - February 2021

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Manufactured by:

GVS S.p.A.

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Bologna -ITALY

Ordering information

Description	Item	Unit Size
Flame Delta Variant Reflex Reagent Kit	FLM0003	48 Test

For further information, visit

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Contacts

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TO SAY FILTRATION**

