



PCRopsis™ RVD Enhancer

(NOT FOR RESALE)

INTENDED USE (in vitro diagnostic use)

PCRopsis™ RVD Enhancer is intended to enhance PCR-mediated amplification of gene targets when used in combination with Reagent RVD or Reagent SRVD.

PRINCIPLES OF THE PROCEDURE

PCRopsis™ RVD Enhancer is engineered to synergize with Reagent RVD and Reagent SRVD for enhanced amplification of gene targets for certain transport mediums and applications. The product consists of a proprietary mixture of peptide, proteins, and salts that minimize nucleic acid secondary structure, improve sequestration of PCR inhibitors, facilitate access to nucleic acids and / or improve the stability of specimens.

WARNINGS & PRECAUTIONS

For in vitro Diagnostic Use.

- Observe approved biohazard precautions and aseptic techniques to prevent contamination of the product. To be used only by adequately trained and qualified personnel.
- Pathogenic microorganisms, including hepatitis viruses and Human Immunodeficiency Virus, may be present in clinical specimens. "Standard Precautions"¹⁻⁴ and institutional guidelines should be followed in handling all potentially bio-hazardous materials.
- Sterilize all biohazard waste including specimens, containers and mediums after their use.
- Directions should be read and followed carefully.
- Do not re-pack.
- The use of this product in association with a rapid diagnostic kit, diagnostic instrumentation or used in a manner not intended should be validated by the user.
- Do not ingest the reagent.
- Avoid skin contact with reagent.

Storage: This product is ready for use and no further preparation is necessary. The product should be transported and stored in its original container at 20–25°C until used. Do not overheat. Do not incubate or freeze prior to use. Improper storage will result in a loss of efficacy. Do not use after expiration date, which is clearly printed on the label.

Product Deterioration: PCRopsis™ RVD Enhancer should not be used if (1) there is evidence of damage or contamination to the product, (2) there is evidence of leakage, (3) the color of the reagent has changed from clear, (4) the expiration date has passed, or (5) there are other signs of deterioration.



PROCEDURES

Materials Provided: PCR*opsis*[™] RVD Enhancer

Optional: Place RVD Enhancer in a 37°C water bath if precipitation or solidification of the product is observed. This does not affect the functionality of the product.

1. Thoroughly mix PCR*opsis*[™] Reagent RVD or PCR*opsis*[™] Reagent SRVD to ensure homogeneity, but avoid creating bubbles unnecessarily
 1. These products have a hazy, white color when homogenized and normal settlement occurs if not regularly mixed
2. Mix 2 volumes of RVD Enhancer with 5 volumes of Reagent RVD or Reagent SRVD
 1. Different ratios of RVD Enhancer to Reagent RVD or Reagent SRVD can be explored if desired results are not observed
3. Substitute Reagent RVD or Reagent SRVD with the mixture of RVD Enhancer / Reagent RVD and RVD Enhancer / Reagent SRVD in respective protocols
 1. Protocols for Reagent RVD and Reagent SRVD are found on PCR*opsis*.com

Quality Control: All lots of PCR*opsis*[™] RVD Enhancer are tested for microbial contamination and the ability to amplify RNA or DNA without nucleic acid extraction using Reagent RVD or Reagent SRVD. If aberrant quality control results are noted, patient results should not be reported.

RESULTS

Results obtained will partially depend on proper and adequate specimen collection, transport and processing in the laboratory.

LIMITATIONS OF THE PROCEDURE

- Performance characteristics of PCR*opsis*[™] RVD Enhancer were validated using SARS-CoV-2 in various transport mediums (e.g., BD[™] UVT). The use of alternative microorganisms, transport mediums, gene targets and / or detection methods may affect the performance of the product.
- PCR*opsis*[™] RVD Enhancer may not improve PCR amplification for all gene targets, test specimens, transport mediums used to transport specimens, or RT-qPCR test kits.
- Repeated freezing and thawing of test specimens may reduce the detection of desired gene targets.
- Follow recommended guidelines for specimen collection, transport and storage as this may affect the ability to amplify gene targets.

PERFORMANCE CHARACTERISTICS

The performance of PCR*opsis*[™] RVD Enhancer in combination with PCR*opsis*[™] Reagent RVD was compared to PCR*opsis*[™] Reagent RVD without PCR*opsis*[™] RVD Enhancer using SARS-CoV-2 spiked into select transport mediums. RT-qPCR was performed using IDT qPCR probe assay and Promega GoTaq® Probe 1-Step RT-qPCR System. PCR*opsis*[™] RVD Enhancer + PCR*opsis*[™] Reagent RVD results in an improvement of more than 2 Ct compared to the same sample processed with PCR*opsis*[™] Reagent RVD alone.



AVAILABILITY – NOT FOR RESALE

Cat. #	Description
783364010	PCRopsis™ RVD Enhancer, 10 mL
783364100	PCRopsis™ RVD Enhancer, 100 mL











MANUFACTURER

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REFERENCES

1. Clinical and Laboratory Standards Institute. 2005. Approved Guideline M29-A3. Protection of laboratory workers from occupationally acquired infections, 3rd ed. CLSI, Wayne, Pa.
2. Garner, J.S. 1996. Hospital Infection Control Practices Advisory Committee, U.S. Department of Health and Human Services, Centers for Disease Control and Prevention. Guideline for isolation precautions in hospitals. Infect. Control Hospital Epidemiol. 17: 53-80.
3. U.S. Department of Health and Human Services. 1999. Biosafety in microbiological and biomedical laboratories, HHS Publication (CDC), 4th ed. U.S. Government Printing Office, Washington, D.C.
4. Directive 2000/54/EC of the European Parliament and of the Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work (seventh individual directive within the meaning of Article 16(1) of Directive 89/391/EEC). Official Journal L262, 17/10/2000, p. 0021-0045.

Glossary of Symbols Used

 IVD	In vitro diagnostic use		Keep away from direct sunlight
 REF	Manufacturer's catalog number		Number of tests
 LOT	Lot number		Consult instructions for use
	Expiration date (year/month)		STERILE A Sterile through aseptic techniques
	Storage temperature		Manufacturer