DRDP™

VIRUS-INACTIVATING AND RNA/DNA/ANTIGEN-PRESERVING TRANSPORT MEDIUM

document reference: FP09 I129 R01 A.1
update: 06/01/2025

For in vitro diagnostic use only
For professional use only

CATALOGUE NUMBER

REF DRDP_0002 IVD CE

PRODUCT DESCRIPTION

REF	product description	packaging
DRDP_0002	*2 mL of DRDP™ in a screw cap polypropylene tube (flat bottom, freestanding)*	*50 tubes per package 8x50 tubes per box or 24x50 tubes per box*

SYMBOL GLOSSARY

symbols as defined in ISO 15223

- REF *catalogue number*
- LOT *batch code*
- *use-by date*
- *manufacturer*
- *distributor*
- *do not re-use*
- IVD *in vitro diagnostic medical device*
- *caution*
- *keep away from (sun)light*
- 2°C 25°C *temperature limit*
- *consult instructions for use*
- *contains a medicinal substance*

symbol as defined in 2017/746 (IVDR)

- CE *CE marking*

TECHNICAL SUPPORT

URL: ***www.inactivblue.com***
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MANUFACTURER INFORMATION / DISTRIBUTOR

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INTENDED USE

DRDP™ is a universal virus-inactivating medium intended for the collection and transport of upper respiratory specimens (saliva, nasal swabs) for in vitro diagnostic testing on the presence of antigens or genetic material (i.e. viral RNA, human RNA/DNA).
DRDP™ can be used in quick antigen lateral flow tests, and in molecular methods such as (RT-)qPCR.
DRDP™ can be suitable for direct PCR in your specific test system upon validation (i.e. no extraction and/or purification needed).
DRDP™ stabilizes nucleic acids up to 8 days after collection when stored between 2-25 °C.

SPECIMEN TYPE

Upper respiratory specimens (saliva, nasal swabs)

INTENDED USER

Sampling is performed by, or under supervision of a healthcare provider in a medical environment. Analysis of the preserved sample is performed by approved medical labs.

GENERAL

- Certificate of analysis
  - *A certificate of analysis per lot is available upon* request
- Storage/disposal
  - Store *reagents between 2-25 °C*
  - *Keep away from direct (sun)light*
  - *Do not use after expiry date*
  - *Shelf life: 24 months*
  - *Dispo*se in accordance with local regulations for disposal of medical devices / hazardous substances
- Materials needed, but not provided
  - Nasal swab: it is advised to only use synthetic (flocked) fiber swabs with plastic or wire shafts and not to use calcium alginate or cotton swabs or swabs with wooden shafts as these may inhibit molecular tests. Ideally, the breakpoint of the swab is not higher than 8 cm (3.15 inch).
  - Saliva collection device
  - Instruments, commercially available extraction- and (RT)-qPCR kits, supported by validation studies performed (see "Results and Performance")
  - PCR mixes and RNA/DNA targets for direct PCR, supported by validation studies performed (see "Results and Performance")
  - Quick antigen lateral flow tests, supported by validation studies performed (see "Results and Performance")

PRINCIPLES OF OPERATION AND COMPOSITION

DRDP™ is not considered as a diagnostic test but as a specimen receptacle:

- Sampling is performed by, or under supervision of a healthcare provider in a medical environment according to nationally accepted guidelines.
- viruses in the sample are inactivated, antigens are preserved for 1 day and DNA/RNA is stabilized in the DRDP™ medium in the tube.
- the tube is hermetically closed, identified and sent to an analysis lab for testing, along with the necessary documentation.

DRDP™ is an isotonic acidic salt solution supplemented with a nonionic surfactant and EDTA. The medium contains gentamicin (250 mg/l) as antimicrobial agent to inhibit and prevent the overgrowth of the normal flora within a clinical sample, improving sample storage at room temperature. The MSDS is available upon request or can be downloaded from the website.

INSTRUCTIONS FOR USE

METHOD FOR SWABS

1 Make sure that you use the required personal protection. Follow the procedure for droplet protection: use gloves, coat, surgical mask, and eye protection (goggles or face shield). Identify the sample.

2 Collect the specimen with a suitable swab according to the instructions of the manufacturer of the swab. **DO NOT PRE-WET** the swab before touching the patient.

3 While holding the swab, remove the cap from the test tube. Insert the swab into the test tube opening without touching the (outer) surface of the tube. Once the specimen is in the medium, spin around the swab.

4 Break off the swab shaft (or alternatively cut the swab handle) so that the breakpoint level corresponds with the test tube opening. Make sure that the breakpoint of the swab is not higher than the tube opening.

5 Hermetically close the tube by the screw cap. The sample is now stable for transport and storage prior to further processing in the laboratory. RNA/DNA is stabilized up to 8 days when stored between 2-25 °C. Antigens are preserved for up to 24 hours (see performance characteristics below).

METHOD FOR SALIVA

Add about 1 mL saliva to the tube. Hereto, follow the instructions for use delivered with an appropriate saliva collection device.

AT TEST LABORATORY

- Samples should be analyzed in the laboratory within 1-8 days (depending on the test performed and/or storage temperature, see performance characteristics below).
- Invert tube 10 times to ensure that the complete inner surface of the tube (and swab) have been in contact with the inactivating buffer solution.
- Use validated procedures for (direct) PCR testing or quick antigen lateral flow testing (LFT).

Note 1 – about the use with quick antigen lateral flow tests: the low pH of DRDP™ is not compatible with detection methods that use colloidal gold (e.g. many lateral flow tests). Consequently, when performing an LFT, the pH of DRDP™ needs to be neutralized immediately before loading the sample buffer on the flow cell. A suitable method is described below:

- Aspirate 200 µL of the specimen using a single-use pipette (e.g. Thermo Scientific 941NL, #15377903) and dispense in a tube. Add 20 µL of a NaOH solution to the tube using a single-use pipette (e.g. Thermo Scientific 783NL, #1559524) and homogenize before loading on a flow cell. For swab and saliva samples, the concentration of NaOH should be 0.70 and 0.47 M, respectively.

Note 2 – about the suitability for direct PCR: laboratories should first validate how much sample in DRDP™ can be added to their specific one-step (RT)-qPCR reaction. The maximum percentage of sample matrix will depend on the choice of master mix and target (PCR assay).On average, 15% of sample can be added without signs of inhibition, but the range is 2.5 to 30%, as some master mixes are consistently more inhibitor-tolerant than others (see "results and performance")

RESULTS AND PERFORMANCE

- DRDP™ completely inactivates viruses within 60 minutes.

Validation study comprised the following viruses, all of them were completely inactivated:

	complete inactivation			
RNA viruses	*MERS-CoV*	*SARS-CoV-2*	*bovine RSV virus*	*H5N1*
DNA viruses	*monkey pox*		*vaccinia*	

- DRDP™ stabilizes DNA / RNA up to 8 days after collection when stored between 2-25 °C (stability is defined as ≤ 2 Cq higher compared to day 0 in (RT)-qPCR)

Validation study demonstrated the following stability for the indicated targets:

	nasal swab		saliva	
assay /storage temperature	*4 °C*	*25 °C*	*4 °C*	*25 °C*
human DNA (GADPH, RSP18)	*8 days*	*8 days*	*8 days*	*8 days*
human RNA (CALR, TEMED2)	*8 days*	*8 days*	*8 days*	*8 days*
viral RNA (SARS-CoV-2 viral particles)	*8 days*	*2 days*	*8 days*	*not determined*

- DRDP™ is resistant to repeated freeze/thaw cycles (stability is defined as ≤ 2 Cq higher after 3 freeze/thaw cycles)
- DRDP™ is compatible with multiple instruments / assays (non-exhaustive list):

DRDP™ has been successfully used with the following instruments / assays:

instrument(s)	nucleic acid extraction / (RT)-qPCR assays
Alinity m *(Abbott)*	***Multiplex Resp-4-Plex***
geneXpert *(Cepheid)*	***Xpert Xpress SARS-CoV-2/Flu/RSV assay***
Panther Fusion *(Hologic)*	***SARS-CoV-2/Influenza A/B/RSV assay***
cobas Liat *(Roche)*	***cobas SARS-CoV-2 & Influenza A/B*** ***cobas Influenza A/B & RSV***
LightCycler 480 *(Roche)*	***MagSi-NA Pathogens*** *(magtivio, MDKT0021096)* ***iTaq Universal One-step RT-qPCR kit*** *(Bio-Rad)* ***One Step PrimeScript III RT-PCR Kit*** *(Takara Bio)*
Seegene STARlet *(Seegene)* ***CFX96*** *(Bio-Rad)*	***STARMag 96x4 Universal Cartridge Kit*** *(Seegene)* ***Allplex SARS-CoV-2/FluA/Flu B/ RSV assay*** *(Seegene)*

- Preservation of antigens in nasal swab/saliva sample: confirmed by testing for up to 24 hours (longer storage periods should be validated by the laboratory prior to use)
- Compatible with quick antigen lateral flow tests after neutralization of pH. Study results demonstrated compatibility with at least the following commercial available tests (non-exhaustive list):
  - Biosynex (Biosynex Swiss SA)
  - Deepblue (Anhui Deepblue medical technology)
  - Newgene (SUNGO Europe BV)
  - Flowflex (Acon Biotech)
  - Abbott COVID-19 Ag Rapid Test Devices (Panbio)
  - SARS-CoV-2 & I Influenza A/B and RSV Antigen Combo test kit # 5501788 (Fluorecare, Microprofit Biotech)
- DRDP™ can be suitable for direct PCR in your specific test system upon validation.

Study results give an indication of the maximum percentage of sample matrix that can be directly applied in the following (RT)-qPCR reactions without inhibition:

sample type	nasal swab				saliva (1:2 v:v)			
target	*endogenous RNA*		*spike-in*		*endogenous RNA*		*spike-in*	
assay	*18S*	*MALAT1*	*E-gene (RNA)*	*Lambda (DNA)*	*18S*	*MALAT1*	*E-gene (RNA)*	*Lambda (DNA)*
PrimeTime One-Step 4X Broad-Range Master Mix *(IDT)*	*10%*	*15%*	*15%*	*15%*	*20%*	*30%*	*5%*	*20%*
LightCycler Multiplex RNA Virus Master *(Roche)*	*5%*	*5%*	*10%*	*10%*	*20%*	*10%*	*15%*	*15%*
TaqPath DuraPlex 1-Step RT-qPCR Master Mix *(Applied Biosystems)*	*15%*	*15%*	*10%*	*0%*	*30%*	*30%*	*30%*	*20%*
TaqMan Fast Virus 1-Step Master Mix for qPCR *(Applied Biosystems)*	*0%*	*5%*	*5%*	*5%*	*25%*	*15%*	*30%*	*25%*
eQo 1-Step ToughMix *(QuantaBio)*	*15%*	*15%*	*15%*	*10%*	*15%*	*20%*	*20%*	*10%*
One Step PrimeScript III RT-qPCR Mix *(Takara)*	*15%*	*15%*	*10%*	*2.5%*	*20%*	*25%*	*25%*	*10%*

PRODUCT SPECIFICATIONS

The following quality control tests are performed before each batch release:

- chemical composition
- pH: 2.70-3.20
- appearance: clear, colorless fluid
- sterility test (test method according to Ph Eur 2.6.1/ USP<71>): no growth
- quick antigen lateral flow test: passed
- functionality test, i.e. (RT-)qPCR test on nasal swab in DRDP™:
  - endogenous RNA stability
  - endogenous DNA stability
  - criteria: ΔCq ≤ 2 between day 0 and day 8 (storage at RT)

WARNINGS AND PRECAUTIONS

- All human, organic material should be considered potentially infectious. Handle all specimens as if capable of transmitting pathogens. Always wear protective clothing when handling specimens and reagents (e.g. gloves, lab coat, surgical mask, eye/face protection).
- Do not use if the product is visibly damaged.
- For specifics, consult the MSDS that is available upon request or can be downloaded from the website www.inactivblue.com.

LIMITATIONS

- DRDP™ is not intended to inactivate fungi or bacteria.
- DRDP™ is not compatible with detection methods that use colloidal gold (e.g. many lateral flow tests). Consequently, the pH of DRDP™ needs to be neutralized immediately before loading the sample buffer on such flow cell.
- DRDP™ might not be compatible with all PCR mixes: each test system should be validated prior to assuming that direct PCR can be performed.

BIBLIOGRAPHY

1. Evaluation of a novel respiratory virus inactivating buffer for parallel RT-Qpcr and quick antigen testing. medRxiv 2024. Deprez et al. (https://www.medrxiv.org/content/10.1101/2024.03.06.24303861v1)
2. Assessment of DNA/RNA Defend Pro: An Inactivating Sample Collection Buffer for Enhanced Stability, Extraction-Free PCR, and Rapid Antigen Testing of Nasopharyngeal Swab Samples. International Journal of Molecular Science 25(16), 9097; Claeys et al., 2024 (https://doi.org/10.3390/ijms25169097)