INACTIVblue

QUALITY IS IN OUR RNA

RUO

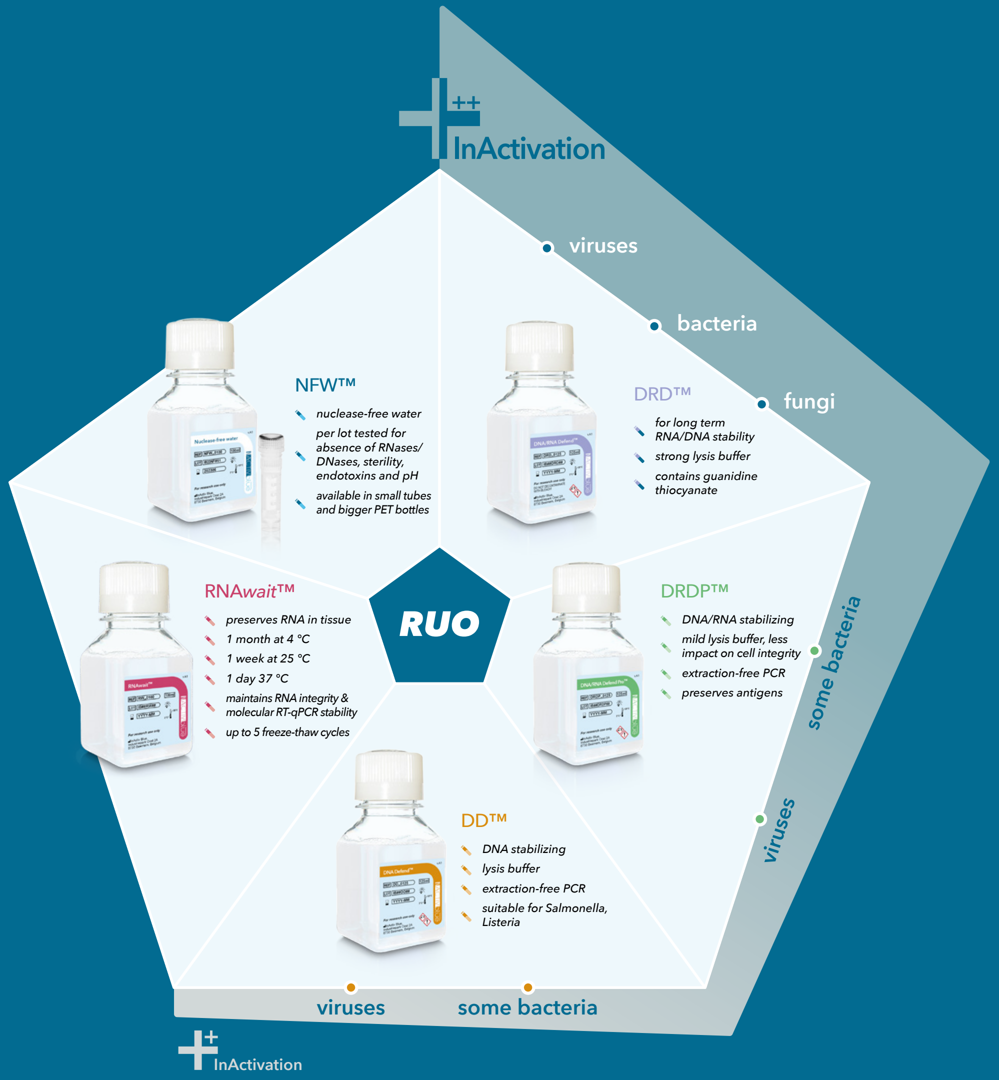
Research Use
Only Products

WE DEFEND YOUR DNA/RNA DURING SAMPLE COLLECTION, TRANSPORT & STORAGE.

Contents

Research Use Only RUO

- for molecular research labs, veterinary labs, food/feed testing labs, …
- product characteristics are based on experimental evidence and reliable feedback from third parties
- application in a specific test system should be validated / tested by the customer



NACTIVblue

QUALITY IS IN OUR RNA

specialized in the development and commercialization of collection, transport and storage solutions for primary biomaterials for (in vitro diagnostic) testing on DNA, RNA, and protein epitopes

founded in 2020

BY

FertiPro NV
Prof. Jo Vandesompele

LOCATED

Industriepark Oost 2a,
8730 Beernem, Belgium

location east

CLOSE COLLABORATION WITH FERTIPRO NV

+ 30 years experience with liquid media manufacturing, quality controls and regulatory compliance

ISO 13485 certified, conform EU IVDR / EU MDR and other industry standards

FertiPro

location north

DRD Blood™

With the growing demand for blood-based gene expression analysis in research and clinical studies, ensuring RNA integrity in blood samples is more important than ever. DRD Blood™ is a solution designed to preserve RNA at the highest quality levels – bringing you robust data you can trust.

For more information, please visit our website

product performance

- whole blood RNA stabilization
  - 5 mL vacuum tube prefilled with 3 mL buffer for collection of 1 mL venous blood
  - 0.5 mL microtube prefilled with 150 µL buffer for collection of 50 µL capillary blood
- RNA stability for 30 days at 4 °C and 3 days at 25 °C
- RNA integrity for 14 days at 4 °C and 1 day at 25 °C
- freeze-thaw stability and integrity for at least 5 cycles
- superior stability, ease of use, and cost-efficiency compared to alternative products on the market
- compatible RNA extraction
  - miRNeasy Micro (Qiagen)
  - VAMNE Magnetic Cell/Tissue Total RNA Kit (Vazyme)

other

- quality controls on each produced batch:
  - chemical composition review
  - appearance
  - RT-qPCR to demonstrate RNA stability in blood
- MSDS on website
- COA per batch available on request

Product codes

DRD Blood™ venous blood (3 mL) *(50 or 1200 pcs)*	REF: **DRDB_1**
DRD Blood™ capillary blood (150 µL) *(36 pcs)*	REF: **DRDB_2**

Excellent freeze-thaw stability

Venous blood (1 mL) from a healthy human donor was drawn in a DRD Blood tube and frozen at -20 °C. Over a three-week period, the blood was thawed to room temperature and frozen again, for up to 5 times. The electropherogram shows intact 18S and 28S ribosomal RNA bands with good RNA integrity (RIN) values.

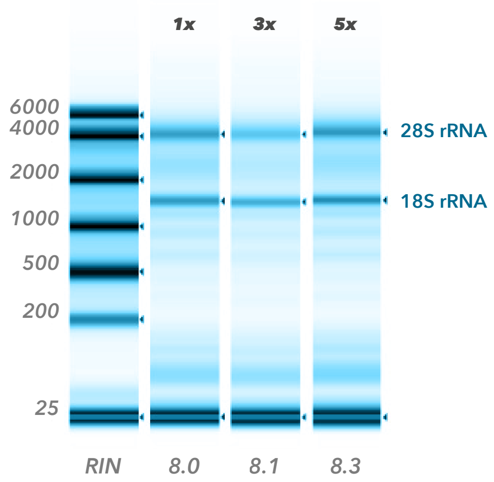


Figure 1: *TapeStation electropherogram of total RNA purified from DRD Blood frozen at -20 °C and thawed up to 5 times over three weeks.*

RNA remains intact in the fridge for 2 weeks

Venous blood (1 mL) from a healthy human donor was drawn in a DRD Blood tube and stored at 4 °C for up to 2 weeks. At time point 0 and days 1, 3, 7, and 14, an aliquot of 200 µL stabilized blood was extracted (miRNeasy Micro). The electropherogram shows intact 18S and 28S ribosomal RNA bands with good RNA integrity (RIN) values.

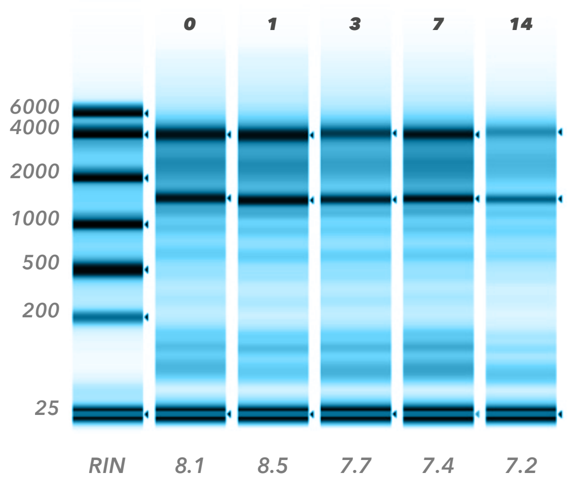
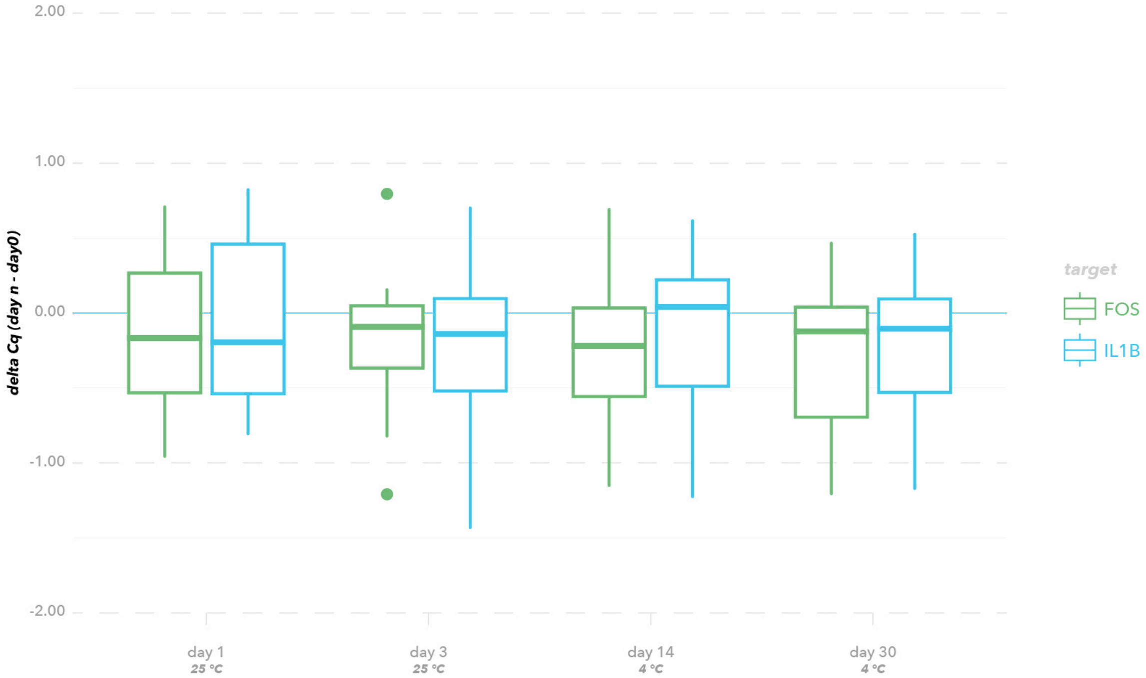


Figure 2: *TapeStation electropherogram of total RNA purified from DRD Blood stored at 4 °C for up to 14 days.*

Expression stability of FOS and IL1B marker transcripts



FOS and IL1B are well-known transcripts in human blood that quickly change their abundance upon stress or perturbation. This figure demonstrates that their expression levels remain stable in DRD Blood collection tubes for up to 30 days at 4 °C and 3 days at 25 °C. This is an exceptional RNA stability result, considering raw data with 5 levels of potential variability, i.e. donor (n=3), DRD Blood production lot number (n=3), RNA extraction (n=1), RT-qPCR (n=2), and experiment (n=2). Each box plot represents 18 independent data points. The median delta-Cq is 0.33, the 95% delta-Cq is 1.08 (comparing a later time point with time point 0).

DNA/RNA Defend™

a guanidine-based medium for pathogen inactivation, stabilization of DNA and RNA, and lysis of biological samples. Requires nucleic acid extraction.

DNA/RNA Defend™ (DRD) is a cost-effective and superior alternative to similar buffers on the market.

For more information, please visit our website

strongly recommended to first test the sample type / protocol of interest with DRD™

the instructions for use provides several suggested methods for testing for suitability in your system

product performance

- the same medium as CE-IVDR InActiv Blue® but without the blue dye and filled in a PETG bottle
- the uses of RUO DRD™ are broader
- strong lysis buffer
- strong pathogen inactivation which makes your sample safe

other

- quality controls on each produced batch:
  - chemical composition review
  - appearance
  - other quality controls on request
- MSDS on website
- COA per batch available on request

Product codes

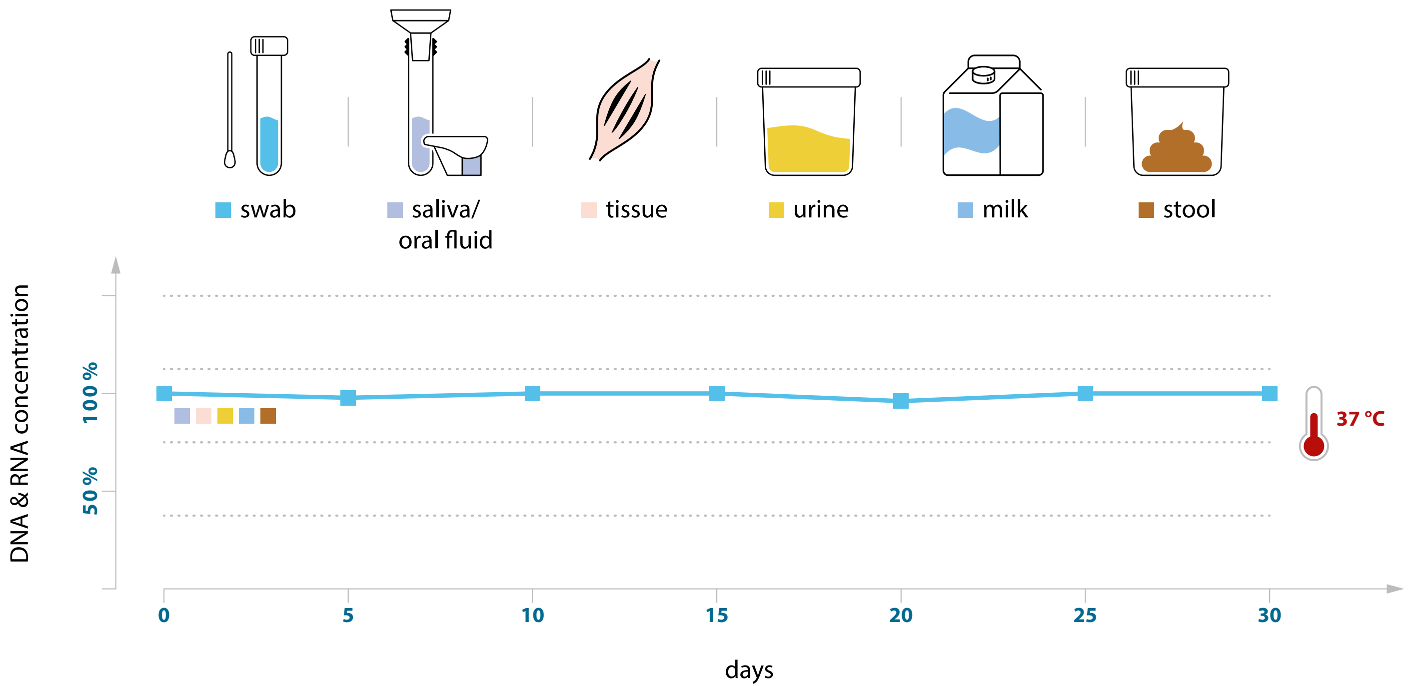
DNA/RNA Defend™ - PETG bottle	*REF:*
30 mL	*DRD_0030*
125 mL	*DRD_0125*
500 mL	*DRD_0500*
1000 mL	*DRD_1000*

DNA/RNA Defend™ - (Micro) tubes	*REF:*
200 µL to 1.5 mL	*on demand*

other volumes on request

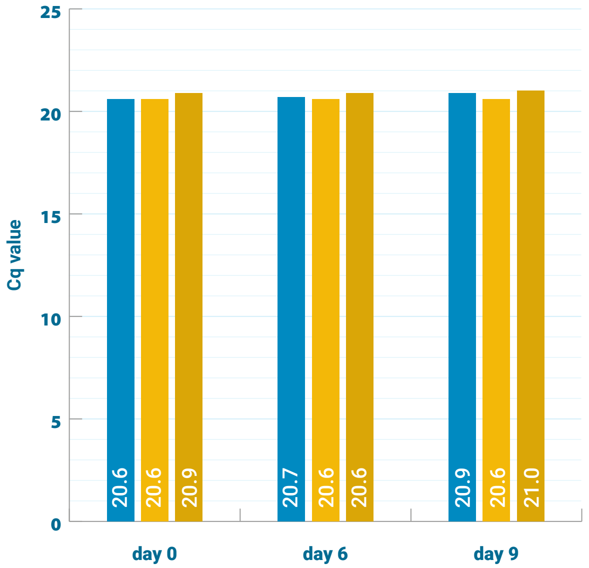
Broad range of sample types

Evidence for effective nucleic acid preservation:



overview of inactivation performance data

complete inactivation			
P. aeruginosa (G-)	*S. pneumoniae (G+)*	H5N1	mpox
SARS-CoV-2	vaccinia	MERS-CoV	bRSV
E. coli (G-)	*S. aureus (G+)*	*M. smegmatis (G+)*	*C. albicans*



excellent RNA stability in urine (25 °C and 37 °C)

RT-qPCR results for KLK3 gene on RNA extracted from urine of 3 healthy donors spiked with LNCaP cells, stabilized with DRD™ and stored at 37 °C.

Similar results for HOXC6 and DLX1 (not shown). Data courtesy of mdxhealth.

urine 1 urine 2 urine 3

DNA/RNA Defend Pro™ *(DRDP™)*

is a nonionic detergent-based acidic medium for pathogen inactivation, stabilization of RNA/DNA/antigens, and lysis of biological samples. Compatible with extraction-free analytical procedures.

For more information, please visit our website

product performance

- stabilization of nasal swab and saliva for DNA/RNA/antigen testing (as claimed in CE-IVDR version of DRDP)
- the uses of RUO DRDP™ are broader:
    - evidence for successful extraction-free PCR in urine, blood, feces, and human single cells
- preservation of antigens , suitable for rapid antigen testing or ELISA
- milder pathogen inactivation, resulting in less damage to cells (mild lysis) and nucleic acids

other

- quality controls on each produced batch:
    - chemical composition review
    - appearance
    - other quality controls on request
- MSDS on website
- COA per batch available on request

Product codes

DNA/RNA Defend Pro™ - PETG bottle	REF:
30 mL	*DRDP_0030*
125 mL	*DRDP_0125*
500 mL	*DRDP_0500*
1000 mL	*DRDP_1000*

DNA/RNA Defend Pro™ - (Micro) tubes	REF:
200 µL to 1.5 mL	*on demand*

other volumes on request

strongly recommended to first test the sample type / protocol of interest with DRDP™

the instructions for use provide several suggested methods for testing the suitability by the end user example:

SUGGESTIONS FOR INITIAL SUITABILITY TESTS

As a starting point for such tests, it is recommended to use the following buffer vs. specimen ratios:

	DNA/RNA Defend Pro™	specimen quantity
cell pellet	***1 mL***	***3 million cells***
tissue, environmental samples	***1 mL***	***100 mg***
biofluids	***1 mL***	***0.5 mL***
swab	***submerge the swab***	***1 swab***
other	***scale the recommended ratios proportionally***	

NOTE: You may want to adjust the ratio of sample vs. buffer. If unsure, start with a larger volume of buffer relative to the sample (up to 9x) and work your way down to lower levels. Use at least 2x the volume of buffer relative to the sample volume.

overview of inactivation performance data

complete inactivation

P. aeruginosa (G-)	*S. pneumoniae (G+)*	H5N1	mpox
SARS-CoV-2	vaccinia	MERS-CoV	bRSV

incomplete inactivation

E. coli (G-)

no inactivation

S. aureus (G+)	*C. albicans*	*M. smegmatis (G+)*

DNA Defend™ *(DD™)*

is a nonionic detergent-based neutral medium for pathogen inactivation, stabilization of DNA and antigens, and lysis of biological samples. Compatible with extraction-free procedures.

product performance

- mild lysis buffer that stabilizes DNA
- the buffer does not contain PCR inhibiting substances, which allows direct PCR on crude lysates
- for use in molecular lab processes to demonstrate the presence or absence of species-specific DNA
- confirmed suitable for Listeria and Salmonella detection in food samples (meat and dairy)
- mild pathogen inactivation

other

- quality controls on each produced batch:
  - chemical composition review
  - appearance
  - other quality controls on request
- MSDS available on request
- COA per batch available on request

Strongly recommended to first test the sample type / protocol of interest with DD™

overview of inactivation performance data

complete inactivation				
P. aeruginosa (G-)	H5N1	mpox	SARS-CoV-2	vaccinia
incomplete inactivation		**no inactivation**		
E. coli (G-)	*S. pneumoniae (G+)*	*S. aureus (G+)*	*C. albicans*	*M. smegmatis (G+)*

RNA*wait*™ *(RW™)*

is a tissue collection and storage solution that quickly permeates fresh tissues to stabilize RNA. It streamlines operations by eliminating the need for immediate downstream processing or freezing of the sample. Instead, the tissue can be submerged in RNA*wait*™ and stored. Hence, the RNA extraction step can wait.

For more information, please visit our website

product performance

- preserves RNA in tissue without immediate need to freeze
- one month at 4 °C, one week at 25 °C, one day 37 °C
- maintains RNA integrity (RIN) and molecular RT-qPCR stability
- allows at least 5 freeze-thaw cycles without impact on RNA quality

Product codes

RNAwait™ - PETG bottle	REF:
100 mL	RW_0100
500 mL	RW_0500

RNAwait™ - Micro tubes	REF:
72x 1 mL	RW_0001

other volumes on request

High RNA quality in tissue stored at ambient temperature

Murine heart and kidney tissues (n=48) were incubated overnight at 4 °C in 3 different lots of RNA*wait*, followed by continued storage at either 4 °C for 30 days (n=12), 25 °C for 7 days (n=12), or 37 °C for 1 day.

After these prolonged incubations, RNA*wait* was removed, and tissues stored at -20 °C for at least 2 weeks, followed by thawing, RNA extraction, and RT-qPCR (12 ng RNA input).

As a comparator, RNA was extracted from fresh hearts and kidneys (n=12). The RNA integrity (RIN, not shown) and molecular stability (RT-qPCR Cq value) is perfectly preserved across these non-freezing storage conditions.

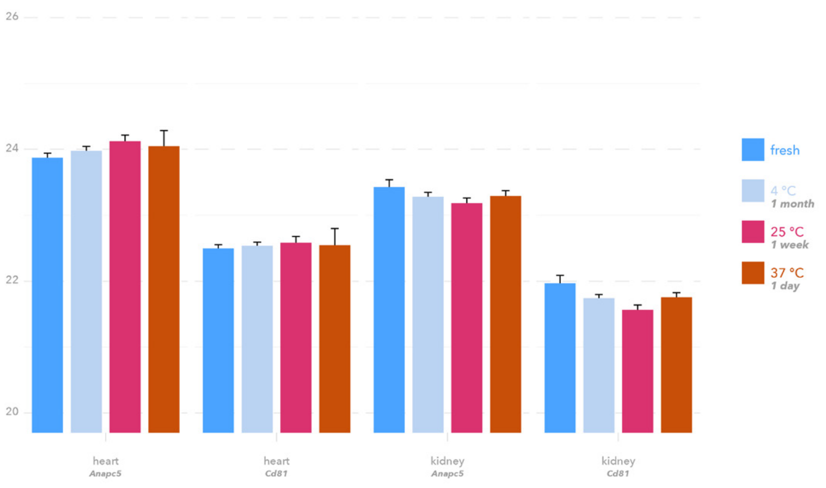
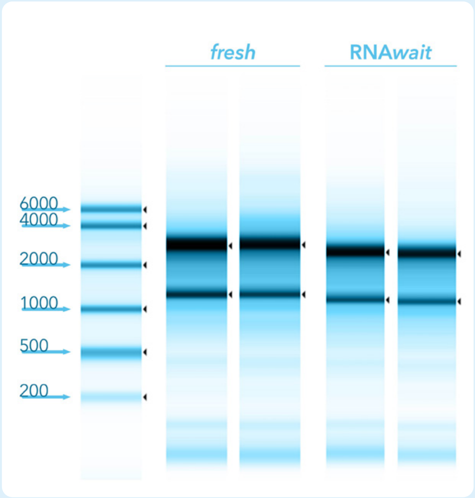


Figure 1: *Bar chart of RT-qPCR Cq values of Anapc5 and Cd81 in murine heart and kidney tissue (n=12) stored at 3 different storage conditions, each using 3 different lots of RNAwait. Error bars denote standard errors of the mean.*

RNA*wait* treatment results in RNA of identical quality to that from fresh tissue

RNA from 6 murine hearts and kidneys was either freshly extracted, or after overnight incubation in RNA*wait* at 4 °C followed by storage at -80 °C for 3 days and thawed. The integrity (RIN) and Cq value (RT-qPCR, not shown) are similar between the 2 conditions, demonstrating that RNA*wait* perfectly preserves RNA in tissue.

Figure 2: *Perfect RNA integrity (intact 18S and 28S ribosomal RNA) from fresh tissue (lane 1,2) and RNAwait treated tissue (3,4) for murine heart (1,3) and kidney (2,4).*



Freeze-thaw cycles do not affect RNA quality

Murine heart and kidney tissues (n=6) were incubated overnight at 4 °C in RNA*wait*, followed by RNA*wait* removal and 5 repeated freeze (-20 °C, 1 day) and thaw (25 °C, 1 hour) cycles. The resulting RNA quality in terms of RT-qPCR Cq value and RIN value (not shown) is similar to that from fresh tissues.

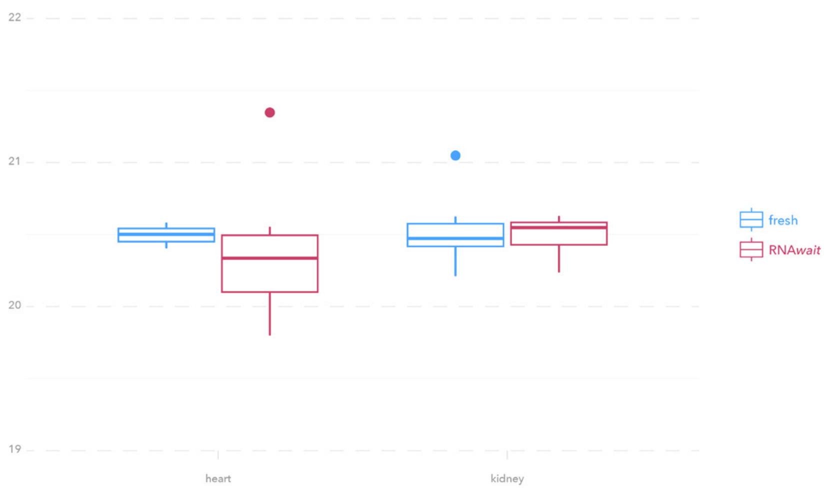


Figure 3: *Identical RT-qPCR Cq value distribution of Cd81 transcripts in murine heart and kidney (n=6) from fresh tissue (blue) or stabilized in RNAwait (pink) prior to 5 freeze-thaw cycles.*

Preservation of histology

Histological examination of FFPE-embedded tissue after RNA*wait* preservation allows recognition of the characteristic tissue structures.

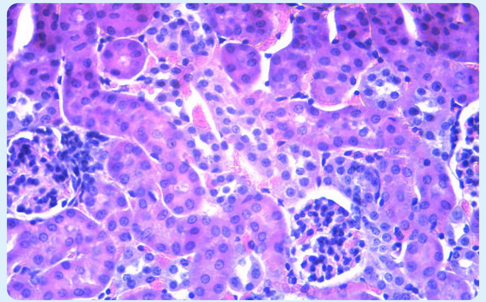


Image 1: *Hematoxylin and eosin (H&E) staining of a formalin-fixed and paraffin-embedded fresh kidney tissue.*

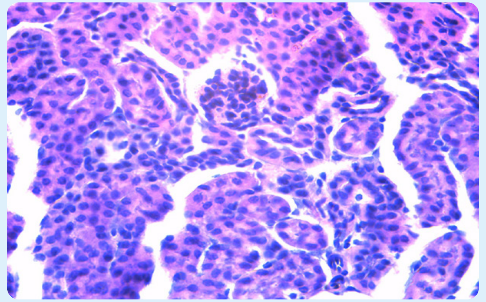


Image 2: Hematoxylin and eosin (H&E) staining of a formalin-fixed and paraffin-embedded RNA*wait*-treated (overnight at 4 °C) kidney tissue.

Nuclease-free water™

To prevent loss of DNA and RNA in samples, it is essential to use ultrapure (type 1), nuclease-free water in applications such as PCR, cDNA synthesis, nucleic acid purification, sequencing, cloning and applications in molecular biology and (stem) cell culture.

For more information,
please visit our website

product information

- deionized ultrapure water, sterile filtered and compliant with Ph. Eur. Monograph 0008
- DNase and RNase-free
- free of mycoplasms
- subject to stringent quality controls batch related to guarantee absence of DNase/ RNase activity, endotoxins and micro-organisms
- nuclease-free PET bottles (1 L, 100 mL) or microtubes (1.5 mL)

other

- quality claims have been extensively validated
- quality controls on each produced batch:
  - before filtration:
    - bioburden (limits: CFU/L conform EP 0008)
    - conductivity (limits: CFU/L conform EP 0008)
    - TOC (limits: < 0.5 ppm)
    - nitrates (limits: < 0.2 ppm NO_3)
    - appearance
  - quality controls on final product:
    - sterility test (limits: no growth)
    - DNase / RNase activity (limits: no detected activity in fluorometric assay)
    - endotoxins (limits: < 0.25 EU/mL)
- MSDS on website
- COA per batch available on request

Product codes

Nuclease-free water - PET bottle	*REF:*
1 x 1000 mL	*NFW_1000*
1 x 100 mL	*NFW_0100*

Nuclease-free water - Micro tubes	**REF:**
72 x 1.5 mL	*NFW_0015*

Table: overview of buffers in function of proven performances

product name	*product code*	*direct PCR*	*specimen type*	*inactivation*	*lysis*	*antigen*	*DNA*	*RNA*
DRD Blood™ *(DRDB)*	DRDB_1 *(vacuum tube)* DRDB_2 *(microtube)*	⛔	E venous blood E capillary blood	I blood pathogens (most likely)	I most likely	⛔	I most likely	E PCR ΔCq ≤2: 30 days at 4 °C, 3 days at 25 °C RIN ≥ 6.5: 14 days at 4 °C, 1 day at 25 °C
DNA/RNA Defend™ *(DRD)*	DRD_0030 DRD_0125 DRD_0500 DRD_1000	⛔	V swab saliva F urine I Stool, tissue	V viruses bacteria fungi	E white blood cells, blastocysts	⛔	E swab saliva PCR ΔCq ≤2: > 30 days at 2-25 °C 8 days at 37 °C	E swab saliva PCR ΔCq ≤2: > 30 days at 2-25 °C 8 days at 37 °C F urine PCR ΔCq ≤2: 9 days at 37 °C
DNA/RNA Defend Pro™ *(DRDP)*	DRDP_0030 DRDP_0125 DRDP_0500 DRDP_1000	V swab saliva E urine stool blood F single human cells	V swab saliva E urine stool blood F saliva	V viruses E several bacteria	E mild lysis of white blood cells, no lysis of blastocysts F mild lysis of cells	V swab saliva lateral flow tests I ELISA	V swab saliva PCR ΔCq ≤2: 8 days at 2-25 °C	V swab saliva PCR ΔCq ≤2: 8 days at 2-25 °C
DNA Defend™ *(DD)*	DD_0030 DD_0125 DD_0500 DD_1000	F food (a.o. meat), single human cells	F food, single human cells	E viruses some bacteria	F Salmonella, Listeria	E lateral flow tests I ELISA	F Salmonella, Listeria, DNA in meat long-term	⛔
RNA*wait*™ *(RW)*	RW_0001 RW_0100 RW_0500	⛔	V tissue E blood spot card	⛔	⛔	⛔	I most likely	V 1 month at 4 °C, 1 week at 25 °C, 1 day 37 °C

E empirical evidence F feedback from 3rd parties I likely suitable, to be investigated V validated ⛔ not suitable / not claimed

Table: available packaging sizes

container	*buffer volume*	*DRD Blood™*	*DRD™*	*DRDP™*	*DD™*	*RNAwait™*	*nuclease-free water*
microtube	150 µL	DRDB_2 *(per 36 pcs.)*					
	1 mL					RW_0001	
	1.5 mL						NFW_0015 *(per 72 pcs.)*
vacuum tube	3 mL	DRDB_1 *(per 50 pcs.)*					
PP flat-bottom tube	2 mL		DRD_0002 *(per 50 pcs.)*		DD_0002 *(per 50 pcs.)*		
PET square bottle	100 mL						NFW_0100
	1000 mL						NFW_1000
PETG square bottle	30 mL	DRDB_0030	DRD_0030	DRDP_0030	DD_0030		
	100 mL					RW_0100	
	125 mL	DRDB_0125	DRD_0125	DRDP_0125	DD_0125		
	500 mL	DRDB_0500	DRD_0500	DRDP_0500	DD_0500	RW_0500	
	1000 mL	DRDB_1000	DRD_1000	DRDP_1000	DD_1000		

We look forward to being successful together!

InActiv Blue bv
Industriepark Oost 2A
B-8730 Beernem
Belgium

VAT BE0758 884 250
+32 (0)50 79 18 07
info@inactivblue.com
www.inactivblue.com

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