

DRD Blood™

Whole blood RNA stabilization medium in vacuum collection tube

document reference: FP09 I130 R01 A.1

update: 23/02/2026

For *in vitro* diagnostic use only
For professional use only

CATALOGUE NUMBER

REF DRDB_1

IVD



PRODUCT DESCRIPTION

REF	product description	packaging
DRDB_1	Prefilled tube with 3 mL DRD Blood™ and vacuum for 1 mL venous blood collection	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

consult instructions for use

IVD *in vitro* diagnostic medical device

keep away from (sun)light

15°C temperature limit

GHS05 corrosive to metals, hazard category 1

GHS07 acute toxicity (oral), category 4

symbol as defined in 2017/746 (IVDR)

CE CE marking

TECHNICAL SUPPORT

URL: www.inactivblue.com
email: info@inactivblue.com

MANUFACTURER INFORMATION / DISTRIBUTOR

FertiPro nv
Industriepark Noord 32
8730 Beernem (Belgium)
Tel: +32 50791805
info@fertipro.com
url: www.fertipro.com

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INTENDED USE

DRD Blood™ is an *in vitro* diagnostic medical device intended for the collection, storage and transportation of human venous whole blood. It contains an RNA stabilization medium that preserves the *in vivo* gene expression profile by reducing RNA degradation and minimizing stress-related gene induction.

DRD Blood™ is a non-automated specimen receptacle intended for use with patients from whom whole blood samples are required for RNA-based molecular diagnostic testing.

SPECIMEN TYPE

Venous blood collected by a standard blood collection set.

INTENDED USER

Sample collection: Sampling is performed by an authorized healthcare provider in a medical environment.

Analysis of preserved sample: Analysis by an approved medical lab or a molecular research lab.

GENERAL

- Certificate of analysis
 - A certificate of analysis per lot is available upon request
- Storage/disposal
 - Store tubes between 15-25 °C
 - Keep away from direct (sun)light
 - Do not use after expiry date
 - Shelf life: 18 months
 - As indicated in the warning section below, contact between the DRD Blood™ fluid and bleach must be avoided.
 - Dispose in accordance with local regulations for disposal of medical devices / hazardous substances
- Material needed, but not provided
 - Blood collection accessories, which include:
 - blood collection set (e.g. butterfly needle)
 - a vacutainer holder
 - alcohol wipes for cleansing
 - tourniquet
 - plaster

PRINCIPLES OF OPERATION AND COMPOSITION

DRD Blood™ is a specimen receptacle for venous blood:

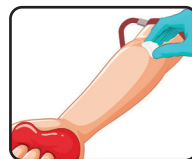
- Sampling is performed by an authorized healthcare provider in a medical environment according to nationally accepted guidelines.
- The collection tube remains hermetically closed at all times. After blood is collected, the tube is identified and sent to an analysis lab for testing, along with the necessary documentation.
- RNA in whole blood is stabilized for 30 days at 4 °C and 3 days at 25 °C. Validation studies demonstrated good RIN values up to 14 days at 4 °C and 1 day at 25 °C.

DRD Blood™ contains guanidine thiocyanate and N-lauroylsarcosine. Complete product composition is described in the MSDS, which is available upon request or can be downloaded from the website.

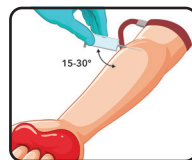
INSTRUCTIONS FOR USE



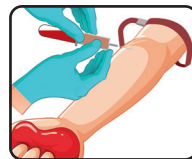
- Preparation
 - Label the required tubes, specifying the name of the patient and department (to exclude errors when identifying the biomaterial sample).
 - Treat your hands hygienically, dry them.
 - Treat your hands with an antiseptic. Do not dry, wait until the antiseptic is completely dry.
 - Put gloves on your hands.
 - Prepare a needle, a holder, alcohol wipes and a plaster.



- Selection and preparation of the venipuncture place
 - Place a tourniquet on the arm 7-10 cm above the venipuncture place. The tourniquet must be applied no more than one minute. A longer vein squeeze time can influence the test results due to changes in the concentration of parameters in the blood.
 - Ask the patient to clench a hand into a fist. Do not give physical exertion to the arm, like "clenching an unclenching of a fist" because this can influence test results.
 - Select the venipuncture place. The ulnar and saphenous veins are the most common but smaller and fuller veins of the wrist and hand can be punctured too. Depending on the characteristics of the vein, select the most convenient option for the venipuncture: a multisample needle or a blood collection set (a butterfly needle).
 - Take the needle and remove the protective cap.
 - Attach the needle into the holder.
 - Disinfect the venipuncture site with a gauze napkin or a pad moistened with an antiseptic solution, in a circular motion from the center to the periphery.



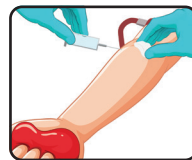
- Puncture of the vein
 - Wait until the antiseptic solution is completely dry.
 - Remove the cap on the other side of the needle. Position the needle along the line with the vein level up and puncture the vein at an angle of 15-30° to the skin.



- Filling tube of DRD Blood™ with venous blood
 - Insert the tube with DRD Blood™ (DRDB_1) into the needle holder until it stops and hold it until the blood stops flowing into the tube. The tourniquet must be removed or released immediately after the blood flow has started leaking into the tube. Make sure the patient unclenches his fist. The blood passes into the tube until it completely compensates for the created vacuum. If the blood does not flow, it means that the needle has gone through the vein. In this case there is need to pull out the needle slightly but not to remove it completely. Do it until the blood goes into the tube. The certainty of filling the tube is ± 10% of the nominal volume.
 - Remove the tube from the holder. Ensure the blood has stopped flowing into the tube before removing the tube from the holder. The DRD Blood™ tube with its vacuum has been designed to draw 1 mL of blood into the tube.



- After filling the tube, it must be immediately gently inverted to mix the sample with the filler (+/- 5 times).



- After all the required tubes are filled, put a sterile cloth on the venipuncture site and remove the needle. Make sure that the patient does not have external bleeding in the area of venipuncture. Apply a pressure bandage on the arm or a bactericidal plaster.

At test laboratory

- Store for a maximum time period at defined temperature as indicated below before further processing:
 - 4 °C for a maximum of 30 days
 - 25 °C for a maximum of 3 days
- Samples can also be stored at temperatures below -20 °C (proven compatibility with freeze/ thaw cycles)
- If further processing is performed after thawing, homogenize the sample by gently inverting 5 times, or vortex when the sample contains visible precipitates
- Perform RNA extraction by a validated lab method
- Perform qPCR (or another RNA-based molecular diagnostic testing method) for the gene of interest

RESULTS AND PERFORMANCE

DRD Blood™ stabilizes RNA in whole blood samples for:

- 30 days at 4 °C
- 3 days at 25 °C
- at least 5 freeze/thaw cycles

Physical RNA integrity (RIN) in a whole blood sample is maintained:

- 14 days at 4 °C
- 1 day at 25 °C
- at least 5 freeze/thaw cycles

DRD Blood™ has been validated with the following commercially available systems:

- RNA extraction:
 - *miRNeasy Micro Kit (#217084, Qiagen)*
 - *VAMNE magnetic Cell/Tissue total RNA kit (#RMA101-C2, Vazyme)*
- cDNA synthesis:
 - *High-Capacity cDNA Reverse Transcription Kit (Applied Biosystems)*
- qPCR kits: Fast SYBR Green Master Mix (Applied Biosystems)
 - *MS2, FOS, IL1B, 18S*
- qPCR instruments:
 - *Light-Cycler 480 (Roche)*

IMPORTANT NOTE: laboratories must validate their RNA extraction method and test system to confirm compatibility with DRD Blood™ prior to use in a clinical setting.

PRODUCT SPECIFICATIONS

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

- chemical composition
- test on vacuum
- appearance: clear, colorless fluid
- functionality test, i.e. RT-qPCR test on a selection of target genes in whole blood samples collected in DRD Blood™: RNA stability; criteria: absolute value of $\Delta Cq \leq 2$ between day 0 and day 3 (storage at RT)

A certificate of analysis per lot is available upon request.

LIMITATIONS

- The DRD Blood™ vacuum collection tube is designed to draw 1 mL of blood, but this volume might vary with temperature, altitude, barometric pressure, tube age and venous pressure. DRD Blood™ performs as specified with a margin of 0.75-1.5 mL of blood added to the 3 mL DRD Blood™ in the tube. Further under- or over-filling will result in an incorrect buffer:blood ratio and may lead to reduced product performance.
- Blood and blood components collected and processed in the tube are not intended for infusion or introduction into the human body.

WARNINGS AND PRECAUTIONS



- **DO NOT DECONTAMINATE TUBES OR LAB ENVIRONMENT WITH BLEACH!** DRD Blood™ contains guanidine thiocyanate that in combination with hypochlorite may form harmful cyanide gas.
- Harmful if swallowed, causes severe skin burns and eye damage, harmful to aquatic life with long lasting effects.
- 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).
- For specifics, consult the MSDS that is available upon request or can be downloaded from the website www.inactivblue.com.
- Do not use if the product is visibly damaged.