H&D Life with less stress	IFU	rev.00 dated 19/11/2025

d-ROMs test 50

REF **IKIT50OG**

50 DISPOSABLE DETERMINATIONS dROMs Test

INTENDED USE

The **d-ROMs test** is an in vitro diagnostic medical device (IVD, Directive 98/79/EC), for professional use, used for the determination of free radicals through the quantitative quantification of peroxides in plasma samples. The test can be performed regardless of the subject's state of health and with different purposes: both for screening and for control. The results refer to the identification of peroxides only in blood samples obtained and stored according to the methods described in this IFU.

PRINCIPLE

The **d-ROMs test** is a non-automated photometric test used to determine the blood concentration of peroxides, potentially oxidizing agents generated in cells by the attack of free radicals, mainly on lipids. The test uses an amine as a peroxide detector which, added to the sample to be analysed, previously diluted in a buffer, gradually changes colour. The color change can be attributed to the oxidation of the amine by alkoxy and peroxyl radicals deriving from the Fenton-dependent cleavage of the peroxides activated, in turn, by the release of iron ions from sample proteins (transferrin) in the acid environment created in vitro.

KIT COMPONENTS

Reagents

- **R1 d-ROMs test**: chromogenic mixture condensed in cuvette, pre-dosed 50 pz.
- **R2 d-ROMs test**: buffer pH 4.8, preservatives and stabilizers in micro test tubes ready to use 50 pz.

Materials contained in the kit

- **Disposable heparinized microvettes 50**50 pz.
- **Disposable sterile lancets** 50 pz.
- **Pipette tips:** 50 PZ.

Materials non contained in the kit

- **Pipette 10 µL** 1pz.
- **Instrument**
  (NOTE: Consult instrument operating manual before testing).

WARNINGS, PRECAUTIONS AND SAFETY INFORMATION

Please read this IFU carefully before using the product. We decline all responsibility for damages deriving from improper use or use not contemplated in this IFU.

- With reference to the DM 28/01/92 and the EEC directive 91/155 the product is not classified as dangerous.
- It is suggested to handle the product with care according to GLP regulations.
- Avoid ingestion, contact with skin, eyes and mucous membranes. The safety data sheets of the individual components are available on request.
- Treat all specimens as if they contain infectious agents. Observe practice precautions against microbiological hazards by following procedures and standards for proper disposal of potentially contaminated specimens.
- Use personal protective equipment (**PPE**) when performing tests.
- Incorrect or inadequate blood sample collection may produce false results.
- Do not use after the expiration date.
- The components of the test are to be considered as **DISPOSABLE**, in case of an incorrect procedure the components cannot be reused.
- Humidity and temperature can negatively affect test results.
- Before carrying out the test, it is advisable to consult the operating manual of the instrument present in the instrument package and always available upon request.
- Do not use hydrogen peroxide as a disinfectant.

LIMITATIONS

- The d-ROM test is intended for professional use only.
- The test must only be used in combination with the FRAS5 instrument for the detection of peroxides in blood samples.
- False positive results may occur if the peroxide concentration in the sample is below the detection limit of the test, or if the sample was collected incorrectly.
- Test results should be considered in conjunction with other clinical data available to the physician.
- A result outside the normal range does not necessarily indicate the presence of disease states in the subject.
- The test can only be performed by specialized and authorized health professionals.

PERFORMANCE CHARATERISTICS

Validated by comparison with the "golden standard" techniques in the study of free radicals.

STORAGE AND STABILITY

Store the reagents at a temperature between 15-25°C.
The test is stable until the expiration date printed on the label. **Do not use beyond the expiration date**.
NOTE: the expiration date refers to the intact kit packaging.
Tests must remain in the sealed pouch until use.
Reagents must be used within a short time of opening their containers.
DO NOT FREEZE the reagents and store away from direct light sources.
NOTE: If R1 has a deep purple/black hue, the reagent is degraded and unusable.

FUNCTIONAL CHECK

The test is equipped with checks during the instrument reading phase which, through the appearance of a message on the screen, communicate that the test has been performed correctly.

SAMPLE

Heparinized plasma obtained from capillary blood by centrifugation. **Do not use plasma treated with citrate, EDTA or other iron chelators. Do not use hemolysed samples.** Only use ethyl alcohol as a disinfectant.
Storing the plasma in order to carry out the test:

18-25°C	0-4°C	-20°C
24 hours	48 hours	1 year

The test can be performed at any time during the day.
There are no significant variations in the value over time if the conditions of the subject do not vary.

SAMPLE PREPARATION

1. Prepare a microvette on the work surface by removing it from its container and detaching the small cap attached to the main cap.
2. Gently massage the fingertip, disinfect it with alcohol (absolutely avoid hydrogenperoxide, a powerful oxidant).
3. Using a sterile lancet, puncture the tip of the fingertip and gently massage thefinger to help expel blood.
4. Remove the first drop of blood (rich in cell fluid) with a cotton swab.
5. Place your finger on the microtube and draw blood through the smaller hole. Fill the microvette up to the end of the fins.
6. Plug the small hole **FIRST** with the plug and **THEN** the main plug. Finally, reinsert the microvette into the appropriate container.

PROCEDURE

Attention: Before carrying out the exams, it is advisable to prepare all the necessary material. The meter must be turned on at least 10 minutes before starting a test and must not be used until the warm-up phase is complete.

Place the microvette in the centrifuge, with a suitable counterweight, and start the exam. The sample will be centrifuged for 90 seconds in order to separate the plasma (NOTE: this step can be skipped if the sample has already

1. Prepare the working solution by depositing 10 µL of plasma into the microtube containing reagent R2 using the white pipette supplied with the instrument and shake by inversion for about 10 seconds.
2. Transfer the contents of the eppendorf, i.e. the working solution in which thesample was diluted, into the cuvette containing the pre-measured reagent R1.
3. Close the cuvette with the stopper and mix by inversion for at least 10 seconds (NOTE: avoid foaming).
4. Insert the cuvette into the reading chamber of the instrument so that the serrated sides are oriented as indicated by the label on the instrument.
5. The result will be calculated by the instrument and expressed in U. Carr.

INSTRUCTIONS FOR USE OF PIPETTES

To withdraw:

- insert the tip into the pipette.
- press the pipette button and insert the tip into the liquid.
- release the button of the pipette and remove the tip, WITHOUT pressing
- further, checking that it has drawn the adequate volume.

To release:

- insert the tip into the liquid WITHOUT pressing the pipette button.
- once inserted into the liquid, press the button on the pipette and hold it down until the tip is removed from the liquid.
- remove the tip from the pipette and dispose of it according to local regulations.

BENCHMARKS AND ANALYTICAL PERFORMANCE

>500 U Carr	Extremely high oxidative stress
400-500 U Carr	High oxidative stress
340-400 U Carr	Moderate oxidative stress
320-340 U Carr	Mild oxidative stress
300-320 U Carr	Limit values
250-300 U Carr	**Normal values**

- Unit of measurement: 1 U Carr = 0.08 mg/dl of hydrogen peroxide.
- Linearity: the method is linear in the range 50-600 U Carr.
- Accuracy: CV% < 5.0%.
- Interferences: the addition of anticoagulants capable of chelating iron, such as EDTA or citrates, give rise to underestimations of the data; the use of disinfectants other than ethyl alcohol may give rise to anomalous results. Small variations to these ranges may be possible. Each laboratory should establish its own reference intervals in relation to its own population.

FREQUENT ASKED QUESTIONS

Q: HOW LONG IS THE TEST?
A: The duration of the test is approximately 7-8 minutes. Of course, the first analyzes will take longer, but after learning the technique a little, the execution will be very fast.

Q: IS CARRYING OUT THE TEST DIFFICULT?
A: The test is very simple to run. The steps appear on the screen and are explained in the illustrated procedures that come with the kit.

Q: IF I GET AN OUTNORMAL VALUE WHAT SHOULD I DO?
A: repeat the test, even twice if necessary. If anomalous data persists, contact the manufacturer for explanations.

Q: HOW TO INTERPRET THE RESULTS?
A: The interpretation of the results is always up to the attending physician. In interpreting the results, the physiopathological state of the subject must be considered, taking into account age, sex, various pathologies.
Generally:

- a **HIGH** d-ROMs (>300) indicates a situation of high oxidative stress in the subject which can cause cell death and is a prodromal condition for the development of pathologies.
- a **LOW** d-ROMs (<250) indicates a lack of free radicals for the body's physiological processes such as the modulation of the immune response – a condition equally dangerous as a high d-ROMs.

Q: CAN I REUSE THE KIT COMPONENTS?
A: No, used kit components should not be reused or stored for use in another kit after use (NOTE: except for the R3 bottle).

Q: IS THERE ANY REFERENCES TO SUPPORT THE TEST?
A: Yes, all the material available is present in our Biblios online archive accessible from our website (http://biblios.hedsrl.it/#/).

BIBLIOGRAPHY

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been separated).

SYMBOLS

LOT	Batch		Consult the instructions for use	IVD	For in vitro diagnostic use only
	Manufacturer		Expiration date		Temperature range at which to store the product
REF	Catalog number		Keep away from direct light sources		Disposable

CONTACS AND ONLY ASSISTANCE

In case of problems or malfunctions, contact:

H&D Srl
Strada Langhirano 264/1 - Parma (PR)

Timetable	Phone number	E-mail	Web site
Mon-Fry 9:00-17:30	(+39) 0521462607	info@hedsrl.it	https://hedsrl.it/