H&D Life with less stress	IFU	Rev.06 dated 25/11/2025

REDOX O.B. OG 50

REF REDOXOBOG50

50 DISPOSABLE DETERMINATIONS dROMs Test

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50 DISPOSABLE DETERMINATIONS PAT Test

INTENDED USE

The **REDOX O.B. OG 50** 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, and for the quantitative determination of antioxidants, in plasma. 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 and antioxidants only in blood samples obtained and stored according to the methods described in this IFU.

PRINCIPLE

The REDOX OG test is a non-automated photometric test used to determine the oxidative stress index of the body, through the determination of free radicals and antioxidants present in the blood. 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 in vitro (d-ROMs test). The antioxidant capacity is measured based on the ability of the blood (specifically of the antioxidants it contains) to reduce ferric ions, which have previously been reacted with the thiocyanate, to ferrous ions. The quantified antioxidant power can be attributed to the main plasma components which act as a barrier to oxidative processes (vitamin C, vitamin E, uric acid, bilirubin) (PAT test).

KIT COMPONENTS

Reagents

- **d-ROMs test**
  - **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.
- **PAT test**
  - **R1 PAT test**: chromogenic mixture condensed in cuvette, pre-dosed 50 pz.
  - **R2 PAT test**: ferric nitrate solution with preservatives and stabilizers in transparent bottle 1x3 mL.

Materials contained in the kit

- **Disposable tips** 150 pz
- **Disposable sterile lancets** 50 pz.
- **Disposable heparinized microvettes** 50 pz.

Materials non contained in the kit

- **Pipette 10 µL** 1 pz.
- **Pipette 40 µL** 1 pz.
- **Instrument**.
  (NOTE: Consult instrument operating manual before testing).

WARNINGS, PREACUTIONS 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 test **REDOX O.B. OG 50** is intended for professional use only.
- The test must only be used in combination with the FRAS 5 instrument for the detection of peroxides and antioxidants in blood samples.
- If the concentration of peroxides and antioxidants in the sample is below the detection limit of the tests, or if the sample was collected incorrectly, false positive results could be generated.
- Test results should be considered in conjunction with other clinical data available to the physician.
- Results not in line with normal values do not necessarily indicate the presence of pathological 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 for the determination of free radicals and antioxidants.

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 the R1 of the d-ROMs has a deep purple/black hue, the reagent is degraded and cannot be used.
NOTE: If the R1 of the PAT has a significantly smaller volume than the other cuvettes, do not use.
NOTE: If the PAT R2 vial has red iridescence, change the vial.

FUCTIONAL 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	48 hours

Carry out on a fasting patient from the previous evening. Food and drinks modify the level of antioxidants at a systemic level and therefore distort the result of the BAP test. 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 hydrogen peroxide, a powerful oxidant).
3. Using a sterile lancet, puncture the tip of the fingertip and gently massage the finger 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 been separated).

d-ROMs test

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 the sample 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.

PAT test

1. Take the cuvette containing reagent R1 and add 40 µl of reagent R2 using the special green pipette supplied with the instrument and the relative disposable tip.
2. Close the cuvette with the stopper and shake by inversion for exactly 10 seconds.
3. Insert the cuvette into the reading chamber of the instrument by positioning the knurled sides as indicated by the label placed on the instrument. The instrument takes the first reading in about 2 seconds. When finished, remove the cuvette.
4. Add 10 µl of plasma to the R1+R2 solution contained in the cuvette. The plasma must be taken using the special white pipette supplied with the instrument and the relative disposable tip.
5. Close the cuvette and mix by inversion for at least 10 seconds. Insert the cuvette into the reading chamber. The instrument takes the second reading in 5 minutes.
6. The result will be calculated by the instrument and expressed in µM.

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

d-ROMs test

>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.

PAT test

>2800 U Cor.	Very high values
2200-2800 U Cor.	**Normal values**
2000-2200 U Cor.	Low limit value
1800-2000 U Cor.	State of slight deficiency
<1800 U Cor.	State of serious deficiency

- Unit of measurement: 1 U Cor = 1,4 µmoles/L of vitamin C.
- Linearity: the method is linear in the range of 500-10000 µM.
- Accuracy: CV% < 5,5%.
- Interferences: No interference was observed in the presence of a phosphate concentration lower than 40 mg/dl. The addition of anticoagulants capable of chelating iron, such as EDTA or citrates, results in overestimation of the data; the use of disinfectants other than ethyl alcohol may lead to abnormal results.

Each laboratory should establish its own reference intervals in relation to its own population.

FREQUENT QUESTIONS

Q: HOW LONG IS THE TEST?

A: The duration of the test, excluding the centrifugation phase, is approximately 4-5 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.
- a **HIGH** PAT (>2800) indicates an excess of antioxidants that can interfere in normal physiological processes involving free radicals.
- a **LOW** PAT (<1800) indicates a lack of antioxidants which, if perpetuated over time, leads to an increase in free radicals, with imbalances in the body's redox balance and greater predisposition for the onset of pathological states.

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 R2 bottle of PAT).

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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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 ONLINE ASSISTANCE

In case of problems or malfunctions, contact:

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