

RDA SPOT DRIED BLOOD SAMPLE COLLECTION KIT INSTRUCTION FOR USE

(RDA001, last revised: 14/09/2022)



RDA Spot dried blood sample collection kit (DBS kit) is CE registered supplied to the market in vitro diagnostic medical device for self-sampling of capillary blood, also suitable for professional use for capillary and venipuncture* blood collection. It can be easily used for patient's blood sample collection both in medical institutions and at home. The DBS kit is intended for the one-time collection of blood samples from one person. The DBS kit contains a card with the specimen area and all the necessary components for blood sample collection and shipping to the laboratory. The DBS kit is not automated and doesn't give any results. The DBS kit is designed for healthy adults from 18 years old. The DBS kit for children must be used with the help and supervision of an adult. DBS sample collection is prohibited or not recommended for mastectomy patients, edematous site, dehydrated patient or with poor circulation to the extremities. Please consult the physician if you have any of the above mentioned or other medical conditions that require special precautions or restrictions for capillary blood collection procedures. DBS sample collection must never be performed on the fingers of a newborn or very young infant under six months old or weighing less than 10 kg. Newborns' blood sample collection (from the heel) is for professional use only.

* Venipuncture sample collection is intended to be performed by trained personnel only. EDTA tubes can be used (no heparin or citrate blood). Apply 60 µL using a micropipette into the middle of each sampling circle. Do not touch the pipette to the sampling medium of DBS sample collection card.

DBS kit doesn't contain any medicines or specific substances that could cause adverse reactions, as well as any ingredients which might influence the measurement. The blood sample collection card included in the DBS kit is suitable for manual and automated laboratory analysis. DBS kit is not designed for a specific instrument and is compatible with most laboratory equipment used for the analysis of DBS samples.

Legal Disclaimer:

The use of this product must be in complete accordance with the enclosed directions. RDA Spot assumes no liability for damages caused by the product being used in any other way.

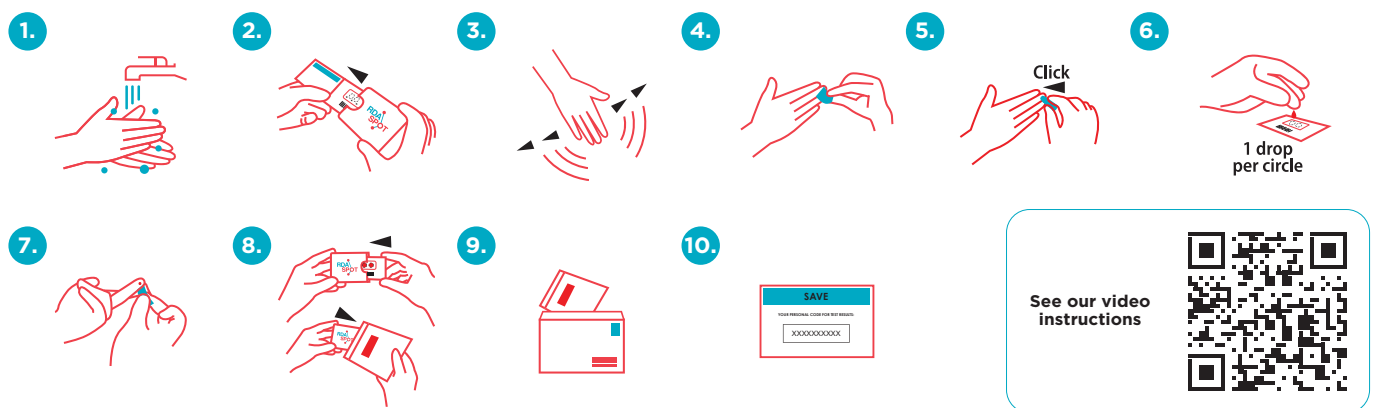
The analysis of the dried blood spot samples is performed in the laboratory. Type of application i.e., what is detected and/or measured from the collected dried blood spot sample, is provided by the laboratory.

Test type, principle and other specific information related to physiological or pathological state, congenital physical or mental impairments, the predisposition to a medical condition or a disease, the determination of the safety and compatibility with potential recipients, the prediction of treatment response or reactions, the definition or monitoring of therapeutic measures are provided by the laboratory.

The results and advice given after the blood samples have been analysed are not meant to replace direct contact, examination or treatment by a doctor or other health care professional. The analysis results and nutritional advice must be viewed in the context of the time in which they were given.

Content:

1 antiseptic wipe, 2 lancets, 1 band-aid, 1 blood sample collection card, 1 card's sleeve, 1 aluminium foil bag, instruction manual and envelope for shipping the samples.



1. Wash hands with soap in warm water and dry them. Drinking enough fluids before the blood collection is highly recommended!

2. Remove the card from the card's sleeve. Tar off the "SAVE" part of the card and keep it for your test results.

3. Stimulate blood flow by waving your hand down for ~20 seconds.
4. Wipe the middle finger with an alcohol wipe and let it air dry.
5. Prick the tip of the middle finger with a lancet*.
 - Remove the transparent safety cap of the lancet.
 - Place the smaller end of the lancet against the side of the middle fingertip. Press the lancet firmly into the finger until you hear a click**.

* Do not use the lancet if its plastic container is damaged or broken. Do not share sterile lancets with other people. Always use a new sterile lancet. Lancets are for single use only.

** It is very important to safely discard the used lancet after each use to avoid accidental injury by the lancet. Be sure to follow the requirements of the local legislation for proper disposal.

6. Drip one large blood drop in each circle. Wait and allow a large hanging blood drop to form. Excessive massaging or squeezing of the puncture site must be avoided! Squeeze the finger lightly and allow a large hanging blood drop to form. Be patient! Place the hanging droplet above the circle on the specimen area. Let the drop, but not the finger, come in contact with the paper. Repeat procedure placing single drops in **all circles**.



Do not touch the specimen area of the card!

Check the backside of the card if the specimen matches the acceptable blood spot (see above). At least 50% of the card circles should be filled in properly. Please use the additional lancet (included in the kit) if needed.

7. Attach the band-aid.

Write the date of sampling on the card.

8. Place the card into the card's sleeve and let it dry for 3 hrs at room temperature. Additional heat sources must not be used to dry the sample. Then place the sleeve with the card into an aluminium foil bag and close it tightly.

Do NOT remove the drying agent inside the aluminium foil bag!

9. Place the aluminium foil bag into the paper envelope***. Store at a temperature no higher than 25°C and avoid direct sunlight.

*** The sender's address should not be indicated on the outer envelope in order to preserve your confidentiality.

Post it immediately, at the latest on the following day.

10. Check your results at WWW / APP (following the additional instructions of the seller) with your unique code, which is on the tear-off flap of the card.

Any serious incident that has occurred in relation to the device shall be reported to the manufacturer (info@rdaspot.com) and the competent authority of the Member State in which the user and/or the patient are established.

- Recyclable
- Do not use if the packaging is damaged
- Expiry date
- Keep dry
- Manufacturer
- In vitro diagnostics
- Do not reuse
- Keep away from sunlight

- Serial number
- Handle with care
- The product meets the applicable requirements of the European Commission directives
- Store in a room temperature
- Read the instruction manual
- Do not touch/hold by the edge