RDA SPOT DRIED BLOOD SAMPLE COLLECTION KIT INSTRUCTION FOR USE

(RDA002, revision 2.)

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 specimen area 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.

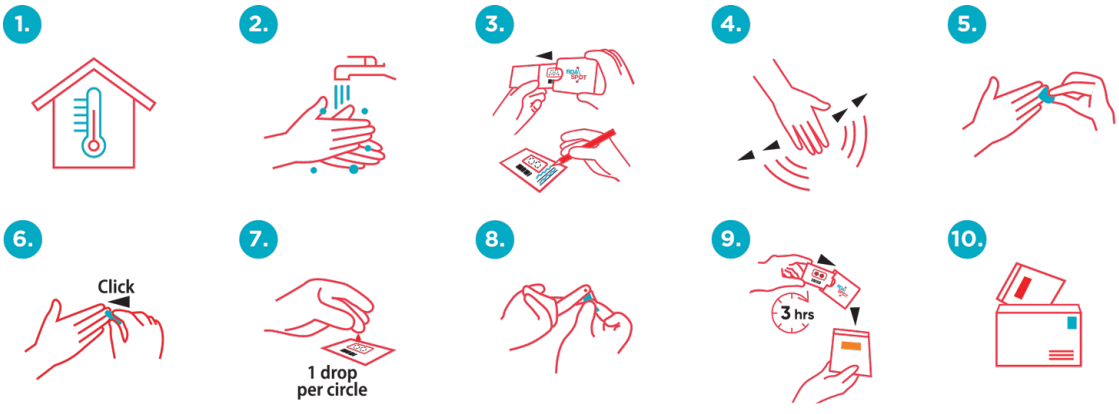
Legal Disclaimer:
The use of this product must be in complete accordance with the enclosed directions. RDA Spot assumes no liability for damages caused by the product being used in any other way.

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



See our video instructions

1. **Wait for the kit to reach room temperature.**

2. **Wash hands with soap and warm water and dry them.**

Stay hydrated before blood collection.

3. **Remove the card from the card's sleeve. Tear off the "KEEP THIS" part and keep it.**
Write the date of sampling on the card.

4. **Stimulate blood flow by waving hand down for ~20 seconds.**

5. **Wipe the ring finger with an alcohol wipe and let it air dry.**

6. **Prick the side of the ring finger with a lancet[1].**
Remove the transparent safety cap of the lancet.
Place the smaller end of the lancet against the side of the ring finger tip. Press the lancet firmly into the finger until you hear a click[2].

7. **Drip one large blood drop in each circle.**
Squeeze the finger lightly and allow a large hanging blood drop to form while keeping it above the specimen area of the card. Excessive massaging or squeezing must be avoided! Patience!
Place the hanging droplet above the circle on the specimen area. Let the drop, but not the finger come in contact with the paper.

Check your blood spots



Check if the blood sample matches the acceptable blood spot (see above). At least 50% of the card circles should be filled in properly. Use the additional lancet (included in the kit) if needed.
Repeat procedure placing single drop in each circle.
Do not touch the specimen area of the card!

8. **Attach the band-aid.**

9. **Carefully insert the card into the card's sleeve without touching the specimen area and let it dry for 3 hrs at room temperature. Then place the sleeve with the card into a foil bag and close it tightly.**
Additional heat sources must not be used to dry the sample. Do NOT remove the drying agent inside the foil bag!

10. **Place the foil bag into the paper envelope[3]. Store below 25°C and avoid direct sunlight.**
If the envelope is not marked as postage prepaid, apply the appropriate number of stamps.
Post immediately, latest the following day.

11. **Check your results following the additional instructions of the seller with your unique code, which is on the tear-off flap of the card.**

[1] Do not use the lancet if its plastic container is damaged or broken. Lancets are for single use only.
[2] Used lancets can be safely disposed with general waste unless otherwise provided by local law.
[3] The sender's address should not be indicated on the outer envelope in order to preserve your confidentiality.

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.

 Consult instructions for use

 Do not use if the package is damaged

 Do not touch/hold by the edge

 Manufacturer

 Do not re-use

 Temperature limit

 Keep away from sunlight

 Keep dry

 Use-by date

LOT Batch code

IVD In vitro diagnostic medical device

CE The device meets the general safety and performance requirements under the In Vitro Diagnostic Regulation 2017/746 (IVDR)

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