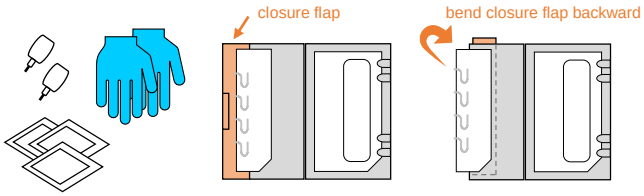
HemaXis™ DB 10

INSTRUCTIONS FOR USE

Before handling device watch instructional video at http://hemaxis.com

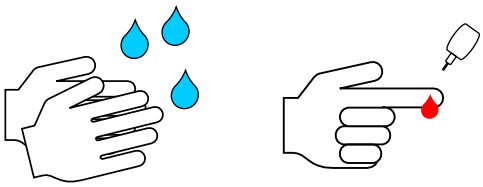
How to use HemaXis™ DB 10

1 Prepare material



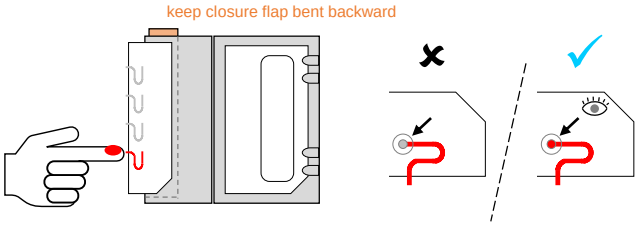
- Prepare material (lancets, disinfectant wipes)
- Wear gloves and remove the device from its packaging
- Open the cover and bend the closure flap backward

2 Generate blood drop



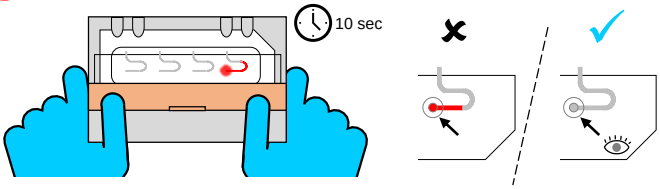
- Wash patient hands and sterilize finger
- Prick fingertip and gently press finger to produce a blood drop
- Wipe off first blood drop with gaze and generate a new drop

3 Fill one collection channel with blood



- Contact blood drop with one channel entrance
- Check channel is completely filled (see 👁)
- If necessary, make several contacts to complete filling

4 Transfer blood to paper card



- Close the cover while maintaining the closure flap bent backward
- Visualize channel emptying until transfer completion (see 👁)
- Repeat steps 3-4 to generate up to 4 samples. Close the closure flap for sample storage or shipping

SINGLE USE ONLY: do not attempt to re-fill a used channel

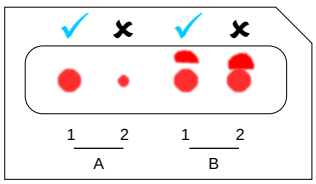
Troubleshooting tips

? Not enough blood produced

- ✓ Warm patient's hands (e.g. wash hands in hot water)
- ✓ Shake and massage fingers to activate blood flow
- ✓ Prick finger again with a new lancet
- ✓ Use a lancet with a longer needle, e.g. 1.8 mm needle

Blood will start coagulating after a few minutes

? Sample acceptability check



A. Spot size

1. Correct spot
2. Spot too small

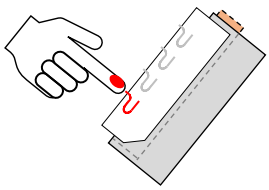
Ensure channel is empty before re-opening panels
Do not wipe off excess of blood at channel entrance

B. Blood overflow

1. Acceptable sample (overflow > 2mm distant to spot)
2. Non-acceptable sample (overflow < 2mm distant to spot)

Avoid touching patient's skin with device

? Channel does not fill completely



- ✓ Slightly incline the device with channels facing up while filling
- ✓ Contact finger 2-3 times to channel entrance
- ✓ Generate more blood from patient's finger

? No transfer

- ✓ Apply more blood to channel to ensure it is completely filled
- ✓ Press and release the cover panels 2-3 times
- ✓ Always perform transfer within 2 minutes following channel filling to avoid blood coagulation
- ✓ Do not apply excessive pressure upon transfer
- ✓ Collect one sample at a time

SINGLE USE ONLY: do not attempt to re-fill a used channel

DBS System SA
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Intended use

HemaXis™ DB 10 is a single use device intended to be used by healthcare professionals, as well as patients or caregivers within healthcare programs supervised by healthcare professionals, to collect, transport and store 4x 10.0 ±0.5 µL (95% confidence interval) of human dried blood spot samples.

Device characteristics

HemaXis™ DB 10 is specially designed to collect capillary whole blood samples of controlled volume (10.0 ±0.5 µL per spot) for analysis in a certified laboratory. The microfluidic chip allows the collection of blood samples from a patient's drop of blood (finger prick for instance) via the collection channels. Samples are transferred onto a filter paper card inserted inside the plastic cover. After collection the plastic cover protects the card containing the samples that can be transported to the analytical laboratory for analysis.

Caution:

- The suitability of HemaXis™ DB 10 for any analytical application must be evaluated and validated by the analytical laboratory.
- The sample volume of 10 µL is guaranteed only if the entire spot is used for analysis.

Materials provided

- HemaXis™ DB 10 device containing a filter paper card into a plastic cover.
- Instructions for use.

Equipment and materials required not provided

- **Capillary blood collection supplies**: sterile retractable lancets, disinfectant wipes, gauze, adhesive bandages/plasters, sharps disposal container.
- **Personal protective equipment (PPE)**: gloves and other PPE as required to provide protection from exposure to blood borne pathogens.

Optional equipment and materials

- **Mailing envelope**: for transport of specimens.
- **Impermeable bag and desiccant**: for transport of specimens.

Warnings and precautions

- For single use only. Do not reuse devices or use the same device for more than one patient to avoid cross-contamination that may affect patient safety and/or test results.
- For *in vitro* diagnostic use only.
- HemaXis™ DB 10 must be handled with gloves at all times to prevent contamination of the sample collection area with material that could be introduced by the operator.
- Remove device from its package just before use to avoid exposure to UV light and moisture.
- Do not use the device if packaging is damaged or if the device appears damaged.
- Do not touch the sample collection area or the sample transfer area.
- Do not attempt to re-fill a used channel.
- Biological samples are potentially infectious. Practice standard precautions according to policies and procedures of your facility. Wear gloves and other PPE to protect from blood splatter during sample collection and preparation for analysis. Discard used devices, sample collection equipment and sharps according to your institution's policies.
- Obtain appropriate medical attention in the event of any exposure to biological sample (e.g. through a puncture injury) since samples may transmit viral hepatitis, HIV, or other infectious diseases.
- Discard device if becoming wet or damaged during sample collection.
- Skin preparation with anesthetic creams is not recommended, as the anesthetic reagent may cause interference with test results.
- Blood samples should not be collected from the fingers of neonates or infants less than one year old. If collecting blood samples from neonates or infants less than one year old, follow instructions and standard operating procedures provided by your facility.
- Blood samples should not be collected from swollen sites or previously punctured sites because accumulated tissue fluid will contaminate the blood specimen. Blood samples should not be collected from earlobes or the fifth finger.
- Failure to allow disinfectant to dry might dilute the sample and adversely affect test results.
- HemaXis™ DB 10 is not compatible with blood containing organic solvents (spiked blood).
- Milking or squeezing a capillary puncture might cause hemolysis and admixture tissue fluids with the sample.
- The filter paper card should not be separated from the plastic cover for shipment, to avoid samples cross-contamination or card damages.

Device storage and handling

- **Unopened devices** can be stored from 4°C to 25°C protected from moisture and sunlight until the expiration date marked on the device. Opened devices should not be stored if not used immediately.
- Devices must be used in a temperature range of 4°C to 25°C.
- **Used devices (i.e. containing samples)** can be stored from -70°C to 40°C prior to shipment. Sample stability and storage conditions must be defined by the analytical laboratory. It is recommended to store the DBS card within its cover in order to prevent card deterioration and facilitate sample integrity check.

Transport of device after sample collection

- Devices should be transported or mailed to the analytical laboratory, and the appropriate tracking documentation maintained, according to local regulations and according to the analytical laboratory procedures and policies.
- Packaging should not lead to excessive compression of the devices.
- Devices should not be shipped in containers that contain other types of specimens or chemicals.
- Where sealed plastic bags or other air-impermeable shipping containers are used to transport samples, devices should be shipped with desiccants to minimize exposure of samples to excessive moisture.

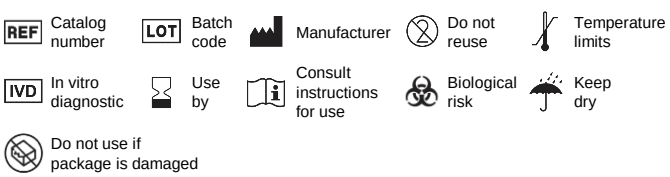
Sample preparation and downstream analysis

- Analysis should be performed by qualified laboratories using validated protocols.
- Check sample integrity before running any analysis. **Do not use spot if blood remains in the corresponding collection channel as the sample volume may not be accurate.**
- No protocols are specified for sample preparation and downstream analysis. Clinical laboratories must qualify the validity and safety of protocols used for any particular laboratory assay, and establish/verify the reference range for a specific instrument. Adequate calibration and standard controls for the assay being undertaken should be applied.
- Where blood spots are sampled for DNA analysis using coring devices, to minimize cross contamination, the coring device should be "cleaned" between sample discs by cutting two sample punches from blank filter unspotted area of the filter paper card and discarding the blank discs to waste.

Performance characteristics

HemaXis™ DB 10 is designed to generate 4x 10.0 ±0.5 µL (95% confidence interval) DBS of human whole blood with normal haematocrit level, with a standard deviation <0.25 µL.

Symbols and mark key



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