

Edinburgh Genetics Complete Whole Blood Collection Kit

Instructions for Use

CATALOG NUMBER

EGCV0083
EGCV0083A
EGCV0083B

UDI DEVICE IDENTIFIER (UDI-DI)

5060774580059
5060774580097
5060774580165

GMDN TERM

Red cell antibody diluent IVD, reagent

INTENDED USE

Edinburgh Genetics Complete Whole Blood Collection Kit is a single-use device intended to be used by healthcare professionals and researchers to collect finger-prick whole blood samples.

DEVICE CHARACTERISTICS

Edinburgh Genetics Complete Whole Blood Collection Kit is designed to collect capillary blood samples for analysis by healthcare professionals and researchers. The lancet is used to produce a small skin piercing, usually on the fingertip. Use the capillary sampler to transfer blood to the buffer solution for further analysis.

MATERIALS

PROVIDED

- A retractable lancet
- A disinfectant wipe
- A capillary sampler
- Buffer solution
- A cotton swab
- Band-aid

EQUIPMENT AND MATERIALS

REQUIRED NOT PROVIDED

- Sharps disposal container.
- Personal protective equipment (PPE): gloves and other PPE as required to protect from exposure to blood-borne pathogens.

PROCEDURE

1. Wear gloves and remove device(s) from packaging.
2. Wash patient's hands and sterilise finger with a disinfectant wipe.
3. Prick fingertip with the lancet and gently press finger to produce blood.
4. Use capillary sampler to collect blood sample.
5. Add the sample into buffer solution, shake sample to mix.
6. Clean wound with cotton swab and cover with band-aid.
7. Follow applicable instructions for downstream analysis.

DOWNSTREAM ANALYSIS

- Analysis should be performed by qualified laboratories using validated protocols.
- 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 the reference range for a specific instrument. Adequate calibration and standard controls for the assay being undertaken should be applied.

Caution:

- The suitability of the kit for any analytical application must be evaluated and validated by the analytical laboratory.
- Band-aid contains **latex** which is a potential allergen

WARNINGS AND PRECAUTIONS

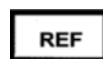
- For single use only. Do not reuse devices or use the same device for more than one patient; this helps to avoid cross-contamination that may affect patient safety and/or test results.
- For in vitro diagnostic use only.
- Edinburgh Genetics Complete Whole Blood Collection Kit must be handled with gloves at all times to prevent contamination of the sample collection area with a material that could be introduced by the operator.
- Remove the device(s) from its package just before use to avoid exposure to UV light and moisture.
- Do not use the device if the packaging is damaged or if the device appears damaged.
- Do not touch the sample collection area or the sample transfer area.
- 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 samples (e.g. through a puncture injury) since samples may transmit viral hepatitis, HIV, or other infectious diseases.
- Discard device if it becomes wet or damaged during sample collection.
- 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.
- Edinburgh Genetics Complete Whole Blood Collection Kit is not compatible with blood containing organic solvents (spiked blood).

MANUFACTURER

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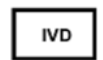
Catalog Number



Lot Number



Do Not Reuse



In Vitro Diagnostic Medical Device



Manufacturer



Storage Temperature
Range: 2-25 °C



Consult Instructions