INTENDED PURPOSE

The Detektor CANCER01 is designed for isolating EpCAM-positive cells (CTCs, circulating tumour cells) from the peripheral blood circulation.

The Detektor CANCER01 can be used in persons with suspected cancer, in cancer patients and, if necessary, in healthy persons by medically trained personnel.

The Detektor CANCER01 comes with a pre-mounted IN plug. The vein in the crook of the arm is accessed via a 20 G indwelling venous catheter (not included). The Detektor CANCER01 is fixed between the IN plug and the indwelling catheter via Luer lock and inserted through the indwelling catheter into a vein in the arm. During the 30-minute application period, EpCAM (epithelial cell adhesion molecule) positive cells can bind to the exposed surface.

Product description

The Detektor CANCER01 has a diameter of 0.5 mm and is made of medical-grade stainless steel and has a biocompatible coating on one side. This 2 cm long section has a golden-yellow appearance. Bonded on the coating are antibodies for the isolation of circulating, EpCAM-positive cells. The functional section is located within the red and yellow plug (IN plug) and is kept moist there.

When you receive the Detektor CANCER01 it will be packaged in multiple layers. The sterile barrier is the transparent bag with 4 sealed seams. Do not use the product if this is damaged. Inside the transparent bag there is a glass tube with screw cap (A). Condensation can form in this glass tube due to the manufacturing process; however, this does not affect the product.

The Detektor CANCER01 is located in the glass tube and should not be removed from it until just before being used.

Performance features

The safety and performance of the GILUPI CellCollector® is continually monitored. The objective of isolating EpCAM-positive cells from the peripheral blood circulation using the GILUPI CellCollector® has been repeatedly confirmed for different entities - including patients with breast, lung or prostate cancer as well as kidney, rectal, neuroendocrine, gallbladder, head and neck, bladder, intestinal or oesophageal cancer. Depending on entity and status as well as the individual disease progression, EpCAM-positive cells could be detected in 35-97% of all applications per group. In a group of patients diagnosed with benign prostatic hyperplasia (BPH), EpCAM-positive cells were isolated in 11 of 45 patients. However, the further course of health was not monitored within the scope of this study and therefore no statement can be made about a possible correlation with a potential later occurrence of the disease.

In healthy subjects, EpCAM-positive cells were isolated in 1.1% of the applications and the further course of health was not monitored here either.

GENERAL GUIDELINES

- For use in countries that accept the CE marking (e.g. EU market). Sterile. Aseptically produced.
- Intended for single use only. Do not resterilise. Do not reuse.
- Use before the expiry date indicated on the packaging.
- Store in a cool, dry place, protected from light, at 2-8°C.
- Do not use if the packaging or product is damaged.
- Minimum patient requirements: The laboratory results (for haematology, clinical chemistry, coagulation) should be in the normal range. It is at the doctor's discretion whether to accept deviations from the normal range.
- Only to be used in health centres or medical practices by medically trained personnel. Read these instructions before use. If necessary, you can also watch the application video at www.gilupi.com. Further training information can only be sent upon request.
- The manufacturer and the competent authority of the Member State where the user and/or patient is based shall be notified of any serious incidents relating to the device.

PRECAUTIONARY MEASURES

- For single use only, reuse may result in infection or other diseases and will damage the product's functionality.
- No parallel examinations should be conducted. There are no reports of interference between the Detektor CANCER01 and other parallel examinations.
- There are no known side effects caused by combined use of the product and a cancer treatment (chemotherapy, radiation therapy etc.).
- Safety is not proven for the following patient categories: Pregnant women; persons under 18 years of age; patients with diffuse symptoms or poor blood circulation.
- In persons who have been sensitised in the past by treatment with murine therapeutic antibodies and are possibly positive for HAMA (human anti-mouse antibodies), the Detektor CANCER01 should only be used after strict indication by the doctor.
- To ensure adequate venous filling and circulatory support, the patient should have taken sufficient fluids immediately before using the Detektor CANCER01.

Possible complications and adverse effects

No clinically relevant side effects are known to date. Residual risks which have been observed in connection with venipuncture and which cannot be ruled out in the event of intolerance reactions after use of the Detektor CANCER01 are:

Probable (1 in 10-100 cases):

- Use of the detector may give rise to haematomas at the insertion site, injuries to the vessel wall or other structures.

Occasional (1 in 100-1000 cases):

- Mild complaints of malaise may occasionally occur in persons with autonomous lability.

Rare (1 in 1000-1 million cases):

- Vagal stimulus during venipuncture may lead to a vasovagal reaction, vasovagal syncope, nerve injuries and/or cardiogenic shock.
- Intolerance to the product may cause an allergic reaction (dizziness, pruritus, skin rash) and, in the worst case, anaphylactic shock.
- In the worst case, an infection can lead to venous thrombosis, thrombophlebitis or sepsis.

MATERIALS TO BE PROVIDED BY THE USER

(required and not included in the scope of delivery)

- 20 G indwelling venous catheter, 32±1 mm (BD Venflon 20 G, colour code: pink; inquire separately for the suitability of other materials)
- Sterile physiological saline solution (max. 5 ml syringe) for rinsing the indwelling catheter (before using the Detektor CANCER01)
- Materials for adhering to the hygiene measures during venipuncture; plasters for fixing the indwelling catheter; material for wound care
- Rinsing solution for washing the cell-binding, golden yellow area after application. Phosphate-buffered saline solution or physiological saline solution, in a vessel for immersing the Detektor CANCER01

Recommended additional items

- Arm splint and bandage for stabilising and immobilising the elbow

Manufacturer

Caution

LOT Lot, batch number

Use by (add date)

STERILE A Sterile, using aseptic methods

Do not reuse

Consult instructions for use

Do not use if the packaging is damaged

Keep away from sunlight

Keep dry

Fragile, handle with care

2 °C 8 °C Temperature limits for safe storage

CE 0197 CE conformity mark with identification number of the notified body

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APPLICATION

The usual hygiene requirements for aseptic work on patients must be adhered to at all times when using the detector.

Place the indwelling catheter at the selected puncture site (easily palpable vein in the inner elbow area) according to the manufacturer's instructions and fix it to the arm with a plaster. If necessary, splint the arm (Caution: Do not apply the bandage too tightly, as the detector has to remain in place for 30 minutes). To optimise the internal sliding capability, always rinse the intravenous catheter with saline solution immediately before use.

When unpacking the Detektor CANCER01 (A), only touch it at the red and yellow plug (B) at first. The red plug must be carefully removed by turning it (C). Liquid will escape when you unscrew the plug! Do not touch the functional, golden area that protrudes from the yellow plug!

Open the venous access (D) and guide the Detektor CANCER01 with the gold-yellow area centrally to the indwelling catheter (E) and fix the IN plug to the indwelling catheter using a Luer lock (F). Then carefully advance the Detektor CANCER01 through the indwelling catheter and into the vein (G) until the first mark is reached. Always hold the area behind the second mark. Slowly advance the Detektor CANCER01 as far as the second mark (H). When in this end position, the cell-binding, gold-yellow area of the Detektor CANCER01 protrudes about 2 cm into the vein.

STOP: if the patient complains of discomfort or pain!
STOP: at the second mark! Do not advance.

Check that the application system (Detektor CANCER01 and indwelling catheter) are properly positioned and the patient is free of discomfort. Take appropriate measures if necessary.
The detector has to remain in place for 30 minutes (H).
After 30 minutes, remove the Detektor CANCER01. This is done by undoing the yellow IN plug (J) and carefully pulling the Detektor CANCER01 out of the indwelling catheter in a straight line (K). Do not pull the Detektor CANCER01 through the IN plug, and do not touch the functional, golden section.
Immediately after removal, place/immerse the cell-binding, gold-yellow area of the Detektor CANCER01 in rinsing solution (rinses off blood components).
If necessary: Remove and dispose of the indwelling catheter according to applicable hygiene regulations. Treat the wound at the puncture site in the same way as when taking a venous blood sample.

Detektor CANCER01 - follow-up treatment

Depending on the diagnostic evaluation method used, further steps may be required. Consultation with the evaluating laboratory is essential!
In all subsequent steps, ensure that the functional section with the isolated cells is not touched or damaged.

Laboratory

The diagnostic evaluation should be carried out in a suitably qualified laboratory. Observe the dispatch conditions stipulated by the laboratory. After the diagnosis has been made, the Detektor CANCER01 should be disposed of in accordance with applicable hygiene regulations in the same way as catheters.