Detektor CANCER01

Instruction for Use

ENGLISH

For use where CE is accepted (e.g. EU market). Sterile. Aseptically produced. Intended for single use only. Do not resterilise. Do not reuse. Use before the expiry date shown on the packaging. Store in a cool, dry place, protected from light. Store at 2°C-8°C. Do not use if the packaging or product is damaged.

Description of the Detektor CANCER01

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

The Detektor CANCER01 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.

The Detektor CANCER01 is packaged in multiple layers. The sterile barrier system is the plastic pouch with 4 sealed seams. Do not use the product if this pouch is damaged. A glass tube with a black screw cap (A) is located inside the plastic pouch. Due to the process of manufacturing moisture can deposit in the glass tube without any negative effect on the Detektor CANCER01.

Insertion system

The Detektor CANCER01 comes with a ready-mounted IN plug. The brachial vein in the crook of the arm is accessed via a 20 G indwelling venous cannula. The Detektor CANCER01 (0.5 mm diameter) is introduced through the indwelling cannula. The Detektor CANCER01 is fixed in place between IN plug and indwelling cannula by means of a Luer lock.

Field of use

The Detektor CANCER01 can be used in healthy subjects, on patients with diagnosed or suspected cancer.

Minimum patient requirements

The laboratory results for haematology, clinical chemistry and coagulation should be in the normal range. In exceptional cases, it is at the doctor's discretion whether to accept deviations from the normal range.

Precautionary measures

This product should only be used in health centres and doctor's practices with medically trained personnel.
No parallel examinations should be conducted.
The Detektor CANCER01 is intended for single use only. Under no circumstances may the Detektor CANCER01 be resterilised or reused, whether in its entirety or in parts.
Before using the Detektor CANCER01, the puncture site must be medically cleaned and disinfected.

Risks which may occur if the product is used in combination with other examinations/treatments

There are no known side-effects caused by combined use of the product and a cancer treatment (chemotherapy, radiation therapy etc.).
There are no reports of interference between the Detektor CANCER01 and other parallel examinations.

Safety is not proven for the following patient categories:

- Pregnant women
- Persons under the age of 18
- Patients with an unclear clinical picture or poor circulation

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 Detektor CANCER01 may give rise to haematomas at the insertion site, injuries to the vessel wall or other structures.
- 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.

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.
The product is intended for single use only. Reuse of the Detektor CANCER01 will affect its functionality and biocompatibility. Resterilisation is not permitted.

Recommended additional items

- 20 G indwelling venous cannula, , 32 ± 1 mm (Recommendation: BD Venflon 20 G, colour coding: pink)
- Materials for ensuring hygiene during venipuncture
- Sterile physiological saline solution
- 20 ml syringe
- Possibly arm splint and bandage for stabilising and immobilising the elbow
- Adhesive dressing for fixing the indwelling cannula
- Wound care materials

Clinical procedure

The Detektor CANCER01 should be used by medically trained personnel. The usual hygiene requirements must be adhered to at all times when using the Detektor CANCER01.

To ensure adequate venous filling and circulatory support, the patient should have taken sufficient fluids before the Detektor CANCER01 is used.

Disinfect the selected puncture site (easily palpable vein on the inside of the elbow). Place the 20 G indwelling venous cannula and fix it on the arm with an adhesive dressing. If necessary, splint the arm (Caution: Do not apply the bandage too tightly, as the Detektor CANCER01 has to remain in place for 30 minutes).

When unpacking the Detektor CANCER01 (A), only touch it on the red and yellow plug (B). Remove the red plug by turning it carefully (C). Liquid will escape when you unscrew the red plug! Do not touch the functional golden section of the Detektor CANCER01!

Remove the stylet from the indwelling venous cannula (D) and dispose of it appropriately. A few millilitres of a physiological saline solution can be injected to ensure smooth insertion and correct positioning of the Detektor CANCER01.

Then position the Detektor CANCER01 with the golden-yellow section centrally on the indwelling cannula (E) and fix it between the IN plug and cannula by means of a Luer lock (F). Then carefully advance the Detektor CANCER01 through the indwelling cannula and into the vein until the first mark is reached (G). The section behind the second mark can be touched for the purpose of insertion. Slowly advance the Detektor CANCER01 as far as the second mark (H). In this final position, the tip of the Detektor CANCER01 projects approx. 2 cm into the vein.

Stop if the patient complains of discomfort or pain!

Now check that the application system (Detektor CANCER01 and indwelling cannula) are properly positioned and the patient is free of discomfort. Take appropriate measures if necessary.

The Detektor CANCER01 should remain in place for 30 minutes (H).

After 30 minutes, remove the Detektor CANCER01 by undoing the yellow IN plug (J) and carefully pulling the Detektor CANCER01 out of the indwelling cannula in a straight line (K). Do not pull the Detektor CANCER01 through the IN plug, and do not touch the functional golden section!

Carefully remove the indwelling venous cannula, and dispose of it in accordance with the applicable hygiene regulations. Treat the wound at the puncture site in the same way as when taking a venous blood sample.

Post-processing of the Detektor CANCER01

The cell-binding Detektor CANCER01 tip should be briefly rinsed (e.g. in phosphate-buffered saline solution) immediately after use.
Depending on the diagnostic evaluation method used, further steps may be required.
In all subsequent steps, ensure that the functional section with the isolated cells is not touched or damaged.

Laboratory

The evaluation should be carried out in a suitably qualified laboratory. Observe the dispatch conditions stipulated by the laboratory.
After evaluation of the Detektor CANCER01 dispose of it in accordance with the applicable hygiene regulations for used cannulas.

Manufacturer

GILUPI GmbH
Hermannswerder 20a
14473 Potsdam
Germany
http://www.gilupi.com
Tel: +49 (0)331-5818 4782, Fax: +49 (0)331-5818 4780

Key to special symbols

Do not use if packaging is damaged		Conformity with Council Directive 93/42/EEC concerning Medical Devices	CE 0197