maintrac® Liquid Biopsy

Innovative Laboratory Diagnostics Before, During and After Cancer Therapy

maintrac

What is maintrac®?

maintrac® is a highly sensitive, minimally invasive laboratory test, that enables the detection of living **circulating tumor cells in the blood (Liquid Biopsy).** The test can be used **before, during and after therapy**[1]. Circulating tumor cells can thus be used as a **biomarker**[2].

Tumor cells can detach from the primary tumor or metastases at very early stages and can enter the bloodstream. These cells are called **circulating epithelial tumor cells** (CETCs/CTCs). They are responsible for the **recurrence of the disease**. Systemic therapy is designed to eliminate circulating tumor cells. During the course of disease, the number and characteristics of circulating tumor cells may change. The **maintrac®** method is **highly sensitive** for the **early detection** of these changes[3].

Approximately 90% of all tumors are of epithelial origin. Using **maintrac® Liquid Biopsy**, circulating tumor cells can be detected in a **blood sample** due to the expression of the surface protein EpCAM[4].

maintrac® Liquid Biopsy can be used for all **solid epithelial tumors**[1,5,6,7].

We offer the following examinations

- maintrac® **Cell Counting**
- maintrac® **Therapeutic Substance Testing**
- maintrac® **Therapy Relevant Tumor Cell Characteristics**
- stemtrac® **Tumorspheres**

maintrac® Quality Features

- **Highly sensitive** detection of living circulating tumor cells without enrichment steps[1]
- **Quantitative** determination of living tumor cells from peripheral blood[3]
- **Fast** and **reproducible**[1]
- Performed in a DIN EN ISO 15189 **certified laboratory**, accredited by DAkkS (ILAC approved)[8]

Recommendations for the time of blood sampling

- Before the start of neoadjuvant chemotherapy
- Before surgery
- 3 weeks after surgery
- 2-3 weeks after a chemotherapy cycle
- 2-3 weeks after completion of a therapy
- Blood samples can be taken at any time during hormone therapy or maintenance therapy.
- Blood samples can also be taken at any time during a therapy-free period.

Requisition

Shipping boxes including the lab request form can be ordered free of charge online at:
www.maintrac.de/en/order/order-maintrac-boxes

Only 15 ml EDTA blood is required for the examination.

Transmission of Results

The results are usually sent **digitally** (DSGVO-compliant) or **by post** within one week.

Costs

At present, the maintrac® diagnostics are not reimbursed by the statutory health insurances, but are a self-pay service. Whether and to what extent privately insured patients can receive reimbursement from their insurance company must be clarified with their own private health insurance company.

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maintrac® Cell Counting

maintrac® Cell Counting makes it possible to **monitor therapy** and **directly observe the activity of the remaining tumor burden** (minimal residual disease) in patients with primary and metastatic tumors prior to the detection by imaging methods[9].

Repeated analysis with **maintrac® Cell Counting** (every 3-6 months), captures the dynamics of the number of circulating tumor cells.

Application:

- **Progression measurements** during and after therapy
- **Monitoring tumour activity** in follow-up care, after the end of therapy and in metastatic situations

maintrac® Cell Counting provides an additional tool for personalized therapy.

Results to date show[9]:

- **Decreasing cell numbers** under systemic therapy indicate a **positive response to therapy**.
- If **cell numbers remain constant** with or without therapy, it can be concluded that the **tumor dynamics** is currently **low**.
- **Repeated increase** of cell numbers indicate an **increased risk of recurrence**

Innovative Laboratory Diagnostics of Circulating Tumor Cells Before, During and After Cancer Therapy

maintrac® Therapeutic Substance Testing

Using **maintrac® Therapeutic Substance Testing,** the **effectiveness of a planned therapy** can be individually **tested in advance** on circulating tumor cells[10].

Depending on tumor type, stage of disease, pretreatments and patient, the **degree of response** of different substances **can vary** considerably.

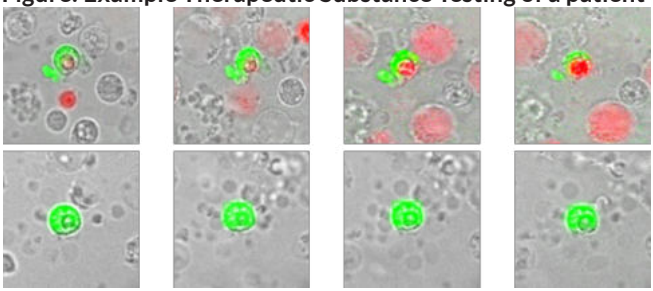
maintrac® Therapeutic Substance Testing shows the **response** (sensitivity) or **nonresponse** (resistance) of **cytotoxic substances** on living circulating tumor cells. These substances can be tested individually or in combination, as well as in different concentrations.

Application:

- **Following the initial diagnosis** of a malignant tumor, before therapy is initiated
- **In the metastatic situation** before a new therapy is started
- In case of **progression** of the disease under treatment

In addition, the effect of **hyperthermia** on circulating tumor cells can also be examined (with or without cytotoxic substances)[10].

Figure: Example Therapeutic Substance Testing of a patient



The upper row shows the **death of a tumor cell** under a **cytotoxic substance** that is **effective** for the patient. In the bottom row, the cytotoxic substance shows no effect.

maintrac® Therapy Relevant Tumor Cell Characteristics

maintrac® Therapy Relevant Tumor Cell Characteristics provide indications of a possible **response** oder **nonresponse** to a chosen therapy.

A series of therapies is only useful if the tumor cells exhibit the respective characteristics. Testing of specific tumor characteristics on circulating tumor cells can provide **additional information** about the **aggressiveness** of the tumor and the **response** to a potential targeted therapy[7].

Both the surface characteristics and the genetic characteristics of the tumor can change during the **course of the disease**. This can influence the efficacy of the therapies applied.

Application:

- When a **tissue biopsy** to obtain information on tumor characteristics is **not possible**
- When a **recurrence/progression** occurs during the course of targeted therapy
- When the **origin of a tumor** is unknown (CUP)

List of biomarkers:

- Hormone receptors (ER, PR, AR)
- Growth factor receptors (Her2/neu amplification, EGFR, EGFR amplification, VEGFR2, c-Kit, IGFR)
- Prostate-associated markers (PSA, PSMA)
- Proliferation markers (Ki67)
- Immunomodulatory molecules (PD-L1, B3-H7)
- Others (apoptosis detection, Mel A / Melan A, PLAP)

stemtrac® Tumorspheres

Tumors release cells into the surrounding tissue and into the blood. They are called circulating epithelial tumor cells (CETCs/CTCs). Amongst them are the so-called **circulating cancer stem cells**, which can be identified with **stemtrac®**. During a period of up to **21 days**, the cancer stem cells grow into **tumorspheres** in vitro. A tumorsphere is a **spherical structure** that results from the cell division of a cancer stem cell[11].

Clinical relevance[11]:

The more stemtrac® Tumorspheres found, **the more aggressive** the tumor and **the higher the risk of metastasis**.

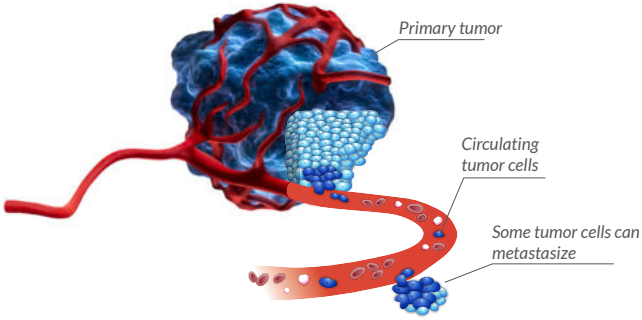
- Metastasized patients have more tumorspheres than non-metastasized patients.
- The number of tumorspheres can be used as a **biomarker** for the presence of already **existing metastases**.
- No tumorsphere growth was observed in subjects without diagnosed cancer.

Application:

The number of **stemtrac® Tumorspheres** can be used in combination with **maintrac®** to monitor the activity of the remaining tumor burden:

- **After the end of therapy** to estimate the aggressiveness and metastatic risk of the remaining tumor cells.
- **In complete remission** when CETCs are increasing.
- **In disease progression** when CETCs are low or undetectable (loss of EpCAM expression, i.e. dedifferentiation of tumor cells)

Your competent partner in oncology.



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[8] The maintrac method is a method produced in the Dr. Pachmann laboratory (in-house production). It is used exclusively in the Dr. Pachmann laboratory and is therefore not marketed.
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