

M371-Test

Diagnosis of
testicular cancer



**CE₂₇₉₇ certified
according
to IVDR**

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Diagnosis of
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HIGHLY SENSITIVE MARKER FOR GERM CELL TUMORS

With more than 20.000 new cases diagnosed each year in Europe (IARC, 2022), testicular germ cell tumors (GCT) are the most common form of cancer among young men.

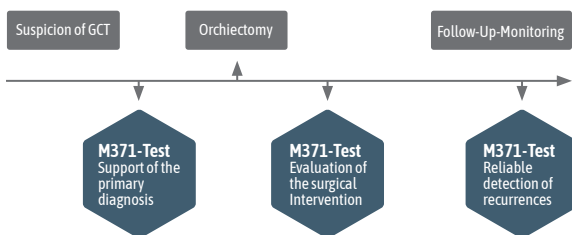
The current gold standard for the primary diagnosis as well as the follow-up monitoring relies on serum tumor markers (AFP, B-hCG, LDH), ultrasound and computed tomography (CT) scans.

However, the classical serum tumor markers offer a limited sensitivity, and CT scans are accompanied by an avoidable exposure to ionizing radiation.

The liquid biopsy test detects the tumor-specific microRNA miR-371a-3p, which is strongly correlated with the presence of germ cell tumors and therefore allows the detection of these tumors with high sensitivity and specificity.

The **M371-Test** detects recurrences during the follow-up monitoring of testicular cancer patients with a sensitivity of 100 %, thus clearly outperforming the classical serum markers.

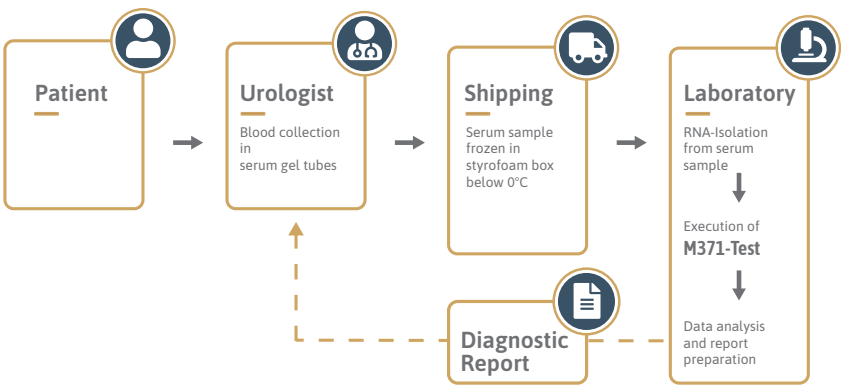
M371-TEST IN USE



OPTIMIZATION OF TREATMENT DECISIONS

- Faster and more reliable diagnosis
- Minimally invasive and patient friendly
- More reliable detection of recurrences

M371-TEST IN YOUR DOCTOR'S PRACTICE



CLINICAL AND SCIENTIFIC EVIDENCE

Marker	Classical serum markers (AFP, BhCG, LDH*)		M371-Test	
Setting	Primary diagnosis ¹	Follow-up ⁶	Primary diagnosis ¹	Follow-up ⁶
Sensitivity**	cSI: 51% cSII/III: 85%	45%	cSI: 89% cSII/III: 99%	100%
Specificity	82%	92%	96%	96%

* LDH was not considered in the follow-up setting (Belge et al., 2024).

** The sensitivity in the primary diagnosis is reported separately for clinical stage I and stages II and III.

- Extent of tumor burden and therapy success correlate with expression of miR-371a-3p.¹
- The level of miR-371a-3p drops to 2.6 % of the preoperative value in patients without metastases within 24 hours after orchiectomy, thus enabling faster staging.²
- The tumor marker miR-371a-3p is not detectable in case of different investigated tumors or testicular diseases and therefore is ideally suited as a biomarker specific for germ cell tumors.^{3, 4}
- Recurrences are detected reliably. In the long term, the use of CT scans in follow-up care can be reduced, thereby decreasing the radiation exposure of predominantly young patients.^{5, 6}



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ISO 13485 certified

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