M371-Test

Optimizing Testicular Cancer Diagnostics

The M371-Test is a qPCR-based assay intended as an **aid for primary diagnosis and follow-up monitoring of testicular germ cell tumors (TGCT)**. It measures the relative quantity of the tumor marker miR-371a-3p from a blood sample with outstanding diagnostic accuracy.

- Unique and innovative product based on patented technology
- Faster, substantially more precise, and reliable diagnosis than classical serum markers
- Minimally invasive technique that avoids unnecessary diagnostic surgeries
- Potential reduction of radiation exposure during follow-up and long-term monitoring
- High sensitivity and specificity in primary diagnosis as well as in follow-up monitoring
- For professional *in vitro* diagnostic use. CE_{2797}-certified according to IVDR

GOLD STANDARD DIAGNOSTICS

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Background

Testicular germ cell tumors (TGCT) are the most common cancer type in men aged 20-45 years with 25.000 new cases per year in Europe (Source: Globocan 2020).

The current gold standard for diagnosis and monitoring, based on serological testing, ultrasound, and CT imaging is unspecific, radiation-intensive and leaves the patient often in doubt.

New Biomarker for Testicular Cancer (TC)

"Micro RNAs (miRNAs) are emerging as potential new biomarkers for TC. A number of studies suggest higher discriminatory accuracy for miRNAs (particularly miR-371a-3p) compared to conventional GCT markers in diagnosis, treatment monitoring, and predicting of residual or recurrent viable disease" - **European Association of Urology (EAU) Guidelines on Testicular Cancer (March 2023).**

Our Solution

- Product: **M371-Test**
- Order No.: **HW/MCS0105**
- Format: **5 Reactions**
- Validated on the following thermocyclers:
  - -LightCycler® 480 II (Roche)
  - -AriaDx (Agilent Technologies)
  - -QuantStudio™ 5 (Thermo Fisher)

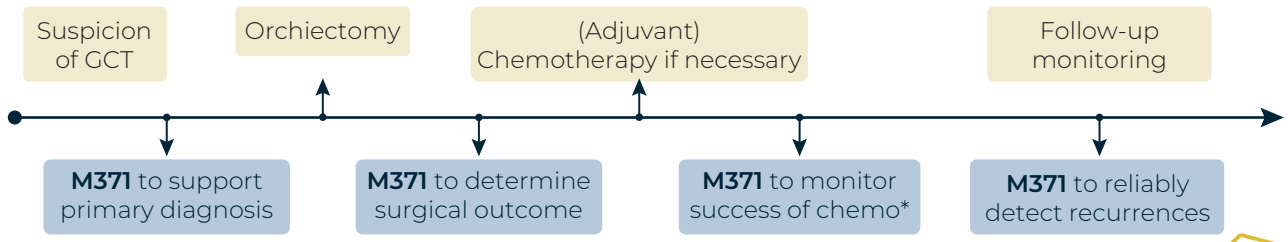
Clinical and Scientific Evidence

Marker	Classical serum markers[1]		M371-Test	
Setting	Primary diagnosis[2]	Follow-up[3]	Primary diagnosis[2]	Follow-up[3]
Sensitivity[4]	cSI: 51 % cSII/III: 85 %	45 %	cSI: 89 % cSII/III: 99 %	100 %
Specificity	82 %	92 %	96 %	96 %

[1] AFP, ß-hCG, LDH. LDH was not considered in the follow-up setting.
[2] Dieckmann et al., 2019, doi: 10.1200/JCO.18.01480.
[3] Belge et al., 2024, doi: 10.1158/1078-0432.CCR-23-0730.
[4] The sensitivity in the primary diagnosis is reported separately for clinical stage I and stages II and III.

By measuring 616 GCT patients and 258 controls in a large European clinical study it was established that tumor size as well as therapy success are highly correlated with the expression of miR-371a-3p. (Dieckmann et al., 2019, doi: 10.1200/JCO.18.01480)

- miR-371a-3p is not expressed by other tumors and can help to differentiate reliably between malignant germ cell tumors and other testicle diseases. (Belge et al., 2021, doi: 10.1007/s00432-020-03429-x)
- miR-371a-3p drops to 2,6% of the pre-surgical value within 24h after orchiectomy. (Radtke et al., 2018, doi: 10.1159/000488771)
- miR-371a-3p allows a more accurate and earlier detection of relapses in comparison to the classical markers. (Lobo et al., 2020, doi: 10.1016/j.euo.2020.11.004; Fankhauser et al., 2022, doi: 10.1038/s41416-021-01643-z)
- In the most comprehensive follow-up study to date, the M371-Test detected recurrences with a sensitivity of 100 % and a specificity of 96 %. (Belge et al, 2024, doi: 10.1158/1078-0432.CCR-23-0730)



*ongoing studies

MANUFACTURED by mir|detect GmbH. DISTRIBUTED by Gold Standard Diagnostics Frankfurt
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