Oncohematology Panel

New Oncohematology molecolular assays based on one-step Real-Time RT-PCR. Innovation and accuracy to help Acute Myeloid Leukemia (AML) diagnosis and monitoring.

In patients with Acute Myeloid Leukemia (AML), qRT-PCR shows significant sensitivity in the detection of the translocations or other chromosomal abnormalities. It represents an important tool in the screening of acute leukemia providing useful information for the diagnosis and prognosis and allowing patients to be assigned to the appropriate risk group for management and therapy.

PML-RARA T(15;17) (Q22;Q21)

In vitro diagnostic test for the identification and quantification of the PML-RARA fusion genes resulting from the t(15;17)(q22;q21), by multiplex one-step Real-Time PCR.

One-tube mix for PML-RARA BCR1, PML-RARA BCR2, PML-RARA BCR3 fusion transcripts and the ABL gene IC

AML1-ETO T(8;21) (Q22;Q22)

In vitro diagnostic test for the identification and quantification of the AML1-ETO fusion gene transcript resulting from t(8;21)(q22;q22), by one-step Real-Time PCR.

One-tube mix for AML1-ETO fusion transcript and the ABL gene IC.

INV(16)(P13Q22) CBFB-MYH11

In vitro diagnostic test for the detection and quantification of the CBFB/MYH11 fusion gene resulting from the Inv(16)(p13q22), by multiplex one-step Real-Time PCR.

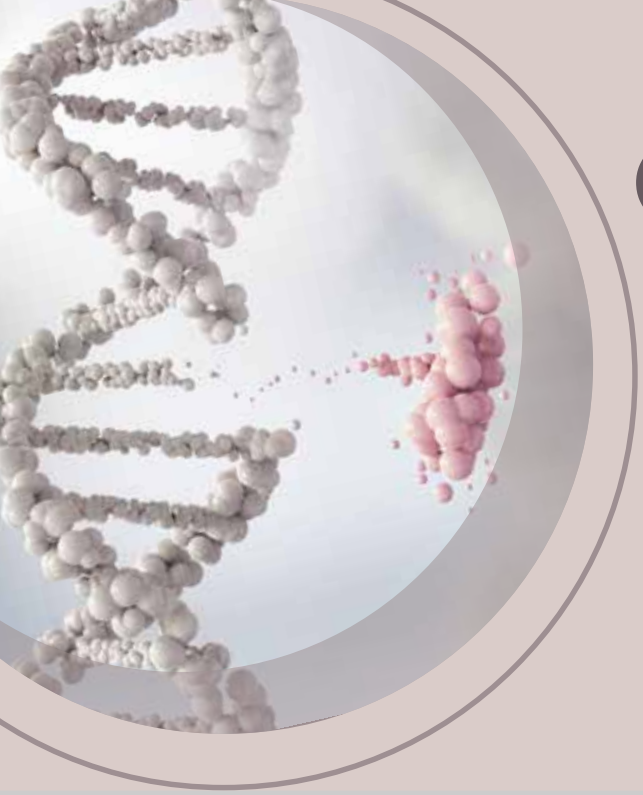
Mix 1: Inv(16) type A, type D, type E variants and the ABL gene IC.

Mix 2 (rare variants): Inv(16) type B, C, F, G, H I, J variants and the ABL gene IC.

Thanks to the Standard set, it is possible to calculate the ratio of the specific fusion transcript signal to the endogenous control gene signal in each sample. This allows the **identification of the Minimal Residual Disease (MRD).**

Clonit Oncohematology panel has been designed with striking and innovative features to ensure a fast, safe and effective diagnosis in patients with Acute Myeloid Leukemia:

- The PML-RARA t(15;17)(q22;q21) allows the identification of all BCR1, BCR2, BCR3 transcripts in a single well
- The Inv(16)(p13q22) - CBFB-MYH11 can detect all the 10 variants of the CBFB-MYH11 transcript described in the literature
- The Standard set for quantification is always included with the kits



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The CE IVD kits are compliant to the "Europe Against Cancer (EAC) Guidelines - Leukemia 2003"

GENERAL INFORMATION

- **Protocol:** one-step Real-Time RT-PCR

The kits share the same thermal profile

- **Time to result:** 1h and 30 minutes
- **Quantification Standards:** synthetic sequences corresponding to target fusion region and ABL; 4 points (10^2 cps/µL – 10^5 cps/µL). The standard sets are included with the kits.
- **Starting samples:** peripheral blood or bone marrow
- **Validated PCR Real time Systems:**
  Applied Biosystems 7500 Fast (ThermoFisher SCIENTIFIC)
  Rotor-Gene Q MDx (QIAGEN)
  CFX96 Real-Time PCR Detection System (Bio-Rad)
- **Manual RNA extraction:** RNeasy Mini Kit (QIAGEN)
- **Automated RNA extraction:** CloNext 12 or CloNext 24
- **Package:** 24 tests
- **Storage:** -20°C

INFORMATION FOR ORDERS

DESCRIPTION	REF.	REGULATORY	TESTS
PML-RARA t(15;17)(q22;q21)	RT-100	CE-IVD	24 tests
AML1-ETO t(8;21)(q22;q22)	RT-101	CE-IVD	24 tests
Inv(16)(p13q22) - CBFB-MYH11	RT-102	CE-IVD	24 tests

Clonit
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AGILITY IS OUR DNA

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CE IVD

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