

PML-RAR α , t(15;17) quantitation by RT-PCR

DETECTS AND QUANTIFIES PML-RAR α FUSION TRANSCRIPTS IN PATIENTS WITH ACUTE PROMYELOCYTIC LEUKEMIA

Clinical Background

- PML-RAR α fusion transcripts are found in >97 percent of acute promyelocytic leukemia (APL) patients.
- Treating APL patients with all-trans-retinoic acid and arsenic trioxide results in complete remission in up to 95 percent of cases.
- 30 percent of APL cases that achieve complete remission undergo relapse.
- Monitoring of PML-RAR α fusion transcripts by RT-PCR is a valuable tool for detecting early relapse.

Indications for Ordering

The principal use for this test is to detect and monitor PML-RAR α fusion transcripts in patients with APL.

Limitations

- Results of this test must always be interpreted in the context of morphologic and other relevant data, and should not be used alone for a diagnosis of malignancy.
- Samples that do not show PML-RAR α may still harbor transcripts that exist in too few APL cells to be detected by this test.
- This test detects BCR1, BCR2, and BCR3 fusion transcripts but does not distinguish BCR1 from BCR2.

Methodology

- Total RNA is extracted from whole blood or bone marrow samples, reverse transcribed, and subjected to PCR amplification of BCR1/2 and BCR3 fusion products.

- A separate amplification of the ABL gene ensures RNA quality and allows data normalization.
- Normalized copy number (NCN) is calculated for BCR1/2 or BCR3 relative to ABL copy number.

Interpretation

- Not Detected: There is no evidence of the PML-RAR α fusion transcript by RT-PCR analysis. This result does not entirely exclude the presence of the PML-RAR α fusion transcript in the specimen below the detection limit of the assay.
- Positive: Copy number of PML-RAR α fusion transcripts is provided.

References

- Kern W, et al. Monitoring of minimal residual disease in acute myeloid leukemia. *Cancer* 2008;112(1):4–16.
- Rossi V, Levati L, Biondi A. Diagnosis and monitoring of PML-RARA-positive acute promyelocytic leukemia by qualitative RT-PCR. *Methods Mol Med* 2006;125:115–26.
- Ravandi F, et al. Effective treatment of acute promyelocytic leukemia with all-trans-retinoic acid, arsenic trioxide, and gemtuzumab ozogamicin. *J Clin Oncol* 2009;27(4):504–10.
- Reiter A, Lengfelder E, Grimwade D. Pathogenesis, diagnosis and monitoring of residual disease in acute promyelocytic leukemia. *Acta Haematol* 2004;112(1-2):55–67.

Test Information

2002871

PML-RAR α , t(15;17) Translocation by RTPCR, Quantitative

For specific collection, transport, and testing information, refer to the ARUP website at www.aruplab.com.

For information on test selection, ordering, and interpretation, refer to ARUP Consult[®] at www.arupconsult.com.