CytoCell

FISH Probes for AML and MDS

CytoCell FDA-cleared FISH probes

Guide to expected abnormal clinical results

AML1/ETO (RUNX1/RUNX1T1) Translocation, Dual Fusion FISH Probe Kit
Cat. No. **USA LPH-026** (AML)

Expected normal signal pattern

In a normal cell, two red and two green signals (2R, 2G) are expected.

Expected abnormal signal pattern

In a cell with a t(8;21)(q22;q22) translocation the expected signal pattern will be one red, one green and two fusions (1R, 1G, 2F).

Other signal patterns are possible in aneuploid/unbalanced specimens.

Characterization of Normal Cut-off Values*

Abnormal signal pattern	Number of samples analyzed to generate the cut-off	Number of nuclei evaluated per sample	Maximum number of false positive signal pattern	Normal cut-off value (per 200 nuclei)	Normal cut-off value (%)
1R, 1G, 2F	1290	200	1	5	2.3

*The device has not been specifically validated in patients with <20% blast count.

Del(20q) Deletion FISH Probe Kit
Cat. No. **USA LPH-020** (MDS)

Expected normal signal pattern

In a normal cell, two red and two green signals (2R, 2G) are expected.

Expected abnormal signal pattern

One red and one green signal pattern (1R, 1G) will be observed in cells with either monosomy or hemizygous deletion of both bands on 20q.

Other signal patterns are possible in aneuploid/unbalanced specimens.

Characterization of Normal Cut-off Values

Abnormal signal pattern	Number of samples analyzed to generate the cut-off	Number of nuclei evaluated per sample	Maximum number of false positive signal pattern	Normal cut-off value (per 200 nuclei)	Normal cut-off value (%)
1R, 1G	1300	200	6	12	5.7

CBFß (CBFB)/MYH11 Translocation, Dual Fusion FISH Probe Kit
Cat. No. **USA LPH-022** (AML)

Expected normal signal pattern

In a normal cell, two red and two green signals (2R, 2G) are expected.

Expected abnormal signal pattern

In a cell with an inv(16)(p13q22) or a t(16;16)(p13;q22) the expected signal pattern will be one red, one green and two fusions (1R, 1G, 2F).

Other signal patterns are possible in aneuploid/unbalanced specimens.

Characterization of Normal Cut-off Values*

Abnormal signal pattern	Number of samples analyzed to generate the cut-off	Number of nuclei evaluated per sample	Maximum number of false positive signal pattern	Normal cut-off value (per 200 nuclei)	Normal cut-off value (%)
1R, 1G, 2F	1300	200	1	5	2.3

*The device has not been specifically validated in patients with <20% blast count.

EVI1 (MECOM) Breakapart FISH Probe Kit
Cat. No. **USA LPH-036** (MDS) (AML)

The three-color strategy shows the presence of either a translocation or an inversion and allows for each different type of rearrangement to be distinguished.

Expected normal signal pattern

In a normal cell, two red/green/blue fusion signals (2RGB) are expected.

Expected abnormal signal pattern

In a cell with a t(3;3)(q21;q26.2) translocation, one red signal, one green/blue fusion signal and one red/green/blue fusion signal will be observed (1R, 1GB, 1RGB).

In a cell with an inv(3)(q21q26.2) inversion, one red/green fusion, one separate blue signal and one red/green/blue fusion signal will be observed (1RG, 1B, 1RGB).

Other signal patterns are possible in aneuploid/unbalanced specimens.

Characterization of Normal Cut-off Values

Abnormal signal pattern	Number of samples analyzed to generate the cut-off	Number of nuclei evaluated per sample	Maximum number of false positive signal pattern	Normal cut-off value (per 200 nuclei)	Normal cut-off value (%)
1R, 1GB, 1RGB	25	200	3	8	4
1RG, 1B, 1RGB	25	200	3	8	4

Del(5q) Deletion FISH Probe Kit
Cat. No. **USA LPH-024** (MDS) (AML)

Expected normal signal pattern

In a normal cell, two red and two green signals (2R, 2G) are expected.

Expected abnormal signal pattern

A cell with a hemizygous deletion of 5q31.2 will have one red and two green signals (1R, 2G).

Other signal patterns are possible in aneuploid/unbalanced specimens.

Characterization of Normal Cut-off Values

Abnormal signal pattern	Number of samples analyzed to generate the cut-off	Number of nuclei evaluated per sample	Maximum number of false positive signal pattern	Normal cut-off value (per 200 nuclei)	Normal cut-off value (%)
1R, 2G	1300	200	7	13	6.3

MLL (KMT2A) Breakapart FISH Probe Kit
Cat. No. **USA LPH-013** (MDS) (AML)

Expected normal signal pattern

In a normal cell, two red/green fusion signals are expected (2F).

Expected abnormal signal pattern

In a cell with a balanced MLL (KMT2A) rearrangement, the expected signal pattern will be one red, one green and one fusion (1R, 1G, 1F).

Other signal patterns are possible in aneuploid/unbalanced specimens.

Characterization of Normal Cut-off Values

Abnormal signal pattern	Number of samples analyzed to generate the cut-off	Number of nuclei evaluated per sample	Maximum number of false positive signal pattern	Normal cut-off value (per 200 nuclei)	Normal cut-off value (%)
1R, 1G, 1F	1600	200	3	8	3.8

Del(7q) Deletion FISH Probe Kit
Cat. No. **USA LPH-025** (MDS) (AML)

Expected normal signal pattern

In a normal cell, two red and two green signals (2R, 2G) are expected.

Expected abnormal signal pattern

One red and one green signal pattern (1R, 1G) will be observed in cells with either monosomy 7 or hemizygous deletion of both CDRs on 7q.

Other signal patterns are possible in aneuploid/unbalanced specimens.

Characterization of Normal Cut-off Values

Abnormal signal pattern	Number of samples analyzed to generate the cut-off	Number of nuclei evaluated per sample	Maximum number of false positive signal pattern	Normal cut-off value (per 200 nuclei)	Normal cut-off value (%)
1R, 1G	1300	200	9	15	7.4

P53 (TP53) Deletion FISH Probe Kit
Cat. No. **USA LPH-017** (MDS) (AML)

Expected normal signal pattern

In a normal cell, two red and two green signals (2R, 2G) are expected.

Expected abnormal signal pattern

A cell with a TP53 deletion, will have one red and two green signals (1R, 2G).

Other signal patterns are possible in aneuploid/unbalanced specimens.

Characterization of Normal Cut-off Values

Abnormal signal pattern	Number of samples analyzed to generate the cut-off	Number of nuclei evaluated per sample	Maximum number of false positive signal pattern	Normal cut-off value (per 200 nuclei)	Normal cut-off value (%)
1R, 2G	1600	200	8	14	6.8

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[1]See disease indication roundels. (AML) Acute myeloid leukemia (MDS) Myelodysplastic syndromes