**FISH Guide**

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**Notes**
All MetaSystems human FISH probes are classified as IVD products in the EU according to the In-Vitro Diagnostic Medical Device Directive 98/79/EC and are CE labeled, unless otherwise indicated in the product description. Use all MetaSystems Probes products only within the scope of the intended use! FISH analysis is used as an adjunct test to other diagnostic investigations and not to be used as sole base for diagnosis or therapy decisions. Some products may not be available in all markets.

**Literature**
Grinde et al. (2016) Blood 127:29-41
Dehner et al. (2015) Blood 125:2449-2457
Sawtell et al. (2017) WHO Classification of Tumours of Haematopoietic and Lymphoid Tissues (Revised 4th edition)
Elias et al. (2016) Leukemia 30:1851-1857

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**Ordering Information**

<table>
<thead>
<tr>
<th>Product</th>
<th>Size</th>
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<tr>
<td>XL 5q31/5q33</td>
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<td>D-5065-100-OG</td>
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<td>XL 5q31/5q33</td>
<td>100µl</td>
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<td>D-5089-100-OG</td>
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<td>XL TP53/NF1</td>
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<tr>
<td>XL t(3;3)(q21.3;q26.2), GATA2, MECOM</td>
<td>100µl</td>
<td>D-5125-100-TC</td>
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<tr>
<td>XL t(4;7)(p21.3;q36)</td>
<td>100µl</td>
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<td>XL t(4;7)(p21.3;q36)</td>
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<td>D-5125-100-TC</td>
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<td>XL t(6;9)(p23;q34.1), DEK-NUP214</td>
<td>100µl</td>
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The highlighted probes are not yet available, but will be offered soon. This kit is also offered in 60µl and 600 µl sizes.

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**MetaSystems FISH Probe Acute Myeloid Leukemia**


The WHO category ‘AML with recurrent genetic abnormalities’ recognizes eight balanced translocations and inversions. Whereas a blast count of ≥20% is required for the diagnosis AML in general, the presence of characteristic genetic alterations allows for the diagnosis of AML, without regard to cell blast count. Translocations and inversions often result in frame fusions between the genes involved and can be detected by appropriate FISH probes. MetaSystems FISH probes provide fast results are required, chromosome banding analysis has failed. If a submicroscopic rearrangement, cryptic or chromosome banding analysis, is suspected or to confirm or exclude chromosome rearrangements with prognostic implications if their presence is in doubt.

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<td>XL BCR/ABL1</td>
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<td>D-0125-120-OG</td>
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<td>XL BCR/ABL1 plus</td>
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<tr>
<td>XL CBFB/MYH11</td>
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<td>D-5052-100-OG</td>
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The molecular landscape in AML patients provides important prognostic and therapy relevant information. Differences in event-free and overall survival in AML patients are, to a large extent, the result of particular genetic lesions. Current risk stratification strategies combine cytogenetics, FISH and key mutations analysis in the decision-making process. Two widely accepted stratification schemes are the recommendations of the European LeukemiaNet (ELN) 2017 and a study based on analysis of patients treated in successive United Kingdom national AML trials for younger adults. The presence, absence or combination of certain structural rearrangements and gene mutations assign patients to one of the three prognostic risk groups - favorable, intermediate or adverse.

### AML risk category 'Favorable'

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<tr>
<th>ELN risk stratification</th>
<th>Independent prognostic risk stratification in younger adults</th>
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</tr>
</thead>
<tbody>
<tr>
<td>1. t(8;21)(q22;q22), RUNX1-RUNX1T1</td>
<td>t(11;q23.3), KMT2A-mutated</td>
<td>n.a.</td>
</tr>
<tr>
<td>2. t(16;16)(p13;q22), CBFB-MYH11</td>
<td>n.a.</td>
<td>n.a.</td>
</tr>
<tr>
<td>3. t(16;16)(p13.1;q22); CBFB-MYH11</td>
<td>t(9;11)(p21.3;q23.3); MLLT3/KMT2A</td>
<td>n.a.</td>
</tr>
<tr>
<td>4. FLT3-ITD &amp; NPM1 mutation (in absence of FLT3-ITD or DNMT3A mutation)</td>
<td>n.a.</td>
<td>n.a.</td>
</tr>
<tr>
<td>5. Wild-type NPM1 and FLT3-ITD (≥ 0.5)</td>
<td>n.a.</td>
<td>n.a.</td>
</tr>
<tr>
<td>6. t(11;19)(q23;p13), CBFB/MYH11</td>
<td>n.a.</td>
<td>n.a.</td>
</tr>
<tr>
<td>7. Wild-type NPM1 with FLT3-ITD or with FLT3-ITD (≥ 0.5)</td>
<td>n.a.</td>
<td>n.a.</td>
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</table>

### AML risk category 'Intermediate'

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<th>ELN risk stratification</th>
<th>Independent prognostic risk stratification in younger adults</th>
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</thead>
<tbody>
<tr>
<td>1. t(5;11)(q35;p15.5)/NUP98-NSD1</td>
<td>t(5;11) NSD1/NUP98 DF, D-5141-100-OG; XL NUP98, D-5077-100-OG</td>
<td>n.a.</td>
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<tr>
<td>2. Wild-type NPM1 and FLT3-ITD (≥ 0.5)</td>
<td>n.a.</td>
<td>n.a.</td>
</tr>
<tr>
<td>3. t(11;19)(q23;p13), MLLT3/MLT2A</td>
<td>n.a.</td>
<td>n.a.</td>
</tr>
<tr>
<td>4. Wild-type NPM1 with FLT3-ITD or with FLT3-ITD (≥ 0.5)</td>
<td>n.a.</td>
<td>n.a.</td>
</tr>
<tr>
<td>5. t(11;19)(q23;p13), MLLT3/MLT2A</td>
<td>n.a.</td>
<td>n.a.</td>
</tr>
<tr>
<td>6. Wild-type NPM1 and FLT3-ITD (≥ 0.5)</td>
<td>n.a.</td>
<td>n.a.</td>
</tr>
<tr>
<td>7. t(9;22)(q34;q11)/BCR-ABL</td>
<td>n.a.</td>
<td>n.a.</td>
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<tr>
<td>8. t(9;22)(q34;q11)/BCR-ABL</td>
<td>n.a.</td>
<td>n.a.</td>
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### AML risk category 'Adverse'

<table>
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<th>Independent prognostic risk stratification in younger adults</th>
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<tbody>
<tr>
<td>1. t(8;21)(q22;q22), RUNX1-RUNX1T1</td>
<td>t(11;q23.3), KMT2A-mutated</td>
<td>n.a.</td>
</tr>
<tr>
<td>2. t(16;16)(p13;q22), CBFB-MYH11</td>
<td>n.a.</td>
<td>n.a.</td>
</tr>
<tr>
<td>3. t(16;16)(p13.1;q22); CBFB-MYH11</td>
<td>t(9;11)(p21.3;q23.3); MLLT3/KMT2A</td>
<td>n.a.</td>
</tr>
<tr>
<td>4. FLT3-ITD &amp; NPM1 mutation (in absence of FLT3-ITD or DNMT3A mutation)</td>
<td>n.a.</td>
<td>n.a.</td>
</tr>
<tr>
<td>5. Wild-type NPM1 and FLT3-ITD (≥ 0.5)</td>
<td>n.a.</td>
<td>n.a.</td>
</tr>
<tr>
<td>7. t(11;19)(q23;p13), MLLT3/MLT2A</td>
<td>n.a.</td>
<td>n.a.</td>
</tr>
<tr>
<td>8. t(11;19)(q23;p13), MLLT3/MLT2A</td>
<td>n.a.</td>
<td>n.a.</td>
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</tbody>
</table>

1. Döhner et al., 2017; 2. Arber et al., 2016; 3. Without adverse risk genetic lesions; 4. The presence of t(8;16)(p11.2;p13) takes precedence over t(11;19)(q23;p13) and t(9;22)(q34;q11), i.e., 5. (8;16)(p11.2;p13) > t(11;19)(q23;p13) > t(9;22)(q34;q11), m5c or m5c/m4, with or without NUP214/DEK. 6. Defined by the presence of 2 or more chromosomal abnormalities by G-banding analysis. 7. Complex karyotype is defined as >4 unrelated abnormalities in the absence of recurrent chromosomal abnormalities. 8. Mutations are defined as those resulting in a loss of function. 9. The highlighted probes are not yet available, but will be soon.
The molecular landscape in AML patients provides important prognostic and therapy relevant information. Differences in event-free and overall survival in AML patients are, to a large extent, the result of particular genetic lesions. Current risk stratification strategies combine cytogentic, FISH and key mutations analysis in the decision making process. Two widely-accepted stratification schemes are the recommendations of the European LeukemiaNet (ELN) 2017 and a study based on analysis of patients treated in successive United Kingdom national AML trials for younger adults. The presence, absence or combination of certain structural rearrangements and gene mutations assign patients to one of the three prognostic risk groups: favorable, intermediate or adverse.

### AML risk category: Favorable

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<tr>
<td>1. Döhner et al, 2017 6. Defined by the...</td>
<td>t(8;21), inv(16) or t(16;16), t(9;11), t(v;11)(v;q23.3), t(6;9), inv(3) or t(3;3); AML with BCR-ABL1; presence of 1 single monosomy (excluding loss of X or Y) in association with at least 1 additional monosomy or structural...</td>
<td>MetaSystems FISH Probe</td>
</tr>
</tbody>
</table>

#### MetaSystems FISH Probe

- ELN: BCR/ABL1 plus, BCR/ABL1/ASS
- XLL RARA BA
- XLL RUNX1
- XLL CBFB/MYH11 plus
- XLL CBFB
- XLL TP53/17cen, XLL TP53/NF1
- XLL 5q31/5q33, XLL 5q31/5q33/5p15, XLL Del(5)(q31), XLL Del(5)(q33)
- XLL 7q22/7q36, XLL del(7)(q22q31), XLL del(7q22q36)
- XLL 11q23 (excluding t(9;11)(p21~22;q23) and t(11;19)(p13;q13.2); BCR-ABL1
- XLL MLLT3/KMT2A DF, XLL t(9;11) MLLT3/KMT2A DF, XLL t(11;19) KMT2A/MLLT1 DF
- XLL t(11;19) KMT2A/ELL DF
- XLL t(6;9) DEK/NUP214
- XLL TP53/17cen, XLL TP53/NF1
- XLL 24XCyte (Human Multicolor FISH)

### AML risk category: Intermediate

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<tr>
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<th>Metasystems FISH Probe</th>
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<tr>
<td>2. Grimwade et al, 2016; 3. Without adverse-risk genetic lesions; 4. The presence of the t(11;19)(p21~22;q13) takes precedence over rare, consistent adverse-risk gene mutations; 5. 11q23; 6. Defined by the presence of a single monosomy (excluding loss of X or Y) in association with at least 1 additional monosomy or structural chromosome abnormalities excluding one (or both) of 5q and/or 7q; 7. Monosomy should not be counted as an adverse prognostic marker if it occurs with favorable-risk AML, cytogenetics, 2. Structural...</td>
<td>MetaSystems FISH Probe</td>
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#### MetaSystems FISH Probe

- XLL RUNX1
- XLL CBFB/MYH11 plus
- XLL CBFB
- XLL TP53/17cen, XLL TP53/NF1
- XLL 5q31/5q33, XLL 5q31/5q33/5p15, XLL Del(5)(q31), XLL Del(5)(q33)
- XLL 7q22/7q36, XLL del(7)(q22q31), XLL del(7q22q36)
- XLL 11q23 (excluding t(9;11)(p21~22;q23) and t(11;19)(p13;q13.2); BCR-ABL1
- XLL MLLT3/KMT2A DF, XLL t(9;11) MLLT3/KMT2A DF, XLL t(11;19) KMT2A/MLLT1 DF
- XLL t(11;19) KMT2A/ELL DF
- XLL t(6;9) DEK/NUP214
- XLL TP53/17cen, XLL TP53/NF1
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### AML risk category: Adverse

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<td>5. t(8;21), inv(16) or t(16;16), t(9;11), t(v;11)(v;q23.3), t(6;9), inv(3) or t(3;3); AML with BCR-ABL1; presence of 1 single monosomy (excluding loss of X or Y) in association with at least 1 additional monosomy or structural...</td>
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- XLL CBFB
- XLL TP53/17cen, XLL TP53/NF1
- XLL 5q31/5q33, XLL 5q31/5q33/5p15, XLL Del(5)(q31), XLL Del(5)(q33)
- XLL 7q22/7q36, XLL del(7)(q22q31), XLL del(7q22q36)
- XLL 11q23 (excluding t(9;11)(p21~22;q23) and t(11;19)(p13;q13.2); BCR-ABL1
- XLL MLLT3/KMT2A DF, XLL t(9;11) MLLT3/KMT2A DF, XLL t(11;19) KMT2A/MLLT1 DF
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### Independent prognostic risk stratification in younger adults

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<td>Favorable</td>
<td>t(8;21)/PBX1; RUNX1</td>
<td>MetaSystems FISH Probe</td>
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<tr>
<td>Intermediate</td>
<td>Wild-type NPM1 and FLT3-ITD (≥ 0.5) or Monosomy 5/7</td>
<td>MetaSystems FISH Probe</td>
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<tr>
<td>Adverse</td>
<td>Wild-type NPM1 (ex. T22;21; q22;q21)/RUNX1-RUNX1T1</td>
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- XLL 7q22/7q36, XLL del(7)(q22q31), XLL del(7q22q36)
- XLL 11q23 (excluding t(9;11)(p21~22;q23) and t(11;19)(p13;q13.2); BCR-ABL1
- XLL MLLT3/KMT2A DF, XLL t(9;11) MLLT3/KMT2A DF, XLL t(11;19) KMT2A/MLLT1 DF
- XLL t(11;19) KMT2A/ELL DF
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Literature
note

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www.metasystems-probes.com

**FISH GUIDE**

**Acute Myeloid Leukemia FISH Guide**

The WHO category ‘AML with recurrent genetic abnormalities’ recognizes eight balanced translocations and inversions. Whereas a blast count of ≥20% is required for the diagnosis AML in general, the presence of ≥15% blasts allows the diagnosis of AML, without regard to cell count. Translocations and inversions often result in intrachromosomal, interchromosomal, genetic abnormalities that can be detected by appropriate FISH or CGH analysis. However, when fast results are required, chromosome banding analysis has failed, if a submicroscopic rearrangement, cryptic by chromosome banding analysis, is suspected or to confirm or exclude chromosomal rearrangements with prognostic implications if their presence is in doubt.

Notes

All MetaSystems human FISH probes are classified as IVD products in the EU according to the In-Vitro Diagnostic Medical Device Directive 98/79/EC and are CE labeled, unless otherwise indicated in the product description. Use all MetaSystems Probes products only within the scope of the intended use! FISH analysis is used as an adjunct test to other diagnostic investigations and not to be used as sole base for diagnosis or therapy decisions. Some products may not be available in all markets.

Probes

**Ordering Information**

**Probes**

**Notes**

Swerdlow et al. (2017) *WHO Classification of Tumours of Haematopoietic and Lymphoid Tissues (Revised 4th edition)*

Döhner et al. (2017) *Blood* 129:424-447

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Rack et al. (2019) *Leukemia* 33:1851-1867

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**Literature**

Gräbe et al. (2016) *Blood* 127:29-41

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