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21.08.2018

## Field Safety Notice:

**Product Category:** Fluorescent labeled DNA probe  
**Reference Number:** D-5124-100-OG and D-5124-999-OG  
**Product Name:** XL t(3;3) GATA2/MECOM DF  
**Affected Lots:** 20191, 20191-A

Dear valued customer and distributors,

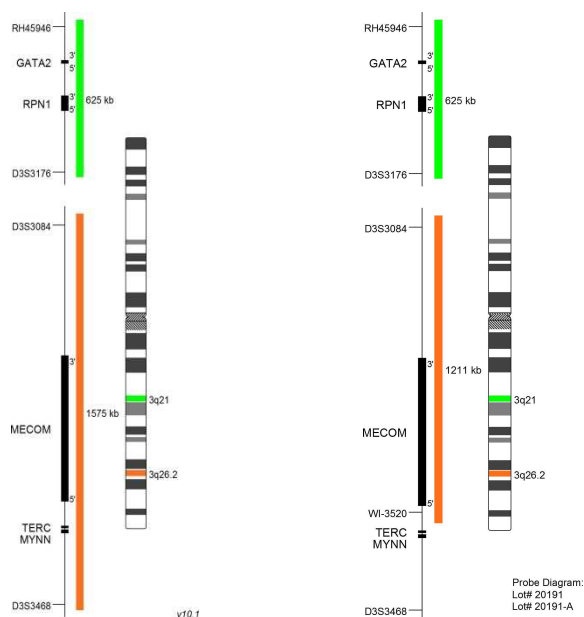
in the course of a quality checkup we found that the orange labeled part of the products **D-5124-100-OG** and **D-5124-999-OG**, Lots **20191** and **20191-A**, delivered from 06/18 to 08/18, is distally shorter than expected and does not match the indicated size in the probe map of the respective product insert.

### Product Specification:

XL t(3;3) GATA2/MECOM DF is designed as a dual fusion probe. The orange labeled probe spans the breakpoint at 3q26 (MECOM), the green labeled probe spans the breakpoint at 3q21 (GATA2 and RPN1).

### Technical Details:

The orange labeled component of the probe is listed being 1575kb while the actual size of the orange component, delivered with Lots 20191 and 20191-A, is 1211kb. As a consequence, the orange component does not extend up to marker D3S3468, but only up to marker WI-3520 (see maps below). Next generation sequencing and breakpoint mapping studies at chromosomal location 3q26.2 have identified two breakpoint clusters characteristic for inversion and translocations, respectively. Inversions account for about 45% of all patients harboring a 3q26 rearrangement whereas translocations are less common with a frequency of about 19%. Breakpoints in inv(3) cases are clustered within or centromeric to the EVI1 gene, breakpoints in t(3;3) cases are located upstream to EVI1 in the MECOM gene locus. In rare cases, translocation breakpoints distal to MECOM can occur.



### Conclusions:

The majority of breakpoints are located within the region covered by the affected probe and the described signal pattern will be observed. Unexpected signal pattern occur only if breakpoints are located distal to MECOM. In these cases a t(3;3) will result in a signal pattern of 2G1O1GO. A translocation with a breakpoint distal to MECOM and a partner other than chromosome 3 will result in a signal pattern of 2G2O. Thus, in this relatively unlikely event, a false-negative result is obtained.

### Recommended Action:

Please do not use the product D-5124-100-OG or D-5124-999-OG, Lots 20191 and 20191-A, for analysis. We already have informed you by phone to discard the vials. We will provide the replacement product shortly and recommend the re-analysis of cases tested with Lots 20191 or 20191-A.

### Literature:

Bobadilla et al (2007) Brit J Haematol 136:806-813  
 De Braekeleer et al (2011) Anticancer Res 31:3441-3448  
 Gröschel et al (2014) Cell 157:369-381  
 De Braekeleer (2015) Fut Oncol 11:1675-1686  
 De Braekeleer et al (2015) Blood Cells Mol Dis 54:160-163

### Acknowledgement of Receipt:

Please confirm with your signature that you have received and understood the information above.

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Date

Position

Name

Please return this document to MetaSystems Probes by mail, email or FAX to the address in the letterhead.