

February 2025

## Important Notice: *ipsogen* BCR-ABL1 mbc Kit and *ipsogen* WT1 ProfileQuant Kit LOTs with incorrect ABL Control Gene Standard Dilutions

Dear valued customer,

We are writing to inform you that we have identified *ipsogen* kit LOTs that could contain incorrect ABL Control Gene Standard Dilutions.

Based on our records, you have received at least one of the affected kit LOTs listed in this table:

Catalog number (REF)	Kit	LOT numbers affected
670023	<i>ipsogen</i> BCR-ABL1 mbc Kit CE	97800183
676923	<i>ipsogen</i> WT1 ProfileQuant Kit CE	97800477 97800560

Affected Kit components of the affected kits:

Affected Kit component	Tube label	Material number	Affected LOT number
ABL Control Gene Standard Dilution (10 <sup>4</sup> copies/5 µL)	C2-ABL	1071635	97800161
ABL Control Gene Standard Dilution (10 <sup>5</sup> copies/5 µL)	C3-ABL	1071636	97800162

### Description of the issue

Investigations done at QIAGEN revealed that the ABL Control Gene Standard Dilution (10<sup>4</sup> copies/5 µL) (C2-ABL) and/or the ABL Control Gene Standard Dilution (10<sup>5</sup> copies/5 µL) (C3-ABL) contained in the above listed kit LOTs may not perform as expected.

The following failure patterns might occur with the affected kit LOTs:

- ABL Control Gene Standard Dilution (10<sup>4</sup> copies/5 µL) (C2-ABL) could lead to the same Ct value as the ABL Control Gene Standard Dilution (10<sup>3</sup> copies/5 µL) (C1-ABL). When using such an affected C2-ABL, the ABL Standard curve R<sup>2</sup> value will be out of its quality criteria.

- ABL Control Gene Standard Dilution ( $10^5$  copies/5  $\mu$ L) (C3-ABL) could lead to the same Ct value as the ABL Control Gene Standard Dilution ( $10^3$  copies/5  $\mu$ L) (C1-ABL). In these cases, the ABL Standard curve  $R^2$  value and the slope of the curve will be out of the quality criteria.

For reference, the quality criteria in the respective Handbooks are:

“A slope between  $-3.0$  and  $-3.9$  is acceptable as long as  $R^2$  is  $>0.95$ . However, a value for  $R^2 >0.98$  is desirable for precise results.”

### Consequence of the issue:

The ABL standard curves obtained with an affected C2-ABL or C3-ABL tube will not meet all quality criteria as described in the respective handbook and should therefore not be used for sample interpretation. The calculated NCN (Normalized Copy Number) results obtained with an affected run will be incorrect and should not be reported.

Only a percentage of tubes of the ABL Control Gene Standard Dilution C2-ABL or C3-ABL contained in the above listed kit LOTs is affected of the issue.

Runs for which the ABL Standard curve  $R^2$  value and slope value of the curve are both within the acceptable quality criteria are not affected by the issue.

### Potential risk associated with this issue

The issue would essentially cause delayed results as the affected ABL standard curves should not be used for sample interpretation and the testing has to be repeated.

### Actions to be taken by customer/user

- Forward this information to all users of the above-mentioned product in your organization. If you are not the end-user, please forward it to the end-user.
- Verify that the ABL standard curves obtained with the affected kit LOTs meet all quality criteria as described in the respective Handbooks.
- Results from runs with ABL standard curves that don't meet any quality criterium as described in the respective Handbooks should not be used.
- Do not use the remaining stock of the above listed kit LOTs. Dispose of these LOTs immediately in accordance with your national and local safety and environmental regulations.
- Review this notice with your laboratory manager/medical doctor.
- To obtain a free-of-charge replacement, please contact your local QIAGEN Technical Service Department.



## Actions for Commercial Partners

Forward this Important Notice to your customers.

## Actions taken by QIAGEN

The root cause was identified and revealed that no other LOTs of the above-mentioned material is affected.

If you have any questions or concerns regarding this matter, please contact your local QIAGEN Technical Service Department.

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We apologize for any inconvenience this may cause and thank you in advance for your cooperation.

Regards,

QIAGEN

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