

Sanquin Reagents B.V.
Plesmanlaan 125
1066 CX Amsterdam
Postbus 9190
1006 AD Amsterdam
The Netherlands
www.sanquin.org/reagents

IBAN: NL19ABNA0524629471
BIC: ABNANL2A
CoC Amsterdam 67177565

Date 26 October 2017
Reference # GD/26-10-2017

Telephone +31 20 512 3507
Mobile +31 6 82452042
E-mail g.vandongen@sanquin.nl

Urgent Field Safety Notice ref.no. 103549

Concerns: K1148 – Screening panel 123, lot **8000242932** with expiry date **2017-11-23**
K7210 – Cellbind P3, lot **8000242940** with expiry date **2017-11-23**
K7211 – Cellbind P3-P, lot **8000242941** with expiry date **2017-11-23**
K5010 – Column Screen 123, lot **8000242937** with expiry date **2017-11-23**

Dear distributor,

Your customers have one or more of the above-mentioned screening panels in use at the moment. A quality check has revealed that cell 3 of these panels (donor code 384549) is erroneously displayed on the antigram as K positive and Le(a) positive, whereas both antigens are negative for this cell 3. We are currently investigating the cause of this. Attached you can find the full antigen profile of this cell 3 received by you.

Becoming effective immediately this cell 3 can only be used for antibody screening provided an additional cell which is positive for the K and Le(a) antigen is used as well. We will send you a replacement cell 3 with the originally intended antigen profile as soon as possible. The K3005 PeliPIP software cannot be used until your customers have received this replacement cell 3.

For now, for antibody screening your customers could use, if available to them, cell 1, cell 2, and/or cell 8 as an additional cell, respectively, of the following identification panels, all with expiry date 2017-11-23:

K1385 Makropanel 16 (lot 8000242934)
K7230 Cellbind ID16 (lot 8000242942)
K7231 Cellbind ID16-P (lot 8000242943)
K5020 Column panel 16 (lot 8000242938)

These cells are positive for the K and Le(a) antigen.

If these identification panels are not at your customers' disposal it would be wise to contact our Marketing department (mobile: +31 6 82452042) as soon as possible in order to obtain a replacement cell 3. As known a Le(a) antibody is clinically not relevant. Until receipt of a replacement cell 3, we advise your customers to select K negative blood for a

blood transfusion and to undertake a complete crossmatch test, if also recommended by the attending physician.

Furthermore, we advise your customers to check their databases as soon as possible whether K positive blood has been released for transfusion, as of the first use of above mentioned cell 3 up to now of the screening panels involved, since there is a risk that this release was based on a false negative antibody screening test.

Should the latter be the case we advise your customers to repeat the antibody screening tests performed with a cell positive for the K and Le(a) antigen.

We kindly request you and your customers to destroy the erroneous cell 3 of the above mentioned screening panels after having received the replacement cell 3 and to confirm this to us by filling out and returning the attached questionnaire to us.

We have already started the production of a replacement cell 3 (K and Le(a) positive) which will be sent to you ultimately on Friday 27 October 2017 in order to replace cell 3 delivered to you(r customers). The lot numbers of the replacement cell 3 are, respectively:

8---242932 (K1148 Screening panel 123);

8---242940 (K7210 Cellbind P3);

8---242941 (K7211 Cellbind P3-P) and

8---242937 (K5010 Column Screen 123).

The replacement cell 3 of the Cellbind cell panels can be used normally in the Magister fully automated system.

NOTE: the '000' in the lot number is replaced by '---' in order to identify the correct cell.

Should you have any questions, please contact Mr. De Jong, Customer Relations Manager (mobile: +31 6 51296268).

Our sincere apologies for any inconvenience caused.

With kind regards,



Harry Bos
General Director



Kees Keuning
QA/QC Officer



Rianne Koopman
Manager Department
of Transfusion Medicine

Attachment: Antigen profile erroneous cell 3
Questionnaire

Form, with reference to Urgent Field Safety Notice 103549

Please fill in this form, sign and e-mail to reagentsorders@sanquin.nl

Please return this form within 3 working days after you have received the replacement cell 3.

Productcode, productname, lotnumber and expiry date	Number of vials of cell 3 received	Number of vials of cell 3 used	Number of vials of cell 3 destroyed
K1148 – Screening panel 123, lot 8000242932, expiry date 2017-11-23			
K7210 – Cellbind P3, lot 8000242940, expiry date 2017-11-23			
K7211 – Cellbind P3-P, lot 8000242941, expiry date 2017-11-23			
K5010 – Column Screen 123, lot 8000242937, expiry date 2017-11-23			

Name distributor / hospital:

Name signatory:

Position:

Signature:

Date:

Screening panel 123 K1148 **LOT** 8000xxxxxx **CE 0344**
Column screen 123 K5010 **LOT** 8000xxxxxx **CE 0344**
Cellbind P3 K7210 **LOT** 8000xxxxxx **CE 0344**
Cellbind P3-P K7211 **LOT** 8000xxxxxx **CE 0344**



Sanquin Reagents B.V.	Phone: +31 20 5123599
Plesmanlaan 125	Fax: +31 20 5123570
1066 CX Amsterdam	Reagents@sanquin.nl
The Netherlands	www.sanquin.org/reagents

IVD yyyy-mm-dd

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+ = positive; положительн; pozitivní; positiv; positif; θετικ; positivo; positive; pozitiv; positivo; pozitiv; pozytywny; positivo; pozitiv; pozitivne; positiv
 o = negative; отрицателн; negativní; negativ; negativ; αρνητικ; negativo; négative; negativ; negativo; negativ; negatywny; negativo; negativ; negativny; negativ
 / = not tested; не е тестван; netestováno; ikke testet; nicht getestet; δεν έχει δοκιμαστεί; no analizado; non testée; nem tesztelt; non analizzato; nav pārbaudīts; nie testowane; não testado; netestat; netestované; inte testad
 w = weak; слаби; slabý; svag; schwach; αδενής; débil; positive faible; gyenge; debole; vāj; slaby; fraco; slab; slabý; svag
 s = strong; силно; silný; stærk; stark; ισχυρή; fuerte; positive forte; erősen; forte; spēcīga; silny; forte; puternic; silny; kraftig
ID = donor number; брой на донорите; počet dárců; donornummer; Donor-ID; αριθμός δότη; número de donante; numéro du donneur; donor száma; numero del donatore; donoru skaitis; liczba dawców; número do dador; numărul de donator; počet darcov; donaturnummer