



Cressier, October 07th, 2019
Channel Partner/Customer Field Action Letter_FA- 2019-06

Subject: Field action ID-Diacell I-II-III lot 45184.85.1

Dear Valued Channel partner and Customer, cc Chairman Medical Board and relevant Head of Departments

We have been made aware that the cell III of the ID-Diacell-I-II-III lot mentioned in the table below presents a Quality issue. The cell III of this lot shows a positive DAT.

Following the guidelines implemented in your laboratory, a positive DAT leads to further investigation before any transfusion. This situation could cause a potential delay in reporting final results.

We kindly advise you to stop using and scrap this lot of ID-Diacell I-II-III:

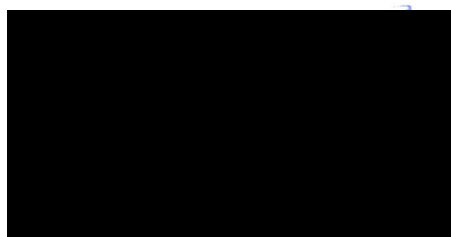
Product UDI	Product Name	CATALOG N°	Serial/ Lot No	Expiry Date
45184	ID Diacell I-II-III	004310	45184.85.1	21.10.2019

Please note that the below lot is available for replacement by ordering through the usual channels, quoting this field action reference number.

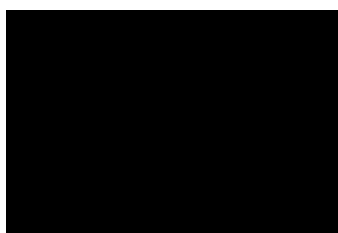
Product UDI	Product Name	CATALOG N°	Serial/ Lot No	Expiry Date
45184	ID Diacell I-II-III	004310	45184.05.1	18.11.2019

We apologize for any inconvenience this might have caused to you and your organisation. If you require any additional information on this matter then please kindly contact your local Bio-Rad contact quoting this field action.

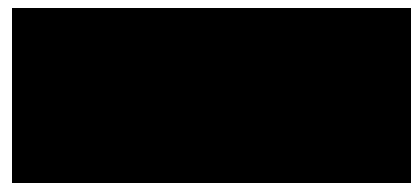
Yours sincerely,



Hiba Temimi
Immuno Hematology Division
QA complaint officer



Remco Tieleman
Immuno Hematology Division
Divisional Customer Service Manager



Audrey hinderer
Immuno Hematology Division
RA specialist