

Urgent Field Safety Corrective Action concerning QConnect HIVp24

Date: 29 May 2018

Product: **QConnect HIVp24**
Lot DM17085

included in the following kits:

REF: SR01103 Lot: DM17148 (4 x 2.5 mL Lot DM17085)
REF: SR01105 Lot: DM17150 (1 x 1 mL Lot DM17085)

**Explanation and
consequence on
patient results:**

The HIVp24 values of the QConnect HIVp24 positive control lot DM17085 showed reduced or negative values when tested with the Siemens ADVIA Centaur HIV Ag/Ab Combo Assay. These results were confirmed by internal control tests.

Negative results were only obtained with the Siemens ADVIA Centaur. All other tests which may be used for QConnect HIVp24 (Abbott Architect HIV Ag/Ab Combo, Abbott PRISM HIV Ag/Ab Combo, DiaSorin Liaison XL MUREX HIV Ag/Ab und Roche Elecsys HIV Combi PT ECLIA) are not affected by the problem and show expected positive results. For these tests the control can be used without restrictions.

Patient results are not affected. QConnect HIVp24 is an external quality control to scrutinise the assays through an additional control beside the internal quality control.

**Actions to be
taken by the
user:**

- Please check if you are using the QConnect HIVp24 control Lot DM17085 (included in the kits DM17148 and DM17150) or have it on stock.
- The mentioned lot DM17085 is not more suitable for use with Siemens ADVIA Centaur.
- Lot DM17085 may be used with Abbott Architect, Abbott PRISM, DiaSorin Liaison XL MUREX and Roche Elecsys according to the instructions of use without any restrictions.
- To request replacement material or get a credit note please contact the DiaMex GmbH or your local distributor.
- Please pass this notice on to all those who need to be aware within your organization or to any organization where the potentially affected products listed above have been transferred to.
- If you have given the products to third parties, please forward a copy of this information.
- Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.
- Please confirm receipt of this message by completing the enclosed acknowledgement of receipt and return it by e-mail.

**Kontakt-
information:**

We apologize for any inconvenience this field safety notice might have caused. We actually carry out investigations to solve the problems.

The Paul-Ehrlich-Institute (63225 Langen, Germany) has received a copy of this field safety notice as the responsible federal authority.

If you have further questions concerning this notice please contact the DiaMex GmbH or your local distributor.

Best regards

DiaMex GmbH



Dr. Dirk Podlich

Safety representative for medical devices
podlich@diamex.com
+49(0)6221-894669-18

Annex: Confirmation form

We kindly ask you to fill out this form to confirm that you received the Field Safety Corrective Action and send it back per e-mail until 12 June 2018 to: info@diamex.com

**Confirmation form for users
Field Safety Corrective Action concerning
QConnect HIVp24 , lot DM17085**

We herewith confirm the receipt of the Field Safety Corrective Action.

I have read, understood and carried out the advice on actions to be taken.

Date: _____

Signature: _____

(By signing this document you confirm that you have received and understood this corrective action)

Name: _____

Title: _____

Company/Institution: _____