

10 May 2016

Our reference: FSCA 2827

Dear

IMPORTANT : URGENT FIELD SAFETY NOTICE

ARGENE® reagents and Rotor-Gene consumable interaction

Our records indicate that your laboratory performs Real Time PCR tests using one or more of the ARGENE® products referenced in the following table.

REF #	Product Name	REF #	Product Name
69-010B	ADENOVIRUS R-gene KIT®	69-002B	EBV R-gene®
69-013B	BK VIRUS R-gene KIT®	69-003B	CMV R-gene®
69-004B	HSV1 HSV2 VZV R-gene KIT®	69-100B	CMV HHV6,7,8 R-gene®
68-006	QUANTI FluA QS r-gene®	69-019B	Parvovirus B19 R-GENE®
68-008	QUANTI HHV8 QS r-gene®	69-005B	Enterovirus R-gene®
69-100R6	HHV6 Premix r-gene®	71-012	Bordetella parapertussis r-gene®
69-100R7	HHV7 Premix r-gene®	71-040	Influenza A/B r-gene®
69-100R8	HHV8 Premix r-gene®	71-041	RSV/hMPV r-gene®
71-106	CELL Control r-gene®	71-042	Rhino&EV/Cc r-gene®
71-020	PARECHOVIRUS r-gene®	71-043	AdV/hBoV r-gene®
71-045	HCoV/PIV r-gene®	71-044	Chla/Myco pneumo r-gene®
71-015	HSV1 r-gene®	71-046	Legio pneumo/Cc r-gene®
71-016	HSV2 r-gene®	71-300	FLU A(M) & H1N1 2009 r-gene®
71-017	VZV r-gene®	69-011B	Bordetella R-gene®



Description of the issue

The use of the ARGENE[®] reagents on RotorGene system was validated during reagent development using the RotorGene consumable “Strips 4 tubes”. This specification on RotorGene consumable associated with ARGENE reagent performance has not been specified in ARGENE reagents IFU.

Following a customer complaint and an internal investigation, it has been confirmed that an interaction between the other RotorGene disposables (such as individual tubes and RotorDisk) could cause validation issues (control samples and/or Internal Control out of range or unreadable curves as not sigmoidal as expected). For the tests including HSV2 parameter, the test’s sensibility is reduced due to the interaction with the consumable causing low positive results to shift to (false) negative results.

NOTE: The rate of valid runs when using consumable different from Strips 4 tubes is greatly reduced (50% only of the run is valid) alerting the user about possible issues with the kit.

Impact:

There is a potential risk to cause delayed results considering the incompatibility between the reagents and the consumable appears immediately and could lead to invalid results. Considering that the configuration is not validated, by definition, it could lead to unexpected results. In relation to HSV2 tests, there is the risk to release a false negative result. To be noted that the probability to obtain a false result associated to a valid run has been estimated as remote.

Required actions:

We request you to take the following actions at this time:

- Please distribute this information to all appropriate personnel in your laboratory, retain a copy in your files, and forward this information to all parties that may use this product, including others to whom you may have transferred our product.
- Validate the use of the other consumables than Strips 4 tubes in your applications, in case you would like to continue using them on the Rotor-Gene system in conjunction with ARGENE[®] reagents.
- **Complete and return the Acknowledgement Form in Attachment A for the attention of Customer Service to fax number 0044 (0) 1256 816863.**

We can advise that the Competent Authority has been informed of this action.

bioMérieux is committed to providing our customers with the highest quality product possible. We sincerely apologise for any inconvenience that this may have caused you. If you require additional assistance or have any questions, please contact our Technical Service Department on 0044 (0) 1256 461881.

Yours sincerely

Customer Service Department





Attachment A: Acknowledgement Form.

URGENT PRODUCT CORRECTION NOTICE

FSCA 2827 – Argene reagents and RotorGene consumable interaction

In order to comply with Competent Authority Regulations it is important that you complete and return this acknowledgement Form

To be returned for the attention of Customer Service to fax number 0044 (0) 1256 816863

- I acknowledge receipt of the bioMérieux letter regarding the “Argene Reagents and RotorGene consumable interaction”
- I will implement the required actions as indicated in the Urgent Field Safety Notice
- Have you received reports of illness or injury related to the ARGENE® Reagents and Rotor-Gene consumable interaction?

Comments :

In order to comply with Competent Authority Regulations it is important that you complete and return this acknowledgement Form

DATE.....

SIGNATURE :

A

