

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 in conjunction with one or more easySTREAM® system, and with Rotor-Gene system.

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



### **Description of the issue**

The use of the ARGENE<sup>®</sup> 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<sup>®</sup> reagents.
- Concerning current configuration with easySTREAM<sup>™</sup> system, use the Strips 4 tubes in combination with Rotor-Gene for ARGENE<sup>®</sup> assays is recommended with the specific adaptor “easySTREAM Universal Cooler” that will be released under ref.421036.
- **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 & e

