

Marnes la Coquette, June 15th 2016

IMPORTANT PRODUCT INFORMATION

This information is intended for the end user of this product
If you are not the end user, please forward this information to the appropriate laboratory personnel

Subject: Monolisa™ HCV Ag-Ab ULTRA V2 5 plates 72562 - lot 6D0528

Dear Valued Customer,

During internal controls to monitor reagents stability, our manufacturing team has observed a decrease of performances for the following product:

Ref. 72562 Monolisa HCV Ag-Ab ULTRA V2 - 5 plates - **Lot 6D0528** - Expiry date: 2017/08/30

The **lot 6D0528** shows a decrease of performance for the detection of HCV capsid Antigen only. As a result for clinical samples, it may lead to a decrease of absorbance (OD) and then to a ratio <1.

There is a risk of non-detection of some seroconversion during the very early phase with Monolisa HCV Ag-Ab ULTRA V2 - Lot 6D0528.

No event from the field has been reported at this time.

The root cause is still under investigation but it involves R7 conjugate raw material.

Waiting for complete investigations, other lots are available, a new one is currently manufactured with a new conjugate R7 and should be available at the end of June.

As a consequence, we ask you to:

- Destroy the kits **lot 6D0258** that may remain in your local inventory
- Stop using kits from this defective **lot 6D0258**
- Fill the attached form to attest of product destruction and send it to your local technical support to request kits replacement
- Verify any negative patient result that may have been approved with this **lot 6D0258**

ANSM (National Security Agency of Medicines and Health Products) has been informed about this communication.

We apologize for the inconvenience, and remain at your disposal for any further information.

Please forward to whomever it may concern.

Sincerely,

Violaine Méle

Regulatory Aff

