13 November 2015

Our reference: FSCA 2695

Dear Sir / Madam

**IMPORTANT**: **URGENT FIELD SAFETY NOTICE**
**MYLA® - All Software versions**

Our records indicate that your laboratory operates one or more MYLA® software. Please read this information regarding an issue that could impact your system.

**Description of the issue**

Under certain conditions MYLA® Software, when connected to a VITEK® 2 system and to a Laboratory Information System (LIS) allowing the re-use of specimen ID, presents the potential to link a result from VITEK® 2 to the wrong patient and then upload those results to the LIS.

NOTE: MYLA® allows the use of already used specimen and/or patient ID in order to align MYLA® functionalities to LIS requirements.

As part of this feature an ID (specimen or patient) is active in MYLA® for a defined timeframe. The "active" status timeframe is set by default to 28 days. However, it could be configured by the user to a different defined timeframe.

In this period of time, when a specimen for a patient ID is "active", any results associated to a specimen ID received by MYLA®, is being compared to find the active specimen ID to link the result to the request (see normal workflow figure below).

NOTE: The request coming from LIS contains the specimen ID, patient ID and other demographic information.

If no active specimen ID is found, MYLA® manage this result as "orphan" and it is sent to LIS without patient ID. At the same time this "orphan" result is stored in MYLA® waiting for an LIS request containing this "unknown" specimen ID (see normal workflow orphan figure).

MYLA allows the management of results received from a connected instrument before the correspondent request is received from the LIS (i.e. in case of emergency during the night).

Normal Workflow:
(shown overleaf)

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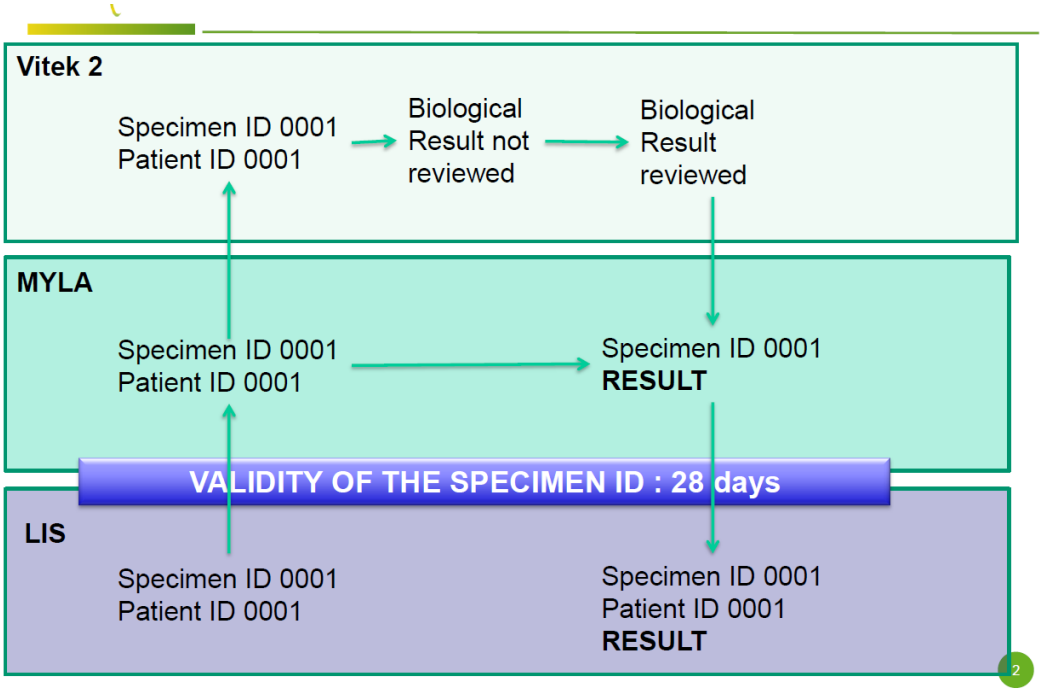
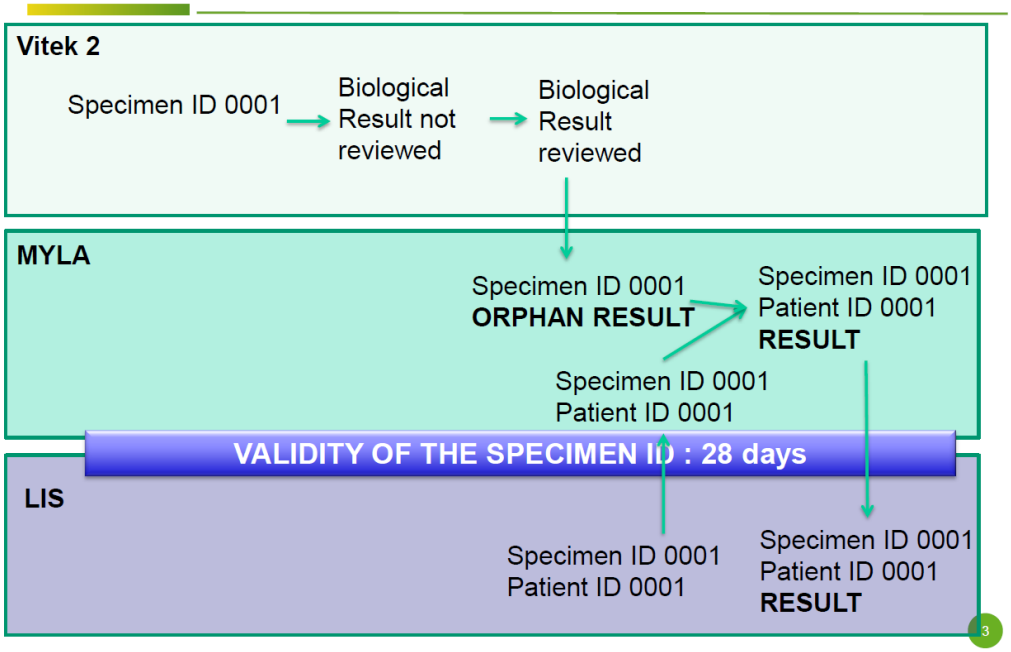


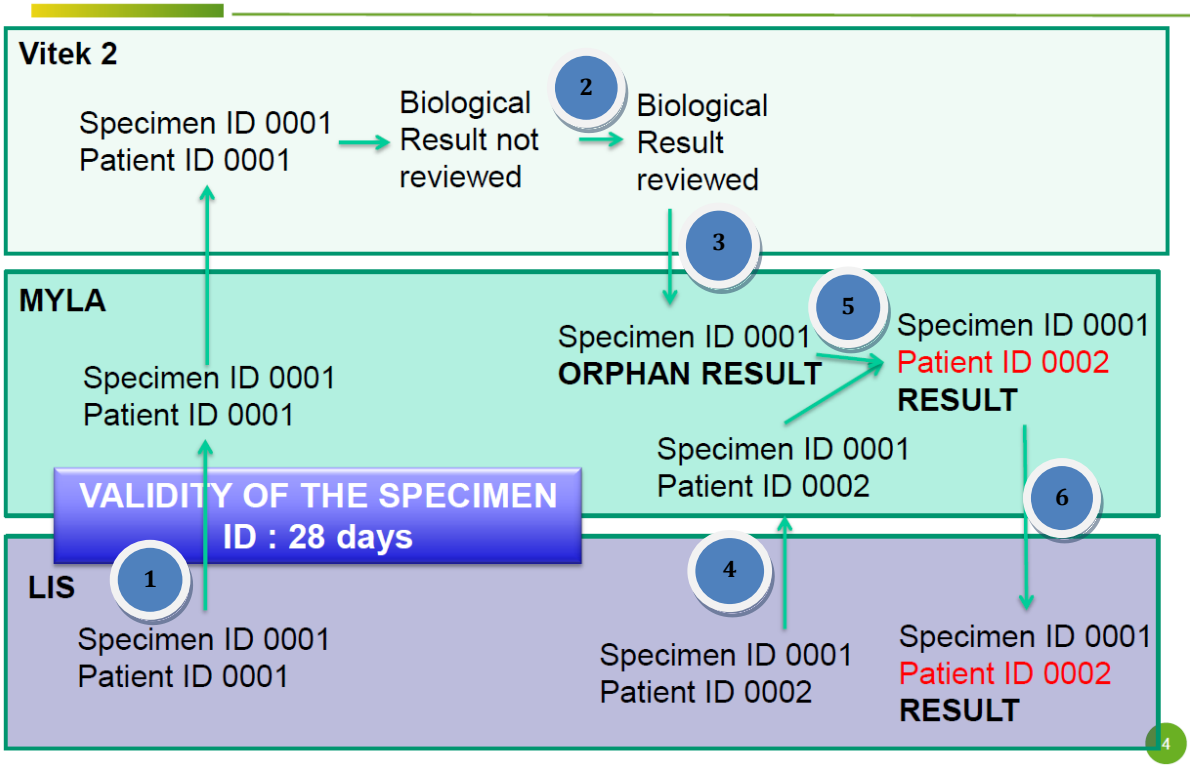

Normal workflow orphan (unknown) specimen:




To summarise:
Each time MYLA® manages a patient/specimen ID, it checks if this patient or specimen ID is already known and active on MYLA® system.
- If Known and Active, MYLA will link patient or specimen ID to the existing one (see normal workflow figure).
- If Known but not Active, MYLA® will create a new occurence of patient or specimen ID with a window timeframe for active periode (see normal workflow orphan figure).

- If UnKnown, MYLA® will create a patient or specimen ID with a window timeframe for active period (see normal workflow orphan figure below).

Workflow of the anomaly:




1. The LIS sent a test request for Patient ID 0001 - Specimen ID 0001 to MYLA and MYLA transferred this request for Patient ID 0001 – Specimen ID 0001 to VITEK® 2 system.
2. VITEK® 2 system ran the test but the result was left in pending status (need review status) on the VITEK® 2 system database.
3. After a period of time, the "Patient/Specimen Reuse Time" of the specimen is expired, the pending result is accepted and transferred to MYLA®. MYLA® transferred the results to the LIS. As no request was associated with the Specimen ID 0001, MYLA® sent the result with an ORPHAN Patient status which kept the result waiting for an LIS request.
4. The LIS sent a new request for another patient (Patient ID 0002) with the same specimen ID 0001 to MYLA®. MYLA® received the LIS request containing Specimen ID 0001 (associated to Patient ID 0002) and locates the results associated with the "ORPHAN Patient status".
5. **MYLA immediately linked the request to the previous result (orphan result) obtained for patient ID 0001.**
6. **MYLA sent back the result obtained for patient ID 0001 to LIS associated to the new patient ID 0002.**

The workflow for the specimen associated to Patient ID 0002 is completed in VITEK® 2 and sent back to MYLA® which associated this result to the correct patient ID and sent to LIS (in conclusion the right result for patient ID 0002 is received by LIS).

Based on the information provided, it has been determined that the reported issue may potentially cause test results to be linked to the incorrect patient.

The investigation confirmed that the reported anomaly is present in all MYLA® clinical versions only when connected to a VITEK® 2 system (all software versions).

MYLA® industry version is not impacted (because it cannot be connected with the VITEK® 2 system).

**Impact:**

Based on investigation results, there is a potential for erroneus test results to be transferred to the LIS; potentially leading to test results linked to the incorrect patient.

In the case where erroneous results are reported to the physician, the impact to the patient depends on the severity of their infection, the coexisting morbidities, the appropriateness of empiric antibiotic therapy, and the need for additional diagnostic (e.g. CT scan) or therapeutic (e.g. surgical drainage of abscess) interventions. In addition, inappropriate antibiotics may be administered.

**Required actions:**

- Ensure this letter has been distributed and reviewed by all appropriate personnel within your organisation.
- Review and validate regularly the results on VITEK® 2 in order not to have "to be review" results older than the "Patient/Specimen Reuse Time Feature" as configured in your MYLA® software.
    - bioMérieux will develop a software solution to reduce the likelihood of occurrence of this issue.
- Discuss any concerns you may have regarding previously reported results with your Laboratory Medical Director to determine the appropriate course of action.
- **Complete and return the Acknowledgement Form in Attachment A to Customer Services on fax number 01256 816863 to confirm receipt of this notice.**

We can advise that the Competent Authorities have been informed of this notification.

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 your local bioMérieux Customer Service representative.

Yours sincerely

Customer Service Department

**Attachment A: Acknowledgement Form.**

**FSCA – 2695**

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

**Please complete and return for the attention Customer Services to fax number: 01256 816863**

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❑ I acknowledge the receipt of bioMérieux Urgent Field Safety Notice informing this laboratory on the MYLA® software when connected to a VITEK® 2 system

❑ I have followed the instructions and implemented the actions as indicated in this Urgent Field Safety Notice.

Have you received reports of illness or injury related to the identified issue?
❑ Yes or ❑ No

**DATE**..... **SIGNATURE :** .....