



Dear bioMérieux Customer,

The VITEK®2 9MR3 maintenance release can be applied to VITEK® 2 releases 9.02 and 9.03. This maintenance release includes fixes to issues that have been identified in the software for these VITEK® 2 releases. Additional information is available in the VITEK®2 9MR3 maintenance release customer letter. Below is a brief description of the scope:

- Makes changes to allow the 9.04 update to be fully functional
- Organism origin issues (3 different anomalies, FLEXprep and isolate view)
- Processing of incomplete/bad Instrument messages.
- Str.equi zooepidem incorrectly displayed as Str.equinus in Isolate Detail View
- 9MR3 can be applied with SRF organisms activated
- End of Day failure because of a deleted Instrument
- HL7 does not send AES corrections for VITEK® tests (Cefoxitin Screen, ICR, and ESBL, etc.) to the Lab Information System (LIS)

The development for the VITEK®2 9MR3 software patch, including the associated verification and validation activities for these fixes, were performed in accordance with bioMérieux, Inc.'s Quality Management System, including Design Control procedures in compliance with the following standards and regulation:

- ISO 9001
- NF ISO EN 13485
- FDA 21 CFR Part 820 Quality System Regulation

bioMérieux, Inc. certifies that the VITEK®2 9MR3 maintenance release applied to either 9.02 or 9.03 satisfied verification and validation acceptance criteria required to meet the standards outlined above. Also, verification and validation included appropriate regression testing. The scope items have been determine to not impact the generation or reporting of results.

In prior agreement with bioMérieux, detailed development documentation, test data and results are available for onsite review at our facility in St. Louis, MO USA.

Due to variability in customer protocols, local applications, and customer-supplied disposables, the customer may perform additional QC testing adapted to its specific environment, at its own discretion and under its sole control, before and after the application of VITEK®2 9MR3 maintenance release.

Thank you,

Bradley Sather, Project Manager