



Dear bioMérieux Customer,

The VITEK®2 9MR4 maintenance release can be applied to VITEK® 2 releases 9.02.3, 9.02.4, 9.03.3, 9.03.4, 9.04.3 and 9.04.4. 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 9MR4 maintenance release customer letter. Below is a brief description of the scope of VITEK® 2 9MR4:

- Getting list of Setup Techs when Myla® 4.9 is integrated with VITEK®
- Improved VITEK® FLEXPREP® workflow related to organism origin
- When 21-CFR-11 enabled, some reports display incorrect information
- Communication between VITEK® FLEXPREP™ and VITEK® DENSICHEK® was not reliable
- Prevent enabling of HL7® communication protocol
- End of Day fails processing inactive isolates
- Application audit events not sorting correctly when searching an archive file
- Approved isolates unexpectedly revert to “to be reviewed”
- The need to accept VITEK® DENSICHEK® certificates multiple times
- Support lab CAP Accreditation related to breakpoint management

The development for the VITEK®2 9MR4 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 9MR4 maintenance release applied to either 9.02.3, 9.02.4, 9.03.3, 9.03.4, 9.04.3, or 9.04.4 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 determined to not adversely 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 9MR4 maintenance release.

Thank you,

Walter Johnson, Project Manager