



Dear bioMérieux Customer,

The VITEK®2 9.03 software is a release that includes enhancements related to the VITEK® 2 knowledge base.

Additional information is available in the VITEK®2 software release 9.03 Customer Communication.

The development for the VITEK®2 release 9.03 Update, including the associated verification and validation activities, 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 9.03 release satisfied verification and validation acceptance criteria required to meet the standards outlined above. Also, verification and validation included regression testing.

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 installation of the VITEK®2 software 9.03 release.

Thank you,

Doreen Martin, Quality Engineer