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Summary of Safety and Effectiveness Information for the *Enterococcus spp.* claims added to the Vitek® GPI Card

The VITEK® Gram Positive Identification Card containing new claims for the identification of

Enterococcus casseliflavus
Enterococcus gallinarum
Enterococcus hirae

is intended for use in conjunction with the Vitek® System for the automated identification of clinically significant streptococci, staphylococci, and a selected group of Gram positive bacilli.

Safety and effectiveness issues for the new software which contains the three additional species claims for *Enterococcus* for the bioMérieux Vitek GPI include the following considerations:

- The study was designed to validate the addition of six new species of enterococcus to the bioMérieux Vitek, Inc. GPI software. After clinical testing was performed it was determined that the addition of *Enterococcus malodoratus, Enterococcus raffinosus* and *Enterococcus mundtii* did not improve the software. Not only was the testing on these organisms irreproducible, the react file lines affected the accuracy of the *Enterococcus faecium* call. *Enterococcus malodoratus* is not a clinical isolate and the other two species have little clinical utility, therefore it was determined to limit the FDA submission data to *Enterococcus casseliflavis, Enterococcus gallinarum* and *Enterococcus hirae.*

- Performance characteristics: Performance of the GPI Card remains the same utilizing the new software compared to the current software as documented by clinical testing. The addition of three new enterococcal species does not affect the performance of the GPI card.

- Reproducibility: The new software reproducibly identifies specified gram-positive organisms.

- The Correlation Studies on enterococcal isolates gave a correct genus call 96.7% of the time after repeat and supplemental testing. Of these, 91.1% also correctly identified to the species level. Mis-identifications occurred at 3.3%.

- Performance of the GPI Card for non-enterococcal isolates remains the same utilizing the new software compared to the current software. The addition of three new enterococcal species does not affect the performance of the GPI Card as documented by clinical testing. In the Equivalency Study, the overall agreement of identification between the new software and the current software occurred at 99.8%.

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- Validation of software design: The software Certification Statement attests to our adherence to design, validation and testing procedures, and that release of this software takes place only when these written criteria are met.

When used within the context of the package insert, the new software containing the new *Enterococcus* species will perform as claimed. Additional information may be found in the package insert and technical bulletin.