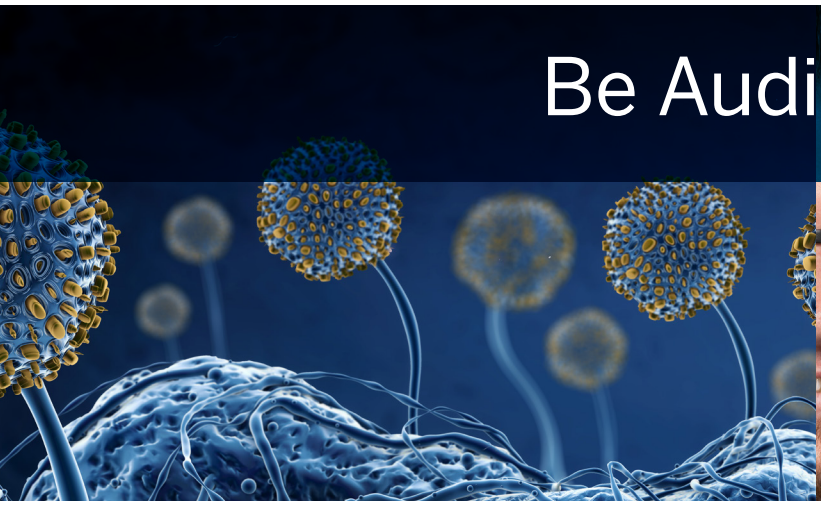
Be Audit-ready with VITEK®.



ENSURING DATA INTEGRITY

As a key challenge facing pharmaceutical manufacturers today, data integrity is a priority for anyone considering an in-lab microbial identification system. Reliable data is important to making the right decisions about the status of manufacturing environments and product quality which is why the world's top pharmaceutical manufacturers trust VITEK systems to safeguard their data. With a suite of data integrity features like audit trail, electronic signatures, date/time stamp, and more, VITEK systems make ensuring compliance easy.

DATA INTEGRITY IS UNDER SCRUTINY BY FDA

Regulatory agencies like FDA expect data to be reliable and accurate and they've provided guidance on how to accomplish this. Issued in 2016, Data Integrity[1] and Compliance with cGMP: Guidance for Industry presents the principles of ALCOA. Further expanded to include all data and process/management, comprehensively these principles are known as ALCOA+.[2] The guidance designates that data should be:

- Attributable
- Legible
- Contemporaneously recorded
- Original or true copy
- Accurate
- Complete
- Consistent
- Enduring
- Available for inspection

IMPORTANCE OF ACCURATE MICROBIAL IDENTIFICATION

Data integrity has been a major issue in the pharmaceutical industry. FDA has cited infringements in warning letters often related to data that is easily manipulated and therefore, inaccurate. Citations leading to costly CAPA measures have covered some of the following issues:

- Did not establish laboratory controls that include scientifically sound and appropriate specifications
- Failure to record activities at the time they are performed
- Failure to provide worksheets for recording microbial test results

HOW VITEK® SYSTEMS ENABLE PRODUCTIVITY AND COMPLIANCE

VITEK systems allow manufacturers to reduce manual workflows while ensuring regulatory compliance with a suite of built-in data integrity features. Integrated into our system requirements, these features remain or are enhanced as our systems evolve with software updates. This allows manufacturers to minimize the risk of analyst errors and generate an objective result, with additional features that help customers ensure their data complies with ALCOA+ principles now and in the future.

ALCOA + PRINCIPLE	Features of VITEK 2 Compact and VITEK MS
Attributable	• User login allows analyst names to be recorded with each sample • Audit trail attributes samples to specific users
Legible	• Final result is validated and e-signature • Data is saved in digital format and cannot be altered • Manual or automated data backup options are available • If failures occur, users are notified and the failure and reason are recorded in the audit trail
Contemporaneous	• Date and time stamps are included on electronic signature of results and all actions recorded in audit trail
Original	• Data recorded electronically is original data
Accurate	• Reports provide complete data including biochemical test results, genus and species level, and % of confidence • Electronic signature allows review of results before finalizing to verify accuracy • QC organisms are designed as controls to ensure accurate card performance • QC organism checks are performed for each target slide acquisition group before and after analysis to ensure accuracy (VITEK MS) • Within the virtual cassette workflow, a reconciliation is performed at the load chamber level that compares the virtual cassette information (barcode, cards, and card type) to the actual cassette loaded into the instrument
Complete	• VITEK DENSICHEK automatically transfers McFarland values to isolate record on VITEK 2 Compact
Consistent	• Audit trail records user actions with date and time stamp
Enduring	• Electronically recorded results may be archived indefinitely • Customers may set a retention period based on their needs • Automatic or manual backup options are available
Available	• Result data can be recalled from the archive • Audit trail actions can be queried and reported

We invite you to read more on the VITEK systems at
biomerieux-industry.com

1. US Department of Health and Human Services Food and Drug Administration 2016. Data Integrity and Compliance with CGMP Guidance for Industry.
2. US Department of Health and Human Services Food And Drug Administration 2018. Data Integrity and Compliance with Drug CGMP Questions and Answers Guidance for Industry

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PIONEERING DIAGNOSTICS