



CLIAC Comment

Currently, bioMérieux recommends one package insert organism to check for degradation of the most labile substrates to ensure proper handling & storage during shipment and upon receipt at the customer lab. Supplemental package insert organisms are provided in our labeling for those customers that require more extensive QC testing due to local requirements. Additional strains will be needed to meet the expectation of one positive and negative for each substrate. See table below

Additional Strains
Required for bioMérieux ID Menu

Product Line	Product Name	Additional Strains	Total Potential Package Insert Strains
VITEK [®] 2	GN	3	10
VITEK [®] 2	GP	6	14
VITEK [®] 2	YST	2*	9
VITEK [®] 2	ID-GNB	2	11
VITEK [®] 2	ID-GPC	1*	9
VITEK [®] 2	ID-YST	1*	8
VITEK [®]	GNI+	1	9
VITEK [®]	GPI	3	10
VITEK [®]	YBC	4	8
VITEK [®]	ANI	2	8
VITEK [®]	NHI	0	6

*Coverage still not complete; additional investigation needed to find strains.

Today we do not have a summary of the additional QC strains that would be needed for our API identification products.

A review of North American complaints regarding ID product failures reflects a very low rate. The added value of additional strains to the end user is not obvious. Identification product lots have not been recalled since the inception of our current investigation database, established December 2002. Within this window of time, we have manufactured ~ 300 lots/year VITEK ID cards and ~ 150 lots/year VITEK 2 cards. Lots/year for API strips has not yet been validated. Representative complaints summarized below.

API

1. One customer complained of false positive QC reactions. bioMerieux replaced their 20E inventory; unable to determine root cause as their side or our side.
2. One customer complained of failing QC & kits replaced. Root cause identified as customer saline, not the kit.
3. For product 50 CHB, a mislabeling investigation opened in France as wells 41-50 were mislabeled; not found by customers testing in their situation.
4. Situations for actual reagent problems, particularly for product Zym A&B, were related to stability, storage or reconstitution.

Certificates of Analysis are available for each lot shipped. This guarantees each biochemical has been tested with two or more organisms yielding both positive and negative reactions



We are committed to meeting our customer needs, however 12-18 months (at minimum) are required to complete the VITEK/VITEK 2 QC organism selection process, plus deliver the associated software with modified QC program. Time required for API products is not known today. Before implementing the activities to make these QC additions we want to thoroughly understand the added value to the end users.