



Certificates - Phenotypes - Authenticity

One element of MicroBioLogics quality assurance is to perform phenotypic or biochemical determinations on reference stock cultures. The main reason for this testing is to provide evidence that a microorganism's phenotypic characteristics are not altered and continue to remain the same following lyophilization.

In some instances, the data provided by the phenotypic testing is provided on certificates of performance for a microorganism. These certificates of performance or certificates of analysis have caused some confusion with a few end-users. The purpose of this technical bulletin is to address and minimize the confusion.

The MicroBioLogics library of reference stock cultures will soon exceed 1,000 strains. Upon receipt of a reference culture and following lyophilization, phenotypic determinations are performed on each strain. The volume of strains and the frequency of testing dictate the use of an identification system that can accommodate tremendous volumes of test isolates. Automated systems can accomplish tremendous work loads and eliminate the variability of interpretation between technologists. The system selected by MicroBioLogics is the VITEK® 2 Compact system by bioMérieux.

Published reports from clinical trials and field testing have validated the excellent performance of the VITEK® 2 Compact system. In-house validation and verifications from MicroBioLogics also support use of the VITEK® 2 Compact system.

On a few occasions, confusion has arisen when an end-user attempts to match the VITEK® 2 Compact legacy system phenotypic profile listed on a certificate of performance with test results from

conventional or other commercial identification systems. Based on the

different technologies employed; different incubation times and conditions; colorimetric versus optical attenuation of light; and, natural occurring variability within a species; simply means that test results between different methodologies will not always be identical. The phenotypic profiles obtained by the VITEK® 2 Compact system are reliable, consistent and contribute to a statement of authenticity for each microorganism. If a laboratory's protocol dictates that the phenotypic profile on a certificate of performance must be validated, an identical system must be employed AND recognition of natural occurring variability within a species must be recognized.

The ultimate value of MicroBioLogics reference stock culture products is its actual use in the laboratory. When a specific strain is recommended for quality control and is processed as directed, MicroBioLogics reference stock cultures will demonstrate correct results, if not the material being challenged is out of control.

The VITEK® 2 Compact legacy system phenotypic profile is used and supports the authenticity of each specific strain.