

Technical Talk Newsletter – September 2014 # 5



How confident are you with your test kits?

Many years ago, in a well-known series of advertisement for Castrol GTS, a family man named Sol uttered the classic phrase <u>"oils ain't oil"</u>. This sentiment is as true for antibiotic test kits today as it is for engine oils.

Today's market is flooded with kits all claiming to perform the same or better than everyone else, but is this really the case. Are the performance of the some kits actually better than others? Are the sensitivity claimed in the kits really that accurate?

In this newsletter, I'll explain the critical elements that goes into a test kit to make it work and how minor changes or variations can greatly affect its performance. More importantly, I'll discuss details on recognised accreditation and validations to look for as verification of its performance.

Since, the microbial inhibition test is commonly used to confirm a rapid test result – I'll be focusing on this test due to its importance in the dairy industry.

Microbial inhibition test

There are 3 critical areas that determine the performance of the test kit. These are:

- The specific strain of bacteria used
- The activity of the bacterial spore suspension
- The unique formulation of the growth medium

Now let's look into these in more detail:

- 1. Every test kit has their own **secret strain** which give rise to various sensitivities of the kits. The strain of bacteria (normally a thermophilic sporeformer such as *Bacillus steraothermophilus*) is not only unique, but specific to the media in which it grows.
- 2. Bacillus stearothermophilus cannot be used in its vegetative bacterial state otherwise the cells will die. It needs to be in their spore state which is nature's way of making them more resistant to the environment. The use of spore, allows for a longer shelf-life, but also the stability of the kits.

The critical element is not the number of spores, but the **activity of the spore** suspension in the kits. In other words, the number of spores that will activate when conditions become favourable.

Formation of Endospores by Sporulation





3. The formulation of the growth media is a closely guarded secret as the recipe provides the optimal grow medium in which the bacterial spore is activated, grows and forms the acid causing the color change.

If all kits are to work the same, they must have exactly the same 3 criteria as discuss above. They use the same strain of bacteria, the same spore activity, and the unique growth medium which when put together determine the sensitivity of the kits to various antibiotics at the stated levels.

The truth is, as complex as it is, every kits are different. They have different strain, different spore concentration and different growth medium. Any slight variations can significantly lead to different shelf-life and different sensitivity to various antibiotics.

Recognised external validations and certifications

So what do you do! You and I don't have the elaborate facility to prove if these kits work correctly day after day and week after week. The only way to verify if they work is to rely on external approval and validations. And I don't mean simple studies either.

There are many organisations (including universities and large laboratories) that can validate test kits, however in terms of proper scientific approval there are only two main bodies that are truly recognised around the world.

They are

- 1. Association of Official Analytical Chemists **(AOAC)** International which is a scientific association that publishes standardised, chemical analysis methods designed to increase confidence in results of chemical and microbiological analyses.
- 2. Association Française de Normalisation **(AFNOR)**, the French national organization for standardization which is a certifying body governed by the European standard EN 45011.

Having either of these recognisable approvals such as AOAC or AFNOR verify the performance of the kits and ensure confidence that the kits works according to the stated claim.

The good news is - the Delvotest is the **only** microbial inhibition test in the world to have **AOAC approval**. It's no wonder as it has one of the worlds most stringent and robust quality control process ensuring the consistent performance of its test kit. As Sol will say "oils ain't oil".

Now that I have explained why test kits are not the same, stay tuned for my next issue where I'll explain how to read the Delvotest correctly.

Davíd

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FMCG Industry Solutions Pty Ltd

81 – 83 Crown Street, St Peters NSW 2044

Ph: 1300 628 104 - Fax: 02 9013 0320 - www.fmcgis.com.au - www.delvo.com.au

