

# Frequently Asked Questions about

## Microbiology Standards

The **LENTICULE®** and **Vitroids™** discs are manufactured under conditions compliant with **ISO 17034** and **ISO/IEC 17025**.

**Quality control is an essential element of a laboratory's quality assurance system and certified reference materials (CRMs) are necessary for effective quality control. The Vitroids™ and LENTICULE® discs from Millipore are specially developed to provide laboratories with the ability to use suitable, ready-to-use microbiological controls for every media quality control test. The Colony forming unit (cfu)-concentrations are designed ensuring that no or only minimal dilution steps are required and are provided under license by National Collection of Type Cultures (NCTC®)/ National Collection of Pathogenic Fungi (NCPF®) and Spanish Type Culture Collection (Colección Española de Cultivos Tipo, CECT®), respectively.**

### Themes:

- Application
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- Handling
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- Orders & Delivery
- Validation

### Application

#### What are Vitroids™ and LENTICULE® (V&L) discs?

They are quantitative certified reference materials with a defined mean CFU number and standard deviation, except for some LENTICULE® discs whose catalogue numbers start with the letters RM. These reference materials are only qualitative. The certified reference materials are checked and certified acc. ISO/IEC 17025 and produced under ISO 17034.

#### What is the difference between Reference Materials (RMs) and Certified Reference Materials (CRMs)?

CRMs must be traceable to an accepted, accurate source, in the case of V&L to a culture from a National Cultures Collection (NCTC, CECT, NCPF). They must be accompanied by a certificate that states the traceability at a certain level of confidence. The traceability and certification requirements for RMs are less stringent. Vitroids™ and LENTICULE® CRMs are certified for the species and their CFU level (it is important to check the growth conditions described on the certificate of analysis for the certified level per disc).

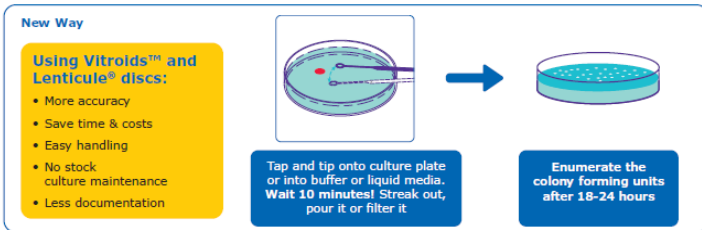
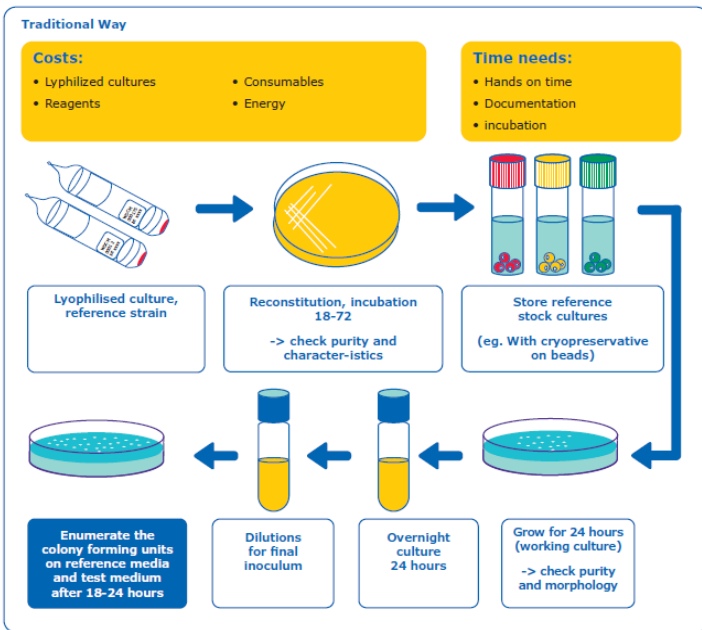
**What can I use the CRMs for?**

Vitroids™ and LENTICULE® discs can be used for quality control/performance testing of culture media and for process controls (including the preparation of spiked samples). Information about usage is provided in the certificates. They can also be used for the validation of tests, to determine the limit of detection or for daily QC routines. In addition, they are regularly used in ring trials, proficiency testing and staff training.

**What is the advantage using Vitroids™ and LENTICULE® discs?**

Compared to self-isolated control strains they have the following advantages:

- Higher accuracy (ID of strain checked, characteristic properties present, average CFU known)
- Time-saving (about 1 hour working per control strain, work steps, documentation, etc.)
- Cost-saving (reagents, consumables, equipment, energy, work time, no maintenance of stock cultures etc.)
- Easy and flexible (very few work steps, no big planning is needed, can be used in liquid media and buffers as well as on solid media, ready-to-use concentration, can be diluted)
- More sustainable (saving reagents, consumables, equipment, energy, less waste etc.)



## Product Information

### What do the V&L CRMs look like?

The Vitroids™ and LENTICULE® discs CRMs are supplied as small discs. These discs come placed over a desiccant in labelled plastic tubes. The CRMs are colored so they can be seen more easily.

### How many passages are V&L away from the reference culture strain?

**LENTICULE® discs** are **maximum 2** and **Vitroids™ discs maximum 3 passages (normally not more than 2)** away from the original reference culture strain.

### For higher or lower CFU concentrations, does the number of passages change?

Changing the concentration does not increase the number of passages. Only the CFU number changes.

### What is the difference between Vitroids™ and LENTICULE® discs?

Vitroids™ discs contain strains derived from CECT, while LENTICULE® discs (licensed from UKHSA) contain strains from NCTC and NCPF. They differ with respect to shelf life, number of passages and their CFU ranges:

Last digit Vitroids™ disc	CFU range
1 or 2	15-80
3	80-130
4	130-300
5 or 6	1,000-3,000
7	50,000-150,000
8	>150,000
9	custom
Last digit LENTICULE® disc	CFU range
L	30-120
M	500-50,000
H	50,000-150,000

### Do the V&L discs come with ATCC equivalence certificates?

Strains that are equivalent to ATCC strains are cross-referenced on our website and can also be found on BacDive (link on our website). Furthermore, we provide an equivalency sheet with the strain's history.

### Why is there desiccant in the vial?

The Vitroids™ and LENTICULE® discs are extremely sensitive to moisture. Desiccant absorbs any moisture in the vial and thus prevents the hygroscopic discs from becoming sticky.

### Can we order single vials (-1VL materials)?

No, we do not sell single vials. 1VL material numbers are only used for labels, we sell only 10 EA pack

### What is the pack size for lower concentration discs?

There are 10 discs in each pack for lower CFU count Vitroids™ and LENTICULE® discs.

### What is pack size for higher concentrations discs?

There are 10 discs in each pack for higher CFU count Vitroids™ and LENTICULE® discs.

### **What is the aluminum bag for?**

The aluminum bag/mylar foil bag protects the discs from humidity.

### **Do we have fluorescent strains?**

Currently we are not able to handle genetically modified strains as this needs a different permit and must also meet different requirements in the QC labs. QC labs would need to have the allowance to handle such products, and MilliporeSigma would need to switch to UN 3245 shipment.

## **Handling**

### **Is dilution from >1,000 CFU to <100 CFU per 0.1 mL possible?**

Yes, each disc can be dissolved in, for example, 100 mL of buffer and thus diluted down to <100 CFU/0.1 mL.

### **Which dilution/rehydration buffer can be used?**

**Never use distilled water for dilution/rehydration** as this adversely impacts recovery.

Phosphate Buffered Saline (Sigma-Aldrich P4417), Maximum Recovery Diluent (MDR, Millipore 07233) or Page's Saline are recommended. Alternatively, any liquid culture medium, normal saline or any other diluent mentioned in USP can be used, but this needs to be validated by individual QC lab.

We are performing a study on this, and an application note is in preparation.

### **Is there a step-by-step preparation sheet?**

Yes, step-by-step instructions are part of the Technical Data Sheet.

Simply turn over the vial to drop the disc into the diluent container (see image) or on to a agar plate.



### **Is dilution from >1000 CFU to <100 CFU per 0.1 mL possible?**

Yes, each disc can be dissolved in, for example, 100 mL of buffer and thus diluted down to <100 CFU/0.1 mL

### **Can I spike samples with V&L?**

Yes, we have an application note for the recommended procedure.

[LINK](#)

## **Storage, Transportation, Shelf life**

### **What is the storage temperature of V&L products?**

Vitroids™ and LENTICULE® discs need to be stored in the freezer at -20 °C +/- 5 °C (see certificate). At -35 °C and below the CFU will be reduced due to damage to the cells.

### **What is the shelf life of V&L products?**

The shelf life is at least 24 months for Vitroids™ discs and at least 16 months for LENTICULE® discs.

### **Can Vitroids™ and LENTICULE® discs be stored at +2 to +8 °C instead of -20 °C?**

For short periods, for example a few days during shipment and goods receipt, the discs can be stored at 2 °C to 8 °C.

If the quantity is not important and no certified material is needed then cooler (2-8°) storage would work as well.

If the discs are stored too long above -15°C, they lose their certification. The CFU will be reduced and cannot be guaranteed anymore. Technically we know there will be still living organisms up to the end of shelf life, with a reduced resistance against selective conditions.

Incorrect storage leads to loss of certification.

Microbiologists working according to ISO then need to follow the guidelines as they would with a working culture and check for purity, morphology and biochemical properties. They may also need to perform an additional enrichment step, dilutions to the needed concentration range and checks against a reference medium. In such cases there is no guarantee from our side, and we do not offer replacement. The sole responsibility is with the individual user.

**When the CRMs arrived at room temperature. Can I still use them?**

Yes, this was examined in the stability studies. But it is important that they only reach ambient temperature, and the discs should be immediately placed into the freezer.

**Can I refreeze a disc after defrosting?**

Once a vial has been taken out of the bag and defrosted it should not be frozen again.

## Orders & Delivery

**Where do I get information on stock?**

Please contact your local office.

**What can I do if the delivery is delayed or interrupted?**

Please contact your local office.

## Validation

**Are there validation studies for Vitroids™ discs?**

For each product a stability study was performed. An application note is available for spiking. Other application notes are in preparation.

### To Place an Order or Receive Technical Assistance

In the U.S. and Canada, call toll-free 1-800-645-5476

Order/Customer Service: [SigmaAldrich.com/order](https://SigmaAldrich.com/order)

Technical Service: [SigmaAldrich.com/techservice](https://SigmaAldrich.com/techservice)

Safety-related Information: [SigmaAldrich.com/safetycenter](https://SigmaAldrich.com/safetycenter)

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