HOHENSTEIN

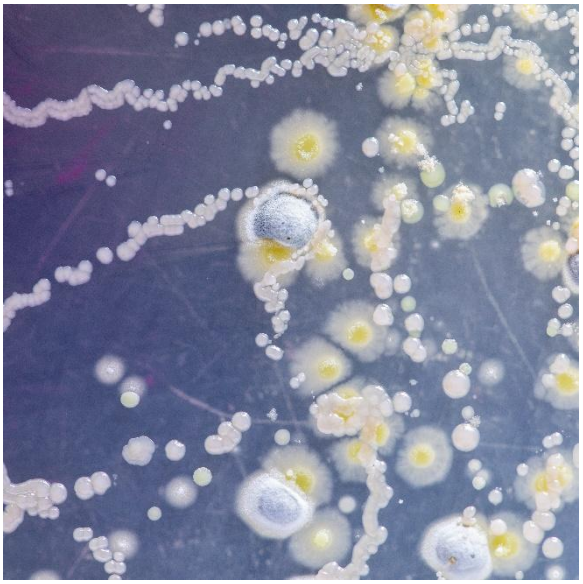
Determination of the bioburden (microbiological cleanliness)

Aim

The determination of the bioburden is used, among other things, to assess microbiological risks, for the final inspection of hygienically sensitive (medical) products or to prove the marketability of consumer goods.

Test standards

- DIN EN ISO 11737-1 for medical devices
- Ph. Eur. for commodities with determination of TAMC (total aerobic microorganism count) and/or TYMC (total yeast and mould count)



The test is suitable for

- Routine monitoring to guide manufacturing processes
- Assessment of the marketability of a product
- Monitoring of raw materials, components or packaging
- Assessment of the effectiveness of cleaning procedures
- Validation and requalification of sterilisation processes
- Part of an overall programme of environmental monitoring

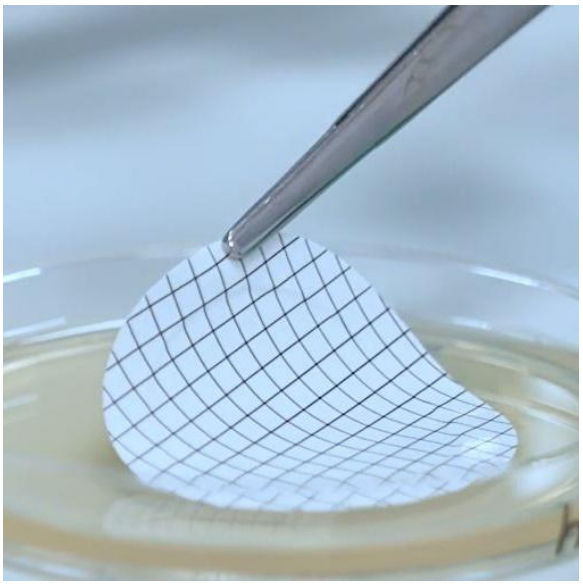
Description

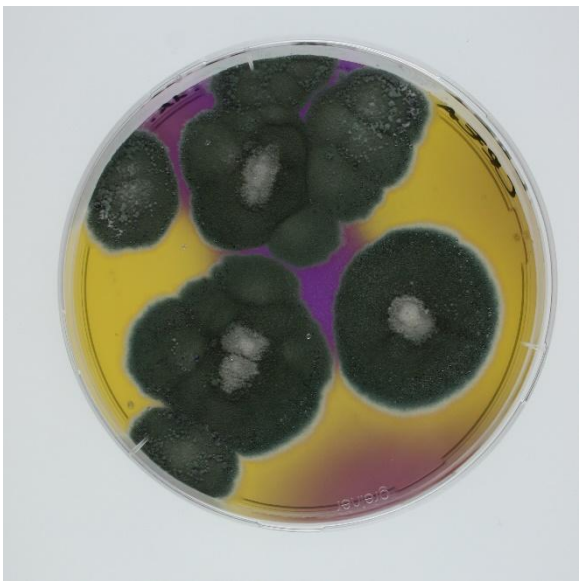
The term "bioburden" is used to describe the population of viable microorganisms found in or on a product and ideally represents the sum of all microorganisms (bacteria, yeasts, moulds).

There are a variety of methods for determining the bioburden. The method to be chosen depends on the product itself and its consistency. For example, liquids can be filtered directly or placed on culture media, while solid products must be eluted. Depending on the flexibility of the products, this can be done in a stomacher (laboratory homogeniser), by shaking or by ultrasonic treatment.

The subsequent culture conditions depend on the expected germs. Specific germs, e.g. pathogens, can also (optionally) be identified or excluded.

If a reliable quantitative statement is to be made, a product-specific validation with determination of the correction factor for the product to be analysed is required. This involves determining the recovery rate specifically for the product using the selected method. This is particularly useful for regular batch tests of the same product and is usually required for medical devices.





Requirements to the test specimen

General information

- Test samples are analysed as sent in.
- When packaging, care must be taken to ensure that neither the handling nor the packaging material changes the microbial count. If possible, the test sample should be left in its original packaging.

Material quantity

- Depending on the issue and the product to be analysed.
- The size of sampling depends on your own quality management system.

Test criteria

- Assessment of the total microbial count and, if necessary, exclusion of indicator strains according to the client's specifications or specifications of the Ph. Eur.
- The normative requirements apply to medical devices. For commodities, we are guided by the Ph. Eur. specifications for non-sterile products.