

Colour reference chart

for *gke* Batch Monitoring Systems (BMS) for formaldehyde sterilization processes

PASS RESULTS

The batch can be released if all 4 colour segments of the processed indicator are brown as shown below to indicate that formaldehyde has penetrated the PCD, and if all other critical process parameters such as temperature, pressure and sterilization time are in accordance with the cycle reference.



all colour segments are brown

→ sufficient formaldehyde penetration

FAIL RESULTS

The example shown below clearly demonstrates an insufficient formaldehyde penetration which may be due to various reasons (see note below).

If this example is found after a sterilization process, the respective batch cannot be released and requires re-processing.



all colour segments are yellow-brown

→ insufficient formaldehyde penetration



all colour segments are yellow

→ no formaldehyde penetration

Note

A failure of the batch monitoring test is not conclusive proof that the fault is necessarily associated to the sterilizer itself (insufficient air removal or leakages), but may well be due to external causes such as unpurged supply pipes at the start of the process, insufficient formaldehyde supply or changing temperature of cooling water. Therefore batch monitoring tests made in subsequent cycles may show different results.

Important

If the chemical indicators already show a clear brown color before usage, the indicators were improperly stored or the expiry date is passed. These indicators must not be used.

If an indicator achieves pass conditions when put unprotected in a sterilizing chamber but not within a process challenge device, this is a clear proof that the formaldehyde concentration is sufficient but the process is unable to penetrate formaldehyde in the inner lumens of hollow devices like tubes and minimal invasive surgical instruments.

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