

False failed

Both

False passed

BP

Diff

WIT

Reasons:
Product residues on the membrane, esp detergents such as Tween 80

Solutions:
Flush with high volume, solvents or determine Product Specific Integrity Test Limits.

Reasons:
Leak in the tubing or in the filtration system

Solutions:
Check system integrity w/o filter

Reasons:
Upstream valve not completely closed

Solutions:
Close valve

Reasons:
Filter not sufficiently wetted

Solutions:
Increase wetting, enforced wetting procedure. Sartopore Platinum can be autoclaved dryly

Reasons:
Temperature of filter too high, e.g. transport from cold room to ambient conditions

Solutions:
Wait! Temperature measurement. Temperature most important for WIT then for Diff and least for BP

Reasons:
Filters, which need to be autoclave or SIPed under wet conditions, sterilized dryly

Solutions:
Wet the filters before sterilization

Reasons:
Wrong pore size

Solutions:
Use bar code scanner for program start

Reasons:
Incorrect net volume input. Is volume measurement enabled?

Solutions:
Activate volume measurement

Reasons:
De-calibrated Sartocheck

Solutions:
Calibration, Document for calibration offset calculation

Reasons:
Wrong filter size programmed

Solutions:
Use bar code scanner for program start

Reasons:
No stable temperature conditions

Solutions:
Sartocheck not at the door or under the AC

Reasons:
Wrong test gas (Nitrogen instead of air)

Solutions:
SOP, use of different connectors

Reasons:
Valve downstream of the filter is closed

Solutions:
Use safety parameters (min/max Volume)

Reasons:
Old WIT limits for WFT test

Solutions:
Bar code scanner / training

Reasons:
Test tube connection is not opened (Stäubli connector)

Solutions:
Safety parameters in the Sartocheck (min flow & min/max volume)

Reasons:
Temperature of filter too low

Solutions:
Wait! Temperature measurement. Temperature most important for WIT then for Diff and least for BP