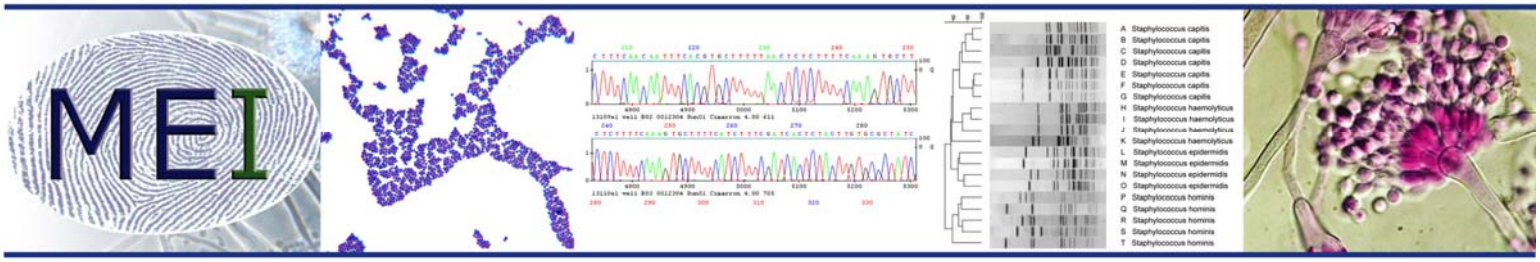
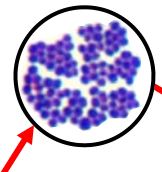


Sterility Failure Investigation

Molecular Epidemiology, Inc.



21 CFR 211.167(a) states, in part, that *"For each batch of drug product purporting to be sterile and/or pyrogen-free, there shall be appropriate laboratory testing to determine conformance to such requirements."*

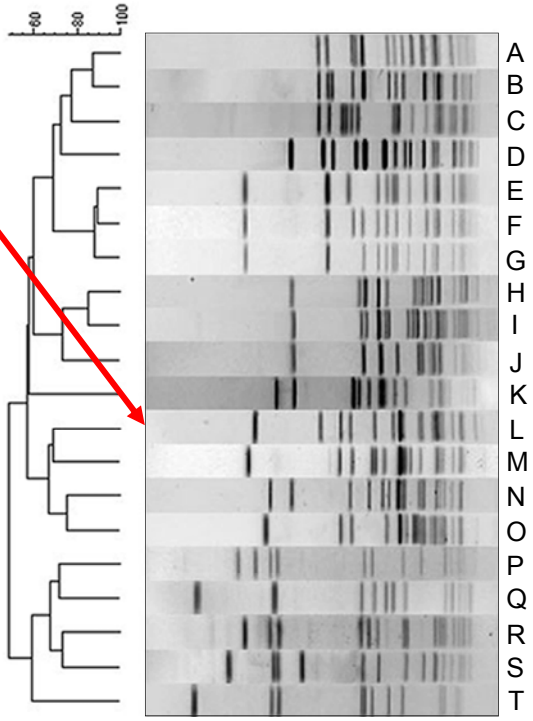
Genetic ID
Comparisons to genetically similar microorganisms

Genetic Distance	Genus	Species
0.0000	Staphylococcus	epidermidis
0.0082	Staphylococcus	caprae
0.0104	Staphylococcus	capitis
0.0122	Staphylococcus	saccharolyticus
0.0245	Staphylococcus	aureus
0.0251	Staphylococcus	pasteuri
0.0262	Staphylococcus	warneri

Notes:
None

Deviations	*None*
Microbial ID Conclusion	***Staphylococcus epidermidis***

"Genotypic methods have been shown to be more accurate and precise than traditional biochemical and phenotypic techniques. These methods are especially valuable for investigations into failures."
FDA Sterile Drug Products Produced by Aseptic Processing—Current Good Manufacturing Practice.



"Sterility positive" is a phrase that manufacturers dread when faced with microbial contamination of a sterile product. MEI's experienced team of scientists conducts sterility failure investigations to precisely determine the exact source of the contamination to the species and strain level.

Environmental samples representing the laboratory, personnel, manufacturing environment, and product bio-burden are analyzed. Using our robust polyphasic microbial identification and DNA fingerprinting approaches, MEI can definitively identify a contaminant to the species and strain level therefore determining the exact source of the contamination. This forensic level of investigation is essential in ensuring product quality and safety, minimizing loss to the manufacturer, and addressing regulatory requirements.

Please contact our Service Representative for more information regarding our Sterility Failure Investigation service.

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