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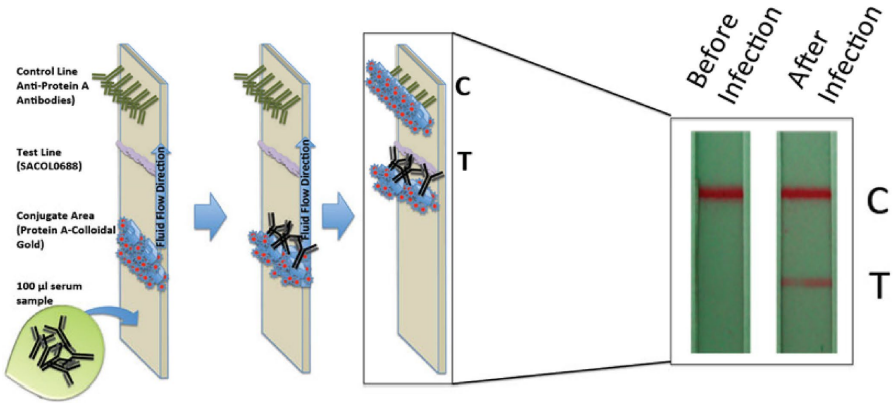
Biofilm Antigen-Based Diagnostic for Chronic *Staph aureus* Infection

Overview

Chronic infections associated with implanted medical devices such as prosthetic joints are difficult to diagnose and treat due to biofilm formation by the causative pathogens. Bacterial infections often persist in the form of protective biofilms (65 - 80% of all infections), a mode of growth which reduces the effectiveness of the host immune system as well as antimicrobial drugs. Pathogen identification often relies on microbial culture that requires days to weeks, and in the case of chronic biofilm infections, lacks sensitivity. Diagnosis of infection is often delayed past the point of effective treatment such that only the removal of the implant is curative.

UMB researchers developed a serological assay to detect antibodies to unique biofilm-associated antigens of *Staphylococcus aureus*. Specific antigens were selected based on their upregulated and sustained expression in a biofilm, both *in vitro* and *in vivo*. In tests with patient samples derived from orthopedic implant infection cases, UMB researchers demonstrated clinical diagnostic utility of the assay, with 100% specificity & 91% sensitivity. The *Staph aureus* biofilm assay promises a rapid, serology-based diagnosis of infection that can lead to earlier, life-saving interventions.



Market & Applications

Implanted medical devices (~ 5 million/year in U.S.) such as pacemakers, artificial heart valves, catheters, replacement hip joints, bone cement and other surgical implants are all prone to biofilm development, as are the chronic wounds associated with surgical sites, trauma, and diabetic foot ulcers (~ 8 million chronic wound patients in the U.S. and EU, per 2016 data). The ability of current diagnostic tests to detect biofilms before clinical symptoms develop is inadequate. Molecular techniques such as PCR have increased sensitivity in the species-level identification of pathogens. However, PCR is prone to false positives, and given that 10 – 40% of the global population is colonized by *S. aureus*, there's quite a potential for misdiagnosis.

Technology Advantages

- High specificity & sensitivity of UMB's assay demonstrated in clinical samples and a rabbit infection model
- Enables earlier-stage detection of infection
- Reliance on unique antigens associated with *S. aureus* biofilm mode

Stage of Development

Clinical diagnostic utility has been demonstrated with patient samples derived from orthopedic implant infection cases (see Harro et al., 2020)

Investigators

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Description

infection, diagnostic, prosthetic joint infection, biofilm, *Staphylococcus aureus*

Field

Diagnostic

Technology Status

Available for licensing
& sponsored research

Patent Status

US Patent 8,541,006 (iss'd 2013); French, German & UK Patents 2176662 (iss'd 2012); Canadian Patents 2,694,974 (iss'd 2016) & 2,943,712 (iss'd 2019)

UMB Docket#

MS-2008-064

References

Harro et al. *J Clin Microbiol*. 2020 Apr 23;58(5):e01414-19. DOI: 10.1128/JCM.01414-19

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