Fast Detection of Hypervirulent Clostridium Difficile (Case 1952)

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Technology description

Brief Description:

This invention, using a single reaction tube, rapidly detects the presence of C.difficile and can identify mutations in the bacterial genome that correspond to clinically relevant markers of pathogenicity. The technology reveals an 18 base pair deletion in a regulatory gene associated with hypervirulent strains of C.difficile, as well as the presence of a binary toxin gene present in emerging strains.

Stool culture and cytotoxicity assay together form the gold standard for detection, with high sensitivity (> 90%) and specificity (> 98 %). But, this method is not practical in most clinical settings since it requires a tissue culture facility and two to three days to complete. A recent enzyme immunoassay specific for C.diff. Glutamate Dehydrogenase, has been reported to have a very good sensitivity, but just like stool culture result, positive GDH EIA only indicates presence of the microorganism, not its toxicity or virulence. Currently marked technologies using PCR have increased sensitivity and give results rapidly, but they are unable to differentiate hypervirulent strains with the 18bp gene deletion and presence of binary toxin gene from non-hypervirulent strains.

Our technology provides a solution -- A rapid test that has high sensitivity and that can alert clinicians to infection with a hypervirulent strain and therefore more likely to need more intensive care, and more likely to spread C.diff from person to person. Our C.diff detection system offers a novel one-tube test allowing for simple, rapid detection of three markers of C.difficile infection that can influence clinical decision-making at a cost and time-scale feasible for application in hospital settings.

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