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Unique FDA nod for Roche mycoplasma test

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Roche's rapid mycoplasma detection test gets FDA nod



Singapore: US FDA accepted Roche's PCR-based mycoplasma detection test MycoTOOL for release testing of one of Roche's biological products. It is the first commercially available mycoplasma PCR test accepted by the FDA for release testing of a biopharmaceutical product that can replace conventional and time-consuming mycoplasma detection assays based on culture methods.

Mycoplasms are frequent causes of contamination in biopharmaceutical production, cell therapy, tissue engineering and vaccine manufacturing. Traditional detection methods, required by pharmacopoeias and drug regulating agencies worldwide, use growth on culture media and in vitro assays to detect contaminating organisms. Requiring as much as 28 days to complete these growth-based methods are time-consuming, making them laborious and difficult to interpret.

"Mycoplasma contamination represents a significant issue during biological drug production," said Mr Ruedi Stoffel, head, custom biotech, Roche. "Fast methods, like our new MycoTOOL test, will greatly enhance the efficiency, quality and safety in the manufacturing process of pharmaceutical and biological products."