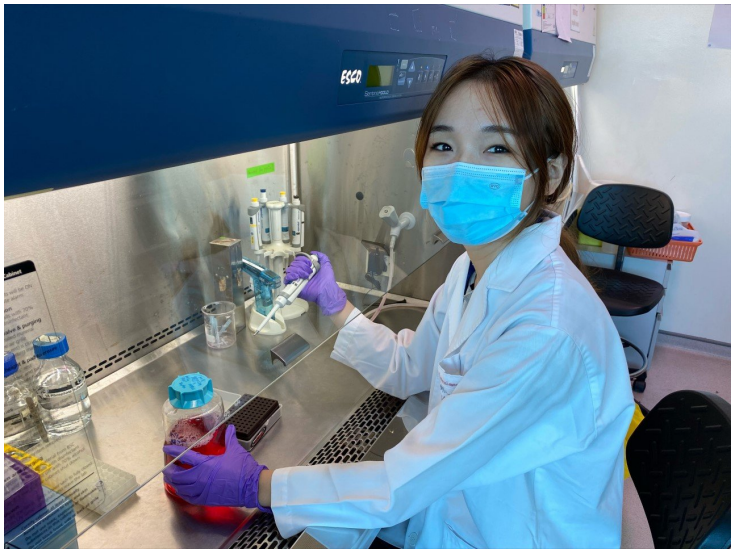
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Singapore researchers enable early-stage detection of microbial contamination in cell therapy

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Scientists at SMART develop a rapid and accurate analytical test method capable of early-stage detection of microbial contaminations enhances the production of high-quality cell therapy products



Researchers from Critical Analytics for Manufacturing Personalized-Medicine (CAMP), an Interdisciplinary Research Group (IRG) at the Singapore-MIT Alliance for Research and Technology (SMART), MIT's research enterprise in Singapore, have identified a critical quality attribute (CQA) that potentially allows the development of a rapid and sensitive process analytical technology (PAT) for sterility. Specifically, this technology enables the detection of early-stage microbial contaminations in human cell therapy products (CTPs).

During the manufacturing process of many CTPs, cells in culture are vulnerable to microbial contamination due to the use of nutrient media, which supports human cell growth but can also support the growth of harmful microorganisms. Therefore, CTPs present a risk of possible transmission of infectious agents from cells to patients, which may cause serious bacterial infections.

To control microbial risks and ensure the product safety of CTPs, sterility testing and monitoring are required in the manufacturing process and before patient infusion. The identification of a secreted metabolite biomarker paves the way toward developing a rapid and accurate sterility test method that could determine microbial safety as early as possible, without also affecting the human cells that serve as the patient's medicine. CAMP's breakthrough is critical in overcoming the challenges of widespread adoption and manufacturing of CTPs.

This method surpasses existing and conventional techniques in terms of both sensitivity and speed. Overcoming existing limitations, the method developed by CAMP is able to detect cell therapy contamination rapidly, using a small volume of spent cell culture medium in a non-cell destructive manner while maintaining the human CTP. Furthermore, this approach can

differentiate between live and dead bacteria. Dead bacteria are non-infectious, and the ability to identify and measure only live bacteria, which pose a health threat, could lead to lower false-positive rates.

The team at SMART CAMP is currently working on translating the research to an innovative sterility PAT to improve CTP quality. The research findings also apply beyond the field of medicine, to detect microbial contamination in other industries, including healthcare, food, cosmetics, and the environment.