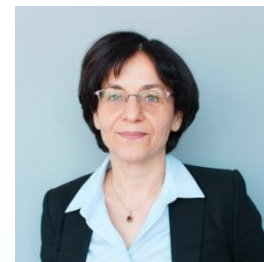


The Monocyte Activation Test

Shabnam Solati

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Abstract

Micro for the purposes of primary health care and patient safety, one of the most important characteristics of a pharmaceutical product is purity and being free of pyrogenic contaminations. Vaccines are being tested for the possible side effects due to the pyrogenic contaminants. Pharmaceuticals worldwide are transitioning from the use of the Rabbit Pyrogen Test (RPT) for batch release of parenteral drugs or for risk assessments where Bacterial Endotoxin Tests (e.g. LAL) are used. This is in accordance with revisions made within the European Pharmacopeia, now starting to be enforced for all producers wishing to distribute across Europe. Using Microbiological testing as risk assessment to assure the drug is free of microbial contaminant is not sufficient. These methods are unable to detect microbial components by which the product quality and patient safety is impacted significantly. Unlike LAL or rFC (solely Endotoxin assays), the MAT is an in vitro pyrogen test that detects both endotoxin and non-endotoxin contaminants. Omitting testing for non-Endotoxin Pyrogens carries significant risks, specifically when biological based products are involved. The proprietary methods we employ in isolating and cryopreserving our PBMCs mean our kits deliver reactivity of fresh blood, highest sensitivity and consistent reproducibility both within and across our large batches of up to 2,000 vials. Using the MAT during COVID-19 vaccine development and manufacturing is an important contribution to ensure human protection based on an effective non-animal based method of quality control.



Biography:

Shabnam Solati developed a Monocyte Activation Test to meet all the end-to-end MAT needs in the industry, with pyrogen detection and quantification levels that are unprecedented. With the expertise of MAT and the knowledge regarding all the test's potential abilities, Shabnam is dedicated to build the future of MAT even beyond where it is today. Therefore, research,

development and innovative technologies are continuous focus points at CTL-MAT.

Speaker Publications:

1. "An improved monocyte activation test using cryopreserved pooled human mononuclear cells"; Innate Immunity, 2015; Vol 21 (7).
2. "Impact of genetic variation in the SMIM1 gene on Vel expression levels"; Transfusion; 2015.
3. "Interaction of Bordetella pertussis filamentous hemagglutinin with human TLR2: Identification of the TLR2-binding domain"; Permitted, 2014; Vol 123 (2).
4. "Nucleosomes and neutrophil activation in sickle cell disease painful crisis"; 2013; Haematologica Vol 98 (11).
5. "Circulating Nucleosomes and Neutrophil Activation As Risk Factors for Deep Vein Thrombosis"; Blood; 2012, Vol 120(21):3387-3387.

[25th International Congress on Pharmaceutical Biotechnology](#); Webinar; June 24 -25, 2020.

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