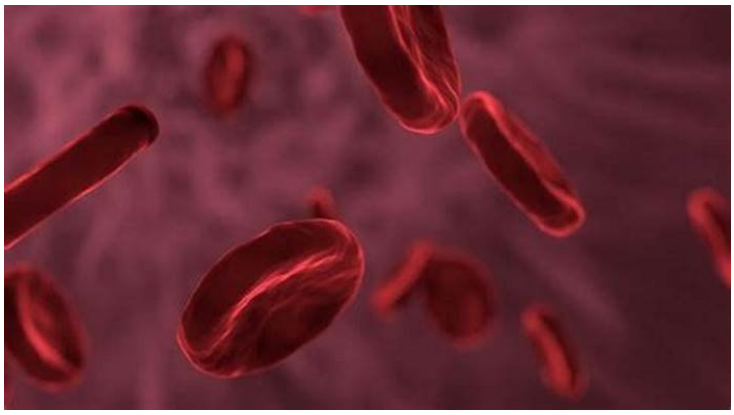
BioSpectrum the business of Bio & Health Sciences ASIA EDITION

Australia approves Immunexpress' sepsis diagnostic device

January 18, 2024 | News

SeptiCyte RAPID by immunexpress receives regulatory clearance from Australian Therapeutic Goods Administration



Immunexpress, a molecular diagnostic company based in Brisbane and Seattle, has announced that SeptiCyte RAPID has received regulatory clearance by the Australian Therapeutic Goods Administration (TGA).

The clearance of the company's flagship medical device by the regulatory body allows for the sale, use and further commercial testing of SeptiCyte RAPID throughout Australia to differentiate infection-positive (sepsis) from infection-negative systemic inflammation response syndrome.

SeptiCyte RAPID will be sold across Australia via Abacus Diagnostics, with whom Immunexpress has an executed Distributor Agreement. Abacus Diagnostics also serves as the distributor for the Biocartis Idylla Platform in Australia.

SeptiCyte RAPID generates a score (SeptiScore, 0-15) based on the increasing likelihood of sepsis. Results are generated in one hour using a small patient blood sample. SeptiCyte RAPID is intended for in-vitro diagnostic use and runs on the Biocartis Idylla Platform.