T2MR® IS THE TECHNOLOGY PLATFORM FOR NEXT GENERATION DIAGNOSTICS

T2 Magnetic Resonance (T2MR) is a diagnostic detection method – utilizing miniaturized magnetic resonance technology– that measures how water molecules react in the presence of magnetic fields. The T2MR technology platform offers a fast, simple and sensitive alternative to existing diagnostic methodologies.

T2MR Technology Highlights

- Detects in a variety of unpurified samples
- Direct from whole blood
  - No blood culture
  - No purification
  - No extraction
- Exquisite sensitivity
  - Detects down to 1 CFU/mL
  - No interference from antimicrobials

T2MR for Molecular and Immunodiagnostics

For molecular and immunodiagnostic targets, T2MR utilizes superparamagnetic particles coated with target-specific binding agents. When the particles are added to a sample containing the target, they bind to and cluster around the target. This clustering changes the microscopic environment of water molecules in that sample, which in turn alters the T2 relaxation signal that is measured, indicating the presence, absence or concentration of the target.

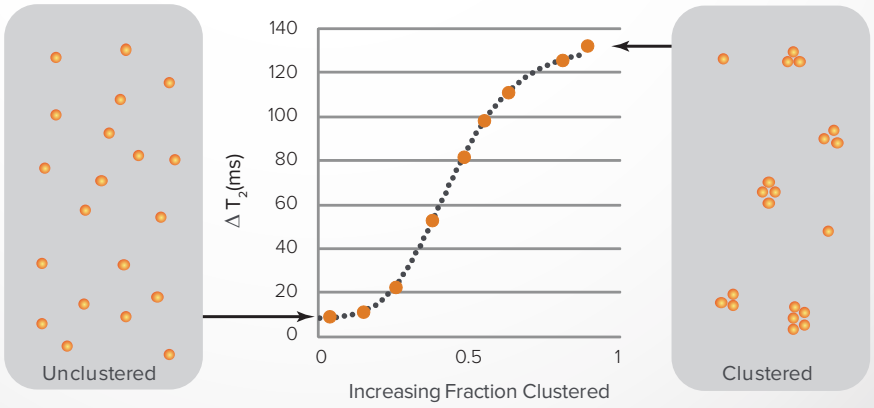

Figure 1: Particles bind to and cluster around the target.

Direct Detection from Sample

Unlike all other detection methods, T2MR is the first detection technology that can quickly and accurately identify molecular targets within patient samples without the need for purification or extraction. T2MR technology can eliminate these time- and labor-intensive steps because the T2 relaxation signal is not compromised or disrupted by the sample background.

This differs entirely from diagnostic systems that rely on traditional polymerase chain reaction (PCR) where purification and extraction are required – which can cause 90% of the target to be lost.[1] Due to these sensitivity limitations, these systems require a time consuming and often insensitive blood culture to enable them to detect at the low levels required for the pathogens associated with sepsis.

Low Limits of Detection and High Sensitivity

T2MR technology enables the T2Dx® Instrument and T2Candida® Panel's low limit of detection, as low as 1 CFU/mL, compared to the 100 to 1,000 CFU/mL required by PCR-based *in vitro* diagnostics. Additionally the T2Candida Panel clinical data has demonstrated 96.4% sensitivity[2] and 99.4% specificity[3]. T2MR performs equally as well in the presence of anti-microbial therapy which has been shown to inhibit blood culture's ability to detect pathogens.

T2MR for Hemostasis

For hemostasis measurements, particles are not required because T2MR is highly sensitive to changes in the microenvironment of a blood sample, such as clot formation, contraction and lysis, which alter the T2 relaxation signal. This enables the rapid identification of clinically relevant hemostasis changes.

T2MR for Other Applications

Over 200 studies published in peer-reviewed journals have featured T2MR in a breadth of applications including the direct detection and measurement of targets such as whole blood, plasma, serum, saliva, sputum and urine.

The potential applications for T2MR extend within and outside of the *in vitro* diagnostics market, including environmental, food safety, industrial and veterinary applications.

The T2Candida Panel is the first sepsis pathogen diagnostic panel requiring no blood culture, delivering faster, easier and accurate results in 3 to 5 hours.[3] Run on the fully-automated T2Dx Instrument, the T2Candida Panel identifies the five clinically relevant species of *Candida* directly from whole blood which enables physicians to initiate appropriate therapy on day zero. Both the T2Candida Panel and T2Dx Instrument are FDA cleared.

[1] PLoS ONE, www.plosone.org, October 2010, Volume 5, Issue 10, e13387

[2] Pfaller, Michael A., Donna M. Wolk, and Thomas J. Lowery. "T2MR and T2Candida: novel technology for the rapid diagnosis of candidemia and invasive candidiasis." *Future microbiology* 0 (2015).

[3] Mylonakis, E., Clancy, C.J., Ostrosky-Zeichner, L., et al. (2015). T2 Magnetic Resonance assay for the rapid diagnosis of candidemia in whole blood: a clinical trial. *Clinical infectious diseases*, 2015: ciu959.

The T2Dx Instrument and T2Candida Panel have received marketing authorization from the U.S. Food and Drug Administration. The T2Plex Instrument and all other T2 Biosystems products are considered investigational and for research use only.

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T2 Biosystems®

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