

## Application of magnetic nanoparticles in diagnostic sector

29 September 2022 | Features | By Dr Ramchand CN, Chief Executive Officer & Chief Scientific Officer, MagGenome Technologies

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The medical diagnostics sector has moved towards active research and development in the area of deep tech, software, and hardware – the only silver lining that was forced on humanity because of the pandemic in recent years. However, it must be noted that the scientists and technocrats in the medical devices sector were already working on advanced prototypes with a focus on improving affordability, accessibility and availability in alignment with the global regulatory guidelines.

## Latest advances in medical diagnostics

The last two years are a testament to the need to develop and improve the performance of current diagnostic assays as well as develop innovative testing strategies to meet new testing challenges. Notably, in recent years, extensive research is undergoing in nanotechnology related to diagnostics and medicine and nanobiotechnology is likely to shape future theranostics.

The development and use of Magnetic nanoparticles (MNPs) has shown better promise to help promote *in vitro* diagnostics to the next level of performance. The most promising nanostructures for *in vitro* diagnostic applications are Quantum dots (QDs), superparamagnetic nanoparticles and gold nanoparticles (AuNPs). In the area of molecular diagnosis, they are presented as promising tools that can be utilised to develop faster, simpler, and cheaper diagnostic tests through the application of magnetic separation processes.

Superparamagnetic nanoparticles can be used for multiplex immunoassays, and as contrast agents in magnetic resonance imaging (MRI) where they have much greater magnetic susceptibility than conventional MRI contrast agents, such as gadolinium. The ultra-small size of the superparamagnetic iron oxide particles used as contrast agents not only have greater magnetic susceptibility but also more widespread tissue distribution resulting in higher tissue absorption. Iron oxide nanoparticles are stabilised by embedding them within polymeric matrices, such as dextran, starch, siloxane, and polyethylene glycol. Iron oxide used for MRI of the liver, spleen and gastrointestinal tract is an established clinical application of commercialised superparamagnetic iron oxide nanoparticles; an example of which is Feridex, which is approved by the US FDA.

Exploratory research is being done using superparamagnetic iron oxide nanoparticles to demonstrate the clinical utility in MRI evaluation of cardiovascular lesions. There is also research underway to develop various immunoassays that use superparamagnetic nanoparticles bound to microbeads to detect antibodies based on their response to magnetic fields. Likewise, rabbit and mouse immunoglobulins could be detected using similar immunoassays.

The advancements in molecular biology have revolutionised our understanding of human diseases. With advancements in DNA diagnostics, today it's possible to analyse diseases at the nucleic acid level. Research has also resulted in automated, rapid, and inexpensive analyses for DNA or RNA sequences associated with genetic, malignant, and infectious diseases. The same technology has also facilitated the identification of disease-associated genes at birth, thus creating new opportunities for preventive medicine. Therefore, there is a need for rapid nucleic acid detection procedures that are highly efficient. MNPs inherent properties and their ability to bind to a broad range of biomolecules (DNA, RNA, proteins) make them potential candidates for isolating DNA/RNA/proteins from complex samples.

## India's role in advancement in molecular diagnostics

In alignment with the medical diagnostics needs of developing countries around the world, advanced research was undertaken in Chennai under the Make in India initiative of the Government of India. This was done to become the global solution provider for molecular diagnostics and genomic research by making the entire process faster, cheaper, and more efficient. The MNP-based products that have been developed and built using indigenous technology, completely developed and customised in India have received much appreciation from the Startup India, Government of India as well as multiple global awards and grants for further research in the field.

The MNP-based products came to the rescue during the COVID-19 pandemic by reducing the time taken for tests from 9 hours to less than an hour. This in itself was able to actively reduce the pressure on the healthcare infrastructure of the country in addition to multiple other contributions during the last two years.

Research in the field of developing uncoated MNP-based products for various applications in the field of life sciences, especially for genomic research and molecular diagnostics resulted in the first bio-nanotechnology companies established in India, bringing first-in-class MNP-based products to the market using its unique cutting-edge technologies by maintaining the highest quality standards. Today with the rising global demand for this one-of-its-kind technology, the prospects for its application in the daily medical diagnostics field are ever increasing and have put India on the global map for the unique solution provider to meet the rising demand in healthcare.

## Research in MNP 2022 and beyond

In recent years, scientists have developed several nucleic acid extraction systems using magnetic nanoparticles, primarily using coated particles. Indian scientists have developed a unique technique using uncoated or bare magnetic nanoparticles and synthesised several kits for the isolation and purification of DNA, RNA, and protein from various biological samples. As the uncoated magnetic beads provide a high surface-to-volume ratio for DNA/RNA molecules to bind to the nanoparticle, recovery and purity are extremely high. While most column-based protocols can result in the loss of a significant amount of DNA/RNA, the strong paramagnetic properties of uncoated magnetic beads minimise the sample loss and ensure integrity and maximum recovery. These technologies have been patented and are now in high demand in India and around the world.

As the next steps in the area of research, scientists have now introduced Next Generation Sequencing (NGS) platforms that have revolutionised the field of molecular diagnostics. Clinical laboratories have adopted NGS as a gold standard for the diagnosis of hereditary disorders because of its analytic accuracy, high throughput, and potential for cost-effectiveness. NGS size selection and clean-up beads offer a straightforward and reliable selection of DNA libraries for different NGS workflows with high recovery rates. The system combines proprietary chemistries with reversible nucleic acid-binding properties of magnetic beads to selectively bind fragments of a specific range and eliminate sub-optimal fragment sizes, leading to more consistent performance. By employing its exclusive technology, scientists are working on developing cell-free DNA extraction kits from serum and plasma for prenatal cell-free DNA (cfDNA) screening tests.

MNPs are inherently endowed with features that can be applied in disease diagnosis, separating, and isolating specific cells and biomolecules from complex samples. Nanoparticle-based diagnostics may open new frontiers for the detection of tumours, infectious diseases, and neurological diseases, to name a few. More work is necessary to fully optimise the utilisation of nanoparticles for clinical diagnosis and to resolve some concerns regarding potential health and environmental risks related to their use.

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