

Your molecular diagnostics partner from concept to commercialization? We IVD that

Molecular diagnostics comprises a broad array of techniques used for detecting and monitoring disease biomarkers. These include established methods such as PCR amplification and gel electrophoresis, as well as more modern approaches like next-generation sequencing (NGS) and CRISPR-Cas9 gene editing.

Our molecular diagnostics division, MedixMDx, has recently grown with the acquisition of myPOLs Biotec GmbH, a company focused on developing DNA polymerase-based tests and engineering novel DNA polymerases. As a result, we now offer even greater flexibility for IVD assay development and manufacturing.

MedixMDx supplies a comprehensive suite of reagents and services for molecular diagnostics applications, backed by the support of our highly experienced team.

Our product offering includes enzymes, master mixes, controls, and clinical specimens, many of which are unique to MedixMDx, and guarantees full compliance with IVD regulatory requirements.

- **Experts in reagent lyophilization for molecular diagnostics**

- **Proven track record in DNA/RNA polymerase engineering**

- **Product citations in numerous journals, including Nature**

Custom services designed to shorten product development timelines? We IVD that

Our capabilities span a wide selection of technologies, including:

- Polymerase chain reaction (PCR) / quantitative polymerase chain reaction (qPCR)
- Droplet digital polymerase chain reaction (ddPCR)
- Reverse transcription polymerase chain reaction (RT-PCR)
- Isothermal nucleic acid amplification technology (INAAT)
- Microarrays
- Next-generation sequencing (NGS)
- CRISPR-Cas9 and TALEN-based gene editing

Cutting edge products for molecular diagnostics? We IVD_o that

Additionally, our agile and innovative approach means we can support other platforms as needed, tailoring our workflow to align with our customers' exacting requirements. Featured products include:

- **HiDi® DNA Polymerase** and **HiDi® Taq DNA Polymerase** - highly selective DNA Polymerase variants for primers with a 3'-end mismatch; capable of detecting <10 copies of a mutation in a background of > 10,000 wild-type copies
- **PlexTaq® 5x qPCR Multiplex Master Mix** - allows direct qPCRs from crude sample material; ideal for DNA barcoding in multiplexed amplifications for NGS
- **Volcano® family** - a unique Master Mix containing a thermostable Taq DNA polymerase with reverse transcriptase activity; eliminates the need for sample extraction or lysis; suitable for RT-PCR-based SARS-CoV-2 detection without the need to extract RNA

Expert advice for your molecular diagnostics? We IVD_o that

Our expertise spans every aspect of molecular diagnostics development and manufacturing – all the way from proof-of-concept to release for sale – meaning you can count on us to shorten assay development time and complexity, helping bring your product to market sooner.

Services we offer include:

- Raw material or master mix testing
- Kits and primer design
- Pre-clinical testing
- Quality Control testing
- Performance testing
- Extensive stability testing
- Kit manufacturing readiness assessments
- Kit manufacturing
- Registration support
- Sales support



These are underpinned by tireless customer support and consolidated supply chain management, making us your preferred partner, whatever the needs of your molecular diagnostics project.

To discuss how we can help deliver on your goals, contact us today: mdx@medixbiochemica.com