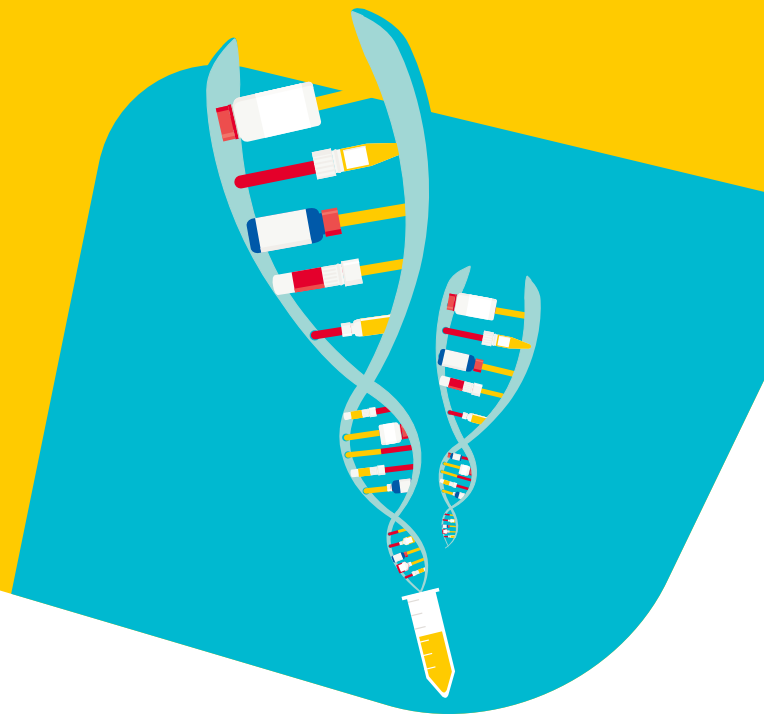
NEWS on diagnostics

2025 Volume 3



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Welcome to the third volume of 2025.

This edition highlights the key products in molecular diagnostic workflows. Through our life science division, we offer a comprehensive molecular diagnostics portfolio that supports everything from sample preparation to assay development and commercialisation.

Molecular Diagnostics

Molecular diagnostics is a rapidly advancing field with significant potential, yet it encounters several critical challenges:

- **Technical Complexity:** The processes involved, from sample preparation to data interpretation, require a high level of precision and specialised expertise.
- **Cost and Accessibility:** The capital costs associated with the equipment can put it out of reach of smaller or resource-constrained laboratories.
- **Regulatory Compliance:** Maintaining the integrity of diagnostic procedures requires strict adherence to quality control measures and regulatory standards.

Addressing and overcoming these challenges is key to advancing diagnostic testing. Read on to find out how Merck can support your assay development goals.

Ultra pure Reagents

Unlike its predecessors, the new Ultra pure DNA-free portfolio undergoes meticulous purification, significantly reducing DNA, nickase, DNase, and RNase contamination. This ensures minimal risk of false results caused by contaminated reagents. Our molecular raw materials are manufactured in ISO-9001 certified facilities, making them an exemplary choice to enhance the accuracy of your diagnostic assays.

Ultra pure JumpStart™ Taq DNA Polymerase

Useful for amplification and detection of DNA targets, enabling gene expression analysis, viral load quantification, and detection of DNA-based pathogens:

- Ultra pure JumpStart™ Taq DNA Polymerase is absent of detectable levels of DNA, DNase, RNase, nickase or endonuclease contamination.
- Antibody inactivated hot-start feature minimises non-specific amplification while increasing target yield.

Product No.	Name	Description
UPJSTAQ	Ultra pure JumpStart™ Taq DNA Polymerase	DNA-free, Nuclease-free Hot-start Taq Polymerase, designed for further manufacture
UPH2O	Ultra pure DNA-free Water	DNA-free, Nuclease-free water
UPTQBF2	Ultra pure 10x Taq Buffer without $MgCl_2$	DNA-free, Nuclease-free 10x PCR reaction buffer without $MgCl_2$, designed for further manufacture
UPMGCL2	Ultra pure 25mM $MgCl_2$	DNA-free, Nuclease-free 25mM $MgCl_2$, designed for further manufacture

Ultra pure MagPrep® Viral RNA & cfDNA Isolation Kits

Newly introduced into the Ultra pure family is the MagPrep® Viral RNA and cfDNA Isolation kits. Our cfDNA Isolation Kit is used for the isolation of cell-free DNA from blood for liquid biopsy and our Viral RNA Isolation Kit is used for the isolation of viral RNA from biological samples like nasal swabs. The components of these kits, which include MagPrep® particles and reagents are:

- Free from DNA, DNase, RNase, nickase, and endonuclease contamination reducing the risk of false-positive results

Other additional features include:

- Fast simple protocol (< 30 mins)
- No Proteinase K or heat needed
- Ambient storage
- Sensitivity matches or beats top competitors
- Consistent yields

Product No.	Name
UPMPVRNA-KT	Ultra pure MagPrep® Viral RNA Isolation Kit
UPMPCFDNA-KT	Ultra pure MagPrep® cfDNA Isolation Kit
UPMPPART	Ultra pure MagPrep® Magnetic Particles
UPMPVRBB	Ultra pure MagPrep® RNA Lysis and Binding Buffer
UPMPCFDBB	Ultra pure MagPrep® cfDNA Binding Buffer
UPMPWB1	Ultra pure MagPrep® Wash Buffer 1
UPMPWB2	Ultra pure MagPrep® Wash Buffer 2
UPMPEB	Ultra pure MagPrep® Elution Buffer

Read the Technical Article 'Achieving Reliable Results with Ultra pure PCR Solutions for Molecular Diagnostics' as well as Technical Article 'Isolation and ddPCR Analysis of cell-free DNA from Plasma for Lung Cancer Research' to learn more about Ultra pure portfolio performance.

Learn more about our portfolio of Molecular Materials for Diagnostics HERE.

MagPrep® Silica

Our MagPrep® Silica magnetic particles offer several advantages for nucleic acid purification, making them a popular choice in both research and clinical laboratories. Here are the key benefits:

High Binding Efficiency

Effectively binds both RNA and DNA under chaotropic or mildly acidic conditions.

Fast, Automation-Friendly Workflow

No centrifugation or organic solvents needed. Magnetic separation completes in under 15 seconds, with stable suspensions for up to 5 minutes—ideal for automated systems.

Safe and Versatile

Ethanol-free wash steps reduce contamination risk. Elution works with any aqueous buffer at pH >8.0. Scalable for high-throughput processing.

Optimised Particle Design

Nanoparticles (100–200nm) with a positively charged surface ensure strong nucleic acid binding and consistent, reproducible results.

In addition to these key benefits for R&D use, they are also suitable in a manufacturing environment, being OEM/IVD compatible. However, for full GMP compliance, you would need to validate the product within your specific process and ensure that all reagents and workflows meet regulatory standards.

For more information on MagPrep® Silica, please read our Technical Article.

Quality Considerations

All our Ultra pure portfolio & MagPrep® Silica reside within the MQ300 segment of our M-Clarity™ Program.

MQ300 is designated for products used in applications requiring enhanced change control and quality agreements. This means:

Enhanced Change Control: Any changes to the product (e.g., formulation, manufacturing process, packaging) are communicated in advance, allowing manufacturers to assess and manage risks.

Quality Agreements: Formal agreements between supplier and manufacturer to ensure consistent quality and compliance with regulatory standards.

MQ300 is a mid-tier quality level, suitable for manufacturing environments that need more control and documentation than basic research.

Oligos

From bench to market, we tailor by stage. In R&D, expect breadth and speed with tailored oligo solutions and rigorous QC, supported by a global manufacturing network (UK, USA, India, Israel). For commercial supply, count on depth and consistency under a robust QMS (ISO 9001/13485), with end-to-end project management and audit-ready processes to scale reliably.

Custom DNA & RNA Oligos:
SigmaAldrich.com/standardoligos

Custom Oligos for commercial use:
SigmaAldrich.com/compliantoligos

Where Oligos Are Used in IVD Assay Development

1. Assay Design

- Primers: Short DNA sequences that initiate DNA synthesis. They define the region of the target DNA or RNA to be amplified.
- Probes: Labeled oligos (e.g., MGB probes) that bind specifically to the target sequence and generate a signal (e.g., fluorescence) upon hybridisation or cleavage.

2. Analytical Validation Oligos are tested for:

- Specificity: Do they bind only to the intended target?
- Sensitivity: Can they detect low levels of target nucleic acid?
- Efficiency: How well do they amplify the target?

3. Reagent Manufacturing

- Oligos are synthesised under cGMP or ISO 13485 conditions for use in regulated diagnostic kits.
- They are often lyophilised or formulated into master mixes.

4. Clinical Validation

- Oligos are used in clinical sample testing to validate the assay's performance in real-world conditions.

5. Kit Assembly

- Final IVD kits include oligos as part of the ready-to-use reagent mix, often with enzymes, buffers, and controls.

6. Post-Market Surveillance

- Oligos may be re-evaluated if mutations in target pathogens (e.g., viruses) affect assay performance.

Custom Oligos for commercial use

We offer custom DNA Primers, qPCR Probes, and Next-Gen Sequencing Oligos for Life Science Research Tools, Molecular Diagnostics, and Laboratory Developed Tests. We can also perform component or complete kit manufacturing, including custom formulations, packaging, and private labelling. Learn about our manufacturing capabilities or request a consultation to determine which type of product best fits your needs. Watch the video HERE.

cGMP Oligos

cGMP oligos are oligonucleotides manufactured under current Good Manufacturing Practice (cGMP) standards. These rigorous standards ensure high-quality production by minimising the risk of contamination, mix-ups, deviations, and other errors.

Risk Mitigation: Manufacturing oligos under cGMP minimises the probability of errors, making them suitable for molecular diagnostics, laboratory developed tests (LDTs), and preclinical research. Learn more about our Quality Management System (QMS) for commercial oligos HERE!

Commercial Use: Merck offers Custom cGMP Oligos, which are oligonucleotides manufactured under current Good Manufacturing Practice (cGMP) standards. These high-quality oligos are tailored for diagnostic and clinical markets. Here are the key points:

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Manufacturing Suite:

- Merck's suite includes three laboratories: Synthesis, Purification, and Quality Control.
- The oligos are manufactured in accordance with US GMP (21 CFR 820) and filled in a classified cleanroom (ISO 14644-1:2015 Class 8).
- The site maintains an ISO 13485 Quality Management System certificate.

Benefits of Custom cGMP Oligos:

- Controlled and validated processes ensure batch-to-batch consistency and reproducible results.
- Extensive materials traceability enhances quality and risk mitigation.

These oligos meet stringent requirements for Molecular Diagnostics (MDx), Laboratory Developed Tests (LDTs), and preclinical research. Varying product applications require different approaches to managing the supply chain. The ideal combination of Strategic Partnership and Supply Assurance can be best achieved through ongoing communication and collaboration.

Learn more HERE!

MGB Probes in qPCR

Minor Groove Binder (MGB) probes are a type of hydrolysis probe enhanced with an MGB molecule at the 3' end, which:

- Raises melting temperature (Tm), enabling shorter, more specific probes.
- Improves specificity in detecting single nucleotide polymorphisms (SNPs).
- Enhances performance in qPCR and genotyping assays.

Merck's MGB Probe Features

1. Dual-labelled with MGB and quenchers (e.g., MGB:EDQ) at the 3' end.
2. We offer three standard fluorophores and are happy to evaluate others.
3. Available with cGMP oligos.

Learn more HERE!

@The lab bench

An IVD R&D focused discussion series

In this series of informal discussions with research and development scientists we aim to illuminate some of the not so obvious tips, trick, and insider information on developing novel IVD molecular assays.

Scan QR code to watch now!

SigmaAldrich.com/atlb

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