

GMP for molecular diagnostics

Oligos for *in vitro* diagnostics (IVDs), analyte-specific reagents (ASRs), next generation sequencing (NGS), and laboratory-developed tests (LDTs)

You have an assay. Let's build it together.

We aim to provide personalized, consistent, and streamlined interactions while demonstrating a dedication to expertise and a commitment to enabling new discoveries in biology and medicine.

As your single point of contact, a dedicated account advocate manages all aspects of your GMP processing experience from feasibility through commercial or clinical production. Our team is ready to collaborate with you to ensure your products are made to your specifications, every time, all the time.

Reproducible manufacturing processes

We have multiple production labs and an expert staff that can facilitate your transition from research oligos to GMP-certified oligos for diagnostics. Our controlled and validated process is governed by the Oligo Master Record, which formally details how we produce your oligos.

- LIMS batch record traceability for every oligo
- Hard-copy analytical QC documentation
- Long-term agreements and contracts to ensure a stable supply of high-quality GMP oligos



benefits

Easily transition from RUO to IVD by aligning specifications and methods from research to GMP.

Receive a full range of OEM services, including customized formulation, labeling, and packaging.

Obtain license-free fluorophores, including fluorescein, Cy[®], rhodamine, and ATTO[™] dyes.

Discover more at
www.idtdna.com/GMP

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Legal and regulatory guidance

With our open-door audit policy, you can be confident that your GMP oligos are manufactured in compliance with all applicable regulations. Our facilities are ISO 13485:2016 certified and compliant with US Food and Drug Administration (FDA) Quality System Regulation (QSR) 21 CFR Part 820. We also produce oligos that can be included in CE-marked kits and other commercial products.

- On-site product or process audits
- Validation programs for all equipment and processes
- Rigorous product-release process

License-free dyes

For affordable development of diagnostic products, use our Freedom Dyes, a selection of fluorophores with no patent licensing restrictions. Freedom Dyes are available for use in commercial and diagnostic applications.

- Proprietary IDT fluorophores available for commonly used dye wavelengths
- Fluorescein, Cy, rhodamine, and ATTO dyes
- ZEN and Iowa Black quenchers for probes with lower background and higher signal



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