IVD-grade oligonucleotides

# High-Purity OEM Oligonucleotides for Reliable Molecular Assays

Oligo-nucleotides

# Quality processes compliant with current standards and regulations

In 2012, QIAGEN acquired Scandinavian Gene Synthesis AB (SGS DNA), adding its highly-pure oligonucleotides to our OEM portfolio.

Synthesis processes of our oligonucleotides are optimized to meet the requirements of sensitive molecular assays, achieving high lot-to-lot consistency.

**+25** years of experience

**IVD** grade oligonucleotides

**FDA** registered

**21 CFR** Part 820

**cGMP/QSR**

**ISO** 9001:2015
13485:2016
14971:2019
certified

For more information, visit our webpage

More certification information

# Oligonucleotide quality levels

One supplier for high-quality oligonucleotides from development grade for pilot testing to IVD grade for full-scale manufacturing requirements.

| | Fast track | Development-LC | Development-HPLC | IVD |
|---|---|---|---|---|
| **Traceability** | None | Partial | Partial | Full |
| **Purification** | LC/HPLC | LC | HPLC | HPLC |
| **HPLC column** | Non dedicated | N/A | Non dedicated | Dedicated |
| **Clean room** | None | Optional | Optional | Dedicated |
| **Quality systems** | ISO 9001 | ISO 9001<br>ISO 13485 | ISO 9001<br>ISO 13485 | ISO 9001<br>ISO 13485<br>21 CFR Part 820 |
| **QC control** | Optional QC | Optional QC | Customized QC | In process/<br>Final |
| **Product release** | Final QC | Technical release | Technical release | QA release |
| **Documents provided** | Compilation of results | Simplified CoA | Simplified CoA | Full CoA |
| **Critical raw material control** | Partial | Partial | Partial | Full |
| **Environmental control** | Yes | Yes | Yes | Yes |
| **Manufacturing documents** | None | Simplified production batch record | Simplified production batch record | Production batch record |
| **Synthesis scale** | 0.04–0.1 µmol | 0.15–60 µmol | 1–60 µmol | 1–60 µmol |

# Why choose QIAGEN oligonucleotides

## High quality and purity

Our oligos are produced using IEX-HPLC and RP HPLC methods, resulting in purities **>90%**

## Lot-to-lot reproducibility – from research to manufacturing

Critical raw materials are tested, synthesis processes are optimized and automated to meet diagnostic applications' requirements

## IVD grade – non-contamination guarantee

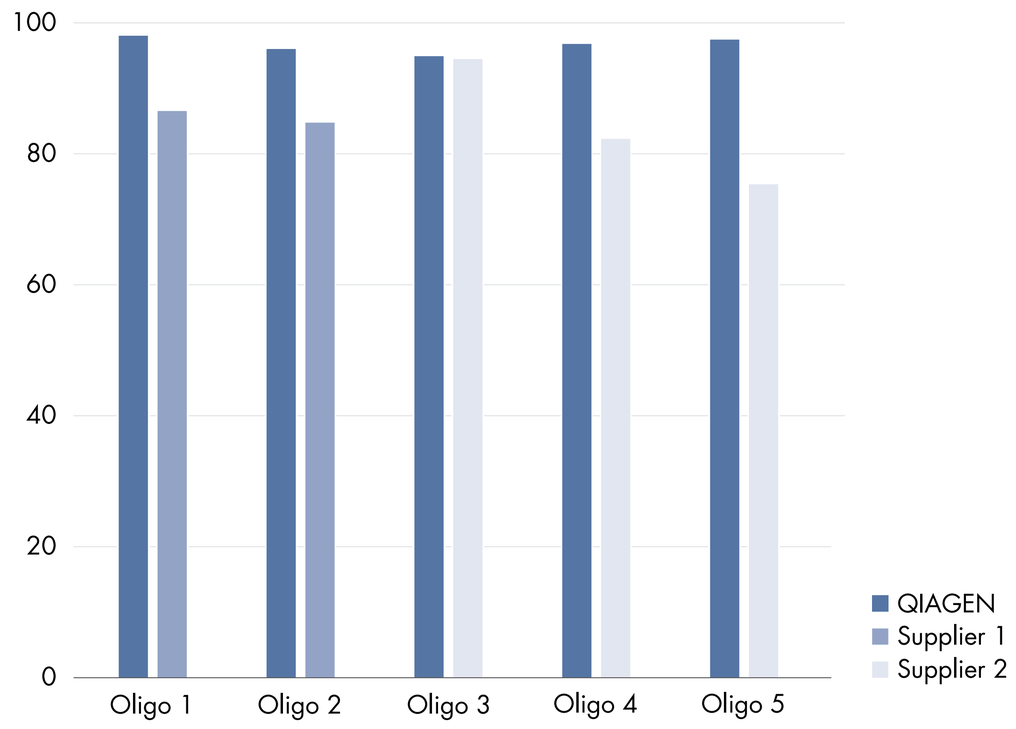
Dedicated LAF cabinets effectively prevent cross contamination

## Extensive quality control (QC) and quality assurance (QA)

cGMP/QSR, ISO certified, full traceability with extensive production batch records

Representative example of purity (%) for 5 different oligos

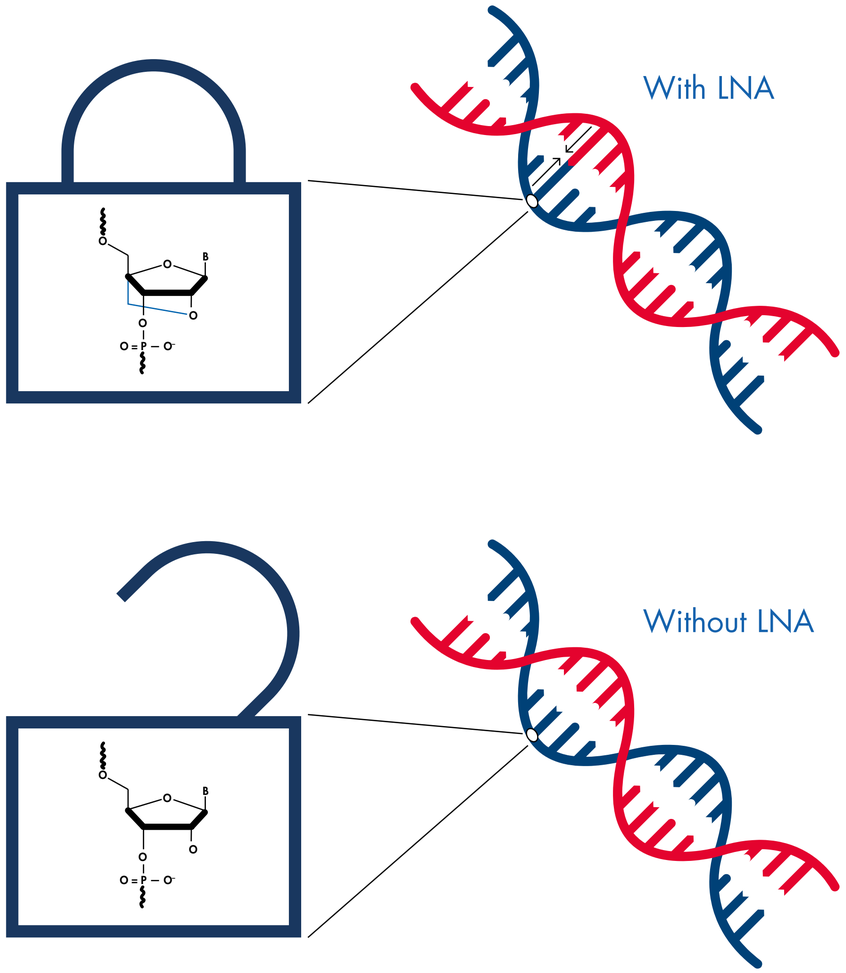
Comparison between QIAGEN, Supplier 1 and Supplier 2, Oligo 1–3: Probes, Oligo 4 and 5: Primers



# Locked Nucleic Acid (LNA) oligonucleotides

## LNA technology allows for high analytical sensitivity and specific detection of DNA and RNA targets

Designing LNA oligonucleotides is complex and requires expertise. We can support you with off-the-shelf or customized LNA oligos.




### LNA Features

- Locked ribose conformation provides stronger base pairing → increased Tm (2–8°C), enables shorter oligo design
- Improved mismatch discrimination, single nucleotide differentiation
- High analytical sensitivity and specificity in probes
- Increased oligo stability and potency in cells
- We can guide you regarding assay design and dye assignment to match your target nucleic acid and controls.

Contact us

# Modifications

| Oligonucleotide categories | Unmodified oligonucleotides | Modified oligonucleotides |
|---|---|---|
| • Primers<br>• Probes<br>• SCORPIONS<br>• Locked Nucleic Acid (LNA)<br>• NGS Adapters<br>• Molecular Beacons | • Unmodified oligonucleotides up to 170 bases<br>• Homopolymers such as polyA and polyT | • Fluorescent groups<br>• Fluorescent groups combined with Quenchers<br>• LNA® containing oligonucleotides<br>• MGB-Eclipse® Dark Quencher<br>• EBQ<br>• Superbases<br>• SuperA®, SuperG® and SuperT®<br>• Biotin<br>• Phosphate<br>• Spacers<br>• Amino<br>… and more |

- Large selection of modifications for various oligonucleotides
- Continually evaluating new dyes, quenchers and other modifications

For more information, visit our webpage

# Modifications (cont.)

| Fluorophores | 5' | Internal | 3' |
|---|---|---|---|
| FAM | ✔ | ✔ | ✔ |
| Fluorescein dT | ✔ | ✔ | – |
| HEX | ✔ | ✔ | ✔ |
| Quasar® 570 | ✔ | – | – |
| Quasar 670 | ✔ | ✔ | ✔ |
| ROX | ✔ | ✔ | ✔ |
| CAL Fluor® Orange | ✔ | – | – |
| CAL Fluor Red | ✔ | – | – |
| Yakima® Yellow | ✔ | – | – |
| TAMRA | ✔ | ✔ | ✔ |
| Chromis 500 | – | – | Inquire |
| Chromis 530 | – | – | Inquire |
| Chromis 645 | – | – | Inquire |

| Fluorophores | 5' | Internal | 3' |
|---|---|---|---|
| Chromis 570 | ✔ | ✔ | E |
| Texas Red | ✔ | ✔ | ✔ |
| DY 530 | ✔ | ✔ | ✔ |
| DY 547 | ✔ | ✔ | ✔ |
| DY 495 | ✔ | ✔ | ✔ |
| Cy 3 | ✔ | ✔ | – |
| Cy 3.5 | Inquire | Inquire | – |
| Cy 5 | ✔ | ✔ | – |
| Cy 5.5 | ✔ | ✔ | – |
| Cyanine 5 | ✔ | ✔ | Inquire |
| Cyanine 3 | ✔ | ✔ | Inquire |
| JOE | ✔ | ✔ | ✔ |

# Modifications (cont.)

| Quenchers | 5' | Internal | 3' |
|---|---|---|---|
| Dabcyl | – | – | ✔ |
| Dabcyl -Succinyl | – | – | ✔ |
| Dabsyl | – | – | ✔ |
| Dabcyl dT | ✔ | ✔ | – |
| Black Hole Quencher® 1 | – | ✔ | ✔ |
| Black Hole Quencher 2 | – | ✔ | ✔ |
| MGB® Eclipse® Dark Quencher | – | – | ✔ |
| Eclipse Dark Quencher | – | – | Inquire |
| TAMRA | ✔ | ✔ | ✔ |
| Tide Quencher 2 | – | – | Inquire |
| Tide Quencher 3 | – | – | Inquire |
| Tide Quencher 4 | – | – | Inquire |
| BBQ 650 | Inquire | Inquire | ✔ |

| Thiol Modifier | 5' | Internal | 3' |
|---|---|---|---|
| Thiol Modifier S-S | Inquire | Inquire | Inquire |

| Spacers | 5' | Internal | 3' |
|---|---|---|---|
| Spacer C12 | ✔ | ✔ | – |
| Spacer 18 (HEG) | ✔ | ✔ | – |
| Spacer C3 | – | – | Inquire |
| Spacer C6 | – | – | ✔ |
| PEO | ✔ | ✔ | – |

| Modified bases | 5' | Internal | 3' |
|---|---|---|---|
| Methyl dC | ✔ | ✔ | – |
| Inosine | ✔ | ✔ | – |
| Inverted dG (dG-5') | – | – | Inquire |
| Inverted dT (dT-5') | – | – | ✔ |
| Inverted dA (dA-5') | ✔ | ✔ | – |
| 2'-OMe-RNA | ✔ | ✔ | – |

# Modifications (cont.)

| Amino | 5' | Internal | 3' |
|---|---|---|---|
| Amino ON | – | – | ✔ |
| PT-Aminomodifier C6 | – | – | ✔ |
| MMT-Aminomodifier C6 | ✔ | – | – |
| MMT-Aminomodifier C12 | ✔ | – | – |
| Aminomodifier C6 dT | ✔ | ✔ | ✔ |
| TFA-Pentylaminolinker | ✔ | – | – |
| Aminomodifier C6 dC | ✔ | ✔ | Inquire |

| $T_m$ Modifiers | 5' | Internal | 3' |
|---|---|---|---|
| MGB | Inquire | Inquire | Inquire |
| Super A® | ✔ | ✔ | – |
| Super T® | ✔ | ✔ | – |
| Super G® | ✔ | ✔ | – |
| pdU | ✔ | ✔ | – |
| pdC | ✔ | ✔ | – |

| Biotin | 5' | Internal | 3' |
|---|---|---|---|
| Biotin C3 | – | – | ✔ |
| 5'-Biotin | ✔ | – | – |
| Biotin-TEG | ✔ | – | ✔ |
| Biotin-ON | ✔ | ✔ | ✔ |

| Phosphate | 5' | Internal | 3' |
|---|---|---|---|
| Phosphorylation | ✔ | – | ✔ |

| Phosphorothiate linker | 5' | Internal | 3' |
|---|---|---|---|
| Phosphorothiate bonds | – | Inquire | – |

# Modifications: Dual-labeled probes

| Dual-Labeled Probes | | 3' Quencher | | | | |
|---|---|---|---|---|---|---|
| 5' Reporter | $Ex_{max}/Em_{max}$ | Dabcyl | TAMRA | BHQ | MGB-EDQ | BBQ650 |
| CHROMIS 500 | 496/506 | Abmax 478 nm<br>QR 400–550 nm | Abmax 557 nm<br>QR 520–570 nm | BHQ 1<br>Abmax 534 nm<br>QR 480–580 nm | Abmax 522 nm<br>QR 390–625 nm | Abmax 522 nm<br>QR 390–625 nm |
| FAM | 495/520 | | | | | |
| DY 495 | 493/521 | | | | | |
| JOE | 520/548 | | | | | |
| Yakima Yellow® | 530/549 | | | | | |
| HEX | 535/556 | | | | | |
| VIC | 538/554 | | | | | |
| CALfluor® Orange | 537/558 | | | | | |
| CHROMIS 530 | 529/561 | | | | | |
| DY 530 | 539/561 | | | | | |
| NED | 546/575 | | | | | |
| Quasar® 570 | 547/570 | | | | | |
| Cy 3 | 552/570 | | | | | |
| Cyanine 3 | 552/570 | | | | | |
| TAMRA | 557/583 | | | | | |
| ROX | 575/602 | | | BHQ 2<br>Abmax 579 nm<br>QR 560–670 nm | | |
| Texas Red | 583/603 | | | | | |
| CAL fluor® Red | 590/610 | | | | | |
| CHROMIS 570 | 573/612 | | | | | |
| Quasar® 670 | 644/670 | | | | | |
| Cy 5 | 649/670 | | | | | |
| Cyanine 5 | 649/670 | | | | | |
| Cy 5.5 | 675/694 | | | | | |

We can guide you with assay design and dye assignment to match your target nucleic acid and controls.

Contact us

# SCORPIONS®

| SCORPIONS | | Internal Quencher | | Synthesis Scale | Purification |
|---|---|---|---|---|---|
| 5′ Reporter | $Ex_{max}/Em_{max}$ | Dabcyl | BHQ | | |
| FAM | 495/520 | Abmax 478 nm QR 400–550 nm | BHQ 1 Abmax 534 nm QR 480–580 nm | 1–4×8 µmol | HPLC |
| DY495 | 493/521 | | | | |
| JOE | 520/548 | | | | |
| Yakima Yellow® | 530/549 | | | | |
| HEX | 535/556 | | | | |
| CAL fluor® Orange | 537/558 | | | | |
| DY530 | 539/561 | | | | |
| Quasar® 570 | 547/570 | | BHQ 2 Abmax 579 nm QR 560–670 nm | | |
| TAMRA | 557/583 | | | | |
| ROX | 575/602 | | | | |
| Texas Red | 583/603 | | | | |
| CAL fluor® Red | 590/610 | | | | |
| Chromis 645 | 641/663 | | | | |
| Quasar® 670 | 644/670 | | | | |

- Bi-functional oligonucleotides enable high analytical specificity and sensitivity
- To limit non-specific amplification, our oligonucleotides contain target-specific PCR primer covalently linked to a probe, with an extension blocker (HEG, hexathylene glycol)
- The unimolecular detection mechanism enables a rapid kinetic reaction and instantaneous generation of a high fluorescent signal
- Our oligonucleotides help ensure reliable and robust probing of the chosen amplicon
- OEM oligonucleotides are a valuable tool for rapid real-time PCR, end-point PCR, SNP detection, allele discrimination, gene expression analysis, pathogen detection and multiplexing
- For NGS adapters we manufacture these oligos at high quality and purity, using controlled annealing procedure to make sure that we have the right and specific duplex.
- OEM by QIAGEN manufactures NGS adapters that can be manufactured at diverse scales and qualities.

# Additional OEM Services

| Formulation capabilities | QC support* | Consulting service |
|---|---|---|
| • Concentration targeting | • Reversed Phase HPLC (RP-HPLC) | • Implement tailored modifications and design |
| • Lyophilized or in the buffer of your choice | • Reversed Phase UPLC (RP-UPLC) | • Manufacturing performance analysis |
| • Bulk or aliquots in tubes | • Anion Exchange HPLC (IEX-HPLC) | • Modification evaluation |
| • Custom mixing | • ESI-TOF Mass Spectrometry | • Sequence design support |
| • Custom labeling on the product vial | • Amino reactivity determination | • Chemical stability studies |
| | | • Process and result documentation |

* Analytical methods for troubleshooting or evaluation of third-party products.

Contact us

# OEM by QIAGEN

## Allow us to be your trusted partner for accelerating your molecular assay development

- Confidentiality and trust
- Quality at scale
- Innovation combined with expertise
- Portfolio breadth

Nucleic acid purification

Enzymes

Oligonucleotides

Master Mixes

For more information, see **www.qiagen.com/oem**

Contact us

Disclaimers

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