

# Ntensify<sup>®</sup> reagent mixes

**HQG · HIGH QUALITY GRADE**

Mixes of reagents for GMP manufacturing — Packaging content mRNA – process 4.5

## WHAT HQG MEANS

**High Quality Grade (HQG)** reagents are manufactured under Quantom's documented quality management system, in controlled and segregated production areas, against defined release specifications. Every lot is produced to a batch record, fully traceable, and released with a Certificate of Analysis. Raw materials are animal-origin-free and qualified suppliers are bound by change notification.

Because these are raw materials, HQG reagents are suitable for use as starting materials in the **GMP manufacturing of RNA drug substance** — as well as for process development, engineering runs, and preclinical and toxicology material. The documentation supplied with each lot is built to support qualification of the reagent under your quality system.

### One grade, from bench to clinic.

Each HQG lot carries the traceability and documentation — CoA, TSE/BSE and animal-origin-free statements, change notification — that a GMP manufacturer needs to qualify a raw material. The same reagents carry you from process development into GMP drug-substance production, with no change of source or specification along the way.

## GRADE SCOPE AT A GLANCE

|                        | R&D                     | HQG                                                                                     |
|------------------------|-------------------------|-----------------------------------------------------------------------------------------|
| Quality system         | Documented QMS          | Documented QMS                                                                          |
| Lot release            | Internal control        | Specification + CoA                                                                     |
| Traceability           | Full batch record       | Full batch record                                                                       |
| Change notification    | ×                       | ✓                                                                                       |
| Documentation supplied | Product datasheet & CoC | CoA, CoC, TSE/BSE & AOF statement                                                       |
| Intended use           | Research use only       | Process development, toxicity studies, preclinical & raw material for GMP manufacturing |

# Ntensify® reagents mixes – HQG – process 4.5

| NAME                  | DESCRIPTION                                                                                | GRADE | 20 mL Kit                           | 200 mL Kit                                                       | STORAGE |
|-----------------------|--------------------------------------------------------------------------------------------|-------|-------------------------------------|------------------------------------------------------------------|---------|
|                       |                                                                                            |       | Vol mL                              | Vol mL                                                           |         |
| ATP                   | Adenosine triphosphate                                                                     | HQG   | 2,35                                | 23,47                                                            | -20 °C  |
| CTP                   | Cytidine triphosphate                                                                      | HQG   | 2,59                                | 25,90                                                            | -20 °C  |
| GTP                   | Guanosine triphosphate                                                                     | HQG   | 2,59                                | 25,90                                                            | -20 °C  |
| Cap analog            | CleanCap® TriLink® AG or AG 3' – supplied under Quantom's commercial licence from TriLink® | HQG   | 1,47                                | 16,17                                                            | -20 °C  |
| Uridine               | rUTP or Pseudo-UTP or NI-methylpseudouridine – all three supplied, select per construct    | HQG   | 1,73                                | 18,60                                                            | -20 °C  |
| Mix 2                 | Enzymes                                                                                    | HQG   | 2,76                                | 31,00                                                            | -20 °C  |
| Mix 3                 | IVT buffer                                                                                 | HQG   | 4,53                                | 50,23                                                            | -20 °C  |
| Mix 4                 | DNA removal                                                                                | HQG   | 1,82                                | 24,15                                                            | -20 °C  |
| Mix 5                 | Quenching                                                                                  | HQG   | 4,74                                | 55,65                                                            | RT      |
| Mix 6                 | Purification (high-salt buffer + beads)                                                    | HQG   | 21                                  | 21                                                               | RT      |
| Mix 7                 | High-salt buffer                                                                           | HQG   | 153                                 | 321                                                              | RT      |
| Mix 8                 | Ethanol 100 %, Ph. Eur. / USP, ≥ 99.5 %, non-denatured                                     | HQG   | 1000<br><i>off-the-shelf bottle</i> | 1000<br><i>For 400 / 600 / 800: supplied in a 2500 mL bottle</i> | RT      |
| Mix 9, Mix 11, Mix 13 | Water for injection, Ph. Eur.*                                                             | HQG   | 500<br><i>off-the-shelf bottle</i>  | 500<br><i>For 400 / 600 / 800: 500, 500 and 2000 mL</i>          | RT      |

## KIT SPECIFICATION

### STORAGE

**-20 °C ± 5 °C** or RT, per component

Shipped on dry ice; excursions ≤ 72 h acceptable\*

### SHELF LIFE

**24 months\***

From date of manufacture, in original container

### QUALITY & DOCUMENTATION

- ✓ Endotoxin – ≤ 1 EU/mL\*
- ✓ Bioburden – ≤ 10 CFU/mL\*
- ✓ RNase / DNase – not detected\*
- ✓ Identity & purity – per component spec
- ✓ Certificate of Analysis – per lot, per component
- ✓ Certificate of Compliance – per kit
- ✓ TSE/BSE & animal-origin-free – all components
- ✓ Safety data sheets – all components

**For further manufacturing use as a raw material. Not a finished drug product; not for direct administration to humans or animals, and not for diagnostic use.**

\* Placeholder information, to be updated. · TK – to be provided. ·

CleanCap® and TriLink® are registered trademarks of TriLink BioTechnologies. Cap analog supplied under licence, including rights for commercial use. Ethanol is included in the kit as supplied. Uridine analogs are supplied as a set of three; the user selects the analog required for their construct.