

## MOLECULAR CONTROLS

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### GENERAL QUESTIONS

#### What is the recommended storage temperature?

- Armored RNA 2 to 8°C
- Armored RNA/DNA Quant -15 to -30°C
- Plasmid DNA -15 to -30°C
- Linearized DNA -15 to -30°C
- *In vitro* transcribed RNA -70 to -85°C

#### What is the recommended storage solution?

- Armored RNA - TSMIII storage buffer, available for purchase through Asuragen, a Bio-Techne brand
- Armored RNA/DNA Quant - TSMIII storage buffer, available for purchase through Asuragen, a Bio-Techne brand
- Plasmid DNA - TE (10mM Tris-HCl pH 8.0, 1 mM EDTA)
- Linearized DNA - TE (10mM Tris-HCl pH 8.0, 1 mM EDTA)
- *In vitro* Transcribed RNA - variable (sodium citrate, 0.1 mM EDTA, nuclease-free water, or as defined by the customer)

#### Do molecular controls remain stable upon freeze-thawing?

- Freeze-thaws should be kept to a minimum for all nucleic acid reagents.
- Armored reagents should not be subjected to more than five freeze-thaw cycles.
- It is recommended to distribute into single-use aliquots upon receipt; we also offer custom aliquoting services to suit your laboratory workflow.

# FREQUENTLY ASKED QUESTIONS

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## Are there assigned expiration dates?

- Expiration dates are assigned only on products that have undergone appropriate stability studies.
- Representative Armored RNA Quant control products have demonstrated stability up to 3 years when stored at -15 to -30°C or 6 months when stored at 2 to 8°C after opening.
- No expiration date is applied to custom molecular controls unless specified by customer; it is the customer's responsibility to apply expiration dating based on their own stability program.

## How are the controls quantified?

- Armored RNA - UV spectrophotometry
- Armored RNA/DNA Quant - analytical phosphate assay that utilizes a NIST-traceable standard
- Plasmid DNA - UV spectrophotometry
- Linearized DNA - UV spectrophotometry
- *In vitro* transcribed RNA - UV spectrophotometry
- Customer-defined quantification methods will be considered.

## Can the controls be subdivided into smaller volumes?

- We offer custom filling services for customer-specified volumes per tube.

## Can the controls be custom formulated to a specific concentration?

- Armored RNA - filled as-is or formulated to  $\leq 0.25$  mg/mL
- Armored RNA Quant/DNA Quant - can be formulated to any concentration equal to or below  $1.0E+12$  copies/mL
- Plasmid DNA - filled as-is or formulated to  $\leq 0.1$  mg/mL
- Linearized DNA - filled as-is or formulated to  $\leq 0.1$  mg/mL
- *In vitro* transcribed RNA - filled as-is or formulated to  $\leq 2.0$  mg/mL
- Customer-defined concentrations outside of these ranges will be considered

## What is the lead time for delivery of custom controls?

- An average turn-around time for custom control delivery is 8-12 weeks.
- Timelines are dependent on project complexity and resource availability.

## How are the controls prepared for shipment?

- All control products are shipped on dry ice unless another shipping format is specified by the customer.

## Is simple heat treatment sufficient to release template DNA/RNA from Armored particles?

- Incubation for at least 5 minutes at 75°C is sufficient to release the DNA/RNA from the protective pseudo-capsid for direct analysis. Armored reagents are compatible with most DNA/RNA extraction methods.
- For samples with low nucleic acid content (e.g. blood plasma), addition of an RNA or DNA carrier is recommended to improve recovery of Armored RNA and Armored DNA.
- For extraction methods that include a white blood cell enrichment step, please ensure the Armored particles are added to the cell pellet before processing into lysate.

## What controls are in place during manufacturing?

- Manufactured under ISO 13485 Quality System.
- Restricted laboratory access and laboratory gowning procedures.
- Physically and spatially segregated equipment and manufacturing processes.
- Dedicated Master Cell Banks.
- All open work performed in ISO Class 5 enclosures.
- Rigorous cleaning regimen: weekly, before and after material manipulation.
- GMP manufacturing available.

## What is the manufacturing process for the controls?

- We are happy to share a basic workflow of our process. Please contact us for more information.

For more information about Molecular Controls | [aus.armored@bio-techne.com](mailto:aus.armored@bio-techne.com)