FUJIFILM
Value from Innovation

Wako

QCdetect™ dsRNA ELISA Kit

During the drug substance manufacturing process for mRNA pharmaceuticals, including mRNA vaccines and mRNA therapeutics, double-stranded RNA (dsRNA) is produced as a by-product (impurity) during the *in vitro* transcription reaction.
Because dsRNA is immunogenic, it is considered an important quality control item for mRNA pharmaceuticals and is listed as a test item in the USP (United States Pharmacopeia).
This product is an ELISA kit for detecting dsRNA. It enables highly sensitive measurement with minimal influence from nucleic acid modifications or RNA chain length.

Features

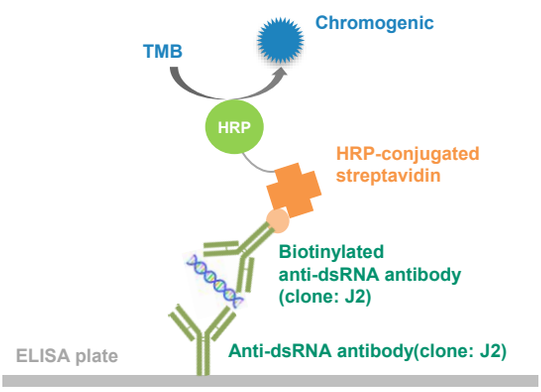
- **Consistent detection regardless of nucleic acid modification (unmodified U or m1ψ), chain length, or matrix effects**
- **Enables highly sensitive detection**
- **Includes not only the antibodies and chromogenic reagents, but also standards, buffers, and wash solutions required for the assay**



Kit Performance

Calibration curve range	UTP : 7.7 - 1,000 pg/mL m1ψ : 15.4 - 2,000 pg/mL
Assay target	dsRNA
Analysis sample	mRNA solution
Measurement duration	Approx. 4.5 hours
Detection method	Colorimetric assay
Measurement Wavelengths	Primary wavelength : 450 nm Secondary wavelength : 620 nm

Assay Principle



This kit detects dsRNA by sandwich ELISA.
Each well of the assay plate is coated with anti-dsRNA antibody clone J2, and the standard solution or sample is added to the wells.
Biotin-labeled anti-dsRNA antibody clone J2 and peroxidase-conjugated streptavidin are then added and allowed to react.
Finally, the peroxidase remaining in the wells is reacted with TMB solution, enabling quantitative measurement of dsRNA by colorimetric detection.

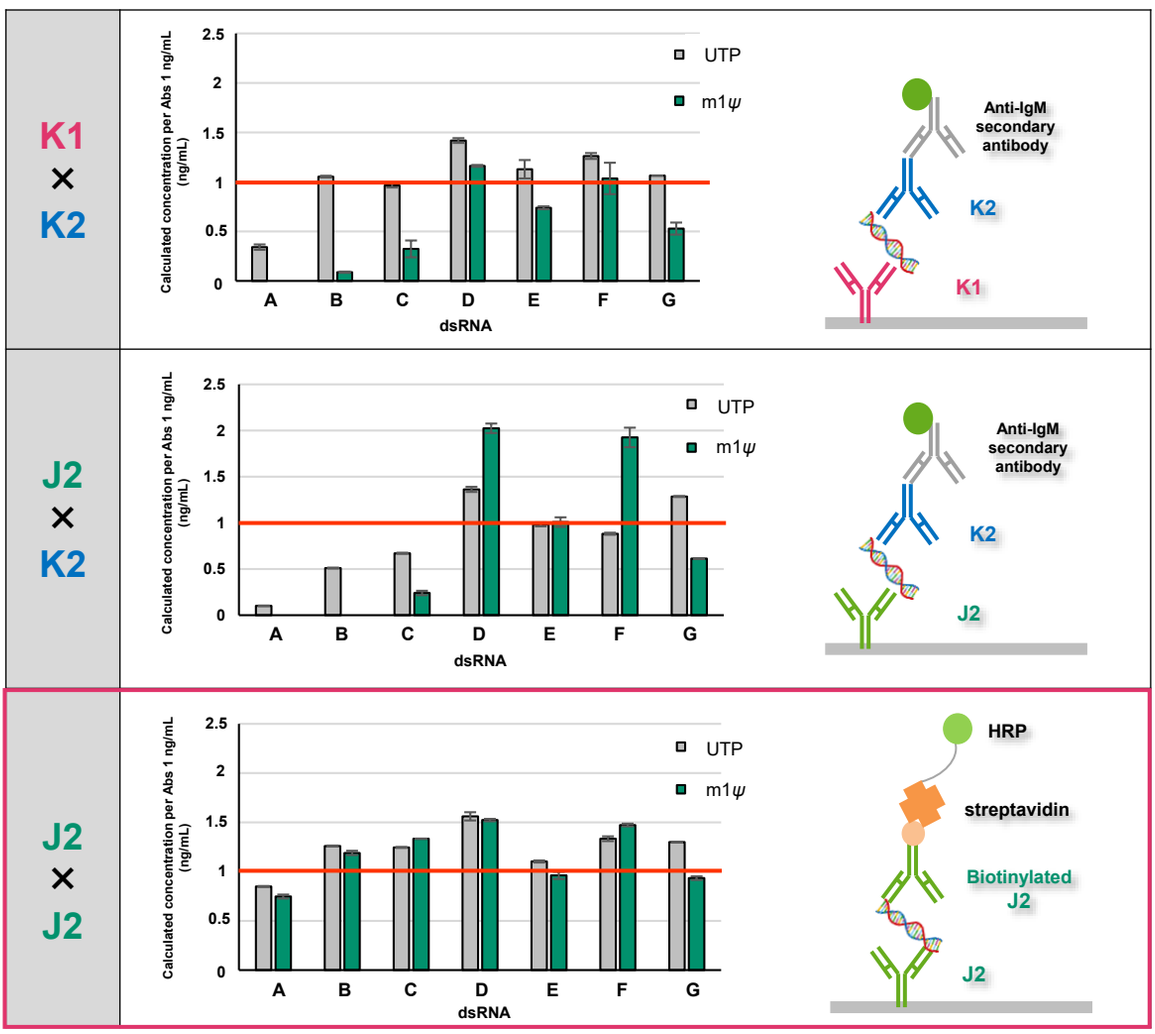
Product No.	Product Name	Grade	Package Size
291-99001	QCdetect™ dsRNA ELISA Kit	for Genetic Research	96 tests

Kit Contents

Components	Amount
Antibody-coated Plate	96 wells (8×12) /1 plate
UTP dsRNA Standard	50 µL/1 bottle
m1ψ dsRNA Standard	50 µL/1 bottle
Sample Reaction Buffer	25 mL/1 bottle
Antibody Reaction Buffer	25 mL/1 bottle
Biotin-conjugated Antibody	1 bottle
Peroxidase-conjugated Streptavidin Solution	120 µL/1 bottle
TMB Solution	12 mL/1 bottle
Stop Solution	12 mL/1 bottle
Wash Solution (10×)	100 mL/1 bottle
Plate Seal	4 sheets

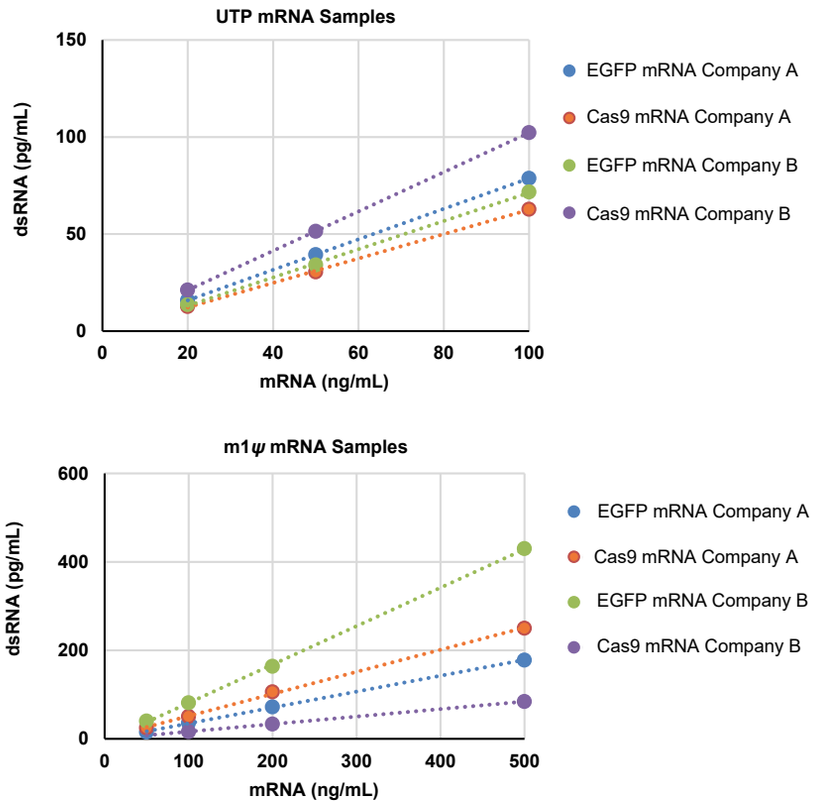
Application Data

Effect of Nucleotide Modification and Chain Length



The detection system of this product (capture: J2; detection: biotinylated J2) was compared with combinations of other anti-dsRNA-recognizing antibody clones. UTP and m1ψ dsRNA standards were used to measure dsRNA of various chain lengths at a concentration of 1 ng/mL.
The results demonstrated that the detection system of this product exhibited the least variation in detected concentration, regardless of m1ψ modification or chain length.

Measurement of dsRNA in mRNA Solutions



Using this kit, the dsRNA concentrations in capped unmodified and m1ψ-modified mRNA solutions were measured.
The measured values were proportional to the mRNA sample concentration and showed linearity over the ranges of 20 to 100 ng/mL for unmodified mRNA and 50 to 500 ng/mL for m1ψ-modified mRNA.

Spike and Recovery Test

UTP mRNA

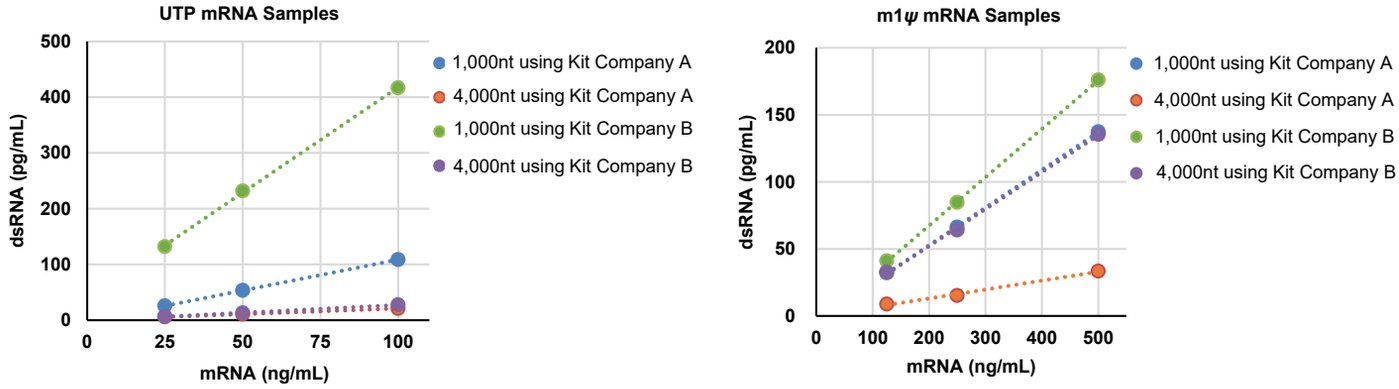
Specimen	Spiked amount of dsRNA (pg/mL)	Measurement value of dsRNA (pg/mL)	Recovery (%)
mRNA solutions 200 ng/mL	-	176	-
	20	197	104
	100	285	109
	500	637	92
mRNA solutions 50 ng/mL	-	44	-
	20	64	100
	100	140	96.5
	500	550	101

m1ψ mRNA

Specimen	Spiked amount of dsRNA (pg/mL)	Measurement value of dsRNA (pg/mL)	Recovery (%)
mRNA solutions 200 ng/mL	-	167	-
	20	186	93
	100	280	113
	500	638	94.1
mRNA solutions 50 ng/mL	-	41.1	-
	20	60	95.7
	100	145	104
	500	521	95.9

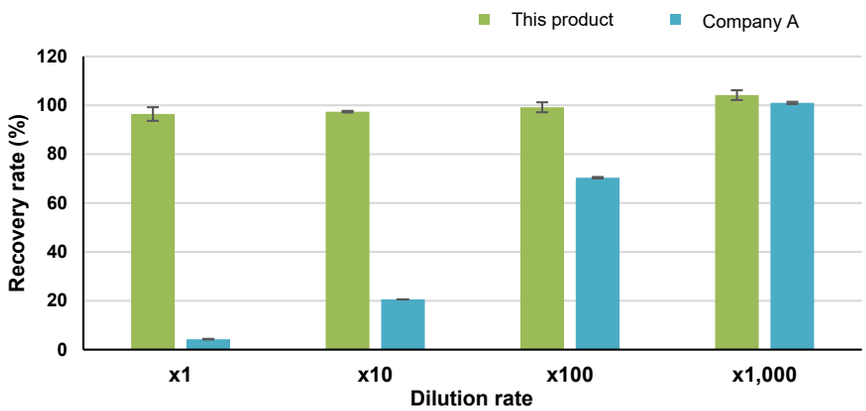
Using this kit, a spike-and-recovery test for dsRNA in mRNA solutions was performed.
The results showed high recovery of dsRNA at mRNA concentrations of 50 ng/mL and 200 ng/mL.

Measurement of dsRNA in IVT Solutions after IVT Reaction



Using two different commercially available *in vitro* transcription (IVT) kits (A and B), two types of mRNA, one long and one short, were synthesized.
Using this product, the dsRNA concentrations in synthesized mRNA solutions were measured.
The measured values were confirmed to be linear with respect to the mRNA sample concentration over the range of 25 to 100 ng/mL for unmodified mRNA and 125 to 500 ng/mL for m1ψ modified mRNA.

Matrix Effect of IVT Reaction Buffer



A comparison was conducted between this kit and another manufacturer's kit to evaluate the recovery of dsRNA spiked into the IVT reaction mixture prior to synthesis.
Unlike the other manufacturer's product, this kit was not affected by the matrix and was able to measure dsRNA accurately without requiring sample dilution.

Related Products

Product No.	Product Name	Grade	Package Size
295-50201	DNA Extractor™ Kit	for Genetic Research	50 tests
294-85201	Qcdetect™ Residual DNA Detection Kit for CHO cells	for Genetic Research	100 tests
290-85301	Qcdetect™ Residual DNA Detection Kit for *E.coli*	for Genetic Research	100 tests





The DNA Extractor™ Kit uses the sodium iodide method to efficiently extract and purify DNA, while our QCdetect™ series enables accurate quantification of residual DNA from host cells like *E. coli* and CHO, supporting regulatory compliance.

Listed products are intended for laboratory research use only, and not to be used for drug, food or human use. Please visit each region's website for product information. This leaflet may contain products that cannot be exported to your country due to regulations. Bulk quote requests for some products are welcomed. Please contact us.

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