

PRODUCT INFORMATION SHEET

EFSA-GMO-NL-2019-162

pDNA-MxY0541-mod3

A plasmid DNA (pDNA) to be used as a reference material (RM) in qualitative qPCR monitoring of *Komagataella phaffii* strain MxY0541. The test strain is genetically modified to produce leghemoglobin from soybean (*Glycine max*).

Komagataella phaffii MxY0541

BSL 1

1

31 May 2024

13 to 19 x 10⁶ copies/μL

20 October 2025

RM Producer

Biosafe – Biological Safety Solutions Ltd

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Intended Use	As quality control material or calibrant in methods for the detection and identification of GMM product.
Health and safety	This reference material is intended for laboratory research use only. It is not intended for any animal or human therapeutic use, any human or animal consumption, or any diagnostic use.
Minimum sample size	85 µL
Period of validity	1 year from the production date of the batch. The validity may be extended when further evidence of stability becomes available. Biosafe will notify customers if problems arise in stability.
Version number	v1
Introduced:	21 October 2025

STORAGE INFORMATION

Product format	Refrigerated during transport
Storage conditions	-20 °C or colder

INSTRUCTIONS FOR HANDLING AND USE

Upon receipt the product should be stored in a sealed container at -20 °C. Centrifuge the vial to aggregate the sample before use.

Avoid exposing genomic DNA to repeated freeze-thaw cycles. Subjecting DNA to repeated free/thaw cycles may result in degradation of the DNA and variations in copies/µL. If the user of this RM intends to use it multiple times, proper protocols must be followed to ensure that the sample retains its integrity.

Characterization

The reference material has been prepared at Biosafe by cloning MxY0541 detection target fragment into a plasmid vector which is then transformed into *E. coli* DH5α host cells.

The plasmid DNA extract is available in sterile, 1 mL microtubes. Each sample contains approximately 90 µL at a concentration of 6 ng/µL.

Homogeneity

Ten packaged samples were tested using qualitative PCR method developed and validated by Biosafe - Biological Safety Solutions Ltd /Oy. The test results confirm the presence of the MxY0541 in samples.

Stability

The RM will be tested for stability at Biosafe on an annual basis and certificates may be extended based on the outcome of this testing. Customers may request extended certificates, but they are informed that results are based on samples that are obtained from Biosafe's inventory. Biosafe cannot guarantee the integrity of samples from batches distributed to client facilities. Biosafe will not guarantee the integrity of samples from batches distributed to client facilities.

Measurement methods

Event-specific real-time PCR (stability and homogeneity), digital PCR (indicative copy number)

Legal notice

This product is sent on the condition that the customer is responsible for the receipt, handling, storage, disposal, and use of the product including all appropriate safety and handling precautions to minimize health or environmental risk.