S-Monovette® cfDNA Exact

For standardising
the pre-analytics of
liquid biopsy samples

Molecular
Diagnostic
Workflow

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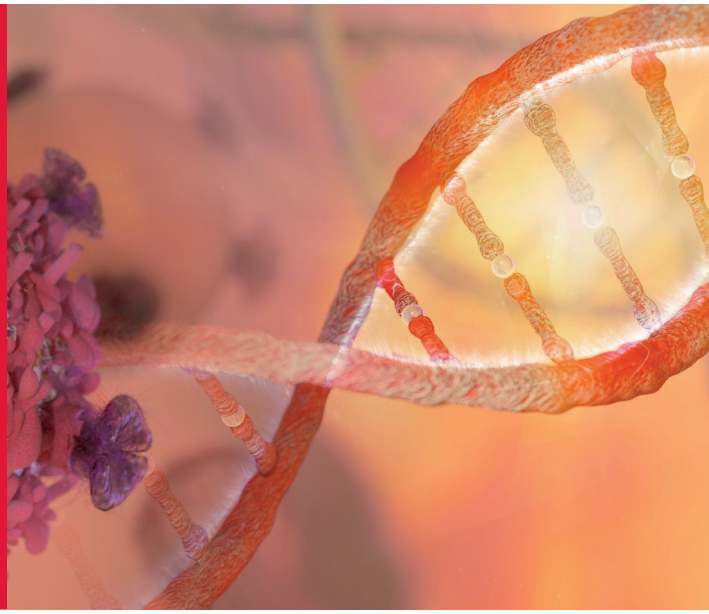
Advantages of the S-Monovette® cfDNA Exact:

- ✓ Blood collection possible using aspiration or vacuum technique
- ✓ Low haemolysis, even at higher temperatures
- ✓ No entry of gDNA from nucleated cells
- ✓ Compatible with a variety of follow-up analyses



The biomarker cell-free DNA (cfDNA) plays an increasing role in the early detection of transplant rejections, non-invasive prenatal tests, as well as the molecular characterisation and treatment monitoring of cancers.
Important pre-analytical factors for good cfDNA sample quality are the protection of the cfDNA against degradation and the prevention of the release of genomic DNA (gDNA) from nucleated blood cells.
The innovative S-Monovette® cfDNA Exact ensures excellent sample quality and accurate results with guaranteed stabilisation performance for **14 days at 4 - 37 °C**.

Fragment size analysis of stored blood samples

In contrast to the competitor product, the innovative preparation of the S-Monovette® cfDNA Exact prevents the introduction of gDNA from nucleated cells:

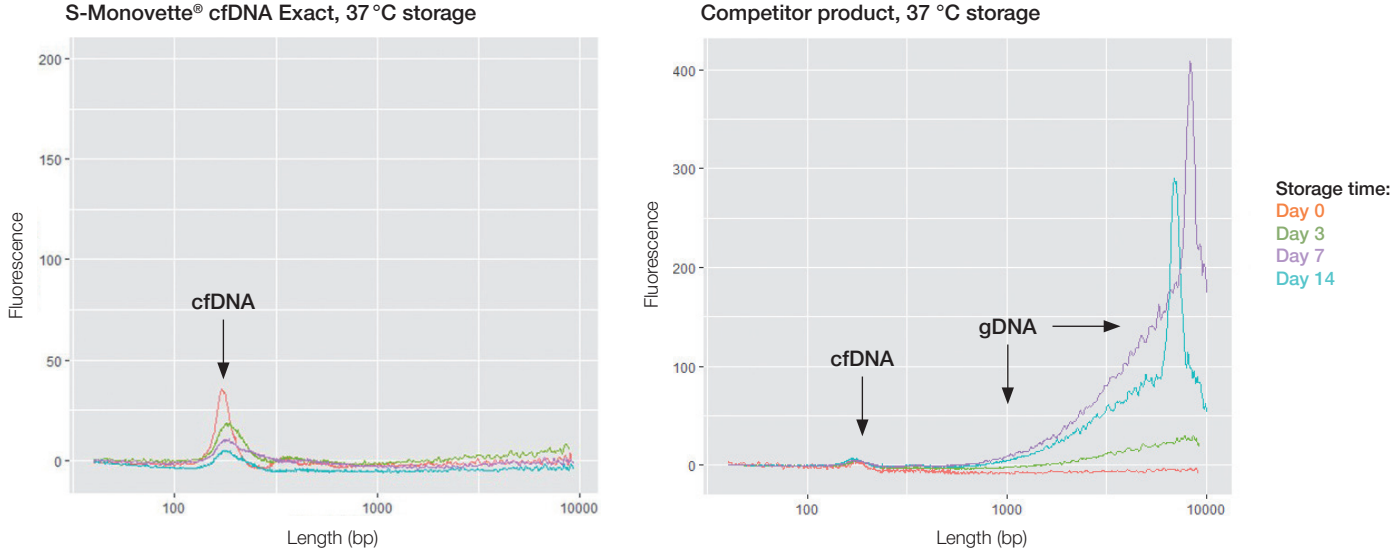


Fig. 1: The blood samples were stored at 37 °C for between 0 and 14 days before the cfDNA isolation (see legend). The DNA fragment sizes were determined by electrophoresis (Bioanalyzer 2100, Agilent) and the isolation was carried out using the InviMag® Free Circulating DNA Kit/ IG and the InviGenius® PLUS device (InvitekMolecular).

Conclusion

The S-Monovette® cfDNA Exact exhibits consistent stabilisation performance, whereas in the case of the competitor product, increasing gDNA release over the storage period can be detected, as a result of which the sample can become unusable for subsequent analyses.

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Lowest haemolysis values

Haemolysis is a measure of cellular stress and indicates the destruction of blood cells during sampling. Lysis of the blood cells during sampling has a direct influence on the introduction of gDNA from nucleated cells into the blood sample. It has already been shown that *in vitro* haemolysis can be associated with increased plasma cfDNA concentrations that originate from gDNA of cells destroyed during sampling. (El Messaoudi S, Rolet F, Mouliere F, Thierry AR. Circulating cell free DNA: Preanalytical considerations. Clin Chim Acta. 2013; 424:222-30. https://doi.org/10.1016/j.cca.2013.05.022).

Correspondingly important for all subsequent analyses of cfDNA is the avoidance of any haemolysis. The gentle aspiration technique during sampling with the S-Monovette® cfDNA Exact ensures the lowest possible haemolysis. In the following, haemolysis values of the S-Monovette® cfDNA Exact are shown in comparison with other commercially available cfDNA-stabilising competitor products over the respective specified stabilisation time.

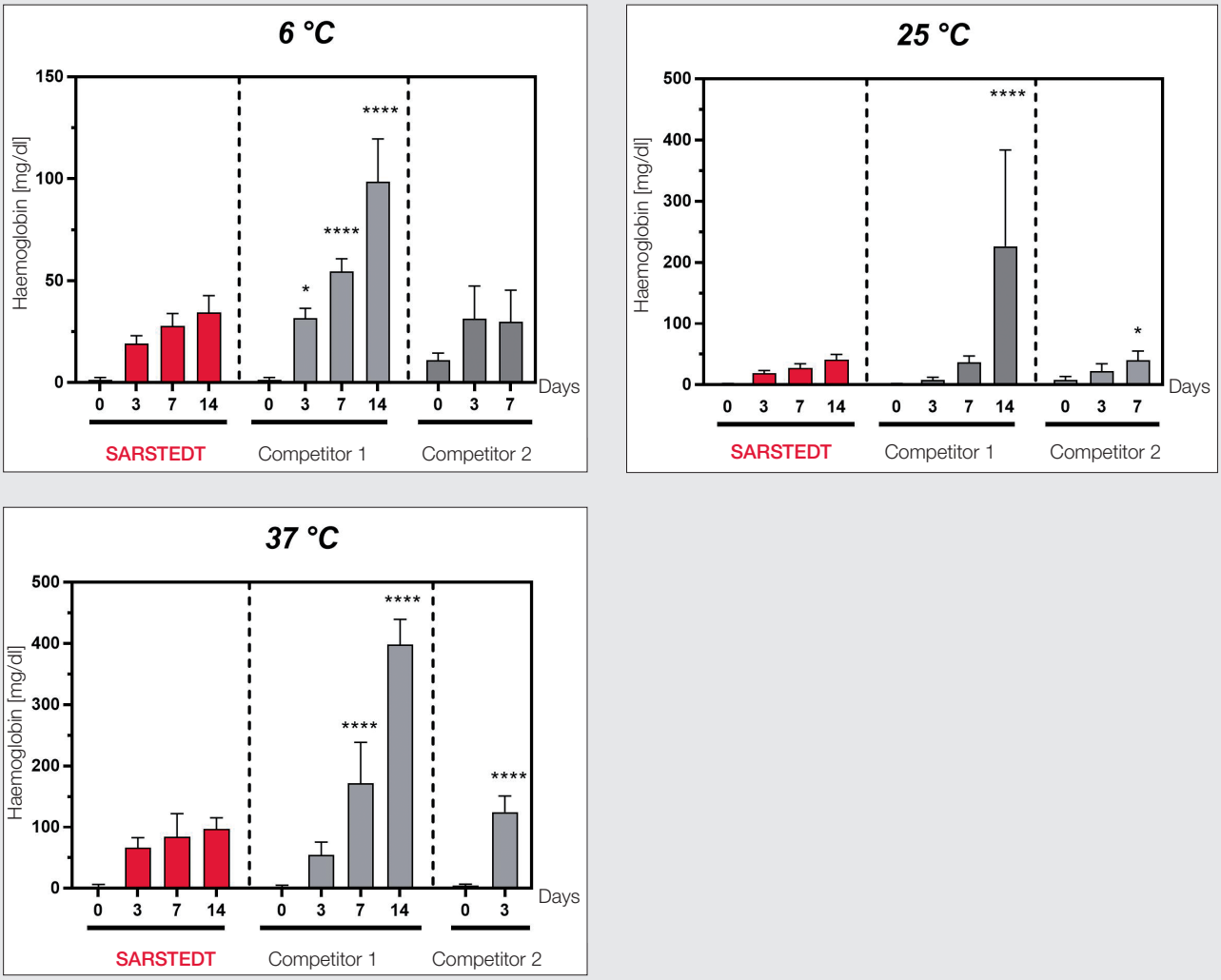

Fig. 2: The blood samples were stored between 0 and 14 days at 37 °C, 25 °C and 6 °C before analysis (see labels). The free haemoglobin in the plasma was determined photometrically (sodium carbonate based). The shorter storage time for competitor 2 is based on the limited product specification for the cfDNA stabilisation performance.

Conclusion

Sampling with the S-Monovette® cfDNA Exact is superior to all other competitor products tested with regard to potentially occurring haemolysis.

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Analysed reference genes

After isolation, S-Monovette® cfDNA Exact stabilised cfDNA is compatible with all analytical methods (e.g. NGS & qPCR). Since the cfDNA plasma concentration in healthy donors is low (1.8-44 ng/mL), the single-copy genes *ERV-3 & MSTN* were investigated by means of qPCR in order to show that even genes with a low number of copies can still be detected after a relatively long storage time. For a good sample quality, the cfDNA content should remain as constant as possible over the storage time.

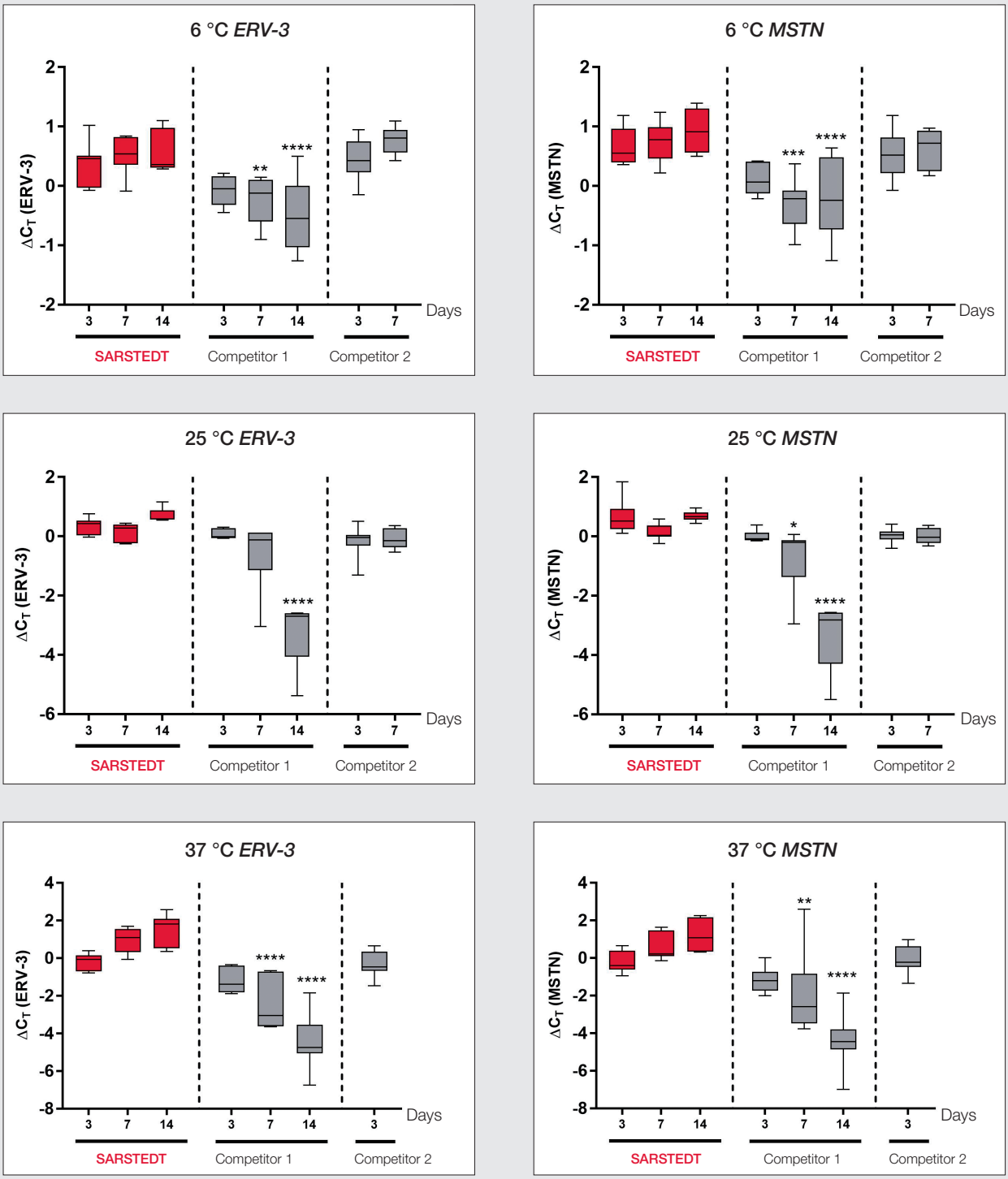

Fig. 3: Real-time PCR analyses of *ERV-3 & MSTN* from S-Monovette® cfDNA Exact stabilised samples compared to products from other manufacturers. All samples were isolated with the InviMag® Free Circulating DNA Kit/ IG and the InviGenius® PLUS device (Invitek Molecular). The RT-qPCRs were carried out with Maxima SYBR green/ROX qPCR Master Mix (Thermo Fisher Scientific) on a mastercycler ep realplex 4S (Eppendorf) or qTOWER³ (Analytic Jena). The indicated delta C_T values represent the difference between the C_T value of the examination time and the freshly prepared day 0 samples. The statistics were determined by means of two-way analysis of variance (ANOVA): * < 0.05, ** < 0.01, *** <0.001 & **** < 0.0001

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Conclusion

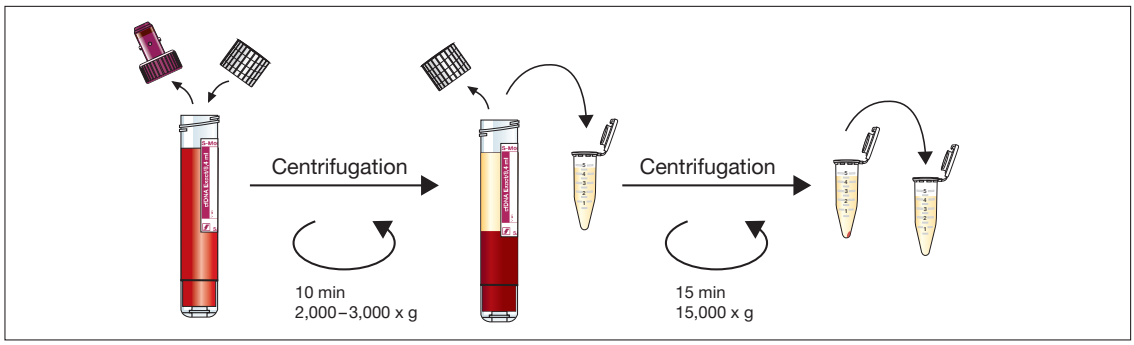
The S-Monovette® cfDNA Exact exhibits a constant stabilisation performance over 14 days at 6-37 °C, whereas in the case of competitor products, increasing gDNA release over the storage period was found in some cases.

Specifications

Sample volume:	**9.2 ml (including 8.4 ml of blood)**
Storage temperature before filling:	**room temperature**

Plasma manufacturing

The plasma separation for obtaining the cfDNA is a multi-stage centrifugation process that is carried out, for example, as follows:



1. **Replacement of the red screw cap by the enclosed centrifugation cap.**
2. Centrifugation for 10 min with 2,000-3,000 × g at room temperature.
3. Transfer of the plasma into reaction vessels (e.g. REF 72.706.200 (1.5 ml), 72.695.200 (2.0 ml) or 72.701.400 (5.0 ml).
4. Centrifugation of the plasma for 15 min with 15,000 x g at room temperature.
5. Transfer of the plasma into new vessels for the isolating the cfDNA or for storage (-80 °C) until isolation.

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FLEXIBLE IN THE CHOICE OF ISOLATION SYSTEM

Compatible cfDNA isolation systems for use with the S-Monovette® cfDNA Exact:

1. Manual isolation systems

- NucleoSnap® DNA Plasma Kit, Macherey-Nagel, REF 740300.50
- NucleoSpin Dx Blood, Macherey-Nagel, REF 740899.50
- QIAamp Circulating Nucleic Acid Kit, Qiagen, REF 55114
- MagMAX Cell-Free DNA Isolation Kit, ThermoFisher Scientific, REF A293192

2. Automated isolation systems

- InviMag Free Circulating DNA Kit/IG, Invitek Molecular, REF 2439320400
- NextPrep-Mag cfDNA Isolation Kit, Revvity chemagen Technologie GmbH, REF NOVA-3825-03
- Chemagic cfNA 5k Kit special H24, Revvity chemagen Technologie GmbH, REF CMG-1104
- MagMAX Cell-Free DNA Isolation Kit, ThermoFisher Scientific, REF A293192

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Order information

Order no.	Name	Packaging
01.2040.001	S-Monovette® cfDNA Exact*	20 per inner carton / 80 per outer carton

* = Centrifugation caps are included

Accessories

Order no.	Name	Packaging
65.729.100	Screw cap, suitable for tubes Ø 15.3 mm	100 per inner carton / 5,000 per outer carton
85.1638.235	Safety-Multifly® needle 21G with 200 mm hose and mounted multi-adapter	120 per inner carton / 480 per outer carton
85.1640.235	Safety-Multifly® needle 23G with 200 mm hose and mounted multi-adapter	120 per inner carton / 480 per outer carton
85.1642.235	Safety-Multifly® needle 25G with 200 mm hose and mounted multi-adapter	120 per inner carton / 480 per outer carton
95.1006	Disposable tourniquet tournistrip®	200 per outer carton
78.898	Protective container 126x30 mm, with suction insert, without closure	50 per inner carton / 250 per outer carton
65.679	Screw cap for protective container 126x30 mm	50 per inner carton / 250 per outer carton
95.900	Shipping box, small 198 x 107 x 38 mm	50 per outer carton
95.901	Shipping box 198 x 107 x 50 mm	50 per outer carton
95.902	Shipping box, large 220 x 170 x 40 mm	50 per outer carton

For more consumables for the PCR (PCR plates, chains and individual vessels), pipette tips and reaction vessels, see www.sarstedt.com.

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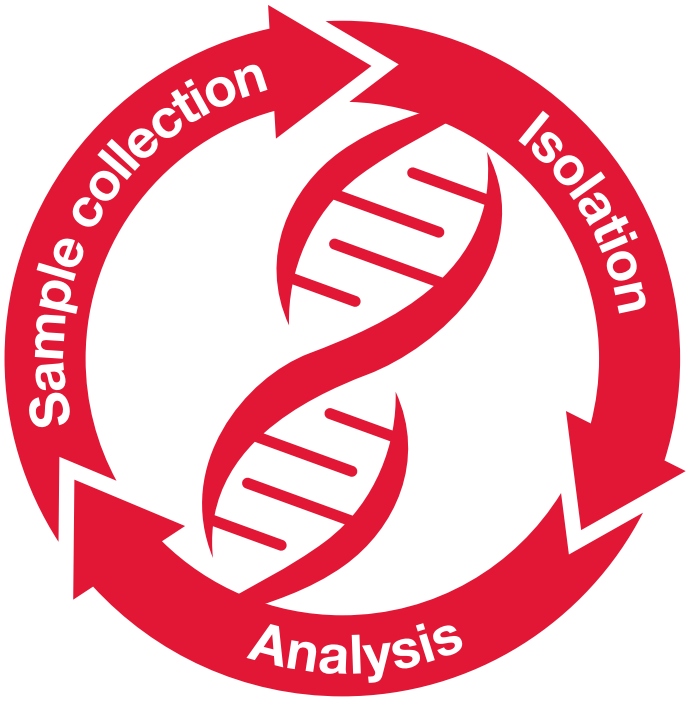

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