BD CD4 (SK3)

Form	Catalog No.	Form	Catalog No.
FITC	345768	PE-Cy7	348809
PE	345769	APC	345771
PerCP	345770	APC-Cy7	341115
PerCP-Cy5.5	332772	BV605	664447

23-5025(09)
2023-07
English

CE 2797 IVD

1. INTENDED USE

CD4 (SK3) is intended for in vitro diagnostic use in the identification of cells expressing the CD4 antigen in peripheral blood, using a BD FACSLyric™ flow cytometer.

Clinical Applications

Expression of the CD4 antigen in the characterization of subjects having, or suspected of having, hematological neoplasia.[1-4]

CD4 (SK3) is a qualitative reagent intended for laboratory professional use only.

2. SUMMARY OF THE TEST

The CD4[5,6] antigen, with a molecular weight of 55 kilodaltons (kDa)[7], is present on T-helper/inducer lymphocytes and monocytes.[8,9]

The CD4 antigen is present on the helper/inducer T-lymphocyte subset ($CD3^+CD4^+$) that comprises 28% to 58%[10] of normal peripheral blood lymphocytes.[6,7] The CD4 antigen is present in low density on the cell surface of monocytes and in the cytoplasm of monocytes.

Principle of Operation

The CD4 (SK3) reagent is a monoclonal antibody conjugated to a specific fluorochrome. The reagent is added to the specimen and incubated, allowing the antibodies to bind to the CD4 antigen on the surface of the leukocytes. After incubation, BD FACS™ Lysing Solution is used to lyse the red blood cells in the sample. Cells are acquired on the BD FACSLyric™ flow cytometer using the BD FACSuite™ application. During acquisition, the cells travel past the laser beam and scatter the laser light. The stained cells fluoresce. These scatter and fluorescence signals, detected by the instrument, provide information about the cell's size, internal complexity, and relative fluorescence intensity. The CD4 (SK3) reagents employ fluorescence triggering, allowing direct fluorescence gating of the leukocyte population to reduce contamination of unlysed or nucleated red blood cells in the gate. The user performs manual gating to analyze the data and identify the $CD4^+$ population.

3. REAGENT

Reagent Composition

CD4 (SK3)[5] is derived from hybridization of mouse NS-1 myeloma cells with spleen cells from BALB/c mice immunized with human peripheral blood T lymphocytes. CD4 (SK3) is composed of mouse IgG_1 heavy chains and kappa light chains.

Each of the following reagents is supplied in buffer containing a stabilizer and preservative. The purity presented is the free fluorochrome at bottling, as measured by size-exclusion chromatography.

Table 1 Bottling concentrations

Form	Number of tests	Concentration (µg/mL)	Stabilizer	Preservative	Purity
FITC	100	3	Gelatin	0.1% Sodium azide	≤5%
PE	100	3.1	Gelatin	0.1% Sodium azide	≤20%
PerCP	100	3.2	Gelatin	0.1% Sodium azide	≤20%
PerCP-Cy5.5	50	1.5	Gelatin	0.1% Sodium azide	≤20%
PE-Cy7	100	12	Gelatin	0.1% Sodium azide	≤20%
APC	100	6	Gelatin	0.1% Sodium azide	≤20%
APC-Cy7	100	12	Gelatin	0.1% Sodium azide	≤20%
BV605[a]	100	12.6	BSA	0.09% Sodium azide	≤25%
a. BD Horizon Brilliant™ Violet 605					

Precautions

- The reagent should be clear. Do not use the reagent if you observe any change in appearance. Precipitation, cloudiness, or change in color indicates instability or deterioration.
- Go to regdocs.bd.com/regdocs/sdsSearch to download the Safety Data Sheet.

Storage and Handling

- Store the reagent at 2–8 °C.
- Reagent in unopened vials is stable until the expiration date shown on the label when stored as directed. Do not use after the expiration date.
- Use reagent within 12 months of opening the vial when stored as directed.
- Do not freeze the reagent or expose it to direct light during storage or incubation with cells. Keep the reagent vial dry.

4. INSTRUMENT

The BD FACSLyric™ system is outlined in the following table. See the corresponding reagent or instrument user documentation for details.

Table 2 BD FACSLyric™ system

Flow cytometer	Setup beads	Setup software	Analysis software
BD FACSLyric™	BD® CS&T Beads BD® FC Beads 7-Color Kit BD® FC Beads 5-Color Kit	BD FACSuite™ application v1.3 or later	BD FACSuite™ application v1.3 or later

The BD FACS™ Universal Loader can be used with this product.

5. SPECIMEN COLLECTION AND PREPARATION

Collect peripheral blood specimens aseptically by venipuncture into a BD Vacutainer® EDTA blood collection tube, or equivalent.[11] We recommend that you follow guidelines described in consensus protocols for flow cytometric immunophenotyping of hematopoietic malignancies.[12,13]

Samples with large numbers of nonviable cells can give erroneous results due to selective loss of populations and to increased nonspecific binding of antibodies to nonviable cells. Viability of specimens should be assessed. A minimum viability of 75% is recommended.[14]

WARNING All biological specimens and materials coming in contact with them are considered biohazards. Handle as if capable of transmitting infection[10,15] and dispose of with proper precautions in accordance with federal, state, and local regulations. Never pipette by mouth. Wear suitable protective clothing, eyewear, and gloves.

Interference

- Lipemic specimens can interfere with the assay.[16,17]
- Monoclonal antibodies in patient treatment can interfere with the assay.

6. PROCEDURE

Reagents and Materials

Reagent provided

The reagent is provided in an amber vial as described in Table 1.

Reagents and materials required but not provided

- Disposable 12 × 75-mm capped polystyrene test tubes
- Micropipettor with tips
- Vortex mixer
- Centrifuge
- BD FACS™ Lysing Solution (Catalog No. 349202)

  See the instructions for use (IFU) for warnings and precautions.
- Wash buffer (1X phosphate buffered saline [PBS] with 0.1% sodium azide)
- (Optional) Fixative solution (1% paraformaldehyde [PFA] solution in 1X PBS with 0.1% sodium azide)

  Store at 2–8 °C in amber glass for up to 1 week.
- (Optional) BD FACS™ Universal Loader

Diluting BD FACS™ Lysing Solution

Dilute the 10X concentrate 1:10 with room temperature (20–25 °C) deionized water. The prepared solution is stable for 1 month when stored in a glass or high density polyethylene (HDPE) container at room temperature.

Staining the Cells

1. Add the appropriate volume of CD4 (SK3) fluorochrome-conjugated monoclonal antibody to 100 µL of whole blood in a 12 × 75-mm capped polystyrene test tube.

Table 3 Reagent test volumes

Fluorochrome	Volume per test (µL)
FITC	20
PE	20
PerCP	20
PerCP-Cy5.5	20
PE-Cy7	5
APC	5
APC-Cy7	5
BV605	5

2. Vortex gently and incubate for 15–30 minutes at room temperature (20–25 °C), protected from light.
3. Add 2 mL of 1X BD FACS™ Lysing Solution to each tube.
4. Vortex the tube 3-5 seconds at low speed and incubate for 10 minutes at room temperature, protected from light.
5. Centrifuge at 300*g* for 5 minutes.
6. Aspirate the supernatant without disturbing the cell pellet.
7. Add 2 to 3 mL of wash buffer to each tube.
8. Vortex gently.
9. Centrifuge at 200*g* for 5 minutes.
10. Aspirate the supernatant without disturbing the cell pellet.
11. Add 0.5 mL of wash buffer to each tube and acquire the samples immediately.

Optional: Instead of adding wash buffer, fix the stained sample as described in the following section.

Fixing the Stained Sample (optional)

1. Add 0.5 mL of fixative solution.
2. Vortex gently.
3. Incubate for 60 minutes at 2–8 °C, protected from light.
4. Centrifuge at 300*g* for 5 minutes.
5. Aspirate the supernatant without disturbing the cell pellet.
6. Add 0.5 mL of wash buffer to each tube.
7. Vortex gently.

Store at 2–8 °C, protected from light, until acquisition. We recommend acquiring the samples within 24 hours of staining.

CAUTION Some APC-Cy7 conjugates, and to a lesser extent PE-Cy7 conjugates, show changes in their emission spectra with prolonged exposure to paraformaldehyde or light. For overnight storage of stained cells, wash and resuspend in buffer without paraformaldehyde after 1 hour of fixation.

For the BV605 conjugate, we recommend acquiring the stained sample within 6 hours of resuspension.

Creating an Experiment

Before you begin:

1. Ensure that Characterization QC (CQC) and lyse/wash reference settings have not expired.
2. Add reagent lots to library, if needed.

   See the *BD FACSLyric™ Reference System* for information.
3. Perform daily Performance QC (PQC) using BD® CS&T Beads.

See the *BD® CS&T Beads* IFU and the *BD FACSLyric™ Reference System* for information.

To create an experiment:

1. Create an experiment and a user-defined assay as described in the *BD FACSLyric™ Reference System*.

Acquiring the Sample

1. Create a worklist.
2. Add the user-defined assay to the worklist as a task, as needed.

   See the *BD FACSLyric™ Reference System* for information.
3. To acquire a specific tube, set the run pointer to the sample you want to run and select **Run from Pointer** from the **Run** menu in the **Worklist Controls** bar.

   Alternatively, select **Run All** from the **Run** menu to run the entire worklist from the beginning.
4. Vortex each stained tube 3–5 seconds at low speed immediately prior to acquisition.[18]
5. Follow the prompts in the software to load or unload tubes.

   NOTE If you are using the BD FACS™ Universal Loader, vortex tubes immediately before placing them into the Loader racks.

   Before acquiring samples, adjust the threshold and voltage to minimize debris and ensure populations of interest are included.

Analyzing the Sample

1. Review the plots created in the assay.
2. Create and review a report, as needed.

   See the *BD FACSLyric™ Reference System* for information.

7. RESULTS

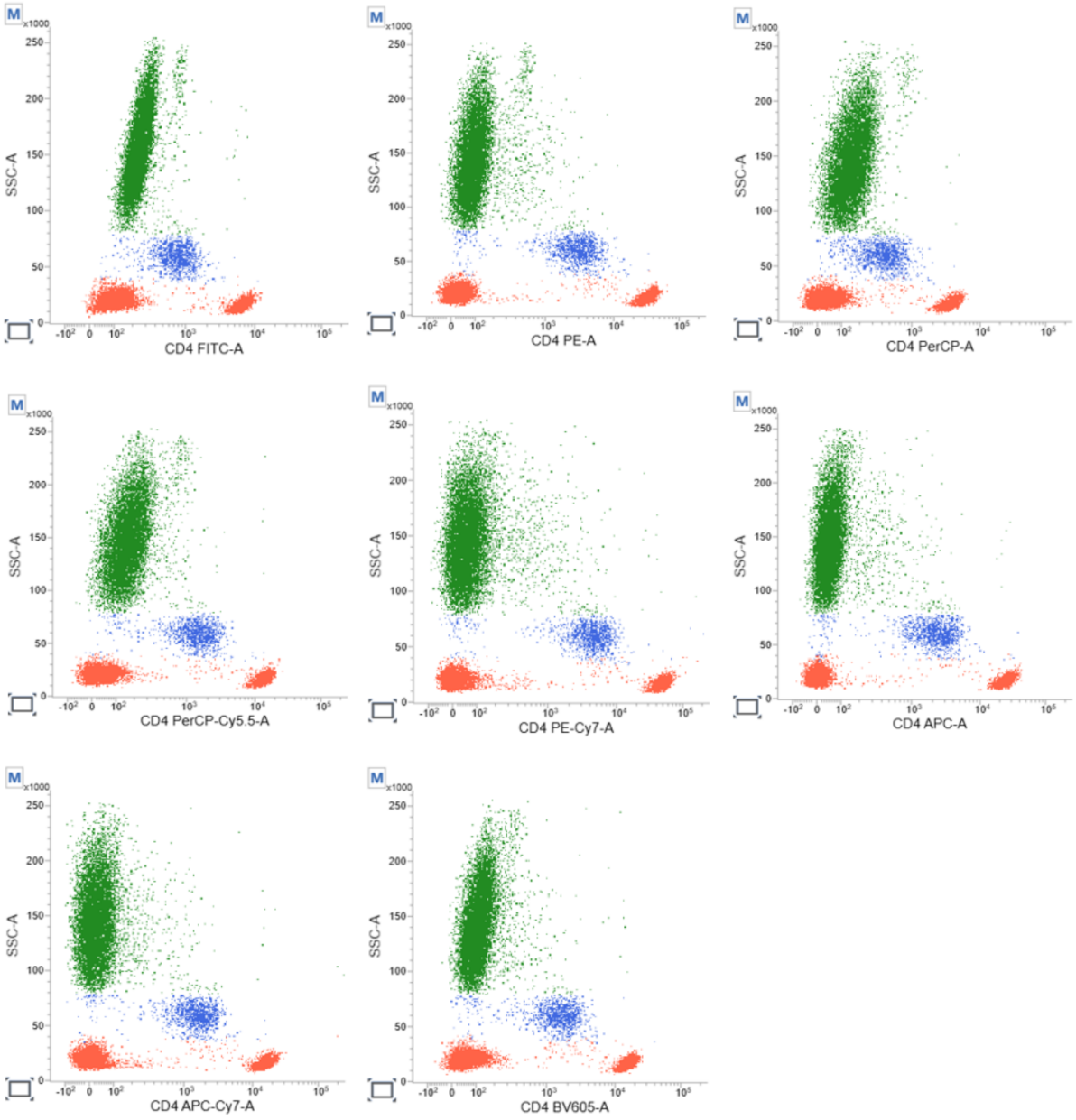
Analytical Results

Abnormal numbers of cells expressing this antigen or aberrant expression levels of the antigen can be expected in some disease states. It is important to understand the normal expression pattern for this antigen and its relationship to expression of other relevant antigens in order to perform appropriate analysis.

Representative Data

A hematologically normal adult peripheral blood sample was stained with each of the CD4 (SK3) conjugates and acquired on a BD FACSLyric™ flow cytometer. Conjugates with brighter fluorochromes (PE and APC) will give greater separation than those with other fluorochromes (FITC and PerCP). When populations overlap, calculation of the percentage of cells positive for the marker can be affected by the choice of fluorochrome. See Figure 1.

Figure 1 Representative data



8. LIMITATIONS

- Use of monoclonal antibodies in patient treatment can interfere with recognition of target antigens by this reagent. This should be considered when analyzing samples from patients treated in this fashion. BD Biosciences has not characterized the effect of the presence of therapeutic antibodies on the performance of this reagent.
- Single reagents can provide only limited information in the analysis of leukemias and lymphomas. Using combinations of reagents can provide more information than using the reagents individually. Multicolor analysis using relevant combinations of reagents is highly recommended.[13]
- Since reagents can be used in different combinations, laboratories need to become familiar with the properties of each antibody in conjunction with other markers in normal and abnormal samples.

- Reagent performance data typically was collected using EDTA-treated blood. Reagent performance can be affected by the use of other anticoagulants.

9. PERFORMANCE CHARACTERISTICS

Precision

A 5-day study was performed at one site to assess repeatability and within-site precision using control material. Estimates of precision were determined across two BD FACSLyric™ flow cytometers and two operators by acquiring BD Multi-Check™ Control cells, stained in triplicate using two lots of each CD4 (SK3) reagent. Two separate runs were analyzed during each of the 5 tested days.

The following table presents the means, coefficients of variation (%CV), and the 97.5% one-sided confidence interval (Upper %CV) for repeatability and within-site precision of CD4 (SK3) MFI of the lymphocyte population.

Table 4 CD4 (SK3) Repeatability and within-site precision, control material, CD4 MFI

Marker	Mean MFI	Repeatability		Within-site Precision	
		%CV	Upper %CV	%CV	Upper %CV
CD4 FITC	6,213.30	1.65	1.89	11.26	12.89
CD4 PE	18,263.07	1.49	1.71	4.59	5.25
CD4 PerCP	2,756.28	1.12	1.29	3.19	3.66
CD4 PerCP-Cy5.5	6,562.71	1.55	1.78	17.17	19.66
CD4 PE-Cy7	27,227.74	3.24	3.73	4.61	5.28
CD4 APC	17,186.90	2.60	2.99	6.12	7.01
CD4 APC-Cy7	8,765.70	3.25	3.74	4.83	5.53
CD4 BV605	14,705.00	2.16	2.48	10.02	11.47

The following table presents the means, coefficients of variation (%CV), and the 97.5% one-sided confidence interval (Upper %CV) for repeatability and within-site precision of CD4 (SK3) % positive of the lymphocyte population.

Table 5 CD4 (SK3) Repeatability and within-site precision, control material, CD4 % Positive

Marker	Mean % Positive	Repeatability		Within-site Precision	
		%CV	Upper %CV	%CV	Upper %CV
CD4 FITC	46.38	1.36	1.56	1.43	1.63
CD4 PE	46.38	1.34	1.55	1.35	1.54
CD4 PerCP	46.66	1.29	1.48	1.48	1.69
CD4 PerCP-Cy5.5	46.67	1.35	1.55	1.45	1.66
CD4 PE-Cy7	46.98	1.42	1.63	1.44	1.65
CD4 APC	46.86	1.41	1.62	1.43	1.64
CD4 APC-Cy7	47.07	1.39	1.60	1.43	1.63
CD4 BV605	46.64	1.56	1.80	1.58	1.81

Reproducibility was estimated for the following components: instrument/operator-to-instrument/operator, run-to-run, lot-to-lot, and day-to-day. The following table presents the means and %CV for reproducibility of CD4 (SK3) MFI of the lymphocyte population.

Table 6 CD4 (SK3) Reproducibility, control material, CD4 MFI

Marker	Mean MFI	%CV
CD4 FITC	6,213.30	11.13
CD4 PE	18,263.07	4.34
CD4 PerCP	2,756.28	2.99
CD4 PerCP-Cy5.5	6,562.71	17.10
CD4 PE-Cy7	27,227.74	3.27
CD4 APC	17,186.90	5.54
CD4 APC-Cy7	8,765.70	3.57
CD4 BV605	14,705.00	9.78

Reproducibility was estimated for the following components: instrument/operator-to-instrument/operator, run-to-run, lot-to-lot, and day-to-day. The following table presents the means and %CV for reproducibility of CD4 (SK3) % positive of the lymphocyte population.

Table 7 CD4 (SK3) Reproducibility, control material, CD4 % Positive

Marker	Mean % Positive	%CV
CD4 FITC	46.38	0.44
CD4 PE	46.38	0.11
CD4 PerCP	46.66	0.73
CD4 PerCP-Cy5.5	46.67	0.53
CD4 PE-Cy7	46.98	0.28
CD4 APC	46.86	0.27
CD4 APC-Cy7	47.07	0.32
CD4 BV605	46.64	0.25

Clinical Performance

Clinical performance studies were not conducted for these devices because single-color reagents generate clinically relevant results when used in combination with other single-color reagents in panels for the diagnosis, monitoring, and prognosis of hematological neoplasia. Single-color devices used alone provide limited information for characterization of neoplastic immunophenotype. Clinical performance characteristics such as diagnostic accuracy and expected values do not apply to single-color devices since they are used for the qualitative identification of target antigen-expressing cells in hematological neoplasia. The clinical performance and relevance of these single-color devices were established with sufficient data from:

- Scientific peer-reviewed literature where the devices were used in panels in combination with other antibodies or cell markers in clinical laboratory routine settings
- Published experience by routine testing

10. TROUBLESHOOTING

Problem	Possible Cause	Solution
Poor resolution between debris and leukocytes population.	Cell interaction with other cells and platelets.	Prepare and stain another sample.
	Rough handling during cell preparation.	Check cell viability. Centrifuge cells at lower speed.
	Inappropriate instrument settings.	Follow proper instrument setup procedures. Optimize instrument settings as required.
	Incomplete lysis.	Complete mixing of BD FACS™ Lysing Solution before and after addition to samples.
Staining dim or fading.	Cell concentration too high at staining step.	Check and adjust cell concentration or sample volume. Stain with fresh sample.
	Insufficient reagent.	Repeat staining with increased amount of antibody.
	Cells not analyzed within 24 hours of staining.	Repeat staining with fresh sample. Analyze promptly.
	Improper buffer preparation (sodium azide omitted).	Use sodium azide in stain buffer, wash buffer, and fixative solution.
Few or no cells.	Cell concentration too low.	Resuspend fresh sample at a higher concentration. Repeat staining and analysis.
	Cytometer malfunctioning.	Troubleshoot instrument.

NOTICE

EU Only: Users shall report any serious incident related to the device to the Manufacturer and National Competent Authority.

Outside EU: Contact your local BD representative for any incident or inquiry related to this device.

Refer to the Eudamed website: https://ec.europa.eu/tools/eudamed for Summary of Safety and Performance.

WARRANTY

Unless otherwise indicated in any applicable BD general conditions of sale for non-US customers, the following warranty applies to the purchase of these products.

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PATENTS AND TRADEMARKS

For US patents that may apply, see bd.com/patents.

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HISTORY

Revision	Date	Changes made
23-5025(08)	2022-04	Updated to meet requirements of Regulation (EU) 2017/746.
23-5025(09)	2023-07	Updated legal manufacturer address. Added EU and Swiss importer addresses and importer symbol. Added Clinical Performance section. Updated symbols glossary and Patents and Trademarks section.

Symbols Glossary

Please refer to product labeling for applicable symbols.

Symbol	Meaning
	Manufacturer
	Authorized representative in the European Community
	Authorised representative in Switzerland
	Date of manufacture
	Use-by date
	Batch code
	Catalogue number
	Serial number
	Sterile
	Sterilized using aseptic processing techniques
	Sterilized using ethylene oxide
	Sterilized using irradiation
	Sterilized using steam or dry heat
	Do not resterilize
	Non-sterile
	Do not use if package is damaged and consult *instructions for use*
	Sterile fluid path
	Sterile fluid path (ethylene oxide)
	Sterile fluid path (irradiation)
	Fragile, handle with care
	Keep away from sunlight
	Keep dry
	Lower limit of temperature
	Upper limit of temperature
	Temperature limit
	Humidity limitation
	Biological risks
	Do not re-use
	Consult *instructions for use* or consult electronic *instructions for use*
	Caution
	Contains or presence of natural rubber latex
	In vitro diagnostic medical device
	Negative control
	Positive control
	Contains sufficient for <*n*> tests
	For IVD performance evaluation only
	Non-pyrogenic
	Patient number
	This way up
	Do not stack

Symbol	Meaning
	Single sterile barrier system
	Contains or presence of phthalate: combination of bis(2-ethylhexyl) phthalate (DEHP) and benzyl butyl phthalate (BBP)
	Collect separately Indicates separate collection for waste of electrical and electronic equipment required.
	CE marking; Signifies European technical conformity
	Device for near-patient testing
	Device for self-testing
	This only applies to US: "Caution: Federal Law restricts this device to sale by or on the order of a licensed practitioner."
	Country of manufacture "CC" shall be replaced by either the two letter or the three letter country code.
	Collection time
	Cut
	Peel here
	Collection date
	Keep away from light
	Hydrogen gas is generated
	Perforation
	Start panel sequence number
	End panel sequence number
	Internal sequence number
	<Box #> / <Total Boxes>
	Medical device
	Contains hazardous substances
	Ukrainian conformity mark
	Meets FCC requirements per 21 CFR Part 15
	UL product certification for US and Canada
	Unique device identifier
	Importer
	Place patient label in framed area only
	Magnetic resonance (MR) safe
	Magnetic resonance (MR) conditional
	Magnetic resonance (MR) unsafe
For use with	For use with
This Product Contains Dry Natural Rubber	This Product Contains Dry Natural Rubber
For Export Only	For Export Only
Instruments	Instruments

Note: Text layout in symbols is determined by label design.

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