



cFluor[®] Anti-Human CD117 (104D2)

Instructions For Use

Catalog No.	Test/Vial	Product Name
R7-11023	100	cFluor [®] BYG610 Anti-Human CD117 (104D2)
R7-11024	25	cFluor [®] BYG610 Anti-Human CD117 (104D2)

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Cytel Biosciences, Inc
47215 Lakeview Blvd.
Fremont, CA 94538
USA
1.877.92.CYTEK (1.877.922.9835)

products@cytekbio.com
cytekbio.com



Emergo Europe
Prinsessegracht 20
2514 AP The Hague
Netherlands

1. Intended use

This product is intended for in vitro diagnostic use to identify human cells expressing CD117 antigen molecules in countries where the regulatory approval has been obtained from the local regulatory authorities.

2. Application

The 104D2 monoclonal antibody binds to human CD117, a 145-kDa protein tyrosine kinase. CD117, also known as c-kit, is the receptor for the hematopoietic cytokine stem cell factor (SCF) expressed on hematopoietic progenitor cell subsets, thymocytes, mast cells hepatocytes and histiocytes. It is also commonly expressed on acute myeloid leukemias (AML). When bound to stem cell factor (c-kit ligand), CD117 activates tyrosine kinase and is involved in cell survival, proliferation and differentiation. The antibody is conjugated to a fluorophore and purified by affinity chromatography.

3. Components

CD117 monoclonal antibody conjugated with the following listed cFluor fluorescent dye is supplied in phosphate-buffered saline, pH 7.2, containing 0.09% sodium azide and 0.2% BSA (BSA Country of Origin USA).

Antibody specificity	CD117
Clone	104D2
Immunoglobulin subtype	IgG1, kappa
Species and genus	Mouse
Fluorescent dye	cFluor [®] BYG610 ¹
Excitation wavelength	488 nm
Emission peak	610 nm

4. Storage and Handling

This product is stable until the expiration date shown on the label when stored away from light at 2 ~ 8 °C. Do not freeze.

5. Other Materials required but not supplied

- RBC lysing solution
- Pipettes and pipette tips of 20 µL, 100 µL and 1000 µL
- 12x75mm tube
- Vortex mixer
- Flow cytometer

6. Specimen Requirements

- 1 Require peripheral blood of not less than 500 µL collected by venipuncture in EDTA anticoagulation tube.

- 2 After collection, the samples should be stored at room temperature (18 ~ 25 °C). Avoid shaking. The storage time should not exceed 24 hours.
- 3 After staining, the samples should be stored at 2 ~ 8 °C away from light and analyzed by flow cytometry within 2 hours.
- 4 Avoid samples with microbial contamination or coagulation.

7. Procedure

- 1 Add 100 µL well-mixed EDTA anticoagulated whole blood to the bottom of a tube. Avoid blood touching the upper tube wall.
- 2 Briefly centrifuge this product before use. Add 5 µL of CD117-cFluor-conjugated reagent to the bottom of the tube.
- 3 Mix well by vortex and incubate for 15-30 minutes at room temperature and away from light.
- 4 Add 2 mL of 1 X lysis buffer into the tube, mix briefly by vortex, and incubate for 10-15 minutes at room temperature in the dark.
- 5 Centrifuge at 300g for 5 minutes, discard the supernatant, add 2 mL PBS with 0.02% BSA, and 0.09% NaN₃ to resuspend the cell.
- 6 Centrifuge at 300g for 5 minutes, discard the supernatant, add 300 µL PBS with 0.02% BSA, and 0.09% NaN₃ to resuspend the cells and keep at 4 °C, and analyze on flow cytometer within 2 hours. If delayed analysis is needed (more than 2 hours), 300 µL of PBS containing 1% paraformaldehyde should be used to resuspend the cells and store the sample in a refrigerator at 2-8 °C away from light, but the storage time should not exceed 24 hours.

8. Quality Control

- Instrument QC: Use the manufacturer recommended controls according to the model of the flow cytometer.
- Refer to the instrument User's Guide for instrument maintenance.

9. Warnings

- This reagent contains traces of sodium azide. Do not pipette by mouth.
- Use appropriate personal protective equipment per the safety data sheet when using this product.
- Follow biosafety practice in compliance with federal, state, and local regulations to handle all biological samples and materials in contact with them.
- Contact Cytex Support or refer to cytekbio.com for details on troubleshooting.

10. Performance Characteristics

10.1. Accuracy

Three replicate tubes were stained with CD117-cFluor-conjugated reagent and analyzed on Cytek Northern Lights™ flow cytometer. The percent CD117+ cells results were within the target range established by Cytek.

Specimen: Normal Blood plus CD117+ Cells	Percent CD117+ Cells				
CD117-Fluorescent Dye	R1	R2	R3	Mean	Target Value Range
cFluor BYG610	23.3	20.2	22.3	21.9	19.9-29.9

10.2. Intra-batch precision

Ten replicate tubes were stained with the same batch of CD117-cFluor-conjugated reagent and analyzed on Cytek Northern Lights™ flow cytometer. The CV of percent CD117+ cells was calculated and was within the acceptance criteria.

Specimen: Normal Blood plus CD117+ Cells	Percent CD117+ Cells		
CD117-Fluorescent Dye	Average (%)	% CV	Criteria
cFluor BYG610	21.7	5.27	CV≤15%

10.3. Inter-batch precision

Three replicate tubes were stained with three batches of CD117-cFluor-conjugated reagent and analyzed on Cytek Northern Lights™ flow cytometer. The CV of percent CD117+ cells was calculated and was within the acceptance criteria.

Specimen: Normal Blood plus CD117+ Cells	Percent CD117+ Cells		
CD117-Fluorescent Dye	Average (%)	% CV	Criteria
cFluor BYG610	21.5	5.97	CV≤15%

10.4. Staining stability

Three replicate tubes were stained with the same batch of CD117-cFluor-conjugated reagent and analyzed on Cytek Northern Lights™ flow cytometer at these timepoints: within 2-hour (T0), 24-hour, and 48-hour after staining. The percent CD117+ cells at each time point were compared to T0, and the mean relative difference was calculated and was within the acceptance criteria.

Specimen: Normal Blood plus CD117+ cells	Percent CD117+ Cells			
CD117-Fluorescent Dye	Average	Relative Difference vs. 2H		Criteria
	(%)	24H	48H	Relative Difference
cFluor BYG610	21.9	6.08%	13.61%	≤20%

11. Limitations

- 1 This reagent can be used with a flow cytometer and is not recommended for fluorescence microscopy and immunohistochemistry.
- 2 This reagent is a fluorescent labeled product. It is easy to quench with extended light exposure and should be handled away from light.
- 3 If not following the lyse wash procedure described above, the reagent performance can be affected.
- 4 The results may be affected by improper storage of reagents, coagulation of specimens, improper storage of specimens, or incomplete lysis of red blood cells in the samples.
- 5 The test results of this reagent are for clinical reference only. Patient history, other laboratory tests, and treatment response should also be considered for diagnosis.

12. References

- Simmons PJ, et al. 1994. Exp Hematol. 22(2):157-165.
- Escribano L, et al. 1998. Leuk Lymphoma. 30(5-1): 459–466.
- Blume-Jensen P, et al. 1991. EMBO J. 10(13): 4121–4128.

¹cFluor® BYG610 is a tandem dye made with R-PE. Caution: Tandem dyes may show changes in their emission spectra with prolonged exposure to light or fixatives.