

# Fetal Cell Count™ kit

## Certificate of Analysis

Product name	:	Fetal Cell Count™ kit
Product code	:	IQP-363
Type	:	25 tests
Lot number	:	L24041
Expiry date	:	2026-05-01

Herewith *IQ Products BV* certifies that the product indicated above has been produced and quality controlled according to standard operating procedures and standard quality control methods, as implemented in the Quality System of *IQ Products BV* acting under the guidelines of ISO 13485:2016 and according to the requirements as specified in Directive 98/79/EC on in vitro diagnostic medical devices.

Results of the product release control obtained using the standard Quality Control Methods were listed in the corresponding Control Sheet ("KOF\_F.F90") were found to meet the specifications as set. No abnormalities were observed.

Groningen, The Netherlands,

IQ Products,

Christine Kebbedies / Manager QA & RA

Signature: 

Date: December 23, 2024

## Results of Analysis

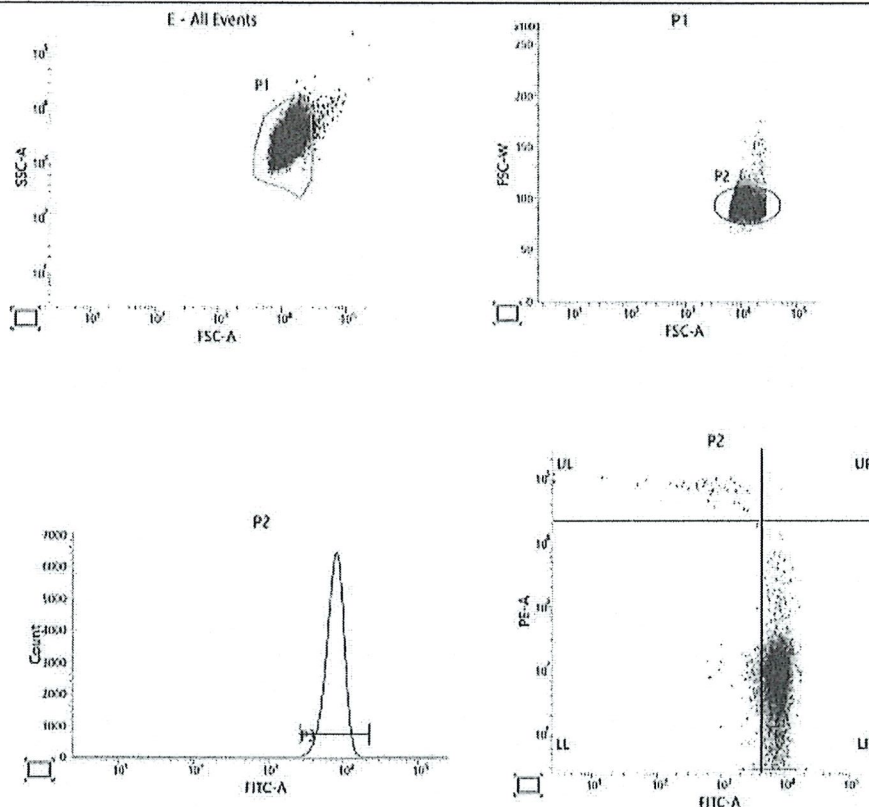
**Lot number: L24041**

**Reagent E** Clone : 15G11-D2 (mouse) Batch no. :240650  
 Specificity: Human Carbonic Anhydrase Expiry date :2026-11-01  
 Form : FITC-conjugated IgG

**Reagent F** Clone : NAM 16-2F4 (mouse) Batch no. :240695  
 Specificity: Human Hemoglobin F Expiry date :2026-12-01  
 Form : R-PE-conjugated IgG1

Physical state : Liquid  
 Buffer : 0.01 M Sodium Phosphate, 0.15 M NaCl, pH 7.3  
 Additives : 10% HS  
 Preservative : 0.09% (w/v) Sodium azide  
 Storage conditions : Store at +2 to +8 °C  
 Application : Flow cytometric analysis of erythrocytes  
 Recommended use : See package insert enclosed

Reagent E and Reagent F were analyzed by flow cytometry using a sample of Biotestcell-C cells in whole blood, following the instructions for use (see package insert). The result is presented below.



Mean fluorescence units Anti-Carbonic Anhydrase	Mean fluorescence units Anti-Hemoglobin F	Positive fetal erythrocytes
8.123	68.545	0.61%