

Macro163™

Certificate of Analysis


| | | |
|--------------|---|------------|
| Product name | : | Macro163™ |
| Product code | : | IQP-383 |
| Type | : | 96 tests |
| Lot Number | : | L26010 |
| Expiry Date | : | 2028-01-01 |

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 ISO13485:2016.

Results of the product release control obtained using the standard Quality Control Methods were listed in the corresponding Control Sheet ("KOF_E.100") were found to meet the specifications as set. No abnormalities were observed.

Groningen, The Netherlands,

IQ Products,



Head of Quality Assurance

2 April 2026

Date

Certificate of Analysis

Monoclonal Antibody: **PHB1, human panHb APC**

Product code : IQP-575A
Product name : Anti-panHb APC
Clone : PHB1 (mouse)
Specificity : Anti-pan hemoglobin (panHb)
Isotype subclass : IgG1
Form : Purified IgG-APC conjugated
Batch number : 250490
Expiration date : 2028-09-01
Quantity : 1 mL
Physical state : Liquid
Buffer : 0.01 M Sodium Phosphate, 0.15 M NaCl, pH 7.3
Additives : 0.2% (w/v) BSA
Preservative : 0.09% (w/v) Sodium azide
Storage conditions : Store in the dark at 2-8 °C. Do not freeze. Avoid prolonged exposure to light.

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 ISO13485:2016.

Results of the product release control obtained using the standard Quality Control Methods were listed in the corresponding Control Sheet and found to meet the specifications as set. No abnormalities were observed.

Approved by Name / title:

Christine Kebbedies / Manager QA & RA

Signature: 

Date: March 11th 2026

Fetal Cell Count™ kit

Certificate of Analysis

| | |
|--------------|-------------------------|
| Product name | : Fetal Cell Count™ kit |
| Product code | : IQP-363 |
| Type | : 25 tests |
| Lot number | : L26005 |
| Expiry date | : 2027-09-01 |

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 Management System of *IQ Products BV* acting under the guidelines of (EN) ISO 13485:2016, according to the requirements as specified in Directive 98/79/EC and to design control procedures as specified in Regulation (EU) 2017/746 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: _____

b/a


Date: _____

March 17th 2026

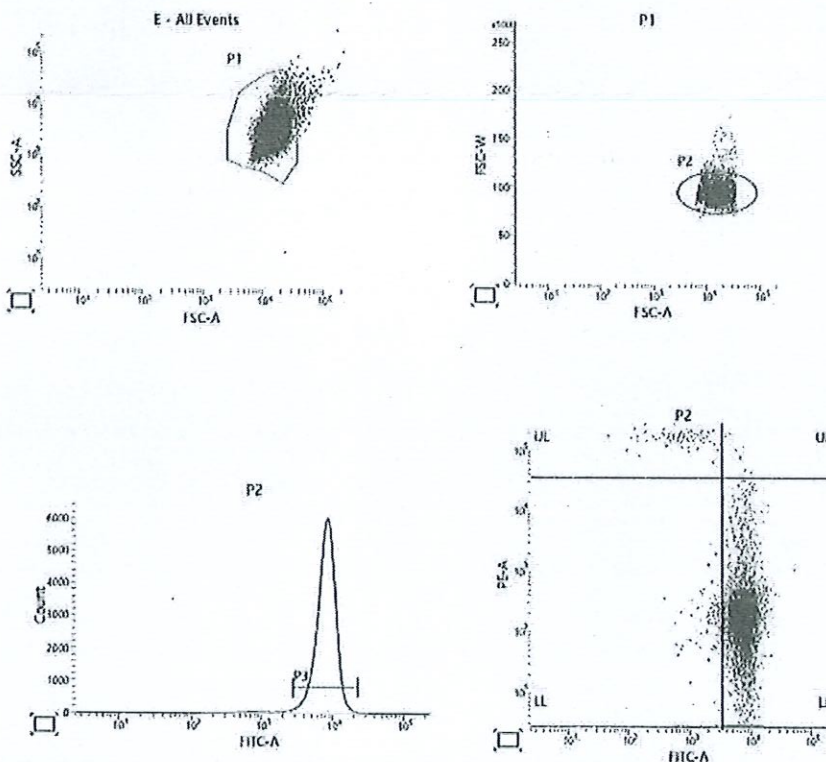
Results of Analysis

Reagent E Clone : 15G11-D2 (mouse) Batch no. :250526
 Specificity: Human Carbonic Anhydrase Expiry date :2027-10-01
 Form : FITC-conjugated IgG

Reagent F Clone : NAM 16-2F4 (mouse) Batch no. :260106
 Specificity: Human Hemoglobin F Expiry date :2028-02-01
 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 |
|--|--|-----------------------------|
| 8.817 | 151.869 | 1.04% |