

# Product Information WBC Reduced RBC Control

## Product description

WBC reduced RBC Control is used as a process control to monitor whitebloodcell-reduced RBC products, including the dilution and staining process, metho set-up and WBC enumeration.

WBC reduced RBC Control is a reliable product that provides means of determining the precision and accuracy of analytical procedures that measure the residual leucocytes in blood products. It is tested in the same manner as blood products used for transfusion purposes.

## Ingredients

WBC reduced RBC Control contains Human leukocytes and mammalian erythrocytes. All cells are suspended in a plasma like fluid with preservatives. WBC reduced RBC Control is an in vitro diagnostic reagent. Assay ranges can be found in the Assay Values sheet included with the product.

## Suitability

WBC reduced RBC Control is intended to be used on Flow Cytometer Instruments.

## Product Stability

WBC reduced RBC Control is stable for 3 months. Opened vials remain stable for 30 days or 21 uses, when used in accordance with the instructions for use.

## Storage

1. Store vials upright, tightly capped, at 2–8°C when not in use.
2. Unopened vials are stable until the expiration date indicated on each vial and on the Assay Values sheet when stored continuously at 2–8°C.
3. Opened vials are stable for 30 days or 21 thermal cycles (uses), whichever comes first, when handled properly. A thermal cycle constitutes performing all steps once under Instructions for Use.

In general, stability is limited by the number of times the vial is removed from the refrigerator, warmed, and mixed (defined as a “use”); by the time from first use; and by the decrease in volume with each use.

4. Protect from freezing, from temperatures above 30°C, and from prolonged time at room temperature (18–30°C).

WBC reduced RBC Control comes in the following levels and values:

Parameter	Low	High
	Target value	Target value
	Example	Example
WBC x 10 <sup>6</sup> /L	3.0	23.0

## Availability

WBC reduced RBC Control is available in the following pack size:

Volume per vial	Type of package	Product Nr.	
		Low	High
3 ml	Screw cap	3698	3699

## Delivery schedule and ordering information

WBC reduced RBC Control is manufactured and delivered on a 6 times per year schedule. Orders are guaranteed when ordered in time, according to the delivery schedule.

**Assay values WBC Reduced RBC Control**

LOT : 108      REF : 3698, 3699  
 : 2006 May 19th

Assay values and expected ranges

Method	Parameters	Low Abnormal		High Abnormal	
		Mean	Range ±	Mean	Range ±
Flow Cytometer	WBC 10 <sup>6</sup> /L	2.0	± 1.0	23.2	± 4.0
Nageotte Chamber	WBC 10 <sup>6</sup> /L	1.9	± 1.0	22.3	± 4.0

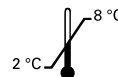
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The devices as mentioned in this insert comply with the In Vitro Diagnostic Medical Devices Directive 98/79/EC.



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