

From
Biotechnology
to Diagnosis

PNH diagnosis

CELLQUANT PNH & REDQUANT PNH

Ref. # 7201 AND 7301

- ✓ **Disorder :**
Paroxysmal Nocturnal Haemoglobinuria
- ✓ **Detection :**
CD55 and CD59 deficiency
- ✓ **Sample :**
Whole blood
- ✓ **Cell populations :**
Granulocytes (ref. 7201)
Red blood cells (ref. 7301)
- ✓ **Technology :**
Flow cytometry
- ✓ **Clinically validated :**
OELSCHLAEGEL U. *et al.*; (Germany)
Clin Lab Haem. 2001, 23 : 81-90

CE marked.
In Europe, For In Vitro Diagnostic Use



140, Chemin de l'Armée d'Afrique - 13010 Marseille - France
RCS Marseille 347 897 985
Tél. : 04 96 12 20 40 - Fax : 04 91 47 24 71
Tél. : Int. + (33) 4 96 12 20 40 - Fax : Int. + (33) 4 91 47 24 71
E-mail : info@biocytex.fr - Website : www.biocytex.fr



PNH disease :

Background :

Paroxysmal Nocturnal Haemoglobinuria (PNH) is a rare acquired and clonal disorder characterized by destruction of red blood cells (Hemolytic anemia) and venous thrombosis. Other complications such as infectious disease and hematopoietic disorders such as leukaemia may occur.

Pathophysiology :

PNH results from a defect in the PIG-A gene involved in the synthesis of glycosyl-phosphatidylinositol (GPI) linkage of proteins to the membrane. CD55 (Decay accelerating factor) and CD59 (Membrane inhibitor of reactive lysis) are GPI-anchored proteins involved in the protection of cells against autologous complement-mediated lysis. In PNH disorder, cells are deficient in CD55 and CD59 and are thus sensitive to complement-mediated lysis.

Diagnostic test :

CELLQUANT and REDQUANT PNH are ready-for-use single color flow cytometry kits for the analysis of CD55 and CD59 antigens on granulocytes and red blood cells, respectively. The relative amounts of CD55 and CD59 deficient cells are determined using a threshold gating method. The method establishes analysis regions in which CD55 and CD59 deficient granulocytes or red blood cells migrate and can be differentiated from normal cells.



Test interpretation :

For a normal sample without CD55 and CD59 expression deficiency, the analysis regions do not contain more than 3% of gated cells.

The relative fractions of CD55-, CD59- deficient red blood cells, CD55- and CD59- deficient granulocytes represent the 4 interpretation parameters of the CELLQUANT and REDQUANT PNH tests.

The PNH diagnosis depends on the number of positive parameters and their combinations.

Nb of positive parameters	CELLQUANT PNH		REDQUANT PNH		DIAGNOSIS
	CD55	CD59	CD55	CD59	
4	> 3%	> 3%	> 3%	> 3%	PNH
3	> 3%	> 3%	> 3%	< 3%	PNH
3	> 3%	> 3%	< 3%	> 3%	PNH
3	< 3%	> 3%	> 3%	> 3%	PNH
3	> 3%	< 3%	> 3%	> 3%	PNH
2	> 3%	> 3%	< 3%	< 3%	PNH
2	< 3%	< 3%	> 3%	> 3%	PNH
2	< 3%	> 3%	< 3%	> 3%	Non PNH*
2	> 3%	< 3%	< 3%	> 3%	Non PNH*
2	> 3%	< 3%	> 3%	< 3%	Non PNH*
2	< 3%	> 3%	> 3%	< 3%	Non PNH*
1	> 3%	< 3%	< 3%	< 3%	Non PNH*
1	< 3%	> 3%	< 3%	< 3%	Non PNH*
1	< 3%	< 3%	> 3%	< 3%	Non PNH*
1	< 3%	< 3%	< 3%	> 3%	Non PNH*
0	< 3%	< 3%	< 3%	< 3%	Normal

Note * : In these cases, it is recommended to perform a follow-up test during the course of the disease for confirmation.

Examples of one normal sample and two PNH samples detected with CELLQUANT PNH and REDQUANT PNH :

	CELLQUANT PNH CD55	CELLQUANT PNH CD59	REDQUANT PNH CD55	REDQUANT PNH CD59
Normal Sample	< 3%	< 3%	< 3%	< 3%
PNH Sample 1	> 3%	> 3%	> 3%	> 3%
PNH Sample 2	> 3%	> 3%	> 3%	> 3%

Note : All 3 analysis have been generated using different instrument settings (e.g. FL1 PMTv lower for normal sample than PNH samples). C and D regions have been positioned accordingly via the threshold gating method.