


Certificate of Analysis QCS Cystine in WBC (PP)




Product name Quality comparison material Cystine in WBC – Protein Pellet samples

Product code	Product code	Colour cap
	CYS-01.1	Silver
	CYS-01.2	Silver
	CYS-01.3	Silver

Date of issue 20 October 2025

Production date  September 2025

Storage temperature -16°C to -24°C

Batch numbers	Batch number
	 2026.0111
	 2026.0112
	 2026.0113

Reconstitution volume 1.0 mL

Expected concentrations	Analyte	Expected concentrations (mg/L)		
		Level 1	Level 2	Level 3
	Protein	400	900	1500

Cystine in WBC (PP samples) ERNDIM QCS

Intended purpose

Not for diagnostic use.

This material is intended solely for the verification of the correct calibration of measurement methods. It is not permitted to use this material (without CE mark) in establishing or assessing patient/client results.

Disclaimer

It is the responsibility of the customer to limit the use of this material to the intended use described above. Streekeziekenhuis Koningin Beatrix (department MCA laboratory) is not responsible or liable for application outside the intended use.

Contents

Lyophilized human protein solution.

Expected concentrations

The expected concentrations are spiked concentrations.

Storage and stability

The stability in lyophilized form has been tested for 2 years and no sign of instability is seen when stored at -16°C to -24°C. It is plausible that stability exceeds 2 year. Stability testing will continue the coming years. In case instability is observed, users will be informed. If not, users will not be informed and can be sure that stability is warranted until September 2030.

The stability of the reconstituted product is comparable to patient samples.

Instructions for use

- a. Remove cap and stopper.
- b. Add 1 mL aqua destillata
- c. Replace stopper
- d. Let stand for 15 minutes at room temperature
- e. Mix carefully during 20 minutes at room temperature
- f. Process product as patient sample

Precautions and warnings

1. For *in vitro* use only.
2. This product should be handled with care, as appropriate for biological materials. Outdated and left-over material should be discarded according to the procedures in your institute.

References

www.ERNDIMQA.nl

