

COAP186-0Bv4/template

## CERTIFICATE OF ANALYSIS HUMAN BLOOD PROTEIN

## Haemoglobin A1c (Ultra Pure)

Code No. Grade Lot No.	P186-0B Highly pure		
	)N		
xpiry Date			
Ianufacture Date			
torage Temperature	Store below -15°C.		
Storage Notes	Avoid freeze thaw cycles.		
Shipping Notes	Dry Ice recommended.		
PRODUCT INFORMATIO	NI .		
Source	Human erythrocytes.		
Jource	Human erythocytes.		
Nominal Purity	> 96%.		
Presentation	Single homogenous batch, 0.2µm filtered, supplied as frozen solution in a proprietary buffer formulation, pH 8.0. Dispensed or the basis of HbA1c not total haemoglobin.		
Recovery	In order to meet our customer needs, it should be noted that the is normally a dispensing overage allowance and the product recovery may, therefore, be greater than expected.		
HEALTH AND SAFETY			
Application	For Research and Manufacturing Only.		
nfectious Disease Tests	6		
	Starting material donor tested using	Result	
	FDA approved tests: HIV 1 & 2 antibodies		
	Hepatitis B Surface Antigen Hepatitis C virus antibodies		
Precaution	No test can guarantee the absence of an infectious agent. Pleas handle as potentially hazardous.		
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## ANALYSIS

TESTS	SPECIFICATIONS	RESULTS
<b>Determination Method</b>		
Total protein (haemoglobin) determined by OD at 415nM (E=7)	>1 mg/ml	mg/ml
Purity by HPLC using a Mono S HbA1c column using detection at 415nM		Pass/Fail
SDS- Polyacrylamide Gel Electrophoresis	To show bands corresponding to haemoglobin molecular weight	Pass/Fail
Bioburden	<100 CFU/mI	Pass/Fail
Physical Appearance C	Clear red frozen solution.	
<b>Purity</b>	Defined by HPLC using a Mono S column	

Name:	Position:	
Signed:	Date:	

Part of **BBI Group**