

RECOMBINANT HUMAN MYOGLOBIN (MB)

Myoglobin is a low molecular weight globular heme-binding protein that transports oxygen to muscles. Its increased concentration in bloodstream helps in early detection of any cardiac necrosis or muscle damage, and thereby provides recommendations for prevention or treatment¹. When used in combination with other cardiac markers such Troponin and CK-MB, it makes the prognosis more accurate².

Resolve's Recombinant Human Myoglobin is a 20.6 kDa protein fused to His-tag at N-terminus (153 aa, His-tag), expressed in E. coli and purified by affinity chromatography. It can serve as a control/calibrator for clinical diagnostic assays, on platforms such as ELISA/CLIA/CMIA and point-of-care testing such as Lateral Flow Assays (LFA; rapid tests). High quality, sensitivity and accuracy are the main advantages of Resolve's Recombinant Human Myoglobin.



Technical Specifications

A. Purity:

1. SDS-PAGE

Resolve's Recombinant Human Myoglobin is >95% pure determined by SDS-PAGE (Figure 1).

B. Detection of Antigenic activity:

1. Method 1: Chemiluminescence Assay (CLIA)

Antigenic activity of Resolve's Recombinant Human Myoglobin was tested through a third-party diagnostic laboratory—Manipal TRUtest—and significant antigenic activity was detected (Figure 2) on a Chemiluminescence Assay (CLIA) conducted on the Roche Cobas [Elecys] platform.

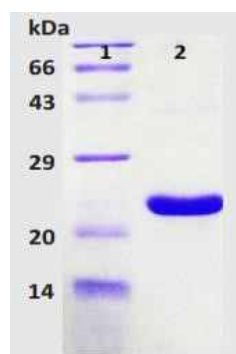


Figure 1: SDS-PAGE of Resolve's Recombinant Human Myoglobin
Lane 1: Ladder, Lane 2: Resolve's Recombinant Human Myoglobin at 20.6 kDa



LABORATORY TEST REPORT		manipal TRUtest	
		FAST. ACCURATE. RELIABLE	
ID : 187066	Collection : 29/05/2024, 05:00 PM	Client Name : Chirag Bidwai(
Name : RESOLVE BIOTECH MYO V7	Received : 29/05/2024, 05:00 PM	Manipal Trutest)-TH1565	
DOB/Age : 0 days	Reported : 30/05/2024, 04:12 PM	Client Address : Thane	
Gender : Other	Ref. Doctor : -		
Nationality : -	Passport No. : -	 2224052410	
Test Description	Value(s)	Unit(s)	Reference Range
Myoglobin, Serum **			
Myoglobin (Serum) (ECLIA)	2495	ng/mL	Up to 48.8

Figure 2: Report from Manipal TRUtest for Resolve's Recombinant Human Myoglobin sample (reconstituted to 3000 ng/mL)

2. Method 2: Lateral Flow Assay (LFA)

Resolve's Recombinant Human Myoglobin was also tested on lateral flow assays—Mytest's Cardiac Combo (CKMB/MYO/TnI) multi panel cassette (Biofootprints Healthcare Pvt. Ltd.) and ImmunoQuick MYO (ImmunoScience India Pvt. Ltd.). The test showed clear bands at 50 ng/mL (Limit of Detection of the test: 50 ng/mL) on the Mytest LFA (Figure 3A) and at 100 ng/mL (Limit of Detection of the test: 50 ng/mL) on the ImmunoQuick LFA (Figure 4A).

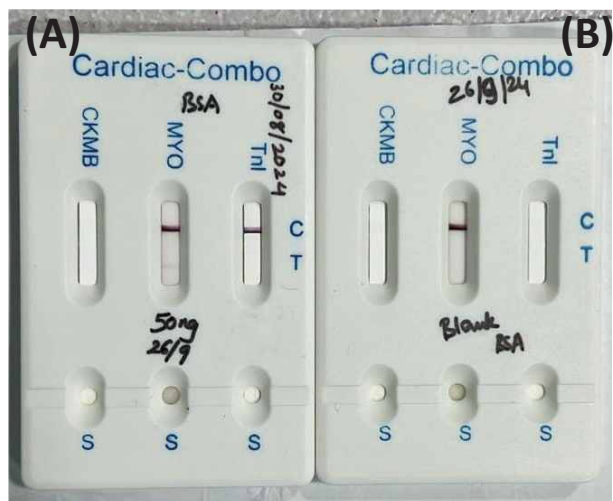


Figure 3: Results of Lateral Flow Assay (Mytest's Cardiac Combo (CKMB/MYO/TnI) multi panel cassette)

(A) Test: Sharp bands at Control and Test lines with Resolve's Recombinant Human Myoglobin (50 ng/mL).
(B) Blank (only diluent buffer): Control line positive but no band at Test line to rule out false positives due to buffer interference



Figure 4: Results of Lateral Flow Assay (ImmunoQuick MYO)

(A) Test: Sharp bands at Control and Test lines with Resolve's Recombinant Human Myoglobin (100 ng/mL).
(B) Blank (only diluent buffer): Control line positive but no band at Test line to rule out false positives due to buffer interference

Resolve's Recombinant Myoglobin exhibited significant antigenic activity as detected with CLIA method by a third-party laboratory (Manipal TRUtest) and also demonstrated positive results on multiple Lateral Flow Assays (Mytest's Cardiac Combo Rapid Test Kit and ImmunoQuick MYO) up to the Limit of Detection of the test (50/100 ng/mL), further validating its utility as a control/calibrator and in innovative point-of-care diagnostic devices.

References

¹Aydin S, Ugur K, Aydin S, Sahin İ, Yardim M. Biomarkers in acute myocardial infarction: current perspectives. *Vasc Health Risk Manag.* 2019;15:1-10. doi:10.2147/VHRM.S166157

²Jacob R, Khan M. Cardiac Biomarkers: What Is and What Can Be. *Indian J Cardiovasc Dis Women WINCARS.* 2018;3(4):240-244. doi:10.1055/s-0039-1679104 A B

³Mytest Cardiac Combo (CKMB/MYO/TnI); MTR07KI-01, Apr/2019; Biofootprints Healthcare Pvt. Ltd., New Delhi, India

⁴ImmunoQuick MYO; PI/MYO/06-22/VER-01; ImmunoScience India Pvt. Ltd., Pune, India