

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 as 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 [Elecsys] platform.



LABORATORY TEST REPORT		manipal TRUtest FAST. ACCURATE. RELIABLE	
ID : 170143	Collection : 07/12/2023, 05:45 PM	Client Name : Badlapur CC - THCCBUD	
Name : RESOLVE DIAGNOSTIC C	Received : 07/12/2023, 05:45 PM	Client Address : THANE	
DOB/Age : 0 days	Reported : 08/12/2023, 04:18 PM	2223120663	
Gender : Other	Ref. Doctor : -		
Test Description	Value(s)	Unit(s)	Reference Range
Myoglobin, Serum **			
Myoglobin (Serum) (CLIA)	819	ng/mL	Up to 48.8

Figure 2: Report from Manipal TRUtest for Resolve's Recombinant Human Myoglobin sample (1000 ng/mL)

2. Method 2: Lateral Flow Assay (LFA)

Resolve's Recombinant Human Myoglobin was also tested on a lateral flow assay—Mytest's Cardiac Combo (CKMB/MYO/Tnl) multi panel cassette (Biofootprints Healthcare Pvt. Ltd.). The test showed clear bands at higher concentrations (>200 ng/mL; Figure 3B) and a faint band at 50 ng/mL (Limit of Detection of the test: 50 ng/mL³).

Note: The Mytest Cardiac Combo test has a Limit of Detection of 50 ng/mL for Myoglobin. Resolve's Recombinant Human Myoglobin was also loaded at 50 ng/mL and a faint band (visible to the naked eye) was observed in the Test line.

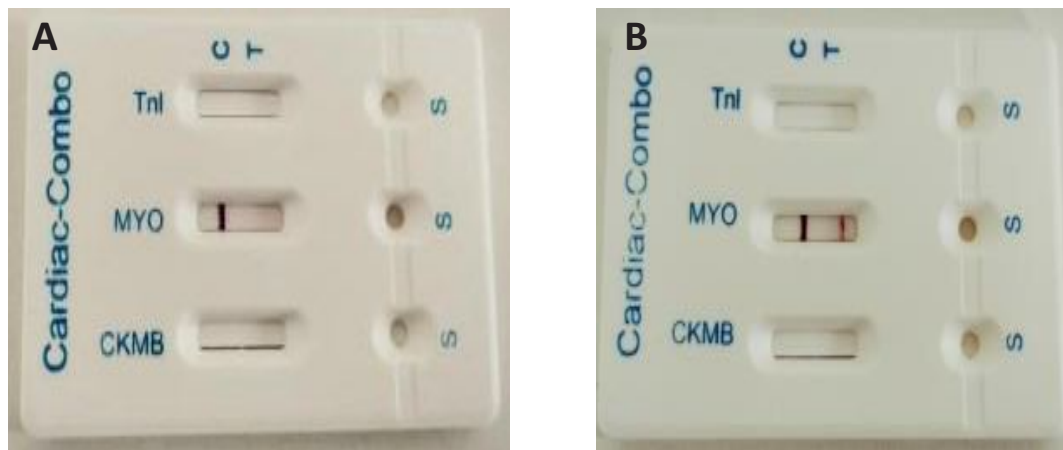


Figure 3: Results of Lateral Flow Assay (Mytest's Cardiac Combo (CKMB/MYO/Tnl) multi panel cassette) (A) Blank (only diluent buffer): Control line positive but no band at Test line to rule out false positives due to buffer interference; (B) Test: Sharp bands at Control and Test lines with Resolve's Recombinant Human Myoglobin (200 ng/mL).

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 a Lateral Flow Assay (Mytest's Cardiac Combo Rapid Test Kit) up to the Limit of Detection of the test (50 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

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