

RECOMBINANT HUMAN CARDIAC TROPONIN-I (TnI)

Troponin is one of the most preferred biomarker for detection of cardiovascular disorders¹. It is a 3-unit complex comprising of Troponin I, T and C. The isoforms cardiac Troponin I (cTnI) and cardiac Troponin T (cTnT) are associated with cardiac specificity and have been accepted as the “gold standard” in the evaluation of patients with acute myocardial infarction (AMI)².

The troponin levels are usually low but high levels of cTnI/cTnT are released into the bloodstream during myocardial necrosis and start increasing 4–9 hours after an AMI and peak at 12–24 hours.² Compared to myoglobin (MB) and creatine-kinase-MB (CK-MB), cTnI is more sensitive and specific to AMI and has been recommended as a fundamental cardiac marker for the diagnosis of AMI in combination with cTnT/MB/CK-MB³.



Resolve's Recombinant Human Cardiac Troponin I is a 27.4 kDa protein fused to His-tag at N-terminus (242 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/ELFA and point-of-care testing such as Lateral Flow Assays (LFA; rapid tests).

Technical Specifications

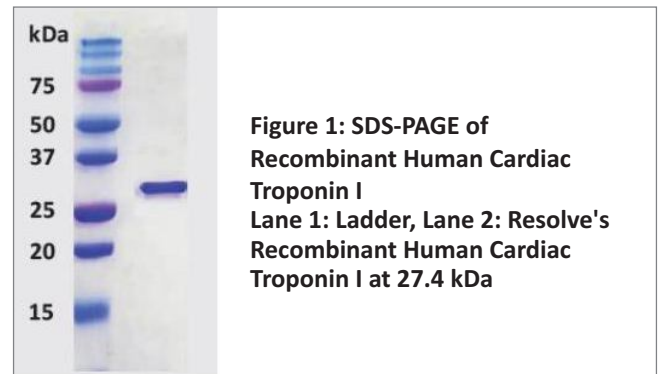
A. Purity:

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

B. Detection of Antigenic activity:

1. Method 1: ELFA

Antigenic activity of Resolve's Recombinant Human Cardiac Troponin I was tested through a third-party diagnostic laboratory—Manipal TRUtest—and significant antigenic activity was detected (Figure 2) on an Enzyme Linked Fluorescent Assay (ELFA) conducted on a bioMérieux VIDAS® platform.



LABORATORY TEST REPORT		 <small>FAST. ACCURATE. RELIABLE</small>	
ID : 177801	Collection : 21/02/2024; 09:01 PM	Client Name : Chirag Bidwai(
Name : RESOLVEDIGONSTICS	Received : 21/02/2024; 09:01 PM	Manipal TruTest)-TH1565	
DOB/Age : 0 days	Reported : 21/02/2024; 11:14 PM	Client Address : Thane	
Gender : Other	Ref. Doctor : -	 ICMR ID : -	
Test Description	Value(s)	Unit(s)	Reference Range
Troponin - I Quantitative			
High Sensitive Troponin-I (Serum, ELFA)	377789.8	ng/L	8 - 29

Figure 2: Report from Manipal TRUtest for Resolve's Recombinant Human Cardiac Troponin-I sample diluted to 40 ng/mL and 37.78 ng/ml was detected.

2. Method 2: Lateral Flow Assay (LFA)

Resolve's Recombinant Human Cardiac Troponin I was also tested on lateral flow assays—CTK Biotech Inc., OnSite Troponin I Combo Rapid Test and Oscar Medicare Pvt. Ltd., India, Troponin I Test⁴. The test showed clear bands at higher concentrations (>50 ng/mL; Figure 3B)

Note: Resolve's Recombinant Human Cardiac Troponin I was also loaded at lower concentrations of 3.0 ng/mL and faint bands (visible to the naked eye) were observed in the Test line on multiple LFA kits (CTK OnSite and Oscar Medicare).



Figure 3: Results of Lateral Flow Assay (CTK Onsite Troponin I Combo Rapid Test)

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

Resolve's Recombinant Human Cardiac Troponin I exhibited significant antigenic activity as detected with ELFA method by a third-party laboratory (Manipal TRUtest) and also demonstrated positive results on Lateral Flow Assays (CTK Biotech OnSite Troponin I Combo Rapid Test and Oscar Medicare Troponin I Test) with clearly visible positive result at concentrations of 3.0 ng/mL further validating its utility as a quality control/calibrator and in innovative point-of-care diagnostic devices.

References

¹Babu, L., & Jaffe, A. S. (2005). Troponin: the biomarker of choice for the detection of cardiac injury. *CMAJ : Canadian Medical Association journal = journal de l'Association medicale canadienne*, 173(10), 1191–1202. Doi:10.1503/cmaj/051291

²Amitava Dasgupta, Amer Wahed (2014). Chapter 8 - Cardiac Markers in Clinical Chemistry, Immunology and Laboratory Quality Control. Editor(s) Amitava Dasgupta, Amer Wahed. Elsevier, Pages 127-144, doi:10.1016/B978-0-12-407821-5.00008-5.

³Cai Y, Kang K, Li Q, Wang Y, He X (2018). Rapid and Sensitive Detection of Cardiac Troponin I for Point-of-Care Tests Based on Red Fluorescent Microspheres. *Molecules*, 23(5):1102. doi:10.3390/molecules23051102

⁴CTK Biotech Inc, San Diego, CA, OnSite Troponin I Combo Rapid Test PI-R-3002C-ATH; 10-08-2018; Oscar Medicare Pvt. Ltd. India, IM/HIT/01-01