

# Clinical sheet – AQT90 FLEX

## Cardiac markers

The AQT90 FLEX analyzer offers a palette of cardiac markers for triaging the chest pain patient.

- Troponin I (TnI)
- Troponin T (TnT)
- CKMB
- Myoglobin (Myo)

### Intended use

The AQT90 FLEX TnI test and the AQT90 FLEX TnT test are indicated for use as an aid in diagnosing myocardial infarction and in the stratification of patients with acute coronary syndromes with respect to their relative risk of mortality. The AQT90 FLEX TnI test is unique. It is standardized according to the NIST standard SRM 2921 and is not influenced by autoantibodies (interfering factors).

The AQT90 FLEX CKMB test and the AQT90 FLEX Myo test are indicated for use as an aid in the diagnosis of myocardial infarction.

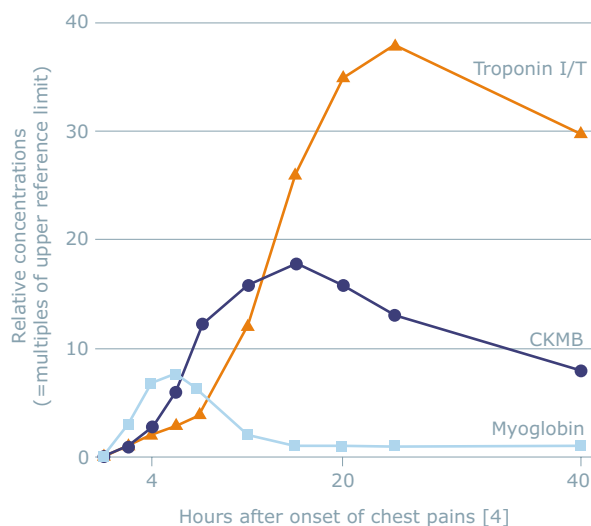
### Summary

Cardiovascular disease continues to be one of the two most prevalent causes of morbidity and mortality in the western world. An estimated 17 million people worldwide die each year of cardiovascular disease [1].

Meanwhile, studies have shown that fast triaging of chest pain patients is essential in ensuring a positive outcome [2].

Troponin is the most specific marker of myocardial infarction and current guidelines recommend troponin for triaging chest pain patients [3].

Troponin I and troponin T are regulatory proteins of the muscular thin filaments and part of the troponin-tropomyosin complex in striated muscle. The troponin complex consists of three components: troponin C (TnC), troponin T (TnT) and troponin I (TnI). This ternary troponin complex is a calcium-sensitive molecular apparatus that regulates the interaction of actin and myosin.



Both troponin I and T exist in skeletal and cardiac isoforms. The fact that the cardiac (c) forms are extremely specific to the heart tissue explains their increased use as specific markers of cardiac muscle damage. The main part of plasma cardiac troponin I is found in the form of a complex, mainly with TnC. Only a small part of circulating cTnI is found in a non-complexed form. The main part of plasma cardiac troponin T is in a free non-complexed form.

The AQT90 FLEX TnI assay is specific to cardiac troponin I, and it detects both free and complexed forms of cardiac troponin I.

The AQT90 FLEX TnT assay is specific to cardiac troponin T, and it detects both free and complexed forms of cardiac troponin T.

## Samples

Blood samples are collected by venipuncture. Whole-blood or plasma samples with either EDTA or lithium heparin as anticoagulant can be used.

## Performance characteristics

### *Analytical specificity*

#### **TnI**

The limit of detection has been determined to be <0.010 µg/L.

Reportable range: 0.010-50 µg/L.

#### **TnT**

The limit of detection has been determined to be 0.010 µg/L.

Reportable range: 0.010-25 µg/L.

#### **CKMB**

The limit of detection has been determined to be 0.53 µg/L.

Reportable range: 2-500 µg/L.

#### **Myo**

The limit of detection has been determined to be 0.1 µg/L.

Reportable range: 20-900 µg/L.

### *Reference values*

#### **TnI**

The 99th percentile was determined to be 0.023 µg/L [4].

#### **TnT**

The 99th percentile was determined to be 0.017 µg/L [4].

#### **CKMB**

The central 95 % of healthy persons ranged as follows: <7.2 µg/L [4].

#### **Myo**

The central 95 % of healthy persons ranged as follows: 23-112 µg/L [4].

NOTICE: These ranges should only be used as examples and each laboratory should establish its own reference ranges.

### Imprecision

Within-day and total imprecision was determined by analyzing plasma pools over 20 days, twice a day, four replicates per run.

Within-run imprecision				Total imprecision			
Sample	mean µg/L	SD µg/L	% CV	Sample	mean µg/L	SD µg/L	% CV
<b>TnI*</b>							
Plasma pool 1	0.015	0.0036	24.2	Plasma pool 1	0.015	0.0042	27.8
Plasma pool 2	0.024	0.0039	16.3	Plasma pool 2	0.024	0.0042	17.7
Plasma pool 3	33.4	0.77	2.3	Plasma pool 3	33.4	1.12	3.4
<b>TnT</b>							
Plasma pool 1	0.027	0.0023	8.2	Plasma pool 1	0.027	0.0026	9.6
Plasma pool 2	0.21	0.0073	3.5	Plasma pool 2	0.21	0.0116	5.6
Plasma pool 3	12.0	0.343	2.9	Plasma pool 3	12.0	0.644	5.4
<b>CKMB</b>							
Plasma pool 1	5.0	0.19	3.9	Plasma pool 1	5.0	0.20	4.1
Plasma pool 2	14.9	0.45	3.0	Plasma pool 2	14.9	0.54	3.6
Plasma pool 3	286	5.37	1.9	Plasma pool 3	286	8.21	2.9
<b>Myo</b>							
Plasma pool 1	42.5	0.98	2.3	Plasma pool 1	42.5	1.48	3.5
Plasma pool 2	106	2.06	1.9	Plasma pool 2	106	3.14	3.0
Plasma pool 3	729	16.16	2.2	Plasma pool 3	729	25.56	3.5

\*The concentration giving the CV of 10 % of the AQT90 FLEX TnI assay is approximately 0.039 µg/L.

### Clinical sensitivity and specificity\*\*

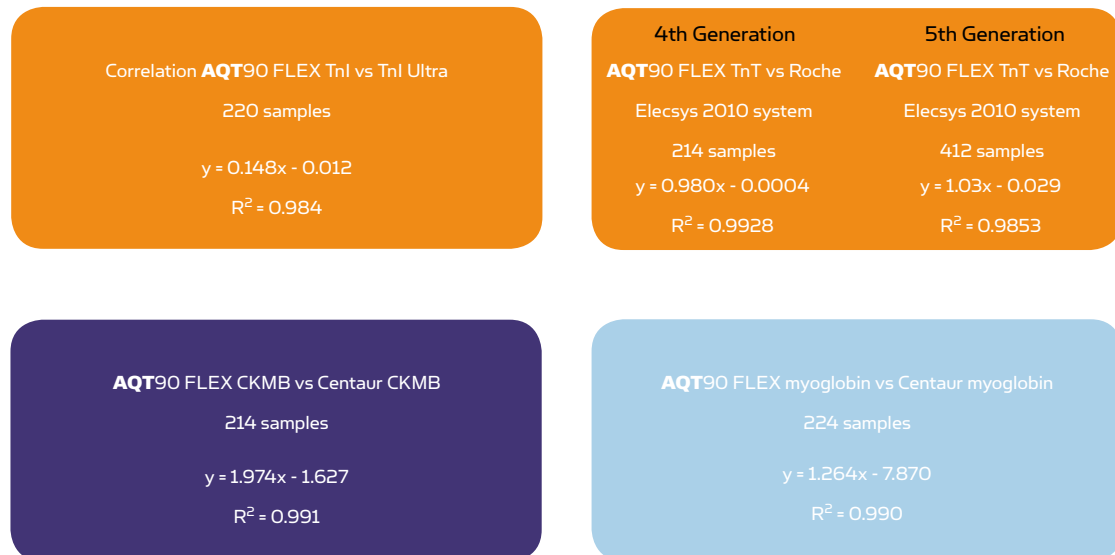
Cut-off	0-2 hours after admission		6-9 hours after admission	
	Sensitivity	Specificity	Sensitivity	Specificity
<b>TnI</b>				
99th percentile: 0.023 µg/L	65 %	91 %	91 %	88 %
<b>CKMB</b>				
Upper reference limit: 7.2 µg/L	44 %	98 %	72 %	96 %
<b>Myo</b>				
Upper reference limit: 112 µg/L	52 %	93 %	53 %	90 %

\*\*Study performed in cooperation with Akademiska Hospital, Uppsala, Sweden [4].

The clinical performance of AQT90 FLEX TnT assay was not tested as the assay correlates to the Roche TnT assay. Therefore, clinical performance will be comparable.

### Correlation studies

The AQT90 FLEX assays TnI, CKMB, and Myo were compared to the corresponding assays with the Centaur analyzer (Siemens). All three assays showed good correlations with the Centaur analyzer assays\*\*\*.



The AQT90 FLEX TnT assay was compared to the corresponding assay with the Elecsys 2010 system (Roche). The assay showed good correlation with the Elecsys analyzer assay, both 4th and 5th generations.\*\*\*\*

\*\*\*Study performed in cooperation with Oulu University Hospital, Finland [4].

\*\*\*\*Method comparison study performed in cooperation with Viborg Hospital, Denmark [4].

### References

1. WHO estimate - [http://www.who.int/topics/cardiovascular\\_diseases/en/](http://www.who.int/topics/cardiovascular_diseases/en/).
2. Johnston S, Brightwell R, Ziman M. Paramedics: Paramedics and pre-hospital management of acute myocardial infarction: diagnosis and reperfusion. Review. Emergency Medicine Journal 2006; 23: 331-34.
3. Thygesen K, Alpert JS, White HD on behalf of the Joint ESC/ACCF/AHA/WHF Task Force for the Redefinition of Myocardial Infarction: Universal Definition of Myocardial Infarction. Circulation 2007; 116(22): 2634-2653.
4. Internal study, data in file.



Data subject to change without notice.

Radiometer, the Radiometer logo, ABL, AQT, TCM, RADIANCE, PICO and CLINITUBES are trademarks of Radiometer Medical ApS.

Windows® is a registered trademark of Microsoft Corporation.