Ortho Clinical Diagnostics

VITROS® High Sensitivity Troponin I Assay

Confidence in Result. Confidence in Decision.

VITROS hsTnI delivers high clinical sensitivity and specificity for diagnostic accuracy, high analytical sensitivity and precision for detecting small changes at the 99th percentile, *and* high negative predictive value for confidence in early rule out of acute myocardial infarction (AMI).

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Precise Decisions

VITROS® hsTnI—When You Have to Be Right

When a patient enters the emergency department presenting with chest pains, it's critical to provide an accurate diagnosis as quickly as possible. High sensitivity cardiac troponin (hs-cTn) assays allow early triage of patients with possible acute myocardial infarction (AMI).

In conjunction with a full clinical assessment, hs troponin provides critical data for a precise diagnostic decision through:

- High analytical sensitivity and precision for the detection of small changes at the 99th percentile, enabling early diagnosis of AMI
- High negative predictive value to provide confidence for an early (1-, 2-, or 3-hr) AMI rule out to reduce emergency department crowding and number of tests needed for diagnosis
- High clinical performance for risk stratification
- High clinical sensitivity and specificity for diagnostic accuracy
- Fully compliant with the IFCC* high-sensitivity definition
- No interference from biotin and minimizes susceptibility to common interferences

Assay Lab Performance

		hsTroponin I
Gender-specific 99th percentile URL (serum)		11 (Overall)
		12 (Male)
		9 (Female)
LOQ	10%CV	1.99 ng/L
	20%CV	1.23 ng/L
LOD		0.39-0.86 ng/L†
Time to First Result		15 minutes
Measuring Range		1.5-30,000 ng/L
Sample Size		60 µL
Calibration interval		28 days
Calibrator Format		Liquid Frozen, 3 levels
Correlation to VITROS Troponin I ES		1.064, r=0.977

†Varies by System

Intended Use

For the quantitative measurement of cardiac troponin I (cTnI) in human serum and plasma (heparin) using the VITROS ECi/ECiQ/3600 Immunodiagnostic Systems and the VITROS 5600/XT 7600 Integrated Systems. Cardiac troponin I elevations are associated with myocardial damage, and in patients with acute coronary syndrome (ACS), troponin values are used to aid in the diagnosis of myocardial infarction (MI). The test is further indicated for risk stratification of mortality, myocardial infarction or coronary revascularization in patients with acute coronary syndrome.

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Data on file, Ortho Clinical Diagnostics.
*IFCC=International Federation of Clinical Chemistry and Laboratory Medicine

Get the Best of Both Worlds: In Lab and In Practice

For Laboratorians: Confidence in Result

Ortho understands the challenges in the laboratory. Clinicians rely on their labs to provide accurate and fast results. VITROS hsTnI is the result of our commitment to continuous improvement of our cardiac assay menu:

True high sensitivity Fully compliant with the IFCC high sensitivity definition: Imprecision (%CV) less than 10% at the 99th percentile upper reference limit; detects troponin at a concentration at or above the limit of detection (LOD) in >50% of healthy individuals

Interference Reduction: Not susceptible to biotin interference; minimizes interference from hemolysis, that can lead to inaccurate results and repeat tests

Excellent analytical performance: LOD at 0.39- 0.86 ng/L, LOQ (10% CV) at 1.99 ng/L[a]

Less workload, better efficiency Long calibration intervals reduces waste and maintenance time

For Clinicians: Confidence in Decision

Delivers the sensitivity and precision to detect small changes at very low troponin concentrations, enabling early diagnosis of AMI

Demonstrated high clinical sensitivity and specificity at 1, 2 and 3 hours to accelerate decision-making with a rapid rule-in/rule-out algorithm, as specified by the European Society of Cardiology

Demonstrates excellent performance for AMI/no AMI discrimination across all collection time points overall and across gender

Clinical Performance - Data from clinical trials demonstrates VITROS hs Troponin I test performance in early rule in/out algorithms based on Overall 99th percentile.

Collection Point	Sensitivity (%)	Specificity (%)	NPV (%)	PPV (%)	AUC
Baseline	81.65%	91.99%	97.15%	60.00%	0.949
1 hour	93.75%	90.67%	99.04%	58.54%	0.964
2 hours	95.79%	89.53%	99.43%	52.91%	0.971
3 hours	94.44%	87.63%	99.13%	51.52%	0.952

Risk Stratification

The VITROS hsTnI assay shows excellent prognostic value as an aid in the assessment of cardiac-related mortality/MI and all-cause mortality over 30 days (d), 6 months (m) and 12 months.

The Cumulative Event Free Rate data support the use of VITROS hsTnI Test to stratify subjects at risk of cardiac related mortality and MI.

Follow up period in Subjects with VITROS hsTnI Test Values ≤ 11 ng/L	Cumulative Event Free Rate (%)
30 days	99.69
6 months	99.07
12 months	98.55

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[a] Varies by System
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VITROS® hsTnI Assay on the VITROS® Systems

All Ortho VITROS systems are designed to deliver the speed, precision, and accuracy required of continuous testing in today's laboratories. Designing an immunoassay system to deliver on these needs takes a level of understanding that only comes from firsthand experience. VITROS design is based upon input from diverse laboratories from around the world which provides consistent, quality results ideal for reference, core, and satellite labs. All VITROS® Systems include:

VITROS® MicroWell Technology Enhanced Chemiluminescence detection enables wide measuring ranges with exceptional sensitivity and precision. Minimizes unnecessary dilutions, repeats, and redraws.

VITROS® INTELLICHECK® Technology Verifies and documents diagnostic checks throughout sample processing. With full traceability and real-time exception documentation, INTELLICHECK prevents reporting of any negatively affected results.

VITROS® MicroSensor Technology Detects endogenous interferences and flags affected results without using any reagent or extra consumables. That means no impact on cost, system workflow, or turnaround with an analysis time of <1 second.

e-Connectivity® World class web-based software tools that minimize unplanned downtime with secure, real-time, remote predictive monitoring and full engineer support.

VITROS® SMART Metering SMART Metering is a combination of key elements designed to deliver accurate results. Elements include: Single-use tips designed to eliminate carryover, Save-the-Sample Clot Detection Management, bubble detection, deep-tube sample metering, intelligent error recovery and self-diagnostics to avoid reporting erroneous results.[1]

Ortho Care™ Award winning leading service and support recognized by **ServiceTrak with the #1 Ranking in 2016, 2017 and 2018.**

A full line of VITROS Quality Cardiac Assays

NT-proBNP, Myoglobin, hsCRP, Apolipoprotein A1, Apolipoprotein B, Cholesterol, CK, CK-MB, Direct HDL, Direct LDL, Homocysteine, Lipoprotein(a)*, Triglycerides

Not all products available in all regions or on all VITROS systems.

* MicroTip Partnership Assay (MPA). Reagents and validated applications available directly from Ortho Clinical Diagnostics. Product availability subject to third party's availability or their agent's capability to support the laboratories.

ORDERING INFORMATION

PRODUCT	CATALOG NO
VITROS® Immunodiagnostic Products hs Troponin I Reagent Pack	684 4436
VITROS® Immunodiagnostic Products hs Troponin I Calibrator Pack	684 4437
Liquid QC Cardiac Marker ("VS") controls Tri-Level	91474
VITROS® Immunodiagnostic Products hs Troponin I Low Control	690 0040

For more information contact your Ortho Clinical Diagnostics representative or visit our website at orthoclinicaldiagnostics.com.

[1] Kavsak PA,Zeidler J. Carryover: More than just a major hangover for the clinical laboratory. Clin Biochem. 2016 Jul;49(10-11):735-6.
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