In vitro Nano-Check™ AMI 2 IN 1 Cardiac Marker Test
Cardiac Troponin I and Myoglobin

One Step Test Strip for AMI Test

For in vitro Diagnostic Use

One–step immuno-chromatographic
assay for the detection of cTnI, and Myoglobin in human
whole blood, serum, and plasma

1. INTENDED USE

The Nano-Check™ AMI 2 IN 1 Test is a rapid immunoassay for the determination of Cardiac Troponin I (cTnI) and Myoglobin in human whole blood, serum and plasma specimens at cutoff concentrations of 0.5 ng/ml and 80 ng/ml respectively, as an aid in the diagnosis of Acute Myocardial Infarction (AMI). The Nano-Check™ AMI 2 IN 1 Test monitors the rise and fall of cTnI and Myoglobin when used in conjunction with Nano-Checker 710 reader. Test results should be interpreted by the physician along with other test results and patient clinical symptom findings.

2. SUMMARY AND EXPLANATION OF THE TEST

When a myocardial infarction (MI) occurs in the hypoperfused region of the myocardium, oxygen can no longer be supplied to the cells in the region. Cell death is inevitable if oxygen is not restored within 10-15 minutes and will result in the release of certain proteins from within cytoplasm into the blood stream. Some proteins are exclusive to and predominant in the cardiac muscle cells; they can function as cardiac makers and be detected in the blood specimens of AMI patients by specialized immunoassays.[1-3] Unfortunately none of cardiac markers discovered show early release, have 100% cardiac specificity, and a substantial life time in circulation. This situation leads to a panel approach for the utilization of markers in patients with AMI. The constituents of this cardiac panel should include a marker that rapidly increases after cardiac injury and is highly cardiac tissue specific. The combination of cTnI and Myoglobin are widely used in panel assays intended for the determination of AMI in chest pain patients.[4]

Troponin I

Troponin is a contractile regulatory protein complex found in skeletal and cardiac muscle. The troponin complex consists of three distinctive polypeptide components, troponin I (TnI), troponin T (TnT), and troponin C (TnC), and plays a fundamental role in the transmission of intracellular calcium signal actin- myosin interaction.[5] TnC of cardiac tissues is identical to that in skeletal tissues, but TnI and TnT of cardiac isoforms are distinctive to those of skeletal isoforms, which enables the development of cardiac specific antibodies.[6] Moreover, cTnI level becomes elevated in the blood as a result of myocardial injury or necrosis. Therefore, cTnI is used as an aid in the diagnosis of MI.[7-8] Studies on the release kinetics indicate that cTnI is not an early marker of myocardial necrosis. It appears in serum 3-6 hours after symptom onset, similar to the release of CK- MB. However, cTnI remains elevated for 4-9 days post-AMI.[9-10] In addition to its utility in diagnosis, elevated cTnI levels convey prognostic information and has been shown to identify patients having an increased risk of death.[11]

Myoglobin

Myoglobin, an oxygen binding heme protein present in muscle tissue including cardiac, skeletal and smooth muscle, has attracted considerable interest as an early marker of MI.[2,14] Following injury to any of these muscles, myoglobin appears in the blood more rapidly than any other marker.[4] Levels may be elevated as early as one hour following the onset of chest pain when CK-MB levels are still in the range of normal.[2,13,19] This rapid appearance is due to the location of myoglobin in the cell and its low molecular weight. Myoglobin typically rises 2-4 hours after the onset of infarction, peaks at 6-12 hours, and returns to normal within 24-36 hours. Normally the level of myoglobin in serum is 30-80 ng/ml. In patients with MI, the level could increase approximately 10 times above the upper limit of normal. Myoglobin exhibits high clinical sensitivity for AMI but poor specificity.[1, 3] Many studies suggest that myoglobin may be a good screening assay in Emergency Rooms for the early diagnosis of AMI. However, elevated myoglobin values should be cautiously interpreted if the patient has renal dysfunction or skeletal muscle injury. Because of these limitations, detection of myoglobin in a patient suspected of AMI may need to be supplemented by the presence of a more definitive cardiac maker. However, a negative result in a patient admitted within 2-9 hours after onset of chest pain may help in ruling out AMI.

3. PRINCIPLE

The Nano-Check™ AMI 2 IN 1 Test is an immunochromatography assay for the determination of two biochemical markers (cTnI and Myoglobin) simultaneously in human whole blood, serum and plasma specimen. The membrane strip contains two test lines and one control line, printed with specific antibodies or receptor against each target molecule, monoclonal mouse antibody against Myoglobin, streptavidin for biotinylated cTnI antibody, and rabbit anti-goat IgG antibody for control line. A dye pad is placed at the end of the membrane containing biotinylated cTnI antibody and gold colloidal particles coupled with cTnI and Myoglobin antibodies. When a sample is applied into the sample well, the cardiac makers present in the sample bind to the specific antibodies coupled with gold particles on the dried dye pad. cTnI in a sample binds to both cTnI specific dye coupled antibody and biotinylated antibody. These primary immune complexes move along the nitrocellulose membrane through the test lines and bind to their corresponding capture antibodies or receptor molecules immobilized on the test line. Unbound immune complexes pass through the test line and are captured by rabbit anti-goat IgG antibody in the control line.

If the concentration of any of these two markers in the sample is above the cutoff level, red bands appear at the corresponding test lines and the control line. If the concentration of the markers in the sample is lower than the cutoff level, only the colored control line can be seen in the test window. This colored control band must always appear at the control line position (Con) for a valid test result. A test result is not valid if the colored control line does not appear in the test window.

To measure the concentration of an analyte, the tested device should be read by the Nano-Checker 710 Reader. The reader analyzes the color intensity of the test line and converts it to the concentration of the analyte in the specimen by a predetermined equation.

4. REAGENT

The Nano-Check™ AMI 2 IN 1 Test contains all the reagents necessary for the detection of cTnI and Myoglobin in human whole blood, serum, and plasma. The device contains a membrane strip coated with monoclonal mouse anti-Myoglobin and streptavidin on the test line, and dye pad infused with biotinylated monoclonal mouse anti-cTnI antibody and gold colloidal particles coupled with anti-cTnI and anti-Myoglobin antibodies. Stabilizer containing 0.05% sodium azide and BSA protein are deposited on the dye pad in dried form.

5. MATERIALS

Provided

- Nano-Check™ 2 IN 1 Test device containing membrane strip in a sealed pouch with desiccant
- Instructions for Use
- Disposable pipette (if applicable)

Required but not provided

- Whole blood, Serum or Plasma Collection Container
- Positive and negative quality control materials
- Timer
- Nano-Checker 710 or equivalent Nano-Checker Reader (For quantitative analysis)

6. STORAGE AND STABILITY

The test kit should be stored at 2°C - 30°C in the original sealed pouch for the duration of shelf life.

7. PRECAUTIONS

- For *in-vitro* diagnostic and professional use only.
- Handle all specimens as potentially infectious. Proper handling and disposal methods should be established.
- To avoid cross contamination, use a fresh transfer pipette for each clinical sample tested.
- Do not use test kit if the pouch is damaged or improperly sealed.
- Do not use test kit beyond expiration date.

8. SPECIMEN COLLECTION AND PREPARATION

- This test can be used for whole blood, plasma, and serum samples. If serum samples are to be used, collect the blood in a tube without anticoagulant and allow clotting for at least 25 minutes before centrifugation. Whole blood or plasma samples using heparin or EDTA as the anticoagulant can be used for testing with this product. Other blood anticoagulants have not been evaluated. Each laboratory should determine the acceptability of its own blood collection tubes and serum separation products. Variation in these products may exist between manufacturers and, at times, from lot-to-lot.
- The samples should be collected under standard laboratory conditions.
- Optimal results were obtained when patient samples were tested immediately after collection. Whole blood samples should be used within 4 hours after collection. Plasma or serum samples may be refrigerated for 24 hours at 2-8oC. If testing cannot be performed within 24 hours, or for shipment of samples, freeze at -20oC or colder.[15,16]
- Sodium azide can be added as a preservative up to 0.1% without affecting the test results.
- Refrigerated or frozen serum or plasma specimen should reach room temperature and be homogeneous prior to testing

9. TEST PROCEDURE AND PROTOCOL

1. Collect specimen according to instructions in “Specimen Collection”.
2. Test device and sample should be brought to room temperature (20°C-30°C) prior to testing.
3. Remove the test device from the sealed pouch immediately before use. Label the device with patient or control identification.
4. Using sample transfer pipette, deliver dropper contents (80 µl) of sample into the sample well.
5. Read the results at 15 minutes. For qualitative interpretation of results, please see section below, “Interpretation of Results”. Do not interpret results after 15 minutes. For the quantitative result, the tested device should be analyzed by the Nano-Checker 710 Reader following by the instruction manual.

10. INTERPRETATION OF RESULTS

Qualitative Analysis

The results of the Nano-Check™ AMI 2 IN 1 Tests are determined visually and interpreted according to the predetermined cutoff values of 0.5 ng/ml for cTnI and 80 ng/ml for Myoglobin. These cutoff levels were determined by comparison to the quantitative assay system of Beckman Coulter, Access AccuTnI™ and Access Myoglobin Assay. These cutoff levels may be different if compared to a quantitative assay system other than Beckman Coulter. We recommend that users should establish a correlation if a quantitative assay system other than Beckman Coulter Access is used.

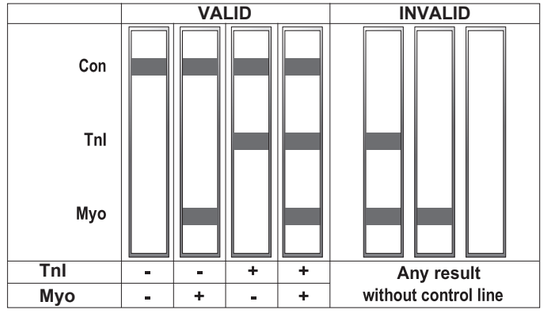
Negative: A single red colored band at the control area (Con) without any other bands at test lines (TnI and Myo) is a valid negative result and indicates the concentrations of cTnI, and Myoglobin in the sample are below the cutoff levels.

Positive: Appearance of red colored band at the control area (Con) and appearance of red colored bands in any of test lines indicate that concentrations of cTnI and/or Myoglobin in the sample, which are shown as the colored band, are at or above the cutoff levels. The intensity of red color in the test line may be weaker or stronger than that in the control line.

Invalid: If no colored band appears in the control area in 15 minutes (Con), the test result is invalid. The test result is inconclusive, and the assay should be repeated.

Note:

- Very faint bands in the test lines indicate that the proteins in the specimen are near the cutoff level of the test. These samples should be re-tested 1-2 hours later or test results should be confirmed by quantitative assay.
- Do not interpret the results after 15 min.



Quantitative Analysis

The signal intensity of the test line can be analyzed by Nano-Checker 710 Reader and reported as the concentration of analytes in the tested specimen. When the test result is valid, and the measured value is in the range of the reference value, the result can be interpreted as a negative for AMI. When the value is above the reference range but below cutoff value, the specimen should be retested after an hour. When the reading value is above the cutoff value, the result can be interpreted as a positive.

11. LIMITATIONS

- The test is for professional and *in-vitro* diagnostic use only.
- A positive test result may only be used as an indicator of myocardial damage and requires further confirmation. Serial sampling of patients suspected of AMI at multiple time points is also recommended due to the delay between onset of symptoms and the release of cardiac marker proteins into the blood stream.
- As with all diagnostic tests, a definitive clinical diagnosis should not be made based on the results of a single test. The test result should be used in conjunction with other clinical information such as clinical signs and symptoms and other test results to diagnose AMI. Confirmation of test results should only be made by a physician after all clinical and laboratory findings have been evaluated.
- Samples containing unusually high titers of certain antibodies such as human anti-mouse or human anti-rabbit antibodies have been known to affect the performance of the tests.[17] However, studies using the Nano-check™ AMI 2 IN 1 Test have not been performed.
- Patients taking more than 30 µg/day of biotin may have falsely negative results and should not use this test, unless it is confirmed that the patient is not taking more than 30 µg/day of biotin.

12. QUALITY CONTROL

The presence of a reddish colored band in the Control area of the window acts as an internal control to ensure that an adequate volume of sample has been added. In the absence of this Control band, the test is invalid and must be repeated. Good laboratory practice recommends the use of control materials to ensure proper kit performance. Quality control specimens are available from commercial sources and should be assayed using the same procedures followed when running patient samples. Controls should be run before using each new lot or shipment of Nano-Check™ AMI 2 IN 1 Test at regular intervals afterwards and any time the validity of the test results are questioned. For the calibration of Nano-Checker 710 Reader, two different levels of calibration cards are supplied with the reader. The reader should be calibrated periodically with the provided calibration card. If the reading value of calibration card is out of the described range, it should be recalibrated.

13. EXPECTED VALUES

The cutoff values of the Nano-Check™ AMI 2 IN 1 Test was determined by comparison to the Beckman Coulter quantitative assay, Access AccuTnI and Access Myoglobin Assay. The cutoff level of each cardiac maker is 0.5 ng/ml for cTnI and 80 ng/ml for Myoglobin. The specimens containing cTnI and Myoglobin at the concentration of equal or above established cutoff levels will give positive results using the Nano- Check™ AMI 2 IN 1 Test. The cutoff levels may be different if a quantitative assay system other than Beckman Coulter Access is used.

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14. PERFORMANCE CHARACTERISTICS

1. Assay Cutoff

Patient plasma containing cTnI, or Myoglobin was diluted in normal human serum to the concentration at or near the cutoff levels. Analyte concentrations in the diluted samples were confirmed by Quantitative Assay, Access AccuTnI and Access Myoglobin Assay of Beckman Coulter. Fifteen devices were tested for each sample at concentrations of 0.31, 0.57 and 1.07 ng/ml for cTnI; 56.5, 80.4 and 141.3 ng/ml for Myoglobin. The results are shown in following table. The cutoff concentrations were assigned as 0.5 ng/ml for cTnI and 80 ng/ml for Myoglobin.

Analyte	Conc. determined by Access Assay (ng/ml)	Test Result		Cutoff level
		Negative(n)	Positive(n)	
cTnI	0.31	7	8	0.5 ng/ml
	0.57	0	15	
	1.07	0	15	
Myoglobin	56.5	14	1	80 ng/ml
	80.4	0	15	
	141.3	0	15	

2. Recovery Studies

Recovery studies were performed with patient serum diluted in normal human serum. Patient sera containing high levels of either cTnI or Myoglobin were sequentially diluted with normal human serum to yield different concentrations. Each diluted sample was tested using Nano-Check™ AMI 2 IN 1 Test in 3 replicates. The data shown in the table below demonstrates recovery rate between observed results and expected results at each concentration of cTnI and Myoglobin.

Analyte	Expected Concentration (ng/ml)	Determined Average Concentration	% Agreement of Expect Values	Total Recovery (%)
cTnI	22.4	24.17	107.8	105.7
	11.2	10.17	90.8	
	5.6	5.00	89.3	
	2.8	3.60	128.6	
	1.4	1.87	133.3	
	0.7	0.80	114.3	
	0.35	0.37	105.6	
	0.18	0.13	76.2	
Myoglobin	716	643.0	89.8	101.5
	358	343.7	96.0	
	179	174.4	97.4	
	89.5	90.8	101.4	
	44.8	61.4	137.2	
	22.4	19.4	86.9	

3. Limit of Detection for Quantitative assay

The analytical sensitivity for each analyte was determined according to CLSI guidance, EP17-A.

Analyte	LoB (ng/ml)	LoD (ng/ml)	LoQ (ng/ml)
cTnI	0.08	0.1	0.1
Myoglobin	10	20	20

4. Reportable range for Quantitative assay

Reportable range of each analyte, cTnI or Myoglobin was determined by Linearity study. Samples prepared by serial dilution was tested in triplicate, and data was analyzed by regression analysis.

Analyte	Reportable range (ng/ml)
cTnI	0.1 - 30
Myoglobin	20-1000

5. Analytical Specificity

Potentially interfering substances were spiked into normal serum and patient serum containing either cTn or Myoglobin about 1.5 times of the cutoff concentration. The substances at the following level do not interfere with the performance of the Nano-Check™ AMI 2 IN 1 Test.

	Substance	Concentration
Endogenous substances	Bilirubin	50 mg/dl
	Hemoglobin	4,000 mg/dl
	Human serum albumin	10 g /dl
	Triglycerides	1,250 mg/dl
	Biotin, Vitamin B7	300 ng/ml

The device was tested for interference by potentially cross-reacting endogenous proteins. Potentially cross-reacting proteins, added into normal human serum up to the following concentrations, do not interfere with test result.

	Substance	Concentration
Cross-reacting endogenous proteins	Cardiac myosin light chain	1,000 ng/ml
	Cardiac Troponin T	1,000 ng/ml
	Cardiac Troponin C	1,000 ng/ml
	Skeletal Troponin I	1,000 ng/ml

6. Reproducibility / Precision Test for Qualitative Assay

Two Clinical sites and one in-house operator were provided with blindly labeled serum samples. Patient serum samples, containing high levels of cTnI and Myoglobin, were diluted in normal human serum to make positive samples of different concentrations. A normal human serum sample was also provided as negative control of the test. Five aliquots from each sample were tested at each testing site. The results shown in the table below demonstrate 100% agreement for between run as well as for within run.

Analyte	Testing Site	Concentration of each analyte (ng/ml) in each sample						% agreement within run
		Sample 1		Sample 2		Sample 3		
		cTnI 0 Myo 0		cTnI 1.03 Myo 119.9		cTnI 2.05 Myo 166.3		
		-	+	-	+	-	+	
cTnI	Site I	5	0	0	5	0	5	100%
	Site 2	5	0	0	5	0	5	100%
	Site 3	5	0	0	5	0	5	100%
	% agreement between run	100%		100%		100%		
Myo	Site I	5	0	0	5	0	5	100%
	Site 2	5	0	0	5	0	5	100%
	Site 3	5	0	0	5	0	5	100%
	% agreement between run	100%		100%		100%		

7. Precision Test for Quantitative Assay

Precision of the Nano-Check™ AMI 2 in 1 quantitative assay system with Nano-Checker 710 Reader was determined in a study using plasma based in-house control materials. Specimens at each level were tested in duplicate for 10 days. The within run and total standard deviation were calculated by the analysis of variance method.

Analyte	Samples	Mean (ng/ml)	SD	Total CV (%)
CTnI	Level 1	0.66	0.15	22.85
	Level 2	2.54	0.32	12.76
	Level 3	18.21	2.31	12.67
Myoglobin	Level 1	83.5	13.64	16.33
	Level 2	252.77	35.56	14.07
	Level 3	843.54	153.83	18.24

8. Correlation Assay between Plasma and Serum Sample

Patient samples were prepared for matched samples of serum and heparinized plasma. Samples were grouped as four levels of concentration ranges. Ten samples in each group were tested using Nano-Check™ AMI 2 in 1 Test, and the results demonstrated in the following table.

Analyte	Conc. range (ng/ml)	Serum Positive	Serum Negative	Plasma Positive	Plasma Negative
TnI	1.2-1.8	10	0	10	0
	0.5-1.0	10	0	10	0
	0.3-0.5	9	1	7	3
Myo	123-248	10	0	10	0
	85-118	10	0	10	0
	64-80	8	2	9	1

9. Correlation Assay between Whole blood and Plasma Sample.

To test correlation of assay results between plasma and whole blood samples in Nano-Check™ AMI 2 IN 1 qualitative test, normal whole blood samples were spiked with clinical specimens containing each analyte, cTnI and Myoglobin to make three different desired levels between negative and 4 times then cut off values of each analyte. Five samples in each group were tested using Nano-Check™ AMI 2 IN 1 Test, prior to removal of cells and after removal of cells by centrifugation. The test results are shown in the following table.

Analyte	Conc. range (ng/ml)	Plasma Positive	Plasma Negative	Whole Blood Positive	Whole Blood Negative
TnI	1.3-2.4	5	0	5	0
	0.5-1.0	5	0	5	0
	0.1-0.47	3	2	2	3
Myo	151-211	5	0	5	0
	83.6-138	5	0	5	0
	63.0-81.5	1	4	1	4

To perform matrix comparison study between plasma and whole blood in Nano-Check™ AMI 2 IN 1 quantitative test, ten different levels of analyte concentrations in reportable range of each analyte were prepared by spiking analyte proteins into whole blood collected from healthy volunteers. Corresponding plasma specimens were prepared from each level of whole blood specimens by centrifugation. Each sample was tested on Nano-Check™ AMI 2 in 1 device in triplicates. The concentrations in matched sample matrix were analyzed using correlation and regression methods. The values of correlation coefficients (0.83-0.95) suggest a good correlation between plasma and whole blood specimens or between plasma specimens treated with different anticoagulants.

Lithium Heparin Plasma vs. Whole Blood

Analyte	n	Observation Ranges (ng/ml)	Intercept (ng/ml)	Slope	Correlation Coefficient
cTn I	30	0.1 - 30	0.0321	0.9575	0.951
Myoglobin	30	20 - 1000	25.545	0.9117	0.827

EDTA Plasma vs. Whole Blood

Analyte	n	Observation Ranges (ng/ml)	Intercept (ng/ml)	Slope	Correlation Coefficient
cTn I	30	0.1 - 30	-0.0436	0.9413	0.936
Myoglobin	30	20 - 1000	21.545	0.8942	0.863

Lithium Heparin Plasma vs. EDTA Plasma

Analyte	n	Observation Ranges (ng/ml)	Intercept (ng/ml)	Slope	Correlation Coefficient
cTn I	30	0.1 - 30	0.0267	0.9175	0.948
Myoglobin	30	20 - 1000	-16.545	0.9342	0.893

10. Method Comparison Study

Qualitative test Comparison

Plasma samples were collected from 206 emergency room patients who were admitted because examination results suggested a cardiac event. Additionally, 50 samples were collected from outpatients who were not suspected of having a cardiac event. The 256 clinical samples were tested using the Nano-Check™ AMI 2 IN 1 Test and the Beckman Coulter Access test system. Results are summarized below.

AMI 2 IN 1 TnI Test Results Compared to Quantitative Access Results (ng/ml)

		Access Accu TnI			
		<0.01-0.29	0.3-0.47	0.52-0.6	0.61->100
Nano-Check™ 2 in1 cTnI	Positive	1	7	6	91
	Negative	143	6	2	0

AMI 2 IN 1 Myoglobin Test Results Compared to Quantitative Access Results (ng/ml)

		Access Myoglobin			
		10.2-60.9	61-79.1	80.4-90.3	91.9->4000
Nano-Check™ 2 in1 Myo	Positive	0	9	11	120
	Negative	98	16	2	0

Quantitative test Comparison

A comparison of cTnI and Myoglobin values of heparin plasma samples with Nano-Check™ AMI 2 in1 assay system using Nano-Checker 710 Reader and Beckman Coulter Access system were carried out. The results of cTnI and Myoglobin values obtained by two different methods were analyzed to give the following statistical data.

Analyte	n	Observation Ranges on Access (ng/ml)	Intercept	Slope	Correlation Coefficient
cTn I	67	0.06-44.80	0.5348	0.9175	0.948
Myoglobin	55	1.0-1587	85.545	0.7242	0.813

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