[tech] guide

Cardiovascular Testing Products

	Beckman Coulter Inc Brea, Calif (800) 526-3821; www.beckmancoulter.com	Beckman Coulter Inc Brea, Calif (800) 526-3821; www.beckmancoulter.com	Diazyme Laboratories Poway, Calif (858) 455-4768; www.diazyme.com
1) What is the name of your company's cardiovascular testing reagent, kit, or system?	AccuTnI+3	CK-MB	Lipoprotein(a) Lp(a) assay
2) What year did the product first appear on the market?	2013	2003	2009
3) Is the product FDA cleared or approved?	Yes	Yes	FDA cleared
4) What is the product's intended use?	To aid in the diagnosis of myocardial infarction	For the quantitative determination of CK-MB levels in human serum and plasma	Clinical diagnostics
5) What condition or biomarker does it detect?	Troponin-I	Creatine Kinase-MB	Lipoprotein(a) (Lp(a))
6) Where is the product used (check all that apply)?	❑ At a community screening event ■ In a hospital or inpatient setting ■ In a physician's office or outpatient setting ❑ In a patient's home or other self-testing ❑ Elsewhere	❑ At a community screening event ■ In a hospital or inpatient setting ■ In a physician's office or outpatient setting ❑ In a patient's home or other self-testing ❑ Elsewhere	❑ At a community screening event ■ In a hospital or inpatient setting ❑ In a physician's office or outpatient setting ❑ In a patient's home or other self-testing ❑ Elsewhere
7) If you answered "elsewhere," explain briefly.			
8) What type of specimen/sample is used?	Lithium heparin plasma or serum	EDTA, heparin plasma, or serum	Serum or plasma (EDTA)
9) Is the product a manual or automated system?	Automated	Automated	Designed to run on open-channel automated clinical chemistry analyzers
10) What method of detection does the product use?	Chemiluminescence	Chemiluminescence	Immunoturbidimetric
11) Does the product interface with laboratory information systems or middleware?	Yes	Yes	No
12) What is the time to first result under ideal conditions?	About 13 minutes	About 15 minutes	10 minutes
13) What is the typical training time?	None. Reagent is ready to use.	None. Reagent is ready to use.	Approximately 1 hour
14) What capabilities, features, or accessories distinguish this product from others on the market?	First troponin assay cleared by FDA since its 2010 guidance to all troponin manufacturers.	15-minute time to first result; 56-day open-pack and calibration curve stability.	Outstanding accuracy and precision; low cost per test; extensive range of instrument parameters; packaging options for labs of all sizes; most feature instrument-specific packaging options.

Diazyme Laboratories Poway, Calif (858) 455-4768; www.diazyme.com	Stanbio Laboratory (An EKF Diagnostics Company) Boerne, Tex (830) 249-0772; www.stanbio.com	Randox Laboratories Kearneysville, WVa (866) 472-6369; www.randox.com	Randox Laboratories Kearneysville, WVa (866) 472-6369; www.randox.com
Myoglobin assay	CK-MB Liqui-UV test	H-FABP	TxB Cardio
2013	1994	2011	2014
FDA cleared	Yes	No	No
Clinical diagnostics	Used as a follow-up test to an elevated CK test result, to determine whether the increase is due to heart damage or skeletal muscle damage.	Detection of heart-type fatty acid binding protein (H-FABP), a biomarker with significant diagnostic and prognostic value in suspected cases of acute myocardial infarction (AMI).	Measurement of the therapeutic effectiveness of the blood-thinning properties of aspirin, including detection of patients who may develop aspirin resistance as a result of regular low-dose use.
Myoglobin	Creatine Kinase-MB	H-FABP as a biomarker for acute coronary syndrome (ACS)	Measures a direct urinary metabolite of thromboxane ($11dhTxB_2$)
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Serum or plasma	Serum	Blood sample (serum/plasma)	Blood sample (serum/plasma)
Designed to run on open-channel automated clinical chemistry analyzers	Manual or automated	Clinical chemistry reagent	Clinical chemistry reagent
Immunoturbidimetric	Immunoinhibition	Latex-enhanced immunoturbidimetric immunoasssay	Immunoturbidimetric immunoassay
No	No	No	No
10 minutes	9 minutes	Dependent on the biochemistry instrument, but typically less than 15 minutes	Dependent on the biochemistry instrument
Approximately 1 hour	n/a	n/a	n/a
High accuracy and precision; low cost per test; extensive range of instrument parameters; packaging options for labs of all sizes.	Liquid-stable reagent	When compared to a range of biomarkers for ACS, H-FABP has shown sensitivity to AMI of 99.1% and negative predictive value of 99.7%. In studies, the H-FABP test would have permitted AMI to be excluded in 48.8% of patients, thereby speeding emergency treatment if needed.	Facilitates personalized treatment with alternative therapies for the 25% to 30% of patients who have developed aspirin resistance, and are therefore thought to have a 2x greater risk of myocardial infarction and a 3.5x greater risk of dying from a cardiovascular incident than those who respond fully to their aspirin therapy.

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	Roche Diagnostics Indianapolis (317) 521-2000; www.roche-diagnostics.us	Roche Diagnostics Indianapolis (317) 521-2000; www.roche-diagnostics.us	Siemens Healthcare Diagnostics Tarrytown, NY (800) 242-3233; www.healthcare.siemens.com
1) What is the name of your company's cardiovascular testing reagent, kit, or system?	Troponin T	NT-proBNP	Stratus CS acute care diagnostic system
2) What year did the product first appear on the market?	1989 (2005 for current TnT gen 4)	2003	1998
3) Is the product FDA cleared or approved?	Yes	Yes	Yes
4) What is the product's intended use?	Can be used as an aid in the differential diagnosis of acute coronary syndrome to identify necrosis (eg, acute myocardial infarction). Further indicated for risk stratification of patients presenting with acute coronary syndrome and for cardiac risk in patients with chronic renal failure. May also be useful for selection of more intensive therapy and intervention in patients with elevated levels of cardiac troponin T.	Used as an aid in the diagnosis of individuals suspected of having congestive heart failure (CHF). Further indicated for risk stratification of patients with acute coronary syndrome and CHF. May also serve as an aid in the assessment of increased risk of cardiovascular events and mortality in patients at risk for heart failure who have stable coronary artery disease.	Provides quantitative cardiac assays for evaluation of patients presenting with suspected myocardial ischemia.
5) What condition or biomarker does it detect?	Acute coronary syndromes (acute myocardial infarction)	Acute and congestive heart failure	ßhCG, CK-MB, D-dimer, hsCRP, myoglobin, NT-proBNP, Troponin-I
6) Where is the product used (check all that apply)?	❑ At a community screening event ■ In a hospital or inpatient setting ■ In a physician's office or outpatient setting ❑ In a patient's home or other self-testing ❑ Elsewhere	❑ At a community screening event ■ In a hospital or inpatient setting ■ In a physician's office or outpatient setting ❑ In a patient's home or other self-testing ❑ Elsewhere	❑ At a community screening event ■ In a hospital or inpatient setting ❑ In a physician's office or outpatient setting ❑ In a patient's home or other self-testing ❑ Elsewhere
7) If you answered "elsewhere," explain briefly.			
8) What type of specimen/sample is used?	Serum, K2-EDTA, K3-EDTA, Li-heparin, and Na-heparin plasma	Serum, K2-EDTA, K3-EDTA, Li-heparin, and Na-heparin plasma	Whole blood
9) Is the product a manual or automated system?	Automated (Elecsys 2010, e411, e601, e602)	Automated (Elecsys 2010, e411, e601, e602)	Automated
10) What method of detection does the product use?	Electrochemiluminescence immunoassay	Electrochemiluminescence immunoassay	Dendrimer-enhanced radial partition immunoassay
11) Does the product interface with laboratory information systems or middleware?	All instruments capable of running TnT can be connected to LIS and/or middleware.	All instruments capable of running NT-proBNP can be connected to LIS and/or middleware.	Yes
12) What is the time to first result under ideal conditions?	9 minutes	9 minutes	14 minutes
13) What is the typical training time?	It is included in the overall training for the instrument (a 4-day class).	It is included in the overall training for the instrument (a 4-day class).	3 to 4 hours
14) What capabilities, features, or accessories distinguish this product from others on the market?	The fastest stat assay currently available (9 minutes) and the unique FDA-approved claim of risk stratification for patients presenting with acute coronary syndrome and for cardiac risk in patients with chronic renal failure.	The fastest stat assay currently available (9 minutes) and the unique claim of aid in the assessment of increased risk of cardiovascular events and mortality in patients at risk for heart failure who have stable coronary artery disease.	Full cardiac menu; results in as little as 14 minutes; used in the acute care setting to decrease turnaround time, patient length of stay, and total patient costs. The system's efficiency and ease of use make it ideal for both point-of-care testing and lab applications.