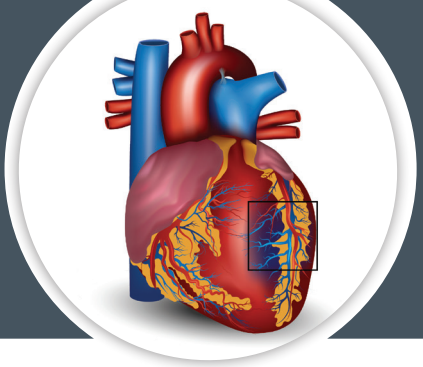
PULS Cardiac Test™

Sample Type
Serum and EDTA Whole Blood

Tube Type
Tiger Top SST and Lavender Top



An elevated PULS Cardiac Test score may identify:

- Coronary heart disease development
- Presence of unstable/vulnerable arterial plaque
- Increased near-term risk of a heart attack

Description

Atherosclerotic disease progression is characterized by chronic endothelial damage and an accumulation of fatty plaque within the arterial wall. Unstable plaque can rupture and lead to arterial blockage causing a heart attack. The first steps in prevention are the identification of individuals at near-term risk of a heart attack, and allowing for more aggressive therapy to potentially avoid a future event.

The PULS (Protein Unstable Lesion Signature) Cardiac Test measures key clinical risk factors including age, sex, diabetic status, family history of heart attack, and distinct protein biomarkers. These markers are associated with the biological pathways underlying cardiac lesion formation, progression and rupture. This refined methodology of cardiac risk assessment provides an improved calculation of a patient's near-term (5 year) risk for a heart attack.

Clinical Use

The PULS Cardiac Test may be performed on individuals at intermediate risk with one or more risk factors for coronary heart disease.

Clinical Significance

- Cardiovascular risk prediction models such as the Framingham Risk Score calculate risk of a cardiovascular event within the next 10 years. When used, these calculations rely heavily on established clinical risk factors[1] which may not fully estimate the prevalence of cardiovascular disease in the general population.[2,3]
- The PULS Cardiac Test measures clinically significant proteins in the blood associated with active unstable lesion formation and when combined with established clinical risk factors, predicts whether a cardiac lesion could rupture within a 5 year period.[4]
- In the Multi-Ethnic Study of Atherosclerosis (MESA), the PULS Cardiac Test outperformed a common risk calculator, yielding a net reclassification index of 42.7% in individuals defined as intermediate risk by the Framingham Risk Score.[4] Reclassification of those initially defined as intermediate risk to high risk may result in more appropriate therapeutic intervention.
- In a large clinical trial, the PULS Cardiac Test identified 61% of patients who went on to have a cardiac event who otherwise would have been missed using established risk factors alone.[5]

Testing Frequency

The frequency of ordering The PULS Test is determined by an individual's medical history, but may be monitored more frequently in those at moderate to high risk for cardiovascular disease.

Sample Type

The PULS Cardiac Test should be performed on a serum and EDTA whole blood sample. Patients do not need to fast for the test.

Commercial Insurance or Medicare Coverage

Coverage guidelines, also known as NCD (National Coverage Determination) or LCD (Local Coverage Determination) have been established or posted by CMS (Medicare & Medicaid). Guidelines should be reviewed for coverage and limitation. Limited information has been provided by the majority of the larger carriers (examples include: Aetna, United Healthcare, Cigna, Blues).

Understanding Medical Necessity

The following ICD-10 codes for The PULS Cardiac Test are listed as a convenience for the ordering practitioner. The diagnosis code that best describes the reason for performing the test should be used.

Diagnosis	Diagnosis Code
Type 2 Diabetes Mellitus with Hyperglycemia	E11.65
Type 2 Diabetes Mellitus without Complications	E11.9
Other Specified Diabetes Mellitus without Complications	E13.9
Pure Hypercholesterolemia, Unspecified	E78.00
Familial Hypercholesterolemia	E78.01
Mixed Hyperlipidemia	E78.2
Other Hyperlipidemia	E78.4
Hyperlipidemia, Unspecified	E78.5
Hyperuricemia without Signs of Inflammatory Arthritis and Tophaceous Disease	E79.0
Essential (primary) Hypertension	I10
Atherosclerotic Heart Disease of Native Coronary Artery without Angina Pectoris	I25.10

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RELATIVE RISK

PULS Cardiac Test™ (%)

<3.50 Normal	3.5-7.49 Borderline	≥7.50 Elevated

Treatment Considerations

These treatment considerations are for educational purposes only. Specific treatment plans should be provided and reviewed by the treating practitioner.

✓ **Assess LDL-C levels**

- If elevated, consider LDL-lowering therapies.

✓ **Assess lifestyle habits**

- Consider diet/exercise/weight reduction efforts if appropriate.

✓ **Assess blood pressure**

- If not at goal, consider initiating, or titrating, anti-hypertensive therapy.

✓ **Assess smoking habits**

- Smoking cessation is essential as individuals who smoke are at increased risk of heart disease and blood clots.

✓ **Assess risk for pre-diabetes/diabetes**

- If abnormal oral glucose tolerance test or insulin levels, consider insulin sensitizing therapy.

✓ **Assess the presence of coronary artery disease (CAD) with imaging techniques such as carotid intima media thickness testing (CIMT) or coronary artery calcium (CAC) scoring**

- If clinically appropriate, consider dual platelet inhibition.

PULS Individual Biomarkers	
MCP-3	Guides immune cell direction & activity
sFas	Prevents cell death
Fas Ligand	Initiates cell death & recycling
Eotaxin	Activates immune cells at areas of injury
CTACK	Helps clean-up damaged tissue
IL-16	Recruits & activates immune cells
HGF	Stimulates tissue repair

Lipid Pathway	
HDL	Removes bad cholesterol

RELATIVE RISK

mg/dl

Women	Men
≥50 Normal	≥40 Normal
<50 Elevated	<40 Elevated

Insulin/Glucose Pathway	
HbA1c	Provides average blood sugar

RELATIVE RISK

%

4.0 - 5.6 Normal	5.7 - 6.4 Borderline	>6.4 Elevated

References

1. Wilson PW et al. Prediction of coronary heart disease using risk factor categories. Circulation. 1998; 97: 1837-1847.
2. Greenland P et al. Major risk factors as antecedents of fatal and nonfatal coronary heart disease events. JAMA. 2003; 290: 891-897.
3. Khot UN et al. Prevalence of conventional risk factors in patients with coronary heart disease. JAMA. 2003; 290: 898-904.
4. Cross DS et al. Coronary risk assessment among intermediate risk patients using a clinical and biomarker based algorithm developed and validated in two population cohorts. Curr Med Res Opin. 2012; 28: 1819-1830.
5. Simonini A and Harrington DS. Early detection of unstable cardiac lesions in asymptomatic individuals at risk of acute coronary syndrome. Cardiology. 2015; 131: 148.

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