

A black and white photograph of a stethoscope lying on a reflective surface. The stethoscope is the central focus, with its chest piece and earpieces clearly visible. The background is a soft, out-of-focus white. The text "Troponin T Gen 5" is overlaid in blue on the lower part of the image.

# Troponin T Gen 5

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# Disclosures

*Arleen Francis* is an employee of Roche Diagnostics and a member of the Medical & Scientific Affairs Department.

The information provided is intended for educational use only and is presented to the participant as scientific, evidenced-based data in compliance with FDA guidelines.

## Conflict declared and resolved

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# Summary of Troponin T Gen 4 and Gen 5



Feature	TnT Gen 4	TnT Gen 5
<b>Claim(s)</b>	Aid in Diagnosis; Risk Stratification of: ACS; Chronic Renal Failure Selection of More Intensive Therapy or Intervention	Aid in Diagnosis
<b>Sample type</b>	Serum; K2/K3-EDTA; Citrate; Li-Hep	Li-Hep only
<b>Measuring Range</b>	0.01 – 25 ng/mL (10-25,000 ng/L)	6-10,000 ng/L
<b>Optimal Precision (10% CV)</b>	0.03 ng/mL	11 ng/L ( <b>cobas e 411</b> ) 5 ng/L ( <b>cobas e 601</b> ) 6 ng/L ( <b>cobas e 801</b> )
<b>99<sup>th</sup> Percentile URL</b>	0.01 ng/mL	19 ng/L (both sexes) 14 ng/L (females) 22 ng/L (males)

\* Values below 6 ng/L and above 10,000 ng/L are reported as < 6 ng/L and > 10,000 ng/L.



# Comparison Chart

*Old vs New Test*

## 4<sup>th</sup> vs 5<sup>th</sup> Gen Troponin T Comparison Guideline

4 <sup>th</sup> Gen Trop T	5 <sup>th</sup> Gen Trop T
0.01ng/ml	30ng/L
0.03ng/ml	53ng/L
0.1ng/ml	100ng/L
1ng/ml	1000ng/L





# Higher Sensitivity and NPV

*Troponin T Gen 5 for early diagnosis of AMI*

APACE trial (all patients) <sup>1</sup>	Sensitivity (95% CI)	Specificity (95% CII)	Negative predictive value (NPV)	Positive Predictive value (PPV)
Roche cTnT Gen 5 99 <sup>th</sup> percentile 14ng/L	<b>95</b> (90-98)	80 (77-82)	<b>99</b> (97-100)	50 (43-56)
Roche cTnT gen 4 <sup>th</sup> 10% CV 0.03ng/ml	72 (60-80)	97 (96-98)	94 (92-96)	85 (76-91)

- The **high NPV (99%)** confirmed that cTnT Gen 5 is a reliable marker to “**rule out**” AMI.

Reichlin T et al. *NEJM* 2009; 36(9): 858-67



# 4<sup>th</sup> Universal Definition of MI

*Differentiates Myocardial Injury and Myocardial Infarction*

## Chronic Myocardial Injury

- Elevated Troponin  $>99^{\text{th}}\%$  ( $>14\text{ng/L}$  Females and  $>22\text{ng/L}$  Males)
- Non significant change in troponin values between serial draws

## Acute Myocardial Injury

- Elevated Troponin  $>99^{\text{th}}\%$
- Significant Rise and/or fall of troponin (Baseline 0hr and 2hr)

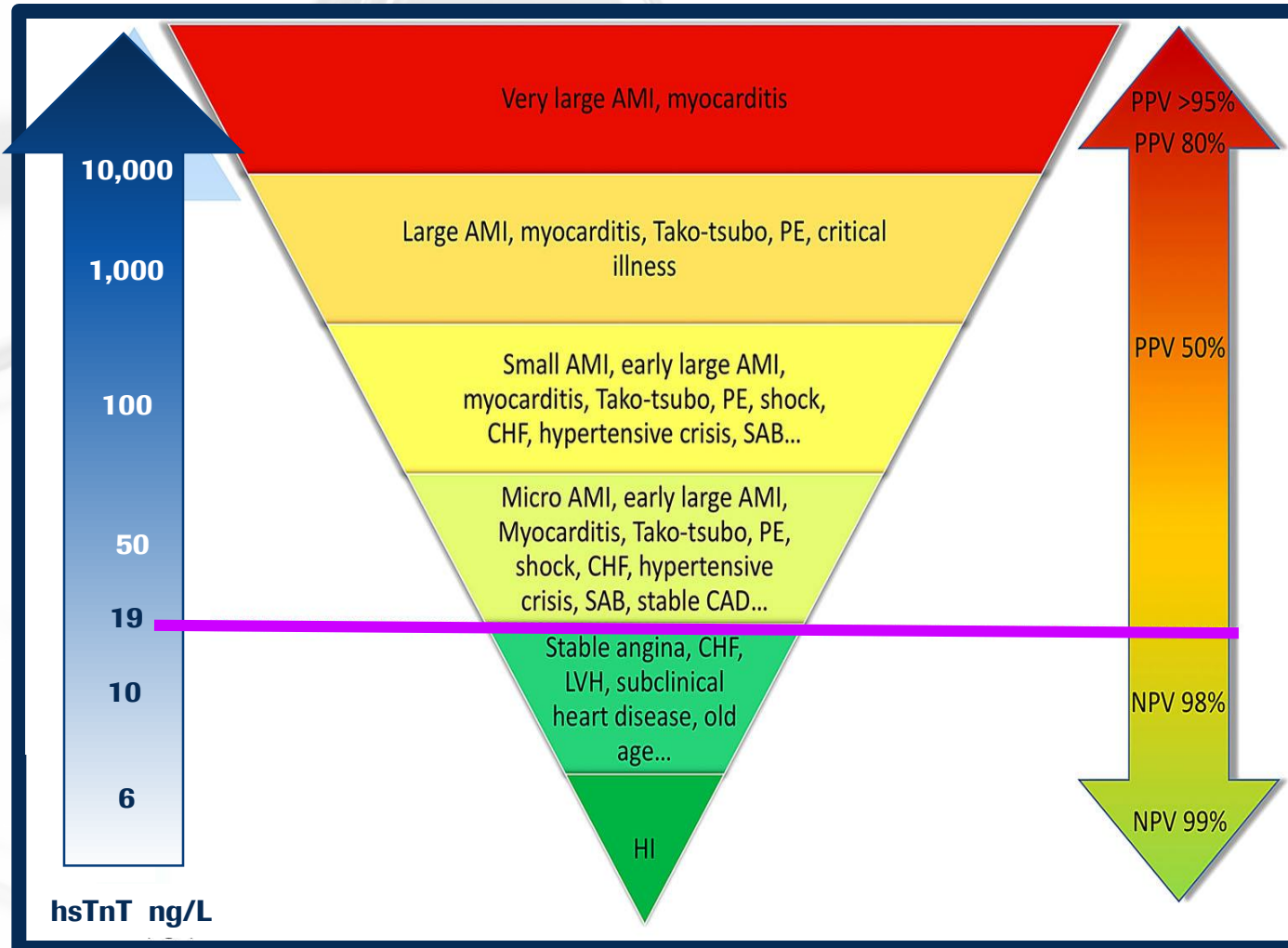
## Myocardial Infarction

- Acute Myocardial Injury with **evidence of ischemia**
- Troponin  $>99^{\text{th}}\%$
- Significant Rise and/or fall Troponin
- Clinical evidence ischemia (symptoms, EKG changes, imaging evidence)

Clinical Biochemistry (2015) 48 (4-5), 201-203

<https://www.aacc.org/publications/clin/clin-stat/2015/april/16/New-Guidance-on-High-sensitivity-Cardiac-Troponin-Testing>

# Quantitative Levels of Gen 5 TnT

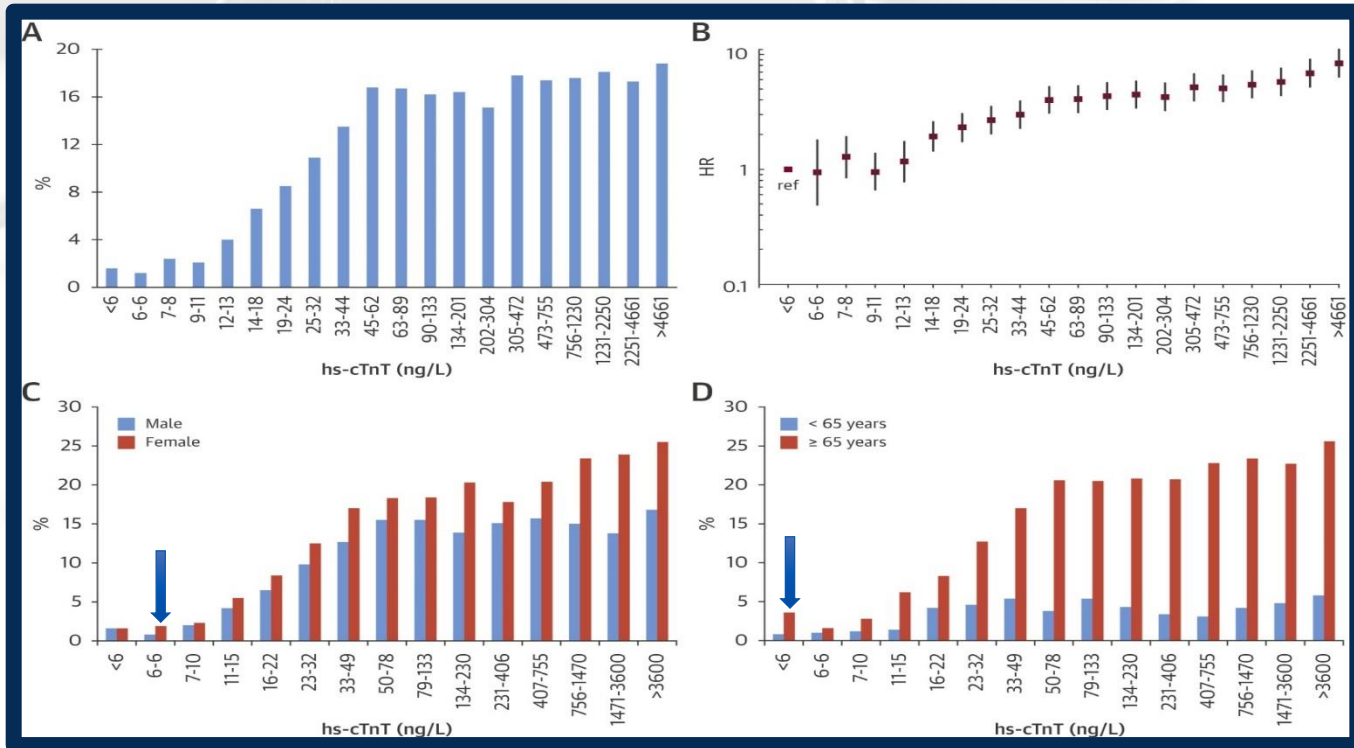


Garg P. et al, Intern Emerg Med. 2017;12:147-155





# Troponin Concentration and Mortality



Medicine 2016; 119: 102-110





# TECHNICAL

November, 2020

## High Sensitivity (hs) Troponin T Testing

### **Background:**

Effective Tuesday December 15th, the hospital laboratories throughout Methodist Healthcare System (Methodist Hospital, Methodist Jennie Edmundson Hospital, and Methodist Women's Hospital) will be switching from Roche standard Troponin T (4th Generation assay) to the Roche hs Troponin T (5th Generation assay).

Troponins are released during myocyte necrosis and/or increased permeability of the cell wall. Generally they are cardiac specific, however are not specific for acute myocardial infarction (AMI). 5th Generation troponin T is a high sensitivity troponin T test and is the biomarker of choice to rule out possible myocardial injury. Elevation begins early after myocardial injury and may remain elevated for more than 14 days. Interpretation and risk stratification requires the integration of clinical data. Elevated values may not be due to acute myocardial infarction however may indicate myocardial injury (acute or chronic). A rising and/or falling pattern distinguishes acute from chronic myocardial injury.

### **There will be NO transition period:**

Beginning December 15<sup>th</sup> at 10:00 am all new troponin orders will be performed as hsTnT. For patients whose series begin prior to the go live time and date the series will be completed with the standard troponin.



## High Sensitivity (hs) Troponin T Testing

### **Order:**

The order has changed to **hs Troponin T (hsTnT)**

Order set for series (0hr + 2hr + 6hr) will be available (when 6hr draw not needed – cancel the outstanding order).

A single level test order will also be available.

### **Specimen Requirements and test performed:**

5 mL Lithium heparin plasma.

The test will be performed 24/7 and the expected turnaround time (TAT) is <1 hour.

### **Reporting:**

1. There is change in units (ng/mL to **ng/L**) hsTroponin is reported in ng/L, which is 1000 times larger than the current standard troponin test.

2. There will be sex specific reference ranges upper limit of normal (ULN):

Female  $\leq 14$  ng/mL

Male  $\leq 22$  ng/mL

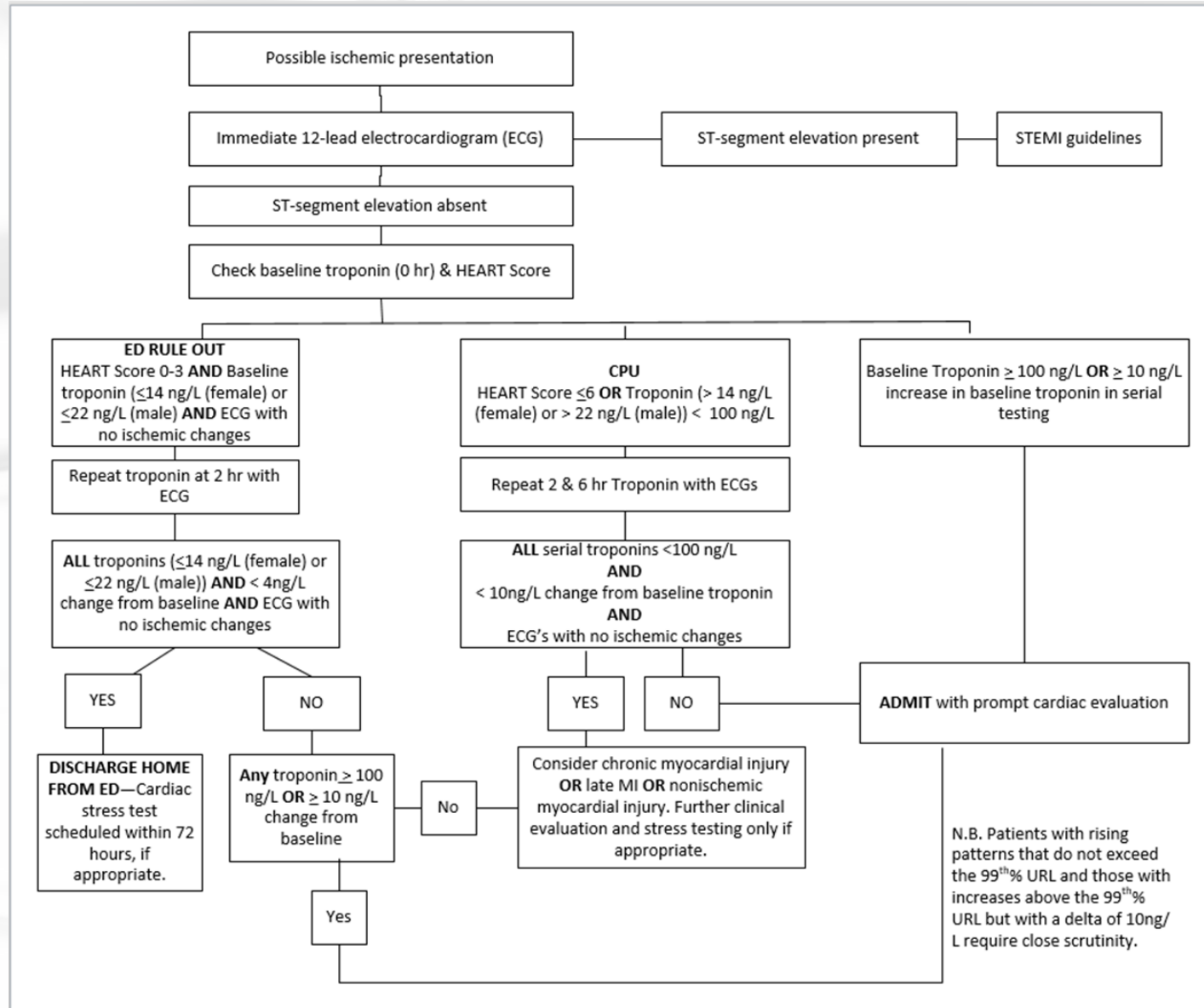
3. The Upper Limit of Normal (ULN) will be used as critical value (only the first critical value will be called).

4. Much more myocardial injury will be detected with hsTnT :

The assay is able reliably to detect lower levels than prior assays and in doing so, there may be a measurable amount of cardiac injury even in patients who present due to non-AMI situations. Results will be reported out with the following comment:

*Other causes that may result in increased hstropoinin (excluding ACS) include sepsis, renal failure, acute respiratory failure, shock/hypotension/hypoperfusion, heart failure, pulmonary embolism, stroke, severe hypertension, malignancy as well as numerous less common diseases.*





Please direct any questions Re: the assay to Dr. George Bedrnicek at 402 955-5528 or to Dr. Deborah Perry at 402 354-4559





A grayscale background image featuring medical equipment. On the left, a clear plastic tube with a connector is visible. In the center, a large, heart-shaped clear plastic component is prominent. To the right, a piece of medical machinery with a circular dial and a handle is shown. The entire scene is reflected on a glossy surface below.

*Doing now what patients need next*

