February 4, 2022

To: SHC and LPCH Medical Staff

From: Stanford Health Care Clinical Laboratories

Subject: Implementation of High-Sensitivity Troponin I (hs-TnI) test at Stanford Medicine

Background:

Effective March 1st, 2022, the clinical laboratory at Stanford Medicine will be switching from a TnI performed on Siemens ExL instruments to the high-sensitivity troponin I (hs-TnI) assay on Abbott Architect instruments. The assay was approved for use in the United States by the Food and Drug Administration in 2019.

The word "high-sensitivity" refers to the ability of the assay to detect troponin at or above the limit of detection in ≥ 50% of a reference ("normal") population. Most healthy patients will have measurable troponin I with the hs-TnI assay.

The hs-TnI assay allows for more accurate and precise TnI results at very low concentrations, thereby shortening the time interval required to identify myocardial injury in acute coronary syndromes (ACS) including acute myocardial infarction (AMI).

There will be **NO transition period** from the current (contemporary) Siemens TnI to the new Abbott hs-TnI assay.

New test information:

- **The EPIC hs-TnI order code: LABHSTNI**
- **Specimen requirements:**
    - K_2EDTA (lavender-top) blood collection tube **MUST** be used for the hsTnI test
    - No other blood collection tube type is acceptable. **The test WILL BE CANCELLED if collected in other blood collection tubes like red-top, mint-top (PST), gold-top (SST) tubes**
    - hsTnI test **CANNOT be shared with or added onto** other existing orders (e.g., CBC, tacrolimus, HbA1c)

Reporting of hs-TnI:

1. Hs-TnI result reported in whole numbers and units of ng/L

The new hs-TnI assay will produce very different results from the current TnI results. The hs-TnI values from the Abbott Architect instruments will be much larger than TnI values on the Siemens ExL instruments. The difference in the hs-TnI and TnI is due to the different units. Hs-TnI on the Abbott Architects **will be reported in ng/L instead of ng/mL** for the TnI on the Siemens ExL instruments. This will allow hs-TnI results to be reported in whole numbers (e.g., 15 ng/L) instead of hs-TnI values with decimal places (e.g., 0.015 ng/mL) and helps to distinguish hs-TnI from TnI. The reporting of hs-TnI in whole numbers is standard practice.

2. Sex-specific reference interval for the hs-TnI result

There will be a sex-specific reference interval for hs-TnI (as defined by the 99th percentile upper reference limit; URL):

- **Male (≥ 18 years):** **≤ 34 ng/L**
- **Female (≥ 18 years):** **≤ 16 ng/L**

Reference values have not been established for patients less than 18 years old.

The following comment will be appended to critical hs-TnI results: "The critical value indicates likely myocardial injury"

3. Interpretation of Hs-TnI values

The hs-TnI assay on the Abbott Architect instruments can reliably detect much lower levels of TnI than the TnI performed on the Siemens ExL instruments. Hence, there may be a measurable amount of hs-TnI even in patients who present without ACS.

Hs-TnI values greater than the 99th percentile URL by gender will be **"flagged in red" as critical** and indicate a high likelihood of myocardial injury.

- **Male:** **≥ 35 ng/L**
- **Female:** **≥ 17 ng/L**

Hs-TnI values ≥ 4 ng/L BUT less than the gender-specific 99th percentile URL are abnormal and will be flagged in **yellow**, as in some scenarios, the trend in Hs-TnI over time may be clinically meaningful (e.g., acute coronary syndrome rule-out)**.** Hs-TnI values < 4 ng/L will be reported in **black.** Neither of these results are consistent with a critical (positive) troponin value, but must be interpreted within the clinical context (e.g., rule out of acute coronary syndrome versus monitoring for therapeutic response in myocarditis). The following result note will be included with ALL Hs-TnI values to aid in interpretation:

"For paired samples drawn at intervals greater than 2 hours but less than 6 hours apart, myocardial injury is unlikely if the difference between adjacent troponin values is < 5 ng/L, but cannot be ruled out if the difference between adjacent troponin values is ≥ 5 ng/L"

"For samples drawn 6 hours apart, myocardial injury is unlikely if both the initial troponin AND the 6-hour troponin are non-critical values (<35ng/L for male biological sex and <17 ng/L for female biological sex)."

4. Hs-TnI result cannot be directly compared to previous Siemens ExL TnI or iSTAT TnI results

Due to differences in TnI assay performance between the Siemens and Abbott chemistry platforms, you should **NOT** directly compare the results of TnI (in ng/mL) from the ExL instruments or point-of-care (iSTAT) to the hs-TnI (in ng/L) on the Abbott Architect instrument by multiplying the result by 1000 to convert ng/mL into ng/L. The following comment will be added to the hs-TnI results: "Warning: different methods give potentially significantly different numerical values. Do NOT compare TnI values reported in ng/mL to hs-TnI values reported in ng/L".

For additional information about the Hs-TnI test, please refer to the online test directory page below:
https://stanfordlab.com/content/stanfordlab/en/test-details/h/HSTNI.html

If you have questions, please contact me at your earliest convenience or call the clinical lab at (650) 736-1061.

Sincerely,

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