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Cardiac Biomarker NEWS: High Sensitivity-Troponin T. Plans for the Calgary Zone Hospitals and Community Practices

Dr. Andrew Lyon – Calgary Lab Services/ Department of Pathology and Laboratory Medicine andrew.lyon@cls.ab.ca
Dr. Steve Clark – Department of Emergency Medicine steve.clark@albertahealthservices.ca
Dr. James McMeekin – Department of Cardiology James.McMeekin@albertahealthservices.ca

Alberta Health Services and Calgary Laboratory Services will implement a new highly-sensitive Troponin T assay (TNT-HS) in the Calgary Zone adult hospitals and community testing in mid-January. This new assay is approximately fifteen fold more sensitive than the current Troponin T assay and will be reported in different units of measurement.

During the introduction phase, two versions of Troponin T test results will be charted. The Troponin T: high sensitivity test will be reported in ng/L units and a derived version of the current 4th generation assay results will be calculated and reported as Troponin-T: calculated (TNT-CALC) in familiar units of µg/L. By providing both the new and old versions of the results, we encourage the ongoing test interpretation based on current practice threshold values for "borderline elevation" and "elevation consistent with myocardial damage or infarction", to enable ongoing treatment of patients with the existing standard of care, Figure 1. An algorithm for management of patients presenting to emergency departments with possible acute coronary syndromes was developed to summarize current practice with both TNT-HS and the current troponin results, Figure 2.

Community Practice: Troponin results for specimens collected from out-patients will be reported in a similar manner to results from patients at hospitals. In accordance with a recent provincial laboratory guideline for community ordering of cardiac biomarkers, should Troponin-HS results exceed 110 ng/L, (similar to 0.1 µg/L of the current assay), the result will be phoned to the ordering physician as a critical result. The comments attached to Troponin –HS results will include a phrase to indicate that the interpretation of results from ambulatory out-patients is highly dependent on clinical presentation and that cardiac risk assessment by the ordering physician or "urgent-access" cardiology clinic (or emergency department) may be indicated. A series

Notifications:

The 2010 CLS Report to the Community is available. If you would like a hard copy, please contact the CLS Communications Department:

communications@cls.ab.ca

It is also available on on our website:

http://www.calgarylabservices.com/who-we-are/company-profile/

Editor:
Dr. Alex C. Chin, Ph.D. DABCC FACB

Alberta Health Services

Calgary Laboratory Services

of "urgent-access" cardiology clinics are now available in Calgary to provide timely referral for patients at moderate to high risk as an alternative to emergency departments, when clinically appropriate.

A Calgary zone TNT-HS implementation group was created among Cardiology, Emergency Medicine and Pathology & Laboratory Medicine/Calgary Lab Services to prepare the implementation strategy and provide education support. Note that testing of "Troponin-I" at urgent care centres and rural hospitals will not be affected by this change in Troponin T. An online forum for discussion and compilation of frequently asked questions & answers related to this topic has been created by the Libin Cardiovascular Institute (website http://libin.ucalgary.ca/). Several rounds will be based on this topic in January and February. Alternatively, suggestions about the transition can be directed to us by email.

Implementation will occur in two phases:

Phase 1: The report will provide both new TNT-HS and TNT-CALC results and interpret the results in the same manner as the current Troponin-T method. This will maintain current patient-care practices related to the time of testing (after onset of chest pain) and result interpretation.

Phase 2: Based on several months of experience in Calgary during Phase 1, we will consider modifying the interpretation of TNT-HS results and the time of testing (after onset of chest pain). In the future, we expect to discontinue reporting the calculated version Troponin results in µg/L.

We expect that provision of the calculated version of troponin results in the current units (µg/L) during the next months will assist everyone involved in the transition.

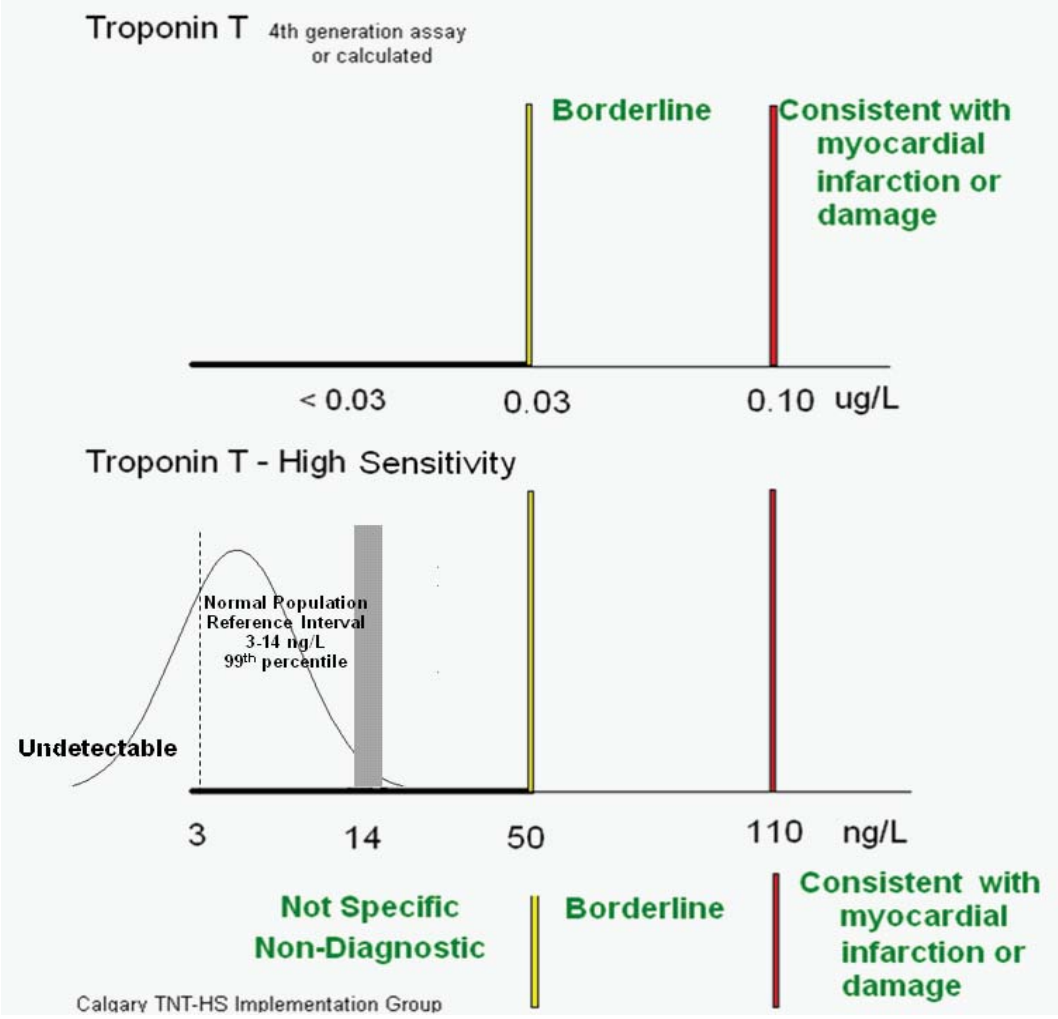

Figure 1 – Correlation between the 4th generation (old) and new high sensitivity troponin T results.

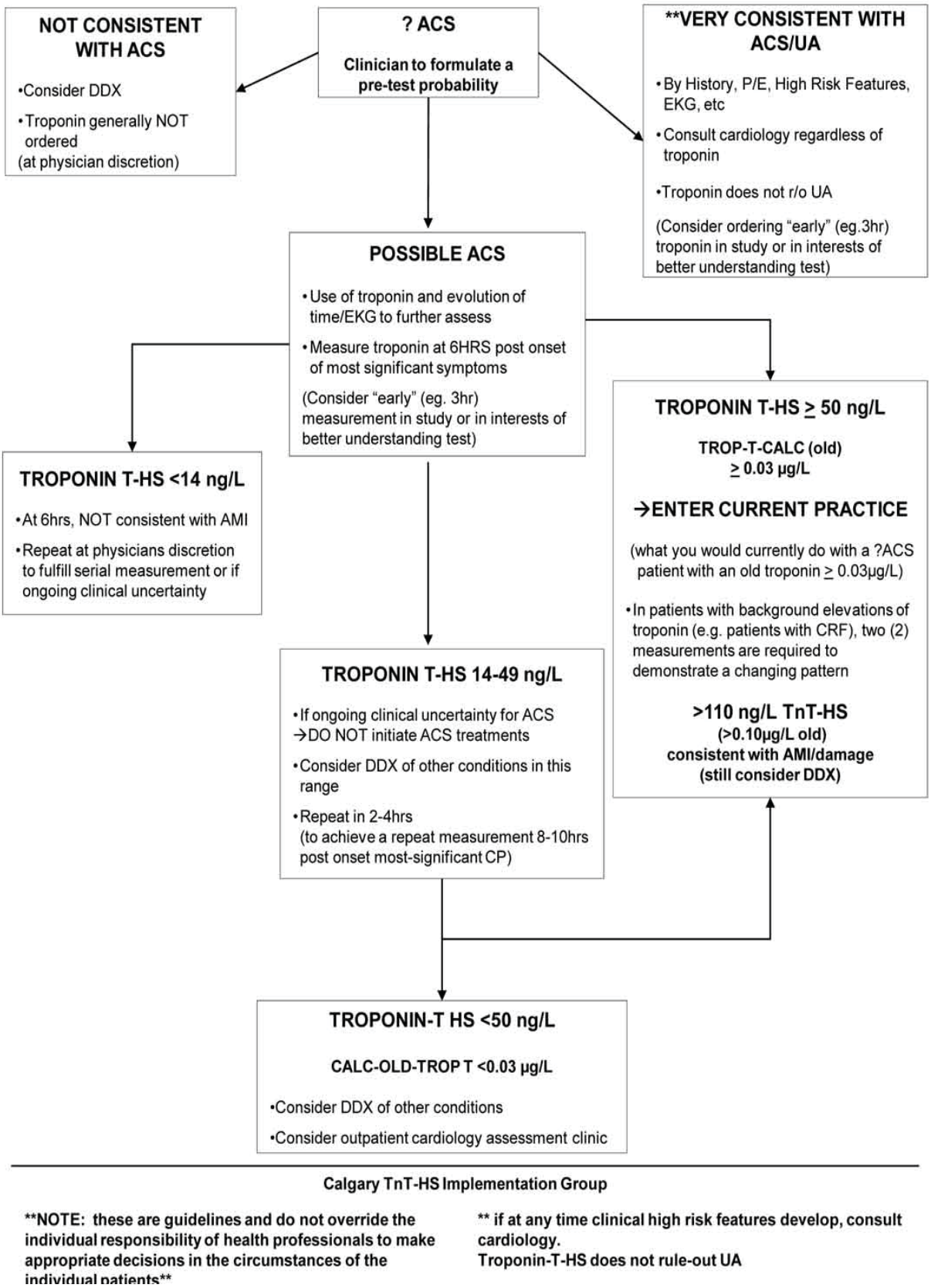

Figure 2 – Proposed algorithm for management of patients presenting to emergency departments with possible acute coronary syndromes

C-Reactive Protein to Assess Cardiovascular Risk

Alex C. Chin, Ph.D. DABCC FACB, Clinical Chemist, Calgary Laboratory Services alex.chin@cls.ab.ca
Richard Krause, Ph.D. DABCC, Clinical Chemist, Calgary Laboratory Services richard.krause@cls.ab.ca

While CRP is used as a marker of inflammation and can be used to monitor infections, high sensitivity CRP (hsCRP) has now been widely accepted as a marker of cardiovascular risk. Measurement of CRP should not be performed on everyone. According to 2009 guidelines from the Canadian Cardiovascular Society[1], CRP >2 mg/L may indicate statin therapy in individuals exhibiting a moderate Framingham risk score (10-19%), are males >50 years or females >60 years, and have LDL cholesterol levels <3.5 mmol/L. Given the potential interference by co-existing inflammatory conditions, patients should be free of acute illness and the lower of two values, taken at least two weeks apart, should constitute the baseline value. High-sensitivity C-reactive protein (CRP) is no longer a user pay test and is now covered by Alberta Health and Wellness.

The "C" in CRP is derived from studies that demonstrated the precipitation of unknown protein with the C-polysaccharide fraction of pneumococci from the serum of acutely sick patients. CRP is an acute phase reactant and is useful for non-specific screening of inflammatory conditions and infectious disease processes. Serum levels of CRP quickly rise within 6-10 hours during inflammation and then quickly decrease during resolution of inflammation with a short half-life of 5-7 hours[2]. CRP levels often complement erythrocyte sedimentation rate (ESR), but may be a better early marker of inflammation. Indeed, CRP levels are elevated within 24 hours of inflammation whereas ESR is normal (Figure 1).

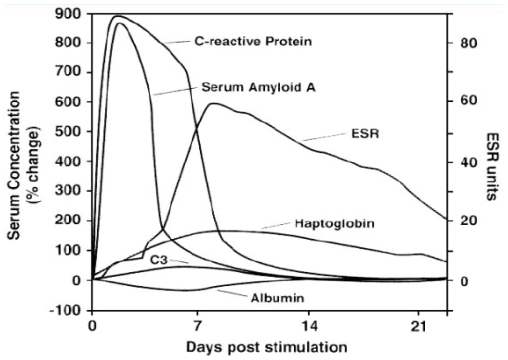

Figure 1 - Components of the acute phase response[2]

In addition to the traditional use of CRP as a marker of acute inflammation, recent studies have determined that lesser increases in CRP may be an indicator of a chronic baseline inflammatory process which may predispose the individual for cardiovascular events. Data obtained from the Justification for the Use of statins in Prevention: an Intervention Trial Evaluating Rosuvastatin (JUPITER) has demonstrated the reduction of cardiovascular events with statin therapy[3]. The Reynolds Risk Score, which combines the Framingham Risk Score and family history with hsCRP levels, was devised to identify the patient population which will benefit most from statin therapy. It should be noted that assessment of hsCRP levels should be targeted towards individuals in the moderate risk category.

At CLS, hsCRP is determined by a specialized automated immunoassay which has a clinical reportable range of 0.1 to 276 mg/L. The regular CRP, for assessing general inflammation, is performed using an automated immunoturbidometric method with a clinical reportable range of 1 to 1730 mg/L and a normal range of <8 mg/L.

Summary

- High-sensitivity CRP is no longer a user-pay test.
- Statin therapy may be indicated when high sensitivity CRP is >2 mg/L and the following are met:
  - Moderate Framingham risk score: 10-19%
  - Males >50 years or Females >60 years
  - LDL cholesterol is <3.5 mmol/L
- CRP is used to assess inflammation while hsCRP is to assess cardiovascular risk

References

[1]Canadian Journal of Cardiology 2009;25(10):567-579.
[2]Pediatric Infectious Disease Journal 1997;16:735-747.
[3]New England Journal of Medicine 2008;359:2195-207.

Benefits and Operation of Automation for High Volume Urinalysis

Submitted by Dr. Valerian Dias PhD, FCACB valerian.dias@cls.ab.ca

In the Calgary Zone, urinalysis is the third most frequently ordered laboratory test and is performed at all hospital and health centre testing laboratories. At the CLS Diagnostic and Scientific Centre (DSC) Laboratory which provides testing for community patients and also supports the testing for many centralized departments, we perform over 35,000 patient requests for Urinalysis per month. Automation was the solution proposed to deal with the high testing volumes to achieve greater efficiencies and improved laboratory workflow. On December 3, 2011 new automated urinalysis instruments were implemented at the DSC. It is a fully automated and integrated macroscopic-microscopic system which offers more standardized results with better precision and reproducibility. The new analytical instrument is the AX 4030 with the IQ-200. The AX 4030 performs the urine macroscopic analysis for established urine chemistries on test strips (glucose, ketones, specific gravity, blood, pH, protein, nitrite, leukocytes), as well as color and clarity. The IQ-200 subsequently performs the automated urine microscopy, based on the results of the macroscopic analysis on the analyzer. The IQ-200 takes 500 digital images automatically on an aliquot of native, uncentrifuged urine for formed elements (eg, cells, casts, crystals) and displays digital pictures of these items on a video screen. The instrument's trained neural network (APR software) classifies and quantitates cells and formed particles. Visual review of the digitized images by a skilled technologist confirms, deletes, or reclassifies the objects in each field before reports are released. Visual manual microscopy will still be required for some samples, namely yeasts, Trichomonas, oval fat bodies, sperm and differentiation of pathological casts and certain crystals.

Automation allows technical staff to let the instrument do the analysis with better and more standardized differential results. "Normal" samples are filtered through a user-defined algorithm and if all criteria are met, the results are released . As a result, the technical skills of laboratory personnel is enhanced and can be better used to review, edit, and release results on more complex, abnormal urine specimens. Plans are in place for additional automated instruments to be installed at other CLS Rapid Response Laboratories in the Calgary Zone.

Discontinuation of "Stat" ECG Requests in the Community

Following long-term discussions with stakeholders and consideration of safety concerns, CLS will discontinue the current practice of performing "stat" ECGs at our Patient Service Centres. This change will take effect on January 15th. To help ease this transition, there will be a grace period of thirty (30) days for any stat ECG requisitions that may have been given to patients prior to January 15. A new CLS community requisition is currently being printed and will reflect this change in practice. Physicians may request that an ECG be given a priority interpretation by one of our default ECG readers. There will be a new box on the CLS requisition to check if this service is requested. These priority interpretations are available between the hours of 8:30 AM and 4:00 PM on business days; the ECG will be interpreted within 2 hours if the patient presents to the Patient Service Centre within these times. If the patient presents outside of these hours, priority interpretations will be reported at the beginning of the next

business day. If the ordering physician wishes to have a priority interpretation from someone other than one of our default readers, it is their responsibility to arrange this with their ECG reader of choice. To facilitate management of patients, the Patient Service Centre will also fax an un-interpreted copy of the ECG to the ordering physician if a fax number is provided on the requisition.

New CLS Community Requisition

An updated version of the CLS community requisition is at our printers and will be distributed to physicians in the near future. There has been some reorganization of the requisition in response to stakeholder feedback. The most significant change is the addition of a "commonly-ordered test" section which includes our most-commonly ordered tests from community physicians. Other changes have been made for increased clarity and to reflect changes in our test menu offerings. Paper and electronic copies of the new requisition will be sent to physicians in the next week or two.

If you would like to automatically receive an email copy of this newsletter and/or be included on the electronic distribution list, please contact the CLS Communications Department:

Communications@cls.ab.ca

DID you know. . .

CLS offers the following services to assist patients with their busy lives?

Appointments for all patients at all the PSCs which can be pre-booked at least a day in advance

Standing order service: for patients who require blood work on a regular basis. This service enables patients to drop into any PSC where their lab work requests are on file electronically thereby avoiding the need to visit their physician each time to obtain a requisition. Physicians notify the Standing Orders Office as to which of their patients should be added to this service and provide the required documentation. To find out if you fit within the guidelines, contact your physician directly for further information.

Second language support services: for those patients for whom English is not their first language

Free parking at most Patient Service Centres