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Laboratory News

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NEW TARGETED DRUG PANEL FOR URINE DRUG SCREEN

Joyce L. Flanagan, PhD, DABCC, Clinical Chemist, Marshfield Labs

Effective July 1, 2019, a new urine drug screen targeted for opioids, benzodiazepines, and amines, for monitoring patients under opioid treatment, will be available to order. The test name is "**Targeted Drug Panel, Urine**", and the lab test code is **TDPU**.

This assay is a semi-quantitative **confirmatory** test by liquid chromatography/tandem mass spectrometry (LC/MSMS). If an analyte or its corresponding metabolites are present in urine, it indicates that the patient has used the drug recently. If a drug is detected, it will be reported as "present" in three concentration ranges (low, middle, high) with the analyte's specific ranges.

The **Targeted Drug Panel, Urine** (**TDPU**) includes:

- **seven amines:**
  amphetamine, methamphetamine, MDA, MDMA, MDEA, methylphenidate, ritalinic acid.
- **six benzodiazepines:**
  7-aminoclonazepam, lorazepam, oxazepam, alphahydroxyalprazolam, nordiazepam, temazepam.
- **eighteen opioids:**
  buprenorphine, norbuprenorphine, oxycodone, nor-oxycodone (oxycodone metabolite), oxymorphone (oxycodone metabolite), morphine, hydromorphone, 6-monoacetylmorphine (heroin metabolite), codeine, hydrocodone, gabapentin, tramadol, nor-tramadol (tramadol metabolite), fentanyl, nor-fentanyl (fentanyl metabolite), carfentanil, methadone, EDDP (methadone metabolite).

Analytes below the level of detection will be reported as negative.

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This test was developed in-house with targeted analytes in consultation with pain management providers. The objective of this test is to provide useful information to help determine patient compliance or identify misuse of other drugs commonly present in our patient population.

Another new test code, **PCS4WO** (**Pain Clinic Survey 4 Without Confirmation, Urine**), will also be available to order along with the **TDPU** test. This test is a qualitative, presumptive assay (not confirmatory) to help providers to screen patients when additional illicit drug class testing is desired. This test will screen for cocaine, marijuana, barbiturates, and ethanol. The method for this test code is by immunoassay. Additional confirmatory testing is recommended for presumptive positive results if treatment may be impacted. This test will also check for specimen validity including creatinine, oxidants, and urine pH. Additional confirmatory tests will not automatically reflex, but are recommended to be ordered based on presumptive positive results if it may influence treatment.

QUESTIONS

- Test information will be available in Marshfield Labs Test Reference Manual or from Marshfield Labs Customer Service Department after July 1, 2019.
- Clinical and technical questions may be directed to Joyce Flanagan, PhD, Clinical Chemist.
- Phone number: 800-222-5835.

HIGH-SENSITIVITY CARDIAC TROPONIN I FOR EVALUATION OF CHEST PAIN

Gene Shaw, MD, PhD, Hematopathologist, Marshfield Labs

Effective July 1, 2019, the Marshfield Medical Center (Marshfield campus) will convert to the recently FDA-approved Siemens high-sensitivity cardiac troponin I assay (**hs-cTnI**). Compared with the current assay, the **hs-cTnI** assay offers greater precision especially in the low end of the measurable range. Now significantly more patients will have a reportable value rather than the <16 ng/L often reported currently. The new assay facilitates more rapid and accurate assessment of chest pain for more timely patient triage.

The algorithm presented in **Figure 1** (below) has been approved by the departments of Cardiology, Emergency Medicine, and Laboratory Medicine. It should only be applied after ST-elevated myocardial infarction has been ruled out by ECG. And, of course, it should always be used in conjunction with all other clinical information, a detailed history of the chest pain characteristics, and physical examination.

This is essentially the same algorithm validated by a multi-national European study of 1755 patients using the Siemens **hs-cTnI** assay and recently published in *Clinical Chemistry*[1]. To ensure best practice, providers should strictly abide to the draw times: at presentation and two hours later. Patients that RULE OUT based on the algorithm have a very low risk of acute myocardial injury (negative predictive value 99%). Additional **hs-cTnI** testing after two hours may be especially helpful in patients not meeting either the rule-in or rule-out criteria.

In the usual emergency department setting, a slight majority of patients can be ruled out for acute myocardial **injury** within two hours using this algorithm. They can usually be safely discharged to

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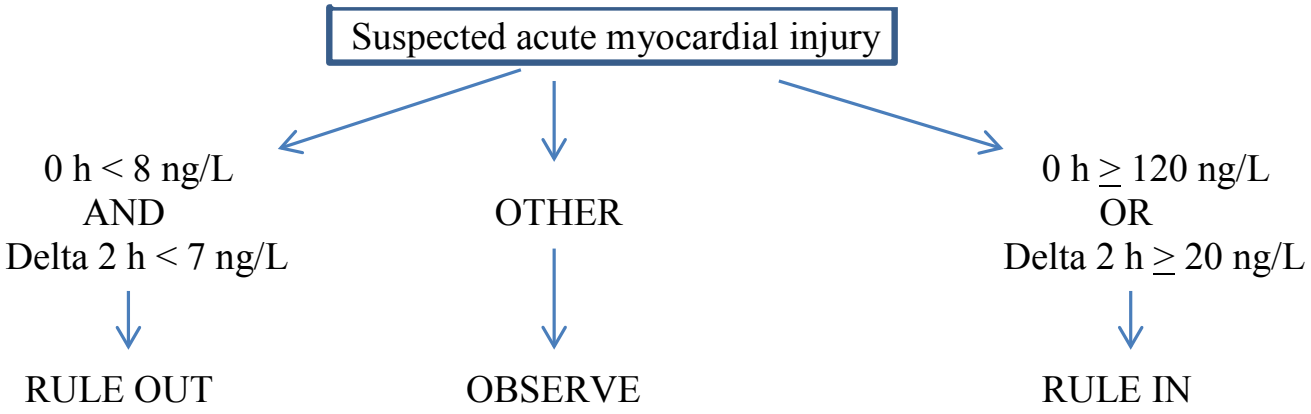
home if there are no other acute medical problems requiring hospitalization. Conversely, about 15% of patients will rule in for acute myocardial injury (most meeting criteria for a non-ST-elevation or NSTEMI). These patients are at significantly higher risk for major adverse cardiac events or death within 30 days and will likely benefit from interventions such as antiplatelet therapy, use of a statin (or other lipid–lowering agent), and potentially revascularization (depending on angiographic findings). A residual approximately 30% of patients will fall into an observation (gray-zone) category. For this subgroup repeat **hs-cTnI** testing will likely be needed along with ongoing clinical assessment. Perhaps 15% of patients in this subgroup will eventually meet criteria for NSTEMI.

Figure 1:



Marshfield Labs has chosen the Siemens assay for a number of reasons. From a cost and ease of implementation standpoint, we currently have instrumentation available (no capital required) to bring the Siemens assay in-house. Also, cTnI offers several advantages over cTnT (Roche assay). These include:

1. Less interference from skeletal muscle injury.
2. No significant increase with age.
3. Less often elevated in patients with renal disease.
4. Minimal, if any, interference in patients taking biotin supplementation.
5. Greater separation between the lowest reportable values and the 99th percentile, thereby providing better precision for delta calculations at the low end.

In some clinical situations, ordering a single **hs-cTnI** level is appropriate; e.g., monitoring congestive heart failure or checking for drug-induced cardiotoxicity. The interested reader is referred to the recently published "Fourth Universal Definition of Myocardial Infarction" article in *Circulation*, available on line, for further discussion on how high sensitivity cTn assays should be used in other settings such as re-infarction or procedure-related myocardial infarction[2].

High sensitivity cTn assays have been available in Europe and Canada for eight years so they have a significant track record demonstrating superiority to prior assays in the assessment of chest pain and potential acute myocardial infarction. The cTnT assay from Roche was approved by the FDA in

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January, 2017. Recently two cTnI assays have been approved, including the one from Siemens. As the USA starts to adopt these assays, institutions will implement different strategies and algorithms as they gain experience. We welcome your input as we strive to improve the care of these patients.

QUESTIONS

- Clinical and technical questions or concerns may be directed to Gene R. Shaw, MD, Sarah Bissonnette, PhD, or Joyce Flanagan, PhD.
- Phone number: 800-222-5835.

INTERPRETIVE COMMENTS

- Normal population 99th percentiles: ≤ 57 ng/L men; ≤ 37 ng/L women. Values greater than these cutoffs will be flagged as high.

SAMPLE TYPE

- Preferred: plasma (lithium-heparin). No clotting time required.
- Acceptable: serum. Requires 10 minute longer turn-around time.

REFERENCES

1. Boeddinghaus J, et al. Clinical Validation of a Novel High-Sensitivity Cardiac Troponin I Assay for Early Diagnosis of Acute Myocardial Infarction. Clin Chem, 64:1347-1360, 2018.
2. Thygesen K, et al. Fourth Universal Definition Myocardial Infarction (2018). Circulation, Online, 2018.