

Anticoagulation Monitoring: The Importance of Having QC Controls on the Test Strips

Background: Anticoagulation therapy with warfarin is widely recognized as a cornerstone therapy in the management of many common and important medical and surgical conditions including mechanical heart valve replacement, chronic non-valvular atrial fibrillation, recurrent deep vein thrombosis (DVT) and severe congestive heart failure (CHF).

Recent Developments: There have been several recent developments that have opened new opportunities for the clinician in the management of oral anticoagulation patients. This includes new, whole blood fingerstick International Normalization Ratio (“INR”) testing devices that can function in the clinical setting or be utilized at home as part of a patient self-testing (PST) program. In addition, the growing body of peer-reviewed clinical data demonstrating that physician-directed programs incorporating PST experience improve outcomes has helped in recent reimbursement decisions where Center for Medicare and Medicaid Services (“CMS”) has eliminated the final obstacles for reimbursement for home patient use of INR devices and strips in patients with artificial heart valves.

Quality Control: These new PST devices are actually sophisticated laboratory grade instruments that have ingenious patient and user interfaces to simplify the test experience. However, like all laboratory devices there are several situations that could compromise the test results. These problems, if not detected, can result in reporting of erroneous results and potentially expose the patient to the increased risk of insufficient or excessive anticoagulation values.

It is therefore of paramount importance that the quality control systems evaluate not just the integrity of the electronic meter, but also the actual chemical assays being performed on the strip. With most commercially available fingerstick INR meters, this means having to perform extra steps by using additional test strips and liquid control solutions of known INR values. However, even the use of these liquid controls does not provide adequate assurance that all potential sources of error are detected. The following are common, real life examples of problems that can be detected by a system of on-board strip controls that may not be detected by external liquid controls:

- The strips are left in a car in the sun, resulting in exposure to extreme heat and degradation of the reagents.
- A patient receives a box of strips and the strip pouches are damaged possibly exposing some of the test strips to environmental damage.

- A patient removes a test strip from its packaging and decides to test at a later time, subjecting the test strip to environmental conditions that compromise the reagents.
- The outer packaging of the test strip is damaged or perforated exposing it to humidity that compromises the test strip reagents.

At least one new PST device, the HemoSense INRatio, has integrated high and low control checks into every strip and has implemented a variety of electronic safeguards built in each meter to insure that the entire test system is working properly. This provides a greater level of confidence in the result, which is particularly important in PST. The following provides a brief overview of the Quality Control technologies built into the INRatio system:

Strip QC: The test strip of the INRatio system contains three test zones, one for determining the patient INR result and one each for the low and high controls. The INR channel contains human recombinant thromboplastin. The control channels contain coagulation factors and buffers. The controls are formulated to clot within a normal (low) and a therapeutic (high) clotting range with the use of any blood sample to activate the test area. If a strip is exposed to extremes of temperature or humidity, as in the examples above, one or both of the control determinations will be out of range. This yields a test error message being reported on the meter display.

Meter QC: The meter performs electronic self-checks that verify performance each time a test is performed. The meter is also designed to detect common test errors, such as an inadequate blood sample, a previously used test strip or a damaged meter. If these conditions are detected, the meter reports an error message and does not display test results.

When warfarin is properly administered and monitored, it delivers compelling reductions in morbidity and mortality with relatively few complications. However, until recently, management of chronic anticoagulation therapy was onerous for both patients and physicians. Checking INR’s meant forcing patients to make frequent trips to the lab for venous blood draws. This in turn required physician offices to expend considerable (and non-reimbursable) energies, tracking and charting INR’s as well as contacting patients to communicate results. New point-of-care and patient self test INR testing devices that integrate two levels of controls into each test strip can improve the confidence of INR results determined at home, in the field or in the clinic, enabling anticoagulation therapy management to be more effective for clinicians as well as more convenient for patients. — David E. Goodman, MD