D5545
(Rev. 140, Issued: 05-29-15, Effective: 05-29-15, Implementation: 05-29-15)

§493.1269 Standard: Hematology

(b) For all nonmanual coagulation test systems, the laboratory must include two levels of control material each 8 hours of operation and each time a reagent is changed.

Interpretive Guidelines §493.1269(b)-(c)

The laboratory performing nonmanual coagulation tests subject to §493.1269 must either establish criteria or verify manufacturer's criteria for an acceptable range of performance as required in §493.1253(b). Use D5421 or D5423 as appropriate.

An automated (nonmanual) coagulation test system samples the plasma, combines the

plasma with the reagents, detects the end point or clot formation and displays the test results without operator intervention.

The International Sensitivity Index (ISI) is the correction factor for variable sensitivities of thromboplastins. The International Normalized Ratio (INR) is a calculation primarily used for monitoring a patient's oral anticoagulant therapy. The INR corrects for the variability in Prothrombin Time (PT) results attributable to the ISI. Therefore, this allows all PT's to be corrected to the international standard.

INR Calculation

The INR is equal to the ratio of the patient's PT (in seconds) to the laboratory's established normal mean PT (in seconds), then raised to the power of the ISI.

$$INR = (\text{Patient PT} \div \text{Mean Normal Range PT})^{ISI}$$

NOTE: A scientific calculator is needed to calculate the INR.

Example:
Patient PT (in seconds) =18.5
Normal mean PT (in seconds) =12.9
ISI value (obtain from the package insert of the laboratory's current lot of thromboplastin reagent) =2.002

1. $18.5 \div 12.9 = 1.434$ (Patient Ratio)
2. $1.434^{2.002} = 2.056$ (INR Result)
3. Report the INR as: INR = 2.1

For International Normalized Ratio (INR) calculations, ensure that the laboratory:

- Establishes a normal patient Prothrombin time mean with each new thromboplastin lot number;
- Verifies that the normal patient Prothrombin time mean study has been performed according to the manufacturer's instructions;
- Incorporates the current and pertinent normal patient Prothrombin time mean and ISI value for each lot of thromboplastin (manual, instrument, or LIS);
- Documents the manual check of the INR calculation for each new lot number;
- Documents each thromboplastin lot number, with the normal patient Prothrombin time mean and the ISI value provided by the manufacturer (manual or instrument);

- Periodically verifies, for each thromboplastin lot number in use, the correct normal patient Prothrombin time mean and the International Sensitivity Index (ISI) value are being used for calculating the INR value; and

- Periodically verifies the accuracy of the INR calculation (manual, instrument or LIS).

To verify prothrombin time testing with INR calculations:

- Check the accuracy of normal patient Prothrombin time mean calculation (manual, instrument or LIS).

- Verify that the ISI used in the calculation correlates with the ISI specified in the reagent package insert. Select an abnormal low or abnormal high prothrombin time result and verify the calculation.

Probes §493.1269(b)-(c)

Is the laboratory using the ISI value from the current manufacturer's package insert in calculating the INR values?

How does the laboratory ensure that the ISI values are changed with each change of thromboplastin lot number?

Has the laboratory established its own normal patient mean with each lot of thromboplastin?

For coagulation testing, do the records include timer checks and temperature checks as necessary?