Objective

To evaluate and compare PF4-R performance with heparinase in neutralizing unfractionated heparin (UFH) in routine coagulation tests (aPTT, PT, TT) and factor assays.

Methods

• Plasma samples used in this study include: cercheck™ Pooled Normal Plasma (CCN), cercheck Normal Donor Set (CCNS), cercheck Heparin Control (CHC).

• Clinical samples were collected from patients with unexplained, elevated aPTT (Target population) and from patients medicated with UFH (Positive population).

• PF4-R treatment was performed as follows: Frozen PF4-R vials were thawed for 30 to 60 sec at room temperature before adding 0.5 ml of citrated plasma per vial. Vials were re-capped and gently inverted 3 to 5 times to mix. Samples were tested immediately or within 8 hours of treatment.

• Heparinase (Hepzyme) treatment was performed according to the manufacturer’s instructions.

• Testing was performed on a STA-R Evolution® using STA®-PTT Automate, STA®-Neoplastine Cl+, and STA®-Thrombin reagents according to the manufacturer’s instructions.

Results

Heparin Neutralization Capacity of PF4-R

Neutralization of Heparinized Normal Donor Samples

Comparison of PF4-R with Heparinase on Clinical Samples

Conclusions

• PF4-R is a novel, ready-to-use, stable reagent capable of fully neutralizing the anticoagulant activity of at least 2 IU/mL of UFH in plasma in routine clotting tests.

• PF4-R does not interfere with the clot time of non-heparinized plasma.

• PF4-R and heparinase treated patient samples showed a strong correlation in clot times in all tests.

• PF4-R and heparinase treatments gave similar aPTT and PT results, however the TT of heparinase treated samples was prolonged by a mean of 6 sec relative to PF4-R. This bias was due to an interference by heparinase in the TT assay.

References


3. Patent: CA 2810334

4. Patent pending: US 13/984,335

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