SACT II Reagent

X9601

RESEARCH USE ONLY (RUO)

INTENDED USE

This reagent is a clear, stable, phospholipid-free suspension of an aluminosilicate mineral which activates contact factors similarly to kaolin or silica. The SACT reagent can thus be used as a substitute for kaolin suspension in kaolin (KCT, 1) or silica clotting time (2) tests for lupus anticoagulants (LA), running in regular APTT mode on automated clotting instruments. The correlation between KCT and SACT results on various LA plasmas is usually very good (r^2=0.99) and a typical example is shown below. The simplicity of the reagent means it is not expensive. As the reagent is inorganic in nature, product stability is unlimited, but just to reduce potential contamination it should be stored at 4C. Mix briefly before using in tests.

CONTENTS OF PRODUCT

This product is available in 5 x 10ml vial packs.

PRECAUTIONS

Avoid contact with skin and eyes. Use suitable protective clothing. Use proper disposal procedures. Specimens should be obtained, processed and tested as recommended by CLSI (8). For professional use only.

INSTRUCTIONS FOR USE

For manual tests, mix 0.1ml test sample (usually mix of patient and normal plasma) with 0.1ml SACT.
Activate for 3-5 minutes at 37C.
Add 0.1ml of prewarmed 0.025 M calcium chloride.
Time to a clotting endpoint.
For automated tests, use APTT mode preferably with extended acquisition time.

APPLICATION

SACT and KCT tests are usually carried out on mixes of patient and normal plasma (1). These are often 1:1 or 1:4 mixes but the neat normal and patient plasmas should also be tested.

Because SACT reagent is clearer than KCT reagent, the clotting endpoint can be determined in any photoelectric
clot-timing instrument capable of measuring clotting time of up to 300 sec (upper limit).

LIMITATIONS

Because no phospholipid is added in this type of test the clotting time result is strongly dependent on the endogenous content of phospholipid in the plasma samples as well as on the activity of most clotting factors. Thus, residual platelets in freeze thawed plasmas can contribute to a short result, possibly bypassing weaker lupus inhibitors. Conversely, plasmas with unusually low phospholipid levels (eg. as in filtered plasmas or in some plasmas from thrombocytopenic patients) can give grossly prolonged SACTII results when tested on their own.

Heparin can also interfere but can be corrected by the use of HRRS (Heparin Resistant Recalcifying Solution, X9107) instead of the regular M/40 $CaCl_2$.

For these reasons, testing is much more reliable on mixes of patient with normal plasma. This also eliminates any effect from Warfarin. The normal plasma for mixing should be carefully selected to provide results between 80 and 100sec. Normal plasma giving excessively prolonged SACT or KCT results (eg >110sec) can be mixed with freeze thawed platelet containing normal plasma to shorten the baseline results.

PERFORMANCE CHARACTERISTICS

A prolonged SACT (or KCT) result on neat patient plasma indicates a coagulation defect including possible deficiency of baseline procoagulant phospholipid. If the abnormal result persists in a mix with normal plasma a lupus inhibitor or a DOAC (Direct Oral Anti-Coagulant) may be present.

The SACT or KCT (3) is usually more sensitive than most dRVVT and APTT tests to weak LA and it may detect a different subtype of LA (4). However, SACT tests are not as specific as dilute Russells viper venom tests (dRVVT) especially in the absence of phospholipid correction (5). A false positive result with patient on Direct Oral Anticoagulants (DOACs) may persist. Whenever a DOAC interference is suspected, use of correcting procedures such as DOAC-STOP™ (HX9904) is recommended (6).

Lupus inhibitors are a diagnostic feature of antiphospholipid syndrome (APS, 7). Patients with APS may present with recurrent fetal losses, thrombosis or stroke. Occasional patients displaying lupus inhibitor may be asymptomatic or may have a lympho-proliferative condition. Lupus inhibitors only rarely cause bleeding and then mainly in conjunction with low prothrombin levels, detectable by an extended prothrombin time test. The laboratory diagnosis of APS remains complex and should be supported by clinical associations and tests for anti-cardiolipin or anti beta 2GPI antibodies (8).

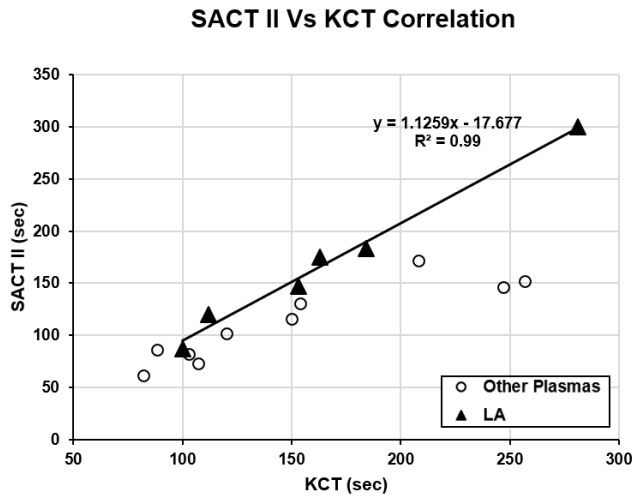

Figure shows the correlation between SACT II and KCT results on LA (▲) and other plasmas (○).

INDEMNITY NOTICE

Follow procedures and refer to precautions that may affect the stated or implied claims and performance of this product. Haematex Research Pty Ltd and its agents or distributors are not liable for damages.

REFERENCES

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