137 mm x 218 mm

CE

PROFACT™

Buffered 3.2% Tri-sodium Citrate solution for coagulation assays and ESR by Westergren method

SUMMARY

Accurate coagulation testing is dependent on numerous preanalytical variables, which may affect the results of routine coagulation assays. To improve the precision and accuracy of laboratory testing, it is important to identify these variables and control their potential effects on results.

Preanalytical variables pertinent to routine coagulation testing can be classified into three major categories: specimen collection, specimen processing and specimen storage and transport.

3.2% Citrate is also the anticoagulant of choice for performing ESR by Westergren method.

PRESENTATION

REF	10660020
PROFACT™	20 ml
Packinsert	1

REAGENT

In vitro diagnostic reagent. NOT FOR MEDICINAL USE.

PROFACT™ is a unique ready to use 3.2% buffered Tri-sodium citrate solution formulated for collection of blood for routine coagulation assays. The reagent contains 0.01% Thimerosal as preservative.

PROFACT™ can be used for sample preparation in the following clot based assays such as PT, APTT, TT, Quantitative estimation of Fibrinogen, Test for factor deficiency, Test for Lupus anticoagulants, Protein C and Protein S tests.

PROFACT™ can also be used for collection of blood to perform ESR by Westergren method.

PRINCIPLE

3.2% Tri-sodium citrate is the anticoagulant of choice for coagulation studies. When anticoagulated blood is centrifuged for preparing PPP for routine coagulation assays, the centrifugation process leads to release of carbon dioxide CO_2. The end result being shift in pH, which has an adverse impact on the results of clot based assays.

PROFACT™ incorporates 3.2% Tri-sodium citrate in a unique protective solution, which arrests shift in pH due to the release of carbon dioxide (CO_2), during centrifugation. Also labile Factor-V and Factor-VIII are well preserved and the results of clot based assays are more accurate.

Also **PROFACT™** incorporating 3.2% citrate is the anticoagulant of choice for ESR by Westergren method.

STORAGE AND STABILITY

Store the reagent at 2-8°C.

Stability of unopened vial: 12 months from the date of manufacturing.

Stability of opened vial: 90 days from the date of opening, provided it is not contaminated.

MATERIAL REQUIRED BUT NOT PROVIDED

Sterile and clean 0.5 / 1 ml micropipettes, micropipette tips or glass blow out pipettes, ESR tube.

SAMPLE COLLECTION AND PREPARATION

For Coagulation Assays

Though no special preparation of the patient is required prior to sample collection by approved techniques, it is preferable that patients are not heavily exercised before blood collection. Fasting or only light non-fatty meals prior to blood collection provide samples with a desirable low opacity.

Withdraw blood without undue venous stasis or frothing into a plastic syringe fitted with a short needle of 19 to 20 SWG. The venepuncture must be a 'clean' one and if there is any difficulty, take a new syringe and needle and try another vein. Transfer the blood into tubes containing **PROFACT™**, after detaching the needle from the syringe. Do not delay mixing blood with **PROFACT™**. Avoid foam formation during mixing.

Mix exactly nine parts of freshly collected blood with one part of **PROFACT™** (0.11 mol/l, 3.2%). For occasional patients with hematocrit less than 20% or greater than 55%, this ratio must be readjusted to ensure valid results. Centrifuge immediately for 15 minutes at 1500-3000 rpm (approximately 1500 g) on a laboratory centrifuge and transfer the plasma into a clean test tube. It should be ensured that the plasma is free from platelets (PPP). Cap the test tubes to prevent deterioration of samples. **Plasma must be tested preferably immediately.** However if the specimen is held at 22-24°C then they may be tested within 2 hours and if the specimen is held at 2-4°C then they may be tested within 3 hours.

Also plasma samples obtained after collection with **PROFACT™** may be stored at -20°C for 2-3 weeks before testing.

For ESR by Westergren method

For performing the test, venous blood is mixed accurately in the proportion of 1 part of **PROFACT™** and 4 parts of whole blood. The sedimentation rate is reduced in stored blood, hence the test should be carried out within 4 hours of collecting the blood, and a delay upto 6 hours is permissible provided that the blood is kept at 4°C.

PRECAUTIONS

1. Take every possible aseptic precaution to minimize contamination while drawing the reagent.
2. Avoid dipping contaminated pipettes / micropipette tips in the reagent vial. Ideally pour the required quantity for the days work into another sterile clean vial.
3. Recap and replace the reagent vial immediately back at 2-8°C.

REMARKS

1. Since most of the routine coagulation assays use PPP each laboratory must calibrate the necessary force and time required during centrifugation to yield PPP.
2. Incorrect mixture of blood and **PROFACT™** is a potential source of error both in coagulation assays and ESR estimation.
3. If the reagent vial develops turbidity, do not use the reagent as this would lead to erroneous results.

WARRANTY

This product is designed to perform as described on the label and the package insert. The manufacturer disclaims any implied warranty of use and sale for any other purpose.

BIBLIOGRAPHY

1. Quality Assurance for Routine Hemostasis Laboratory, Technical Series, Tulip Group, 2000.
2. Human Blood Coagulation, Haemostasis and Thrombosis, Edited by Rosemary Biggs, 1972, Blackwell Scientific Publication, Oxford.
3. Practical Haematology, Sir John V. Dacie, S.M. Lewis, Eight Edition, 1995, Churchill Livingstone.
4. Data on file: Tulip Diagnostics (P) Ltd.

SYMBOL KEYS

Temperature limitation	Manufacturer	Contains sufficient for <n> tests
Use by	Consult Instructions for use	PS — Production Site
Date of Manufacture	REF — Catalogue Number	This side up
LOT — Batch Number/ Lot Number	IVD — *In vitro* Diagnostic Medical Device	EC REP — Authorised Representative in the European Community

TULIP DIAGNOSTICS (P) LTD.

PS

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