

Blood Test Soil

Blood Test Soil (BTS) is a blood-based standardized soil and is used for simulated use testing and cleaning validations studies of medical devices coming in contact with the vasculature. The soil primarily comprises of the markers: albumin and hemoglobin in known quantities and is a reproducible formulation.

The components of the soil cross link to form alginate hydrogels. These 3-D protein hydrogels simulate the fibrin hydrogels in clotted blood.

To compare the properties of BTS and coagulated sheep's blood, protein and hemoglobin assays and adhesion and viscosity testing were done.

Assay Results

Sample	Concentration Protein (mg/mL)	Concentration Hemoglobin (mg/mL)
Coagulated Blood	158	115.6
BTS	156	123

Adhesion Testing Results

Coupon	Average % Soil Removed
Coagulated Blood	88%
BTS	45%

Viscosity Testing Results

Sample	Viscosity @ 30 RPM & 21 °C (mPas)
Coagulated Blood	5.93
BTS	12.46

BTS comes in a powdered form. The dried soil is mixed with the provided solution and water, specified in the instructions for use.

Storage: The soil can be stored up to 1.5 years at room temperature in the dried form. Reconstituted blood test soil should be used within 48 hours.

Suggested (not exclusive) Cleaning Markers for residual analysis: Protein, Hemoglobin, TOC.

Application of soil on the test articles/devices:

The test articles can be soiled by applying the soil using a pipette, by soiled gloves, by painting the soil on the device using a paint brush, or by immersing a test device in the soil.

To challenge disinfection and sterilization, the soil can be inoculated with a suitable microbiological marker.