

# Complement CH50 and AP50 Test Kits

HaemoScan is a research laboratory specialized in blood compatibility and biomarker detection. We are specialized in (safety) testing of medical devices and new drug candidates that come into contact with blood. We develop new methods and design new test kits based on these methods. The HaemoScan complement test kits provide a quick and simple test procedure based on measurement of haemolytic activity. Complement haemolytic activity is a functional test for the classical (CH50) and alternative (AP50) pathway of complement and can be measured in citrate plasma or serum.

## Complement CH50 Assay

The CH50 assay allows you to assess the functional capability of serum complement components of the classical pathway to lyse sheep red blood cells pre-coated with rabbit anti-sheep red blood cell antibodies.

This method is suited to measure complement consumption or inhibition by biomaterials, medical devices and pharmaceuticals.

**The HaemoScan test kits are:**

- Quick and simple
- Easy to compare using the provided positive and negative references
- Designed for small sample volumes (50 µL or less)
- Easy to measure using a 96 well microtiter plate and a spectrophotometer



## Complement AP50 Assay

The alternative pathway method is based on lysis of rabbit erythrocytes in the presence of Mg<sup>++</sup>. This method is also suited to measure complement consumption or inhibition by biomaterials, medical devices and pharmaceuticals.

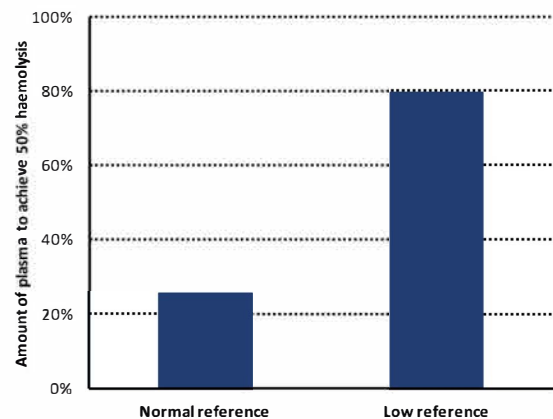


Figure 1. An example of CH50 or AP50 reference results.

# Haemocompatibility Test Kits: CCA, TGA and Haemolysis

Blood contacting medical devices may activate the natural host defense mechanism of blood by foreign-body reaction (e.g., activation of the alternative pathway of the complement system). Additionally, activation of the coagulation cascade or erythrocyte lysis may occur. Therefore, haemocompatibility of blood contacting medical devices has to be evaluated before their application in a clinical setting. The HaemoScan Complement Convertase Assay (CCA), Thrombin Generation Assay (TGA) and Biomaterial Hemolytic Assay (Hemolysis) test kits provide sensitive and specific methods for measurement of complement activation, thrombin generation and haemolysis according to the international standard ISO 10993-4:2002.

## Complement Convertase Assay

The complement convertase method is based on binding of plasma complement factors to the biomaterial surface followed by the formation of the complement convertase complex. The biomaterial complement convertase activity is analyzed using a specific chromogenic (colorimetric) substrate. The rate of color development depends on the amount of complement convertase on the biomaterial surface.

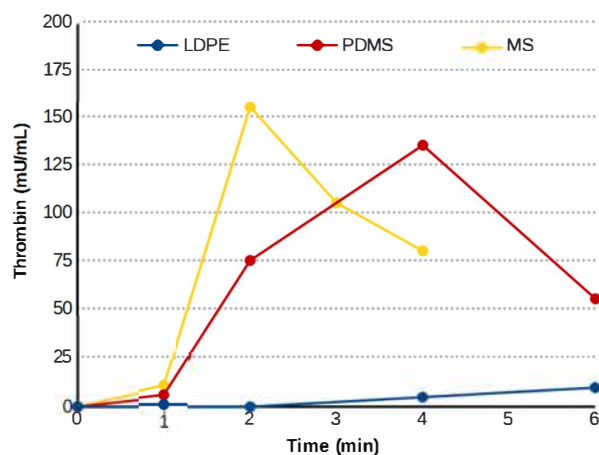


Figure 2. An example of TGA reference results.

## Thrombin Generation Assay

The thrombin generation method is based on the formation of thrombin, a key enzyme of the coagulation cascade. In normal plasma, thrombin is captured into the fibrin meshwork bound to biomaterial surfaces and is rapidly inactivated by antithrombin III or other antiproteases. The short half-life of thrombin hampers its accurate enzymatic measurement. Therefore, the thrombin generation method is based on a special plasma product that enables measurement of thrombin activity in an incubation medium after exposure to a biomaterial.

## Biomaterial Hemolytic Assay

The biomaterial hemolytic method is based on the lysis of erythrocytes induced by contact, leachables, toxins, metal ions, surface charge or any other cause of erythrocyte lysis. The kit is based on direct contact of the biomaterial sample or a biomaterial extract, and an erythrocyte suspension. Over time, hemolysis results in the release of hemoglobin, which can be measured spectrophotometrically.

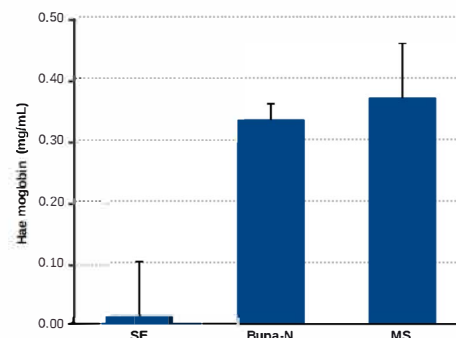


Figure 1. An example of hemolytic reference results, corrected for negative control.