Hemolysis Test

The hemolysis test is designed to evaluate the hemolytic properties of finished medical devices which have direct or indirect circulating blood contact by determining the degree of red blood cell lysis and the release of hemoglobin.

Types of Device in Contact with Blood

- **External communicating devices**
- External communicating devices serving as an indirect blood path

Include but not limited to cannulae, blood collection devices, devices for the storage and administration of blood and blood products, cell savers, et al.

- External communicating devices in contact with circulating blood

Include but not limited to blood monitors, catheters, guidewires, intravascular endoscopes, intravascular ultrasound, intravascular laser systems, haemodialysis / haemofiltration equipment, donor and therapeutic apheresis equipment, extracorporeal membrane oxygenators, interventional cardiology and vascular devices, et al.

- **Implant devices**

Include but not limited to mechanical or tissue heart valves, prosthetic or tissue vascular grafts, circulatory support devices, embolization devices, endovascular grafts, implantable defibrillators and cardioverters, intravascular membrane oxygenators, stents, pacemaker leads, internal drug delivery catheters, et al.
It is critical to perform hemolysis test on medical device, because several adverse effects will be caused by hemolysis in the health of patients, including:

- Compromised capability of oxygen transport due to significant reduction of red blood cells may result in damage of organ or tissue;
- Toxic effect and alteration of kidney function due to increase of free plasmatic hemoglobin;
- Formation of thrombi due to extra-vascular hemolysis.

STEMart provides in vitro hemolysis test to help manufacturer demonstrate the regulatory compliance of product to blood/device interaction.

Standard

ISO 10993-4: 2002

Test Method

Hemolysis tests are conducted through exposure of the medical device or device extract to mammalian (typically human or rabbit) red blood cells.

1. Incubate blood cells with addition of test samples for sufficient time to allow any hemolysis to occur.
2. Evaluate the presence of hemoglobin in the supernatant fluid after centrifugation of cell containing liquid.

If you have additional questions about Hemolysis Test or would like to find out more about our services, please feel free to contact us.

Reference

- International Organization for Standardization. Biological evaluation of medical devices — Part 4: Selection of tests for interactions with blood. ISO 10993-4; (2002).