Human CH50 controls for use on the SPAPLUS®

For *in vitro* diagnostic use only

Product Code: NQ095.S

Product manufactured by:
The Binding Site Group Ltd., 8, Calthorpe Road, Edgbaston, Birmingham, B15 1QT
www.bindingsite.co.uk
Telephone: +44 (0)121 456 9500
Fax: +44 (0)121 456 9749
E-mail: info@bindingsite.co.uk

CE

1 INTENDED USE

The Human CH50 controls are intended for use in conjunction with the Binding Site Human CH50 reagent pack for use on the SPAPLUS (product code: NK095.S).

2 SUMMARY AND EXPLANATION

Refer to the reagent pack insert for details of the CH50 assay.

3 REAGENTS

3.1 Elevated, High and Low controls: These consists of pooled human plasma and are supplied in lyophilised form. Contain 0.099% sodium azide.

4 CAUTION

All donors of human plasma supplied in this product have been tested and found negative for hepatitis B surface antigen (HBsAg) and antibodies to human immunodeficiency virus (HIV1 and HIV2) and hepatitis C virus. The assays used were either cleared by the FDA (USA) or cleared for *in vitro* diagnostic use in the EU (Directive 98/79/EC, Annex II); however, these tests cannot guarantee the absence of infective agents. Proper handling and disposal methods should be established as for all potentially infective material, including (but not limited to) users wearing suitable protective equipment and clothing at all times. Only personnel fully trained in such methods should be permitted to perform these procedures. Adherence to the given advice is recommended.

WARNING: This product contains sodium azide and must be handled with caution; suitable gloves and other protective clothing should be worn at all times when handling this product. Do not ingest or allow contact with the skin (particularly broken skin or open wounds) or mucous membranes. If contact does occur wash with a large volume of water and seek urgent medical advice. Explosive metal azides may be formed on prolonged contact of sodium azide with lead and copper plumbing; on disposal of reagent, flush with a large volume of water to prevent azide build up.

This product should only be used by suitably trained personnel for the purposes stated in the Intended Use. Strict adherence to these instructions is essential at all times. Results are likely to be invalid if parameters other than those stated in the instructions are used.

5 STORAGE AND STABILITY

The CH50 controls are stable until the expiration date on the vial label when stored at 2-8°C. Once reconstituted, the solution must be stored at 2-8°C or on ice and used within 10 hours. Discard any unused solution after this time.

6 METHODOLOGY

6.1 Materials provided

6.1.1 4 x *Human CH50 SPAPLUS low control* (lyophilised)
6.1.2 4 x *Human CH50 SPAPLUS high control* (lyophilised)
6.1.3 4 x *Human CH50 SPAPLUS elevated control* (lyophilised)

6.2 Additional materials required

6.2.1 Distilled water (stored at 2-8°C).
6.2.2 A fully operational and equipped SPAPLUS.
6.2.3 Current analyser operating instructions: SPAPLUS Reference guide, Insert Code FIN012.
6.2.4 NK095.S Human CH50 reagent pack for use on the SPAPLUS.
6.2.5 NC095.S Human CH50 calibrator set for use on the SPAPLUS.
6.2.6 Equipment for collection and preparation of test samples e.g. sample tubes, centrifuge etc.
6.2.7 Sample Diluent (99: Dil 1) Binding Site Product Code: SN080.S.

6.3 Reagent preparation

Reconstitution of the controls:

6.3.1 Remove the cap and stopper and gently tap down all lyophilised material to the bottom of the vial.
6.3.2 Immediately add the volume of cold (2-8°C) distilled water stated on the Quality Control Certificate (SIN194.QC) and vial label to the lyophilised material.
6.3.3 Replace the stopper securely.
6.3.4 Make sure that all the lyophilised material is covered with fluid and allow the vial to stand at room temperature for 5 minutes, gently shaking it occasionally.
6.3.5 When all the material has been reconstituted, turn the vial on its side and rotate it slowly in order to mix the contents thoroughly.
6.3.6 Invert the vial and allow the fluid to cover the stopper for 20-30 seconds with gentle shaking.
6.3.7 Return the vial to the upright position and remove the stopper to allow the liquid to drain down into the vial.
6.3.8 Replace the stopper and place the vial at 2-8°C for a further 20 minutes with occasional gentle shaking.

7 RESULTS

The controls should give results within the ranges quoted on the quality control certificate (SIN194.QC) in order to validate the assay.

8 LIMITATIONS

Should a control measurement be out of range when assayed with a stored curve, the measurement should be repeated. If the repeat is out of range the assay must be recalibrated. If on recalibration the control values measured with the new curve are still out of range, the instrument and the assay parameters should be checked before repeating the assay. If problems persist, refer to supplier.

US Distributor: The Binding Site Inc,5889 Oberlin Drive#101, San Diego, CA 92121. Tel: 800 633 4484.