HUMAN ANTI-TETANUS TOXOID IMMUNOGLOBULIN LIQUID REAGENT KIT for use on SPAPLUS

For In-Vitro Research Use Only
Product Code: LK710.S.U

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1 INTENDED USE

This kit is intended for the quantitative in vitro measurement of specific antibodies against Tetanus toxoid in heparinised or EDTA human plasma, using the Binding Site SPAPLUS turbidimetric analysers.

2 SUMMARY AND EXPLANATION

Anti-tetanus toxoid antibodies are raised in response to vaccination with Tetanus toxoid protein. A patient’s response to the immunization may be assessed, subsequently, by the serological determination of their anti-tetanus toxoid antibody levels using this quantitative turbidimetric method.

3 PRINCIPLE

The determination of soluble antigen concentration by turbidimetric methods involves the reaction with specific antiserum to form insoluble complexes. When light is passed through the suspension formed a portion of the light is transmitted and focused onto a photodiode by an optical lens system. The amount of transmitted light is indirectly proportional to the concentration of the antigen.

4 REAGENTS

4.1 Latex reagent to a-Tetanus toxoid immunoglobulin, Latex particles coated with inactivated Tetanus toxoid antigen. Supplied in stabilised liquid form. The reagent contains 0.033% sodium azide, 0.1% E-amino-n-caproic acid (EACA), 0.01% benzamidine and 0.05% ProClin™ as preservatives.

4.2 Calibrators and Controls. These consist of pooled human serum and are supplied in stabilised liquid form. They contain 0.099% sodium azide, 0.1% EACA and 0.01% benzamidine as conservatives. The assay is calibrated against the 1st International Standard for Tetanus Immunoglobulin TE-3, supplied by the National Institute for Biological Standards and Control (NIBSC; www.nibsc.ac.uk).

4.3 Supplementary Reagent (Dispersion Buffer). This contains 0.099% sodium azide as a preservative.

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4.5 Supplementary Reagent (Dispersion Buffer). This contains 0.099% sodium azide as a preservative.

5 CAUTION

All donors of human serum supplied in this kit have been serum 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 approved 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.

WARNING: This product contains sodium azide and ProClin 300 and must be used 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 with lead and copper plumbing; on disposal of reagent, 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 these instructions are used.

Reagents from different batch numbers of kits are NOT interchangeable. If large numbers of tests are performed care should be taken to ensure that all the reagents are from the same batch.

6 STORAGE AND STABILITY

The unopened kit should be stored at 2-8°C and can be used until the expiry date shown on the kit box label. DO NOT FREEZE. The latex reagent, calibrator, and control may be stored for up to three months after opening providing that they are capped to avoid evaporation and kept at 2-8°C in a refrigerator.

The Latex Reagent and Supplementary Reagent (Reaction Buffer) may be stored, uncapped, on the analyser for up to 30 days, provided that the main power switch (located at the rear of the left hand panel) is left switched on.

7 SPECIMEN COLLECTION AND PREPARATION

Use fresh or deep frozen plasma samples. Blood samples should be collected by venepuncture, into EDTA or heparin blood collection tubes. The plasma may be stored at 2-8°C for up to 14 days prior to assay, or for prolonged storage kept undiluted at -20°C or below. Repeated freezing and thawing should be avoided. Microbiologically contaminated, haemolysed and lipaemic plasma, and samples containing particulate matter should not be used.

8 METHODOLOGY

8.1 Materials Provided

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8.1.1 5 x 200 Tests Human Tetanus SPAPLUS toxoid Latex Reagent.

8.1.2 5 x 200 Tests Tetanus toxoid SPAPLUS Reaction Buffer.

8.1.3 1 x Human Tetanus toxoid SPAPLUS Calibrator Set 1-6 (6 x 1.0mL)

8.1.4 1 x 1.5mL Human Tetanus toxoid SPAPLUS Low Control

8.1.5 1 x 1.5mL Human Tetanus toxoid SPAPLUS Control

8.2 Materials required but not provided

8.2.1 Equipment for collection and preparation of test samples e.g. sample tubes, centrifuge etc.

8.2.2 A fully operational and equipped SPAPLUS analyser.

8.2.3 Sample Diluent, 99% Di PF Code: SN080.5

8.3 Reagent preparation

Before loading, gently mix by inversion ensuring no foam or bubbles are generated or remain on the surface as these may interfere with reagent aspiration.

8.4 Test procedure

The user should be familiar with the operation of the SPAPLUS analyser before attempting to carry out the test procedures. The analyser should be prepared for use according to the manufacturer’s instructions and the assay protocol entered as described below.

8.4.1 Programming parameters

8.4.1.1 Select Item from the main screen.

8.4.1.2 Select the correct item number (T.Tox = 13,) and click Edit to open page 1 of 4.

8.4.1.3 Enter the parameters as below.

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For reference use only.
8.4.4.2 Enter the position of the blank (sample diluent) and calibrators (standards) on page 1.

8.4.3.8 Repeat for the high control.

8.4.3.5 Enter the control sample name, e.g. TTxLow. Click Update to update the changes.

8.4.5.4 Click on Sample Dilution. Enter the mean value and SD from the lot specific data sheet into the boxes, e.g. B1 – 1, S1 - 1, S2 – 1 etc. Ensure the automatic sample dilution (1/10) will be entered in the sample diluent, which will register 200 µL of each calibrator into a sample cup and place in position B1 on the analyser.

8.4.3.6 Click on QC Range button. Double click on TTxLow from the item list. Enter the mean value and SD from the lot specific data sheet into the boxes. The boxes will automatically be entered in the sample diluent, which will register 200 µL of each calibrator into a sample cup and place in position B1 on the analyser.

8.4.5.5 Click on the assay Name. Fill a sample cup with sample diluent, and place in position B1 on the analyser. The analyser will automatically calculate and enter the correct measuring ranges on items pages 3 and 4 providing the ENTER button is pressed after typing for calibrator 6 on page 1. You may view Item parameter page 4 to ensure correct values entry.

8.4.1.4 Click Save once all parameters have been entered and updated.

8.4.2 Reagent loading and test registration

8.4.2.1 Place reagent bottles into an empty position on the reagent carousel. Note the bottle size (ml) and order. You may view Item parameter page 4 to ensure correct values entry.

8.4.2.4 The same should also be done for the sample diluent, which will register 200 µL of each calibrator into a sample cup and place in position B1 on the analyser. The analyser will automatically calculate and enter the correct measuring ranges on items pages 3 and 4 providing the ENTER button is pressed after typing for calibrator 6 on page 1. You may view Item parameter page 4 to ensure correct values entry.

8.4.3.1 If the controls are to be assayed from a sample rack, repeat the above but check by item in the run sequence section, is selected.

8.4.3.3 Ensure ‘Last’ is checked for the Calibration Tray in the control method section, so that the control will be measured after the measurement of the calibrator samples.

8.4.3.4 Click QC from the main screen, and then select the Control button. The control sample name, e.g. TTxLow, Click Save.

8.4.3.5 Enter the control sample name, e.g. TTxLow, Click Save.

8.4.3.6 Enter the control sample name, e.g. TTxLow, Click Save.

8.4.3.7 Double click on TTxLow from the item list. Enter the mean value and SD from the lot specific data sheet into the boxes. The boxes will automatically be entered in the sample diluent, which will register 200 µL of each calibrator into a sample cup and place in position B1 on the analyser. The analyser will automatically calculate and enter the correct measuring ranges on items pages 3 and 4 providing the ENTER button is pressed after typing for calibrator 6 on page 1. You may view Item parameter page 4 to ensure correct values entry.

8.4.3.8 Repeat for the high control.

8.4.4 Running calibration curves and controls

8.4.4.1 Request the calibration by clicking onto Calib from the main screen and ensure the CH ODR box is checked for the desired assay.

8.4.4.2 Enter the position of the blank (sample diluent) and calibrators (standards) in the calibrator rack into the boxes, e.g. B1 – 1, S1 – 1, S2 – 1 etc. Ensure the calibrator numbers run consecutively.

8.4.4.3 The calibrator and controls are supplied ready for use. Gently mix by inversion just prior to use.

8.4.4.4 Fill a sample cup with sample diluent, and place in position B1 on the analyser.

8.4.4.5 Transfer 150 µL of each calibrator into a sample cup and place them on the calibrator rack in ascending order (i.e. lowest concentration first), in the positions specified in step 8.4.4.2. Click Update to save changes.

8.4.4.6 Controls can be assayed at the same time as the calibration using the same rack. Select Order from the main screen. Enter the control sample number in the Control no. box (C1-C6). Confirm the Order Status box shows ‘Normal’. Select the required number from the drogbin, then confirm the test result is to be measured against. The standard sample dilution (1/10) will be automatically entered in the Dil box (10). As the concentrations of the controls are below the standard measuring range the dilution required must be changed by double clicking on the standard dilution figure (10) to display the redilution options and selecting the empty space above 10 to select neat measurements for both controls. Click on the empty space above 10 to select neat measurement for both controls.

8.4.4.7 To measure the controls, select Control from the main screen and click OK to accept automatically measurement of the control(s).

8.4.4.8 Ensure the controls are in the correct position on the calibrator rack (i.e. C1-C6).

8.4.4.9 If the controls are to be assayed from a sample rack, repeat the above but using the control positions for that rack, i.e. C7 – C12 on rack 1, C13 – C18 on rack 2 etc. Transfer 150 µL of control into a sample cup and place on the rack.

8.4.5 Running patient samples

8.4.5.1 Place the sample on the sample rack in an empty position. Cups or primary tubes may be used.

8.4.5.2 From the Main Menu, click Order.

8.4.5.3 Click on Position No., enter the sample carousel position number for the sample and press enter.

8.4.5.4 Click on Patient ID and enter an appropriate ID (name or sample number). Other patient information, e.g. Name, Sex, Age, DOB may be entered as desired according to each laboratories working practice.

8.4.5.5 Click on the assay Name to select the assay name.

8.4.5.6 The standard sample dilution (10) will automatically be entered in the Dil box.

8.4.5.7 Click on Order to complete the sample request.

8.4.6 Measuring range

8.4.6.1 Place reagent bottles into an empty position on the reagent carousel. Note the bottle size (ml) and order. You may view Item parameter page 4 to ensure correct values entry.