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Wellcogen™ Bacterial Antigen Kit

REF ZL26/R30859602 .....30 Tests **EN**

1 INTENDED USE

The Wellcogen™ Bacterial Antigen Kit provides a series of rapid latex tests for use in the qualitative detection of antigen from Streptococcus group B, Haemophilus influenzae type b, Streptococcus pneumoniae (pneumococcus), Neisseria meningitidis (meningococcus) groups A, B, C, Y or W135 and Escherichia coli K1 present in cerebrospinal fluid (CSF) as a consequence of infection. The kit can also be used to test other body fluids or blood culture supernatants for most of these antigens and plate cultures for N. meningitidis group B or Escherichia coli K1. (See Table 1 for indications supported by clinical data).

NOTE: Tests performed directly on clinical specimens are intended for screening purposes and should augment, not replace, culture procedures. Results must be used in conjunction with other data; e.g. symptoms, results of other tests, clinical impressions etc.

2 SUMMARY

Meningitis has a wide variety of potential causes, either infectious or non-infectious. If bacterial meningitis is not treated promptly and effectively, the disease is likely to be fatal. Early identification of the infecting agent can be of considerable value in providing the patient with appropriate and adequate chemotherapy. Many bacterial species have been implicated in meningitis. Streptococcus group B and E. coli K1 are two of the most common causes of neonatal sepsis whilst in older age groups the commonest isolates are H. influenzae type b, S. pneumoniae and N. meningitidis groups A, B, C, Y and W135. These organisms carry specific polysaccharide surface antigens, a quantity of which diffuses into culture media or body fluids such as CSF or serum, and is excreted in the urine. The antigens can be detected by sensitive immunological methods such as counterimmuno-electrophoresis and latex agglutination[2,5,6,10].

3 PRINCIPLE OF THE TEST

The Wellcogen™ reagents consist of polystyrene latex particles which have been coated with antibodies to the bacterial antigens. These latex particles agglutinate in the presence of sufficient homologous antigen. The Streptococcus and H. influenzae reagents are group B and type b specific respectively, the S. pneumoniae reagent is sensitised with antibodies purified from an omnivalent serum and the N. meningitidis polyvalent reagent reacts with groups A, C, Y and W135 antigens. Meningococcus group B antigen is more difficult to detect[6] as well as being structurally and immunologically related to E. coli K1 antigen[7]; both of these react with the N. meningitidis group B reagent.

4 SYMBOL DEFINITIONS

REF	Catalogue Number
IVD	In Vitro Diagnostic Medical Device
Σ	Contains sufficient for <n> tests
	Consult Instructions for Use
2°C 8°C	Temperature Limitation
LOT	Batch Code
	Use By
	Manufacturer
	Add water

5 KIT CONTENTS, PREPARATION FOR USE AND STORAGE

The Wellcogen™ Bacterial Antigen Kit includes sufficient reagents to perform Σ 30 tests.

See also **Precautions,** section **6**.

All components should be stored at 2 to 8°C under which condition they will retain their activity until the expiry date of the kit.

Before use, bring all reagents to room temperature (18 - 30°C) and mix. Return the unused reagents to the refrigerator after use.

Instructions for Use

Disposable Reaction Cards (2 packs)
Disposable Mixing Sticks (5 bundles)
Disposable Droppers (1 container)
Black rubber teat (1)

TEST LATEX

Test Latexes

Strep B (pink cap)
H. influenzae b (pale blue cap)
S. pneumoniae (yellow cap)
N. meningitidis ACY W135 (grey cap)
N. meningitidis B/E. coli K1 (brown cap)

Five dropper bottles, one specific for each of the groups above, containing 0.5% suspensions of polystyrene latex particles in buffer containing 0.05% Bronidox® and/or 0.1% sodium azide as preservative. The latex particles are coated with the appropriate rabbit antibody, as labelled, except for the N. meningitidis group B/E. coli K1 reagent, which is coated with murine monoclonal antibody.

CONTROL LATEX

Control Latexes

5 dropper bottles (dark blue cap) containing 0.5% suspensions of polystyrene latex particles in buffer containing 0.05% Bronidox® and/or 0.1% sodium azide as preservative. The latex particles are coated with an appropriate preparation of rabbit globulin or in the case of the N. meningitidis group B/E. coli K1 latex, a murine monoclonal antibody raised against Bordetella bronchiseptica.

The latex suspensions are provided ready for use and should be stored at 2 to 8°C in an upright position, until the expiry date of the kit. After prolonged storage some aggregation or drying of the latex may have occurred around the top of the bottle. Under these circumstances the bottle of latex should be shaken vigorously for a few seconds until resuspension is complete. DO NOT FREEZE.

CONTROL +

Polyvalent Positive Control

Two bottles (blue cap) containing freeze-dried bacterial extracts containing antigens from representative strains of each bacterial species for which latex is provided. Contains 0.01% bronopol before reconstitution and 0.004% when reconstituted.

Reconstitute using 3.6 ml of sterile distilled water. After the addition of water allow the bottle to stand for a few minutes and then swirl to mix. Store reconstituted antigen at 2 to 8°C for up to 6 months.

CONTROL −

Negative Control

One dropper bottle (white cap) containing Glycine saline buffer, pH 8.2, with 0.05% Bronidox® as preservative.

6 PRECAUTIONS

IVD

The reagents are for in vitro diagnostic use only.

For professional use only.

Please refer to the Safety Data Sheet (SDS) and product labelling for information on potentially hazardous components.

HEALTH AND SAFETY INFORMATION

6.1 The Test and Control Latexes for Streptococcus group B, H. influenzae type b, S. pneumoniae and N. meningitidis ACY W135 contain 0.1% sodium azide. Azides can react with copper and lead used in some plumbing systems to form explosive salts. The quantities used in this kit are small; nevertheless when disposing of azide-containing materials they should be flushed away with large volumes of water.

6.2 In accordance with the principles of Good Laboratory Practice it is strongly recommended that body fluids should be treated as potentially infectious and handled with all necessary precautions.

6.3 When handling radiometric blood culture medium, the basic rules of radiation safety should be followed. These include:

a) Radioactive material should be stored in a designated area in an approved container.
b) Handling of radioactivity should take place in a designated area.
c) No mouth pipetting of radioactive material should be carried out.
d) No eating, drinking or smoking should take place in the designated area.
e) Hands should be washed thoroughly after using radioactive material.
f) The local Radiation Safety Officer should be consulted concerning disposal requirements.

6.4 Non-disposable apparatus should be sterilised by any appropriate procedure after use, although the preferred method is to autoclave for 15 minutes at 121°C. Disposables should be autoclaved or incinerated. Spillage of potentially infectious materials should be removed immediately with absorbent paper tissue and the contaminated areas swabbed with a standard bacterial disinfectant or 70% alcohol. Do NOT use sodium hypochlorite. Materials used to clean spills, including gloves, should be disposed of as biohazardous waste.

6.5 Do not pipette by mouth. Wear disposable gloves and eye protection while handling specimens and performing the assay. Wash hands thoroughly when finished.

6.6 When used in accordance with the principles of Good Laboratory Practice, good standards of occupational hygiene and the instructions stated in these Instructions for Use, the reagents supplied are not considered to present a hazard to health.

ANALYTICAL PRECAUTIONS

6.7 Do not use the reagents beyond the stated expiry date.

6.8 Latex reagents should be brought to room temperature (18 to 30°C) before use. Latex reagents which show signs of aggregation or 'lumpiness' before use may have been frozen and must not be used.

6.9 It is important when using dropper bottles that they are held vertically and that the drop forms at the tip of the nozzle. If the nozzle becomes wet an incorrect volume will form around the end and not at the tip; if this occurs dry the nozzle before progressing.

6.10 The reagents provided with each kit are matched in performance and should not be used in conjunction with reagents from a kit having a different lot number.

6.11 Do not touch the reaction areas on the cards.

6.12 Mechanical rotators may be used in this assay. The following characteristics have been found to be satisfactory:

i) Orbital rotators (also known as dimensional rotators) operating at 25 rpm with approximate rotating angle of 9 to 10.5 degrees or operating at 18 rpm with a rotating angle of 16 to 17.5 degrees.

6.13 Avoid microbial contamination of reagents as this may lead to erroneous results.

7 SPECIMEN COLLECTION AND STORAGE

7.1 **Body fluid samples** (e.g. CSF, serum, urine) should be tested as soon after collection as possible. If the fluid cannot be tested immediately it may be stored overnight at 2 to 8°C, or for longer periods frozen at –15 to –25°C. If bacteriological analyses are required on the sample, these should be set up prior to performing the latex test, to avoid contaminating the sample.

7.2 **Blood cultures** may be sampled and tested after 18 to 24 hours incubation at 37°C and/or as soon as bacterial growth is observed.

7.3 **Plate cultures** (N. meningitidis B/E. coli K1 only). Isolated colonies growing on enriched agar medium (e.g. blood, chocolate agar) may be tested after overnight incubation at 37°C. A Gram stain should be performed to assist with the interpretation of the latex test result.

8 TEST PROCEDURE

REQUIRED MATERIALS PROVIDED

See **Kit Contents**, section **5**.

MATERIALS REQUIRED BUT NOT PROVIDED

Boiling water bath
Laboratory centrifuge or membrane filters (0.45 µm)
Rotator (optional – refer to **Precautions**, section **6**)

PREPARATION OF CLINICAL SPECIMENS

8.1 **Body fluid samples** must be heated before testing by the Wellcogen™ procedure to minimise non-specific reactions[4,6]. The following procedures are recommended:

a) For CSF and urine, heat the sample for 5 minutes in a boiling water bath. Cool the sample to room temperature (18 to 30°C) and clarify by centrifugation or membrane filtration (0.45 µm) prior to testing. For maximum sensitivity urine samples may be concentrated up to 25-fold in a Minicon® B-15 concentrator. Clarify as above before testing.
b) For serum, add 3 volumes 0.1 M disodium ethylenediaminetetra-acetate (EDTA) pH 7.4 per 1 volume serum, heat the sample for 5 minutes in a boiling water bath, cool to room temperature (18 to 30°C) and clarify as above. A suitable EDTA solution (10 ml) is available (Code No. ZL29/R30164501).

8.2 **Blood cultures.** Centrifuge a 1 to 2 ml sample to pellet the red blood cells, for example at 1000 g for 5 to 10 minutes. Perform the latex test on the supernatant.

If a non-specific reaction occurs with a blood culture supernatant (see **Interpretation of Results**, section **10**), heat the sample in a boiling water bath for 5 minutes, cool to room temperature (18 to 30°C), clarify by centrifugation and repeat the test.

8.3 **Plate cultures** (N. meningitidis B/E. coli K1 only). Test directly from the culture plate.

PROCEDURE

It is recommended that the section on **Precautions**, section **6**, is read carefully before performing the test.

Body fluid samples and Blood culture supernatants:

NOTE: If there is only a limited volume of test sample available, it should be used with the Test Latexes first and if a positive result is obtained the sample should be tested with the appropriate Control Latex. If sufficient sample is available, it should be tested against both the Test and Control Latexes simultaneously.

Step 1	Process the sample as described under **Preparation of Clinical Specimens**.	
Step 2	Shake the latex reagents.	
Step 3	Place 1 drop of each **Test Latex** or **Control Latex** into a separate circle on a Reaction Card. Ensure that the dropper bottles are held vertically to dispense an accurate drop. (See **Precautions**, section **6**).	**1 drop**
Step 4	Using a Disposable Dropper, dispense 1 drop (approximately 40 µl) of **Test Sample** next to each drop of latex.	**1 drop**
Step 5	**Mix** the contents of each circle with a Mixing Stick and spread to cover the complete area of the circle. Use a separate stick for each circle and discard it for safe disposal after use.	
Step 6	**Rock** the card slowly and **observe** for agglutination for 3 minutes, holding the card at normal reading distance (25 to 35 cm) from the eyes. Do not use a magnifying lens. Mechanical rotation (3 minutes) may be used (See **Precautions**, section **6**). The patterns obtained are clear cut and can be recognised under all normal lighting conditions.	**3 mins**
Step 7	Discard the used Reaction Card for safe disposal.	

Plate Cultures:

(Wellcogen™ N. meningitidis B/E. coli K1 only):

Step 1	Shake the latex reagents.	
Step 2	For each culture to be tested place 1 drop of **Test Latex** in one circle on a Reaction Card and 1 drop of **Control Latex** in a separate circle. NOTE: it is essential to use the **Control Latex** for suspected E. coli cultures.	**1 drop**
Step 3	Take a Mixing Stick and pick up some of the culture by touching it with the flat end of the stick. As a guide, an amount of growth roughly equivalent to 1 large colony should be picked.	**Sample of growth**
Step 4	**Emulsify** the sample of culture in the drop of **Test Latex** by rubbing with the flat end of the stick. Rub thoroughly, but not so vigorously as to damage the surface of the card. Spread the latex to cover as much of the circle as possible. Discard the Mixing Stick for safe disposal.	
Step 5	Using a separate stick, **emulsify** a similar sample of culture in the **Control Latex**.	
Step 6	**Rock** the card slowly and **observe** for agglutination for 20 seconds holding the card at normal reading distance (25 to 35 cm) from the eyes. Do not use a magnifying lens. The patterns obtained are clear cut and can be easily recognised under all normal lighting conditions.	**20 secs**
Step 7	Discard the used Reaction Card for safe disposal.	

9 QUALITY CONTROL

The following procedures should be carried out initially with each shipment of test kits and with each run of test samples. In practice, a run may be defined as a testing period of up to 24 hours. Any departure from the expected results indicates there may be a problem with the reagents, which must be resolved before further use with clinical samples.

VISUAL INSPECTION

The latex suspensions should always be inspected for aggregation as they are dropped onto the test card and if there is evidence of clumping before addition of the test sample, the suspension must not be used. After prolonged storage some aggregation or drying may have occurred around the top of the bottle. If this is observed, the bottle should be shaken vigorously for a few seconds until resuspension is complete.

POSITIVE CONTROL PROCEDURE

The reactivity of the test can be confirmed by adding Polyvalent Positive Control to a reaction circle in which the test sample has not agglutinated the Test Latex after 3 minutes rotation.

Step 1	Use a Disposable Dropper to add 1 drop of Positive Control to the circle containing Test Latex and specimen.	**1 drop**
Step 2	Mix using a Mixing Stick and discard it for safe disposal.	
Step 3	Rock the card manually or by a rotator for a further 3 minutes. After this time, definite agglutination should be visible in the Test Latex.	**3 mins**
Step 4	Discard the used Reaction Card for safe disposal.	

NEGATIVE CONTROL PROCEDURE

If at least one test sample within a run gives a negative result with Test and Control Latexes (or Test Latex only where no Control Latex has been used), this constitutes a valid negative control for the reagents and no further testing is necessary.

If a test sample gives agglutination with the Test Latex and no agglutination with the Control Latex then the Test Latex should be tested either with the Negative Control or uninoculated blood culture medium, as appropriate (see below).

Step 1	Place one drop of Test Latex in one circle on a Reaction Card.	**1 drop**
Step 2	Dispense one drop of Negative Control or uninoculated blood culture medium next to the Test Latex.	**1 drop**
Step 3	Mix using a Mixing Stick and discard it for safe disposal.	
Step 4	Rock the card manually or by a rotator for a further 3 minutes. After this time, there should be no significant agglutination in the Test Latex.	**3 mins**
Step 5	Discard the used Reaction Card for safe disposal.	

For tests with body fluid samples, the Negative Control provided with the kit should be used.

For tests with blood cultures a sample of uninoculated blood culture medium from the same source as the specimen should be used as a negative control. Note: testing uninoculated media is important as false-positives can occur with some formulations of blood culture media.

Notes:

a) Previously assayed positive and negative samples, aliquoted and stored at –15 to –25°C or below, may be used as positive and negative controls respectively, if desired. The Positive Control can also be used in place of the test sample.

b) For colony identification tests (Wellcogen™ N. meningitidis B/E. coli K1 only), the performance of the Test and Control Latex reagents may be confirmed using fresh, overnight cultures of reference strains of bacteria, following the method described in **Test Procedure**. Suitable reference strains are:
ATCC 13090 – N. meningitidis group B (positive reactivity)
ATCC 23503 – E. coli type K1 (positive reactivity)
ATCC 13077 – N. meningitidis group A (negative reactivity)
ATCC 13090 and ATCC 23503 should give agglutination with the Test Latex and no significant agglutination in the Control Latex, ATCC 13077 should give no significant agglutination with either the Test or Control Latex.

10 RESULTS

READING OF RESULTS

A **positive** reaction is indicated by the development of an agglutinated pattern within 3 minutes (20 seconds for colony testing) of mixing the latex with the test sample, showing clearly visible clumping of the latex particles (Figure 1).

The speed of appearance and quality of agglutination depend on the strength of the antigen, varying from large clumps which appear within a few seconds of mixing, to small clumps which develop rather slowly. In culture identification, most positive reactions will be almost instantaneous.

In a **negative** reaction the latex does not agglutinate and the milky appearance remains substantially unchanged throughout the test (Figure 2). Note, however, that faint traces of granularity may be detected in negative patterns, depending on the visual acuity of the operator. In culture identification, some strains may cause a "stringy" aggregation of the latex with a milky background; this should be interpreted as a negative reaction.

NOTE: The latex particles used in the Wellcogen™ N. meningitidis B/E. coli K1 Test and Control Latex suspensions are not the same as those used for the other reagents, and give a finer agglutination.

Figure 1

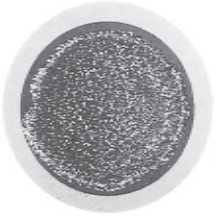

Figure 2

INTERPRETATION OF RESULTS

Positive Result

Clear agglutination of a single Test Latex accompanied by negative reactions with all other Test Latex reagents and the Control Latex indicates the presence and identity of a bacterial antigen in the test sample. As a general rule a positive result with Wellcogen™ N. meningitidis B/E. coli K1 against a neonatal specimen suggests E. coli K1 infection; with older patients, meningococcus group B is more likely.

Negative Result

Negative reactions with all the Test Latex reagents indicates the absence of a detectable level of the bacterial antigens in the test fluid – it does not eliminate the possibility of an infection caused by these organisms, and if symptoms persist it may be desirable to perform the test on subsequent or alternative specimens, or after concentration of the urine specimen.

With a culture, lack of agglutination in Wellcogen™ N. meningitidis B/E. coli K1 reagents indicates that it is unlikely to be N. meningitidis group B or E. coli K1.

Non-interpretable Result

Agglutination of more than one Test Latex reagent or corresponding Test and Control Latexes indicates a non-specific reaction. In most cases, non-specific reactions with body fluids may be eliminated by heating and clarifying the sample[4] (see **Preparation of Clinical Specimens**, section **8**). If a non-specific reaction occurs with a blood culture supernatant, heat the sample in a boiling water bath for 5 minutes, cool to room temperature (18 to 30°C), clarify by centrifugation and repeat the test.

11 PERFORMANCE LIMITATIONS

11.1 **For infant body fluids** (Group B strep only) – False negative test results may occur with specimens containing levels of antigen below the limits of detection of this device. Negative results should be followed up with selective broth culture. A positive result indicates the presence of Group B streptococcal antigen; the result does not necessarily indicate the presence of viable organisms.

11.2 **For infant body fluids** (Group B strep only) – Use of this device should not substitute for microbiological culture. Performance of this device for predicting Group B streptococcal disease from tests of infant urine has not been established.

11.3 Group B streptococcus infections occur primarily in neonates. Positive results obtained with body fluid samples from patients older than six months should be interpreted with caution. Positive results obtained with blood culture supernatants from patients of any age may be significant.

11.4 A positive result in the test depends on the presence of a detectable level of antigen in the body fluid or blood culture medium.

11.5 Limited clinical data are available for the detection of antigen in urine or serum using Wellcogen™ N. meningitidis B/E. coli K1 (Table 6). No clinical data is available for the detection of antigen in urine using Wellcogen™ N. meningitidis ACY W135 (Table 5). However, antigen has been reported in urine ACY W135 samples[5].

11.6 A few examples have been reported of unrelated bacteria which possess common antigens and, as with any immunological test system, the possibility of cross reactions occurring in the latex test can not be ruled out[1,3,8,9].

12 EXPECTED RESULTS

Samples containing a detectable level of group B streptococcal antigen, H. influenzae type b antigen, S. pneumoniae capsular antigen, N. meningitidis A, C, Y, W135 antigens, or N. meningitidis B / E. coli K1 antigen will give an agglutination reaction with the appropriate Test Latex.

13 PERFORMANCE CHARACTERISTICS

13.1 **Body Fluids and Blood Cultures**

Clinical studies were carried out in 15 centres using body fluid samples (fresh and stored frozen) and blood culture supernatants. Both traditional and radiometric cultural techniques were used in the blood culture studies. Stored body fluid samples were not heat treated as described under **Preparation of Clinical Specimens**, section **8**. Extensive laboratory testing has shown no significant loss of antigen after heating by this procedure.

Sensitivity

The sensitivity of each latex in the kit was established from tests on samples culture positive for the homologous organism or for which there was other evidence of infection (clinical diagnosis plus other antigen test positive).

Tables 2 to 6 show the numbers of each type of specimen tested with the individual latexes together with the number of positive results obtained. The sensitivity of each latex in detecting bacterial antigen in CSF was 67% (12/18) for Wellcogen™ Strep B, 97% (87/90) for Wellcogen™ H. influenzae b, 88% (45/51) for Wellcogen™ S. pneumoniae, 71% (29/41) for Wellcogen™ N. meningitidis ACY W135 and 65% (11/17) for Wellcogen™ N. meningitidis B/E. coli K1.

Specificity

The specificity of each of the Wellcogen™ reagents was evaluated using body fluid (fresh and frozen) and blood culture samples from patients with bacterial or aseptic meningitis and other unrelated conditions.

The organisms isolated from the infected samples were H. influenzae b, S. pneumoniae, N. meningitidis including groups A, B, C, Y, E. coli, Staphylococcus aureus, Enterobacter aerogenes, Klebsiella pneumoniae, Mycobacterium tuberculosis, Proteus mirabilis, Staphylococcus epidermidis, alpha-haemolytic streptococcus, beta-haemolytic streptococcus group A, Klebsiella oxytoca, Pseudomonas, Streptococcus sanguis, Toxoplasma gondii and a coliform bacterium.

The specificity of all five Wellcogen™ latexes in tests on CSF was greater than 98%. Details of the number of samples tested and the specificity of each Wellcogen™ with each type of specimen are given in tables 2 to 6.

13.2 **Plate Cultures** (N. meningitidis B/E. coli K1).

N. meningitidis and E. coli cultures grown on an enriched agar medium were tested in hospital laboratories and In-house. All N. meningitidis group B and E. coli K1 cultures were correctly identified. There were no cross-reactions with other groups of N. meningitidis or other E. coli K antigens (Table 7). A high proportion of the E. coli cultures with other K antigens which were tested gave non-specific reactions (Table 7).

Table 1

Specimens which have been evaluated with individual Wellcogen™ latex reagents

Specimen	Wellcogen™				
	Strep. B	H. influenzae b	S. pneumoniae	N. meningitidis ACY W135	N. meningitidis B/ E. coli K1
CSF	+	+	+	+	+
Serum	+	+	+	+	+*
Urine	+	+	+	+*	+*
Blood Culture	+	+	+	+	+
Bacterial colonies	–	–	–	–	+

Key

\+ Data available to support this application.

\+* Limited data available.

– No data available.

Table 2

Results of clinical studies on Wellcogen™ Strep B

Sample	Sensitivity[a]		Specificity[b]	
	No. tested	No. positive	No. tested	No. positive
CSF	18	12	58	1[c]
Serum	19	13	7	0
Urine	20	17	22	1[d]
Blood Culture	9	9	369	4[e]

[a] beta-haemolytic streptococcus group B isolated/indicated (clinical diagnosis/ other antigen test).

[b] Bacteria other than Strep. B/no growth.

[c] E. coli isolated.

[d] P. mirabilis isolated.

[e] Staph. epidermidis; beta-haemolytic strep. group A; E. coli + Enterococcus; Staph. epidermidis + Enterococcus isolated.

Table 3

Results of clinical studies on Wellcogen™ H. influenzae b

Sample	Sensitivity		Specificity	
	No. tested	No. positive	No. tested	No. positive
CSF	90	87	375[a]	2[b]
Serum	21	20	21	0
Urine	10	10	236	0
Blood Culture	54	54	1566[c]	5[d]

[a] One additional CSF sample gave a non-specific reaction.

[b] One sample aseptic; E. coli isolated from other sample.

[c] Two additional blood culture supernatants gave non-specific reactions.

[d] One sample aseptic. Other samples grew: Staph. aureus; E. coli + Staph. epidermidis; K. oxytoca; alpha-haemolytic streptococcus.

Table 4

Results of clinical studies on Wellcogen™ S. pneumoniae

	Sensitivity		Specificity	
Sample	No. tested	No. positive	No. tested	No. positive
CSF	51	45	483[a]	2[b]
Serum	6	6	13	0
Urine	105	46	320[c]	0
Blood Culture	113	109	1512	7[d]

[a] One additional CSF gave a non-specific reaction.
[b] Enterobacter aerogenes; coliform bacterium.
[c] Three additional urine samples gave non-specific reactions.
[d] Pseudomonas; Strep. sanguis; Staph. epidermidis + Enterococcus; Strep. viridans isolated from 4 samples.

Table 5

Results of clinical studies on Wellcogen™ N. meningitidis ACY W135

	Sensitivity		Specificity	
Sample	No. tested	No. positive	No. tested	No. positive
CSF	41[a]	29	423	2[b]
Serum	5	3	36	0
Urine	0	–	229[c]	0
Blood Culture	7	7	1615	2[d]

[a] Includes 8 group A, 25 group C and 1 group Y (the remainder were not grouped).
[b] K. aerogenes; E. coli.
[c] Five additional urine samples gave non-specific reactions.
[d] Strep. sanguis; Staph. epidermidis + Enterococcus.

Table 6

Results of clinical studies on Wellcogen™ N. meningitidis B/E. coli K1

	Sensitivity		Specificity	
Sample	No. tested	No. positive	No. tested	No. positive
CSF				
N. meningitidis B	11	7	128	0
E. coli K1[a]	6	4	128	0
Serum:				
N. meningitidis B	2	1	3	0
Urine:				
N. meningitidis B	2	1	7	0
Blood Culture:				
N. meningitidis B	7	5	461	3[b]

[a] Samples stored frozen. All other samples tested fresh.
[b] Aerobic and anaerobic cultures (beta-haemolytic strep A) for same patient; coagulase negative staphylococcus.

Table 7

Identification of cultures using Wellcogen™ N. meningitidis B/E. coli K1

Culture[a]	+	–
N. meningitidis group A	0	16
N. meningitidis group B	10	0
N. meningitidis group C	0	18
N. meningitidis group 29E	0	8
N. meningitidis group W135	0	7
N. meningitidis group X	0	4
N. meningitidis group Y	0	5
N. meningitidis group Z	0	3
E. coli K1	7	0
E. coli – other antigens	0	13[b]

[a] Cultures identified by slide agglutination.
[b] An additional 10 cultures gave non-specific reactions.

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