


STANTON TERRITORIAL HEALTH AUTHORITY

Yellowknife, Northwest Territories

TITLE: Wellcogen™ (Bacterial Antigen Kit)	Revision Date: 20-April-2018	Issue Date: 20-April-2016
Document Number: MIC51930	Status: Approved	
Distribution: Microbiology Test Manual	Page: 1 of 6	
Approved by: S. Asmussen, Manager of Diagnostic Services	Signed by: 	

PURPOSE:

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*; *Neisseria meningitidis* group A, B, C, Y or W135, and *Escherichia coli* K1 present in positive blood culture supernatants.

Streptococcus group B and *Escherichia coli* are the two most common agents of neonatal sepsis. In older age groups, the more common isolates are *Haemophilus influenzae*, *Streptococcus pneumoniae* and *Neisseria meningitidis* group A, B, C, Y or W135. These organisms carry specific polysaccharide surface antigens.

PRINCIPLE:

The Wellcogen™ reagents consist of latex particles which have been coated with antibodies to the bacterial antigens. These latex particles will agglutinate in the presence of sufficient homologous antigen. *Neisseria meningitidis* group B is more difficult to detect as well as being structurally and immunologically related to *Escherichia coli* K1 antigen; both of these react in the *Neisseria meningitidis* group B reagent.

SAMPLE INFORMATION:

Type	Blood culture, supernatant
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REAGENTS and/or MEDIA:

- Remel Wellcogen™ Bacterial Antigen CAT#R30859602, store at 2-8°C

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SUPPLIES:

The following are supplied with the kit:

- Disposable Reaction cards
- Disposable Mixing Sticks
- Disposable droppers
- Black rubber suction apparatus
- Test and control latexes for:
 - Streptococcus group B
 - *H. influenzae* type B
 - *S.pneumoniae*
 - *N. meningitidis* group A,C,Y,W135
 - *N. meningitidis* group B/*E.coli* K1

SPECIAL SAFETY PRECAUTIONS:

Containment Level 2 facilities, equipment, and operational practices for work involving infectious or potentially infectious materials or cultures.

- Lab gown must be worn when performing activities with potential pathogens.
- Gloves must be worn when direct skin contact with infected materials is unavoidable.
- Eye protection must be used where there is a known or potential risk of exposure to splashes.
- All Wellcogen testing shall be conducted in a biological safety cabinet (BSC).
- The use of needles, syringes, and other sharp objects should be strictly limited.

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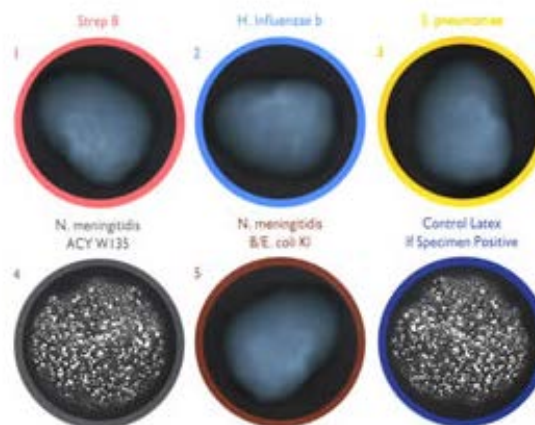
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PROCEDURE INSTRUCTIONS:

All testing is to be performed inside the Biological Safety Cabinet

Step	Action
Wellcogen™ Bacterial Antigen testing	
1	Aliquot 2mLs of a positive blood culture into a glass test tube and parafilm.
2	Using the centrifuge in blood bank, centrifuge for 5 mins at 1000g.
3	Perform testing on the supernatant if the Gram stain from the Positive blood culture is suspicious for any of the above organisms.
4	Allow latex reagents to come to room temperature and mix – latex reagents exhibiting lumpiness prior to use may have been frozen and must be discarded.
5	Place 1 drop of each Test Latex and Control latex into a separate circle on the Reaction card. Ensure droppers are vertical when dispensing drops.
6	Using a disposable dropper, dispense one drop of Test Sample next to each drop of latex.
7	Mix the contents of each circle with a Mixing Stick and spread to cover over the entire circle. Use a separate stick for each circle and discard in the Accel TB discard bucket.
8	Rock the card slowly for 3 minutes and observe for agglutination. DO NOT USE A MAGNIFYING LAMP.
9	Discard the Reaction card in the Accel TB bucket.

Examples of Reactions:



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INTERPRETATION OF RESULTS:

Action	
IF	THEN
Agglutination is observed in the TEST Latex No agglutination in the Control Latex	Positive for the specific antigen – Perform Negative Control Procedure (see below)
No agglutination in Test Latex No agglutination in Control Latex	Negative for specific antigen – Perform Positive Control Procedure (see below)
Agglutination in Test Latex Agglutination in Control Latex	Test is invalid and cannot be reported

QUALITY CONTROL:

Step	Action
Performing a Positive Control - Confirm reactivity of the test sample if no agglutination is observed using the Polyvalent Positive Control	
1	Add one drop of the Positive Control to the circle containing test latex and specimen.
2	Mix using the mixing stick and discard in the Accel TB disinfectant bucket in the BSC.
3	Rock the card manually for 3 minutes – observe for agglutination.
4	Discard the Reaction Card.

Step	Action
Performing a Negative Control - If a test sample gives agglutination with the Test Latex and no agglutination with the Control Latex then the Test Latex should be tested with the Negative Control. If no agglutination is observed in both Test Latex and Control Latex – this constitutes a Negative Control procedure and no further Quality Control testing is necessary.	
1	Add one drop of Test Latex in one circle on the reaction card.
2	Dispense one drop of Negative Control next to the Test Latex – mix using the mixing stick.
3	Rock the card manually for 3 minutes – no agglutination should be visible.
4	Discard Reaction Card.

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COMPUTER STEPS:

Action	
IF	THEN
Positive for : Streptococcus group B	In Result Entry, Add Test AGSGB – using keypad select POSITIVE and Finalize Add Media ^WELLC and using keypad select Positive for AGSGB (workload units)
Positive for: <i>H. influenzae</i> type B	In Result Entry, Add Test AGHIB – using keypad select POSITIVE and Finalize Add Media ^WELLC and using keypad select Positive for AGHIB (workload units)
Positive for: <i>S.pneumoniae</i>	In Result Entry, Add Test AGSPN – using keypad select POSITIVE and Finalize Add Media ^WELLC and using keypad select Positive for AGSPN (workload units)
Positive for: <i>N. meningitidis</i> group A,C,Y,W135	In Result Entry, Add Test AGNMA – using keypad select POSITIVE and Finalize Add Media ^WELLC and using keypad select Positive for AGNMA (workload units)
Positive for: <i>N. meningitidis</i> group <i>B/E.coli K1</i>	In Result Entry, Add Test AGNMB – using keypad select POSITIVE and Finalize Add Media ^WELLC and using keypad select Positive for AGNMB (workload units)
Negative for : Streptococcus group B	In Result Entry, Add Media ^WELLC and using keypad select Negative for AGSGB
Negative for : <i>H. influenzae</i> type B	In Result Entry, Add Media ^WELLC and using keypad select Negative for AGHIB
Negative for : <i>S.pneumoniae</i>	In Result Entry, Add Media ^WELLC and using keypad select Negative for AGSPN
Negative for : <i>N. meningitidis</i> group A,C,Y,W135	In Result Entry, Add Media ^WELLC and using keypad select Negative for AGNMA
Negative for : <i>N. meningitidis</i> group <i>B/E.coli K1</i>	In Result Entry, Add Media ^WELLC and using keypad select Negative for AGNMB

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REFERENCES:

- Remel. (2011, May 03). Wellcogen Bacterial Antigen Kit.

REVISION HISTORY:

REVISION	DATE	Description of Change	REQUESTED BY
1.0	31AUG11	Initial Release	A. Darrach ML. Dufresne
1.1	31-Jul-13	Addition of Computer Steps and Illustration	A. Darrach
1.2	30-Apr-14	Discontinued procedure MTE11930 and moved to MIC51930	L. Driedger
2.0	31Mar16	Update of "Special Safety Precautions" to reflect risk assessment recommendations.	C. Russell

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