

GonoGen II

Code CK7240

an immunoassay for the confirmation of *Neisseria gonorrhoeae* from culture.

Outline

Gonogen II is a monoclonal antibody based test for the confirmatory identification of *Neisseria gonorrhoeae* from cultures. The test does not require instrumentation and is complete in under ten minutes.

Principle

Gonogen II employs a pool of murine monoclonal antibodies prepared against purified outer membrane protein (OMP or Protein 1) of *Neisseria gonorrhoeae*. OMP is a major protein molecule that is exposed on the surface of the organism and its epitopes are largely responsible for serotype variation. The monoclonal antibodies are adsorbed onto suspended metal-sol particles, this forms the test reagent.

When the culture is emulsified in the solubilising buffer, the outer membrane of the organism is stripped off releasing the OMP containing complexes into solution. These released OMP complexes are then captured by the antibody/metal-sol particles. The sample/reagent mixture is then filtered through the special matrix test device; the OMP-antibody/metal-sol complexes are held back by the matrix, resulting in a red spot. Antibody/metal-sol particles that have not bound OMP will pass through the matrix giving a negative result (white to pale pink ring).

General Background

Because of the serious social and medico-legal consequences of misdiagnosing gonorrhoea great care must be taken in the identification of *Neisseria gonorrhoeae*.

No single technique has proved infallible in the identification of *Neisseria gonorrhoeae*:

The classic 'acid detection from carbohydrates' or 'sugars' can give false identification due to the existence of 'Glucose only' strains of *Neisseria meningitidis*, *N. denitrificans*, *N. kochii*, *N. cinerea* and *N. elongata*.

Preformed enzyme tests often include proline aminopeptidase as a marker for *Neisseria gonorrhoeae*, but proline aminopeptidase negative strains have been reported and non-pathogenic *Neisseria* can be proline aminopeptidase positive, although these organisms should not grow through on GC selective agars.

Antigen detection tests are dependant on the exposure of the antigen site and the completeness of the antigen pool used to raise the antibodies.

This product is for In Vitro diagnostic use only.

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Whilst the use of a single test method and clinical findings may be considered sufficient for a presumptive identification we would advise the use of two test methods involving different principles (e.g. biochemical, antigenic or molecular) before issuing a definitive/confirmed identification of *Neisseria gonorrhoeae*.

This advice is given on the CDC website:

www.cdc.gov/ncidod/dastlr/gcdir/neident/ngon

Performance Characteristics

	Total	Gonogen II
Positive	130	127
Negative	60	63

Sensitivity - 98% Specificity - 100%

The following organisms have been tested and found to be negative with Gonogen II:

***Neisseria meningitides* (24 strains)** *N. animalis*, *N. canis*, *N. caviae*, *N. cineria*, *N. cuniculi*, *N. denitrificans*, *N. elongate*, *N. elongate subsp glycolytica*, *N. flava*, *N. flavescens*, *N. lactamica* (4 strains) *N. mucosa*, *N. ovis*, *N.perflava*, *N. sicca* *N. subflava*, *Branhamella catarrhalis*, *Kingella denitrificans*, *Kingella kingelli*, *Lactobacillus casei*, *Klebsiella oxytoca*, *Citrobacter freundii*, *E. coli*, *Proteus mirabilis*, *Pseudomonas aeruginosa* *Staphylococcus aureus* (2 strains) *Flavobacterium spp.*, *Streptococcus faecalis*, *Alkaligenes spp.*

Limitations of the Procedure

No single diagnostic test should be considered conclusive in confirming *N gonorrhoeae*. Depending on exposed antigenic sites and antigenic composition some gonococci may not be identifiable with Gonogen II whilst others may vary in the intensity of colour produced.

Shelf Life & Storage

The expiry date and storage temperature (4⁰C) are indicated on the outer package label.

DO NOT FREEZE

Warning

All reagents contain 0.09% sodium azide. Sodium azide may react with lead or copper plumbing to form highly explosive metal azides.

GonoGen II

Materials provided

Gonogen II Reagent – Monoclonal antibodies to *Neisseria gonorrhoeae* OMP adsorbed onto metal – sol particles. Contains 0,09% sodium azide

Solubilising Buffer – releases the OMP antigen prior to addition of Gonogen II reagent. Contains 0,09% sodium azide

Positive Control – Heat killed *Neisseria gonorrhoeae*. Contains 0,09% sodium azide

Negative Control - Heat killed *Neisseria* (species other than *N. gonorrhoeae*.) Contains 0,09% sodium azide

Test Tray – Consists of wells with special matrix and absorbent material.

Droppers – for delivering controlled volumes of test suspension.

Swabs – for harvesting culture and producing test suspension

Materials required but not provided

Test tubes (11x40mm)

Test tube rack for above

#1 MacFarland turbidity standard

Method

Colonies grown on selective or enriched plated media that are oxidase positive and are Gram negative diplococci can be considered to be presumptively identified as *Neisseria* species and are suitable for testing with Gonogen II.

Test Procedure (see also controls)

- 1 Allow reagents to warm to room temperature
- 2 Label a test tube (11x40mm) for each specimen
- 3 Using the provided dropper dispense 500uL of solubilising buffer into each tube.
- 4 Using a cotton swab harvest sufficient colonies (2-3) and emulsify (VORTEX) in the solubilising buffer to make a suspension equivalent to #1 MacFarland turbidity standard (barely visible turbidity). Too heavy a suspension can lead to false positive readings.

- 5 Discard the swab in disinfectant or appropriate biohazard container.
- 6 VORTEX the Gonogen II reagent
- 7 Add 1 drop of the Gonogen II reagent to each tube.
- 8 VORTEX
- 9 Allow to stand at room temperature for at least 5 minutes, longer incubation increases the clarity of the reaction.
- 10 Using provided droppers; add 2 drops of each test into separate wells in the Test Tray.
- 11 Using a clean pipette add one drop of buffer to each completed test well.
- 12 Interpret Results Red dot =Positive.
Pale pink ring or white = negative.

Controls should be run in accordance with good laboratory practice. To run controls:

- 1 Label a test tube (11x40mm) Positive Control
- 2 Label a test tube (11x40mm) Negative Control
- 3 Dispense 500uL of buffer into each tube
- 4 Add 1 drop of well-mixed Positive Control into the tube marked Positive
- 5 Add 1 drop of well-mixed Negative Control into the tube marked Negative
- 6 VORTEX
- 7 Add 1 drop Gonogen II Reagent to each tube
- 8 VORTEX and wait for at least 5 minutes.
- 9 Add two drops of the Positive test into a well in the test tray
- 10 With a separate dropper - add two drops of the Negative test into a second well in the test tray
- 11 With a separate dropper add 1 drop of buffer to each of the 2 wells
- 12 Read reactions:
Positive – Red Spot in Test Tray well.
- Negative – White to Pale Pink ring in Test Tray well.

If controls do not perform as expected do not use the kit to test patient specimens. Contact BioConnections or your distributor.

Notes

The solubilising buffer has been shown to inactivate micro-organisms and all reagents contain sodium azide which is bactericidal. However observe established precautions against microbiological hazards when using this product and during disposal of reagents/components

If all 8 wells of the Test Tray are not used during a given test run, the unused wells can be used at a later time. Used test wells should be marked. Reacted test wells may be saved as a permanent record.

Too heavy a suspension at step 4 will give a pink background that may lead to misinterpretation.

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