GonoGen II

REF CK7240

Intended Use
GonoGen II is a monoclonal antibody based colorimetric test intended for the confirmatory identification of *Neisseria gonorrhoeae* from culture. The test method does not require instrumentation and is completed in under ten minutes.

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.*

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).

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 dependent on the exposure of the antigen site and the completeness of the antigen pool used to raise the antibodies.

Precautions
This product is for in-vitro diagnostic use and should be used by properly trained laboratory professionals. Universal precautions should be taken in the handling, processing and discarding of all materials used to perform the test. Do not use reagents after the expiration date shown on the product label has expired.

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 (live culture):
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 McFarland turbidity standard (barely visible turbidity). **Too heavy a suspension will give a pink background that may lead to misinterpretation**
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.

Test procedure (kit controls):
1. Allow reagents to warm to room temperature
2. Label a test tube (11x40mm) for each control (positive and negative).
3. Using the provided dropper dispense 500uL of solubilising 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 each tube
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.

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

Results
Positive – formation of a red or dark pink spot in the test tray well
Negative – formation of a white to pale pink spot in the test tray well

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 clearly marked on the test strip. Reacted test wells may be retained as a permanent record.

Limitations

1. This test is for use only on organisms that are oxidase positive, Gram negative cocci.
2. Depending on exposed antigenic sites and antigenic composition, some gonococci my not be identifiable with GonoGen II and others may vary in colour intensity. In the rare cases of extremely weak or non-specific reaction, confirmation by other methods, such as carbohydrate utilisation may be necessary.
3. 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.

Performance Characteristics

	Total	Culture	GonoGen II
Positive	130	130	127
Negative	60	60	63
Sensitivity			98%
Specificity			100%
Positive Predictive Value			100%
Negative Predictive Value			95%

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 friendii, E. coli, Proteus mirabilis, Pseudomonas aeruginosa, Staphylococcus aureus (2 strains), Flavobacterium spp., Streptococcus faecalis, Alkaligenes spp.*

Quality Control

A quality control should be undertaken daily or immediately prior to use. The kit contains both positive (a heat killed *Neisseria gonorrhoeae*) and negative (a heat killed Neisseria species other than *N. gonorrhoeae*) controls that may be run along with test specimens. Additional live culture controls may include:

Quality Control Organisms	Result
Neisseria gonorrhoeae ATCC 19424	Positive
Moraxella catarrhalis ATCC 25238	Negative

Shelf Life & Storage

The expiry date, storage temperature (fridge) and storage conditions are indicated on the outer package label.

Materials provided

Each pack contains sufficient reagent, trays, droppers and swabs to conduct 40 tests

Materials required but not provided

Test tubes (11x40mm) and rack

References

Standards Unit, Microbiology Services, PHE. UK SMI, ID6-Identification of Neisseria species, Issue 3, 26.06.15.
Dillon, J.R. et al. 1988. Evaluation of Eight Methods for Identification of *Neisseria* Species: Neisseria-Kwik, RIM-N, Gonobio-Test, Minitek, Gonochek II, Gonogen, Phadebact Mononclonal GC Omni Test and Syva MicroTrak Test. J. Clin. Microbiol. **26**:493-497

External Resources

Traditionally, tests used to identify strains of *Neisseria* species were performed as individual non-commercial tests. Although these tests have, in many cases, been superseded by commercially available products, reference laboratories may use additional individual tests to identify strains of *Neisseria* and related species. Table 1 in the following web link provides a list of traditional tests that can be used to differentiate human *Neisseria* spp., *M. catarrhalis,* and *K. denitrificans.*
https://www.cdc.gov/std/gonorrhea/lab/biochemical.htm

REF	Catalogue number
LOT	Batch number
	Use by date
IVD	In-Vitro Diagnostic device
Σ	Contains sufficient for <n> tests
	Temperature storage limitations
	Consult instructions for use
	Manufacturer

Issue	Date	Comments
8	26/11/2020	IFU format revision.

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