

**CK7240**  
40 Tests

## GonoGen II

An immunoassay for *Neisseria gonorrhoeae*

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 ten minutes.

- **SAFE** – no boiling step
- **SIMPLE** – no instruments, clear-cut results  
no agglutination guesswork
- **RAPID** – total test time under 10 minutes
- **DAY 1** – no pure culture or heavy inoculum required
- **SPECIFIC** – 100%, no false positive results
- **COMPLETE** – positive & negative controls included

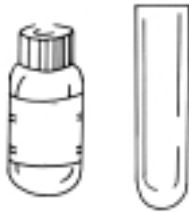
GonoGen II uses a solubilising buffer to strip the cell wall off the test organisms, thus exposing the outer membrane proteins which contain the species specific antigens.

A pool of monoclonal antibodies linked to a red metal-sol carrier is used to detect the antigens specific to *Neisseria gonorrhoeae*.

The subsequent antigen/antibody-carrier complex is detected by a filtration device giving rise to a clear-cut red dot endpoint.

The finished test can be stored as a permanent record of the result.

1



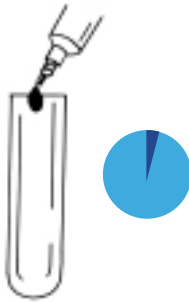
Dispense 500ul of solubilizing buffer

2



Harvest colonies and prepare suspension to McFarland#1

3



Add 1 drop GonoGen II reagent to tube.  
Wait 10 minutes

4



Dispense 2 drops of the suspension in reaction tray well followed by 1 drop of buffer.

Positive – red dot  
Negative – clear to pale pink ring

## Performance Characteristics

	Total	Gonogen II
Positive	130	127
Negative	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. elongata*, *N. elongata subsp glycolyticum*, *N. flava*, *N. flavescens*, *N. lactamica* (4 strains) *N. mucosa*, *N. ovis*, *N.perflava*, *N. sicca* *N. subflava*, *Moraxella 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.*

## 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. elongate*.

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.

Both classic sugars and preformed enzyme tests are dependent on the purity of the inoculum. A contaminated inoculum will lead to incorrect results.

Antigen detection tests are dependent on the exposure of the antigen site and the completeness of the antigen pool used to raise the antibodies although they are less dependent on the purity and viability of the inoculum.

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](http://www.cdc.gov/ncidod/dastlr/gcdir/neident/ngon)