



» Discover the Promise.

The *illumigene*[®] CT/NG system, includes the following products:

- ✓ **MSwab**[™] - Sample Collection Kit (REF. 6E028N.MER)
- ✓ **MPrep**[™] - DNA Sample Preparation Kit (REF. 281110) for *illumigene*[®] CT & *illumigene*[®] NG
- ✓ *illumigene*[®] Chlamydia (CT) DNA Amplification Assay (REF. 280450)
- ✓ *illumigene*[®] Gonorrhea (NG) DNA Amplification Assay (REF. 280850)

Related instrumentation and accessories

- ✓ **illumipro-10**[™] (REF. 610172) & accessories
- ✓ **MPrep**[™] **Workstation** (REF.610165) – for **MPrep**[™] DNA Sample Preparation

PRODUCTS DETAILS

Product name	MSwab™ COPAN
Description	Collection, Preservation and Transport System for Molecular and Culture Applications
Meridian Catalog No (REF)	6E028N.MER
Kit size	50 units
Intended use	The MSwab Collection Kit is used to collect, transport and preserve vaginal and endocervical swabs samples. The MSwab Collection Kit is validated to be used with <i>illumigene</i> ® CT and <i>illumigene</i> ® NG
Specimen type	vaginal swab specimens (self-collected) and endocervical swab specimens
Assay format	Single use sample collection packs containing: 1 screw cap tube containing 2 ml MSwab™ transport and preservation medium - 1 FLOQSwab™ applicator regular size with flocked nylon fiber tip, sterile and individually wrapped - 1 cleaning swab with large tip
CE marked	YES
FDA cleared	NO
Shelflife	18 months
Storage requirements	5-25°C
Manufacturer	Copan Flock Technologies
EDMA code	14.01.02.21
GMDN code	30636
Availability	European Union (Not for sale in USA)

Product name	M-prep™ DNA Sample Preparation
Description	DNA Sample Preparation Kit for use with <i>illumigene</i> ® DNA Amplification Assays
Meridian Catalog No (REF)	281110
Kit size	50 DNA sample preparations
Intended use	The <i>M-prep</i> ™ DNA Sample Preparation Kit, for use with the <i>illumigene</i> ® DNA CT/NG Amplification Assays, is a size exclusion chromatography system for purification of genomic nucleic acids from biological specimens. The extraction and purification process is performed by gravity flow and does not require specialized laboratory equipment.
Specimen type	Endocervical/vaginal swabs and male/female urine
TAT	~30-50 min
CE marked	YES
FDA cleared	NO
Shelf life	18 months
Storage requirements	2-30°C
Required Instrumentation	Vortex, Microcentrifuge, Micropipettes
EDMA code	15.90.40.01
GMDN code	N/A
Availability	European Union (Not for sale in USA)

PRODUCT DETAILS

Product name	<i>illumigene</i> [®] Chlamydia DNA Amplification Assay
Description	DNA Amplification Assay for the Detection of <i>Chlamydia trachomatis</i>
Meridian Catalog No (REF)	280450
Kit size	50 tests
Intended use	The <i>illumigene</i> [®] Chlamydia DNA amplification assay, performed on the <i>illumipro-10</i> [™] , is a qualitative <i>in vitro</i> diagnostic assay for the detection of <i>Chlamydia trachomatis</i> in human samples
Assay target	The assay targets a 240 base pair (bp) sequence of <i>Chlamydia trachomatis</i> cryptic plasmid. The target DNA sequence is found in a region of the plasmid which codes for an unnamed protein product and is found in all 33 strains of <i>C. trachomatis</i> in which the cryptic plasmid sequence is reported
Specimen type	Endocervical swabs, self-collected vaginal swabs, male urine and female urine
Assay Format	Qualitative NAAT based on LAMP technology
Sensitivity (all samples combined)	97.1%
Specificity (all samples combined)	97.9%
Time to result	~ 40 minutes
CE marked	YES
FDA cleared	NO
Shelflife	12 months
Storage requirements	2-30°C
Required instrumentation	<i>illumipro-10</i> [™] (REF.610172) – software REF. 119758-001 Rev.A
Related products	<i>MSwab</i> [™] COPAN , <i>M-prep</i> [™] , <i>illumigene</i> [®] Gonorrhoea
GMDN code	30677
EDMA code	15.01.01.40
Availability	European Union (Not for sale in USA)



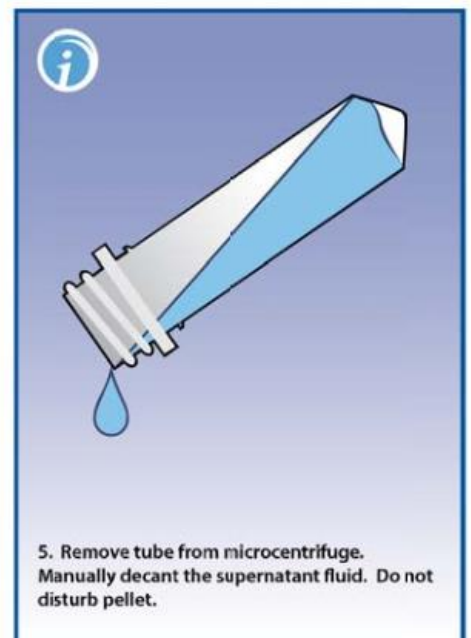
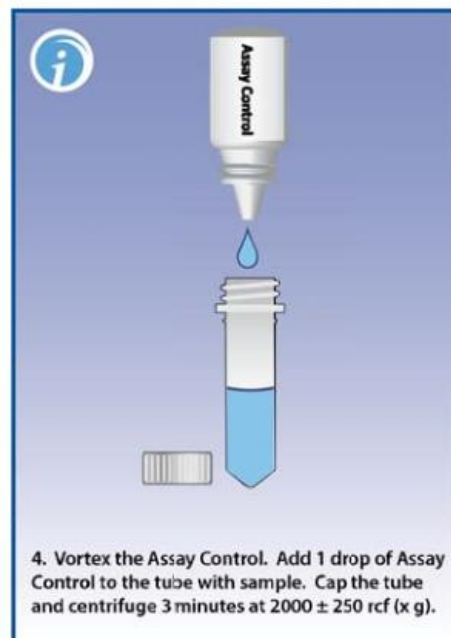
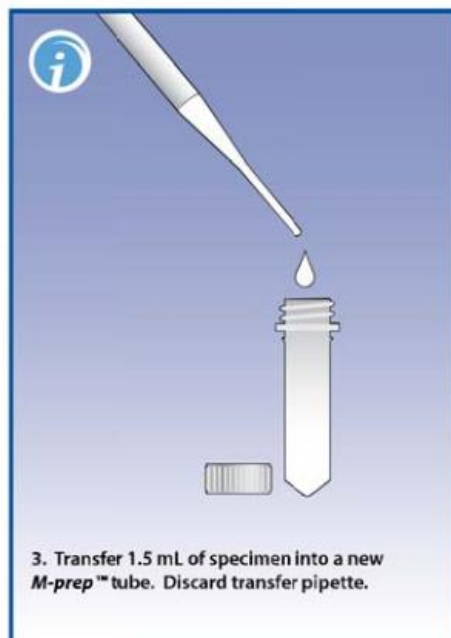
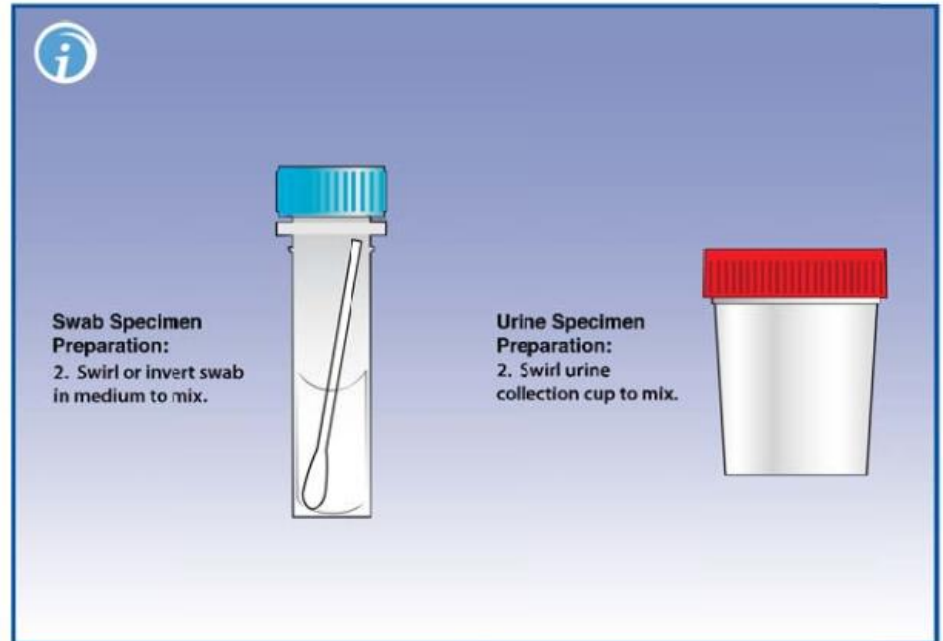
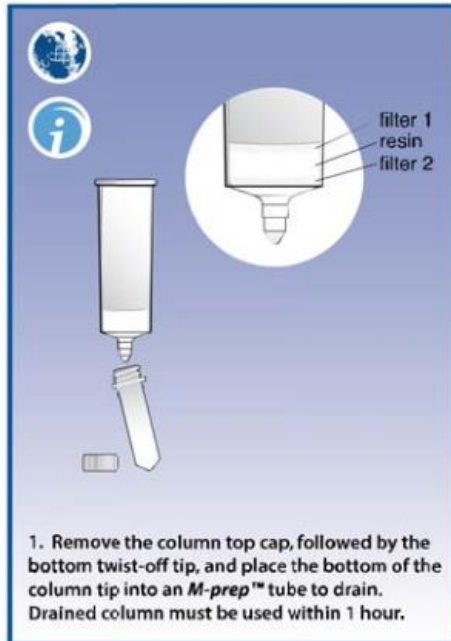
PRODUCT DETAILS

Product name	<i>illumigene</i> [®] Gonorrhoea DNA Amplification Assay
Description	DNA Amplification Assay for the Detection of <i>Neisseria gonorrhoeae</i>
Meridian Catalog No (REF)	280850
Kit size	50 tests
Intended use	The <i>illumigene</i> [®] Gonorrhoea DNA Amplification Assay, performed on the <i>illumipro-10</i> [™] , is a qualitative <i>in vitro</i> diagnostic assay for the detection of <i>Neisseria gonorrhoeae</i> in human samples
Assay target	The assay targets a 194 base pair (bp) sequence of the <i>Neisseria gonorrhoeae</i> genome. The target DNA sequence is found in a putative phage associated protein gene and is found in all three complete genomes of <i>N. gonorrhoeae</i> reported.
Specimen type	Endocervical swabs, self-collected vaginal swabs, male urine and female urine
Assay Format	Qualitative NAAT based on LAMP technology
Sensitivity (all samples combined)	93.5%
Specificity (all samples combined)	98.0%
Time to result	~40 minutes
CE marked	YES
FDA cleared	NO
Shelflife	12 months
Storage requirements	2-30°C
Required instrumentation	<i>illumipro-10</i> [™] (REF.610172) – software REF. 119758-001 Rev.A
Related products	<i>MSwab</i> [™] COPAN , <i>M-prep</i> [™] , <i>illumigene</i> [®] Gonorrhoea
GMDN code	30683
EDMA code	15.01.02.40
Availability	European Union (Not for sale in USA)




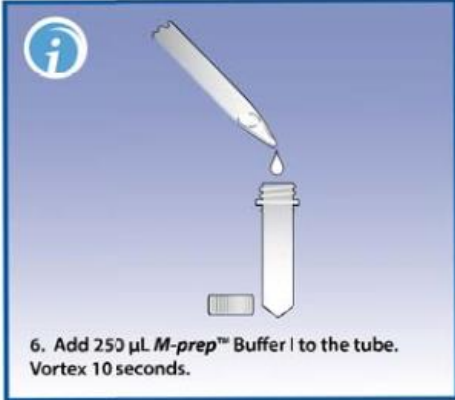
SHORT PROCEDURE

DNA Sample Preparation, Amplification and Detection

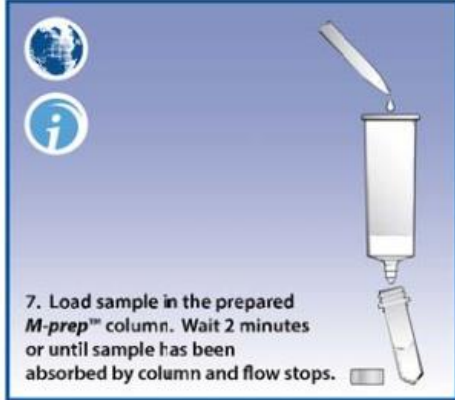


 Refer to the *M-prep*[™] DNA Sample Preparation Kit Package Insert.

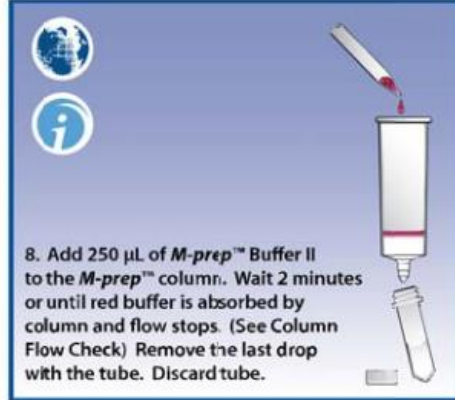
 Refer to the *illumigene*[®] Chlamydia or *illumigene*[®] Gonorrhea Package Insert.



6. Add 250 µL *M-prep*[™] Buffer I to the tube. Vortex 10 seconds.

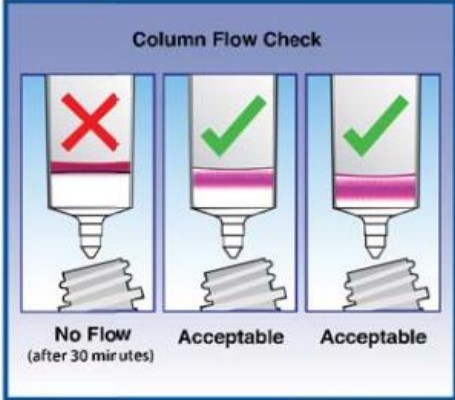


7. Load sample in the prepared *M-prep*[™] column. Wait 2 minutes or until sample has been absorbed by column and flow stops.




8. Add 250 µL of *M-prep*[™] Buffer II to the *M-prep*[™] column. Wait 2 minutes or until red buffer is absorbed by column and flow stops. (See Column Flow Check) Remove the last drop with the tube. Discard tube.

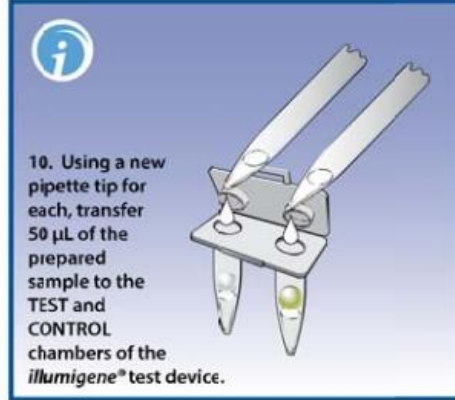
Column Flow Check




No Flow (after 30 minutes) Acceptable Acceptable



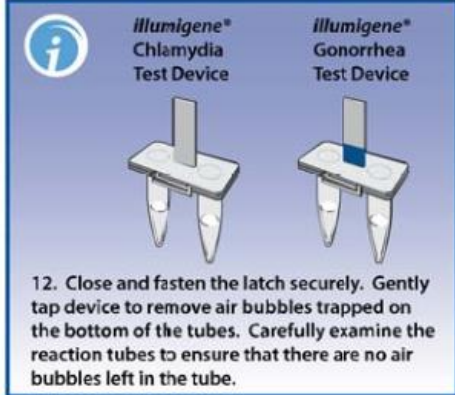
9. Place a clean *M-prep*[™] tube under the *M-prep*[™] column. Add 250 µL *M-prep*[™] Buffer III to the *M-prep*[™] column. Wait 2 minutes or until flow stops. Remove the last drop with the tube.




10. Using a new pipette tip for each, transfer 50 µL of the prepared sample to the TEST and CONTROL chambers of the *illumigene*[®] test device.



11. Add 1 drop of Mineral Oil to the TEST and CONTROL chambers.




12. Close and fasten the latch securely. Gently tap device to remove air bubbles trapped on the bottom of the tubes. Carefully examine the reaction tubes to ensure that there are no air bubbles left in the tube.



13. Insert *illumigene*[®] Test Device into the *illumipro-10*[™] and initiate amplification reaction and detection.

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 This illustration is representative of the current Package Insert at the time of publication. Please refer to the most current version of the Package Insert for complete instructions.

For More Information about the Products and for Brochure, Complete Instructions for Use and MSDS:

www.MeridianBioscience.eu