GENOMICA

MULTIPLEX · MICROARRAY MDX

Zeltia **GEN•MICA**

Zeltia **GEN•MICA**

CE

CLART® by GENOMICA

GENOMICA's Clinical Array Technology, CLART®, is a diagnostics platform based on a Multiplex-PCR amplification step and the subsequent analysis of the amplified material on a low density microarray (LD-Microarray).

The combination of both allows the simultaneous detection of multiple targets in a single assay, providing detailed information and thus facilitating the decision-making process for the clinicians.

The analysis of the sample is simple, straightforward and robust making it suitable for every molecular diagnostic laboratory.

INNOVATION
& RELIABILITY

CAR®

Clinical Array Reader is a colorimetric array reader unit, running our proprietary software, SAICLART®, for the analysis and interpretation of the array images. SAICLART® has been designed and validated for interpreting the arrays images turning them automatically into clinically relevant data.

The reader displays an interface called CLEIS (CLART® End-user Interface Software), based on the extensive experience and the customers feedback provided, thus obtaining a very intuitive user-friendly format.

Technical characteristics:

> Integrated PC.
> Touch screen.
> Easy data management:

- LIS bidirectional connection.
- HTML and bmp formats.
- Printable, exportable and storable reports.

SAICLART®

SAICLART® is GENOMICA's proprietary image processing software for the analysis and interpretation of microarrays images. Its advanced recognition algorithm is able to discerns spots from artifacts like speckles, fibers or bubbles, greatly reducing false positive and false negative results.

The image analysis is completely automated, avoiding subjectivity as result of user interpretation, thus providing fast, accurate and reproducible results, improving the overall performance of the assay.

autoclart®

Autoclart is the latest GENOMICAs automation system. It's designed for microplate processing and provides reagents addition, liquid handling, heating, cooling and microplate shaking.
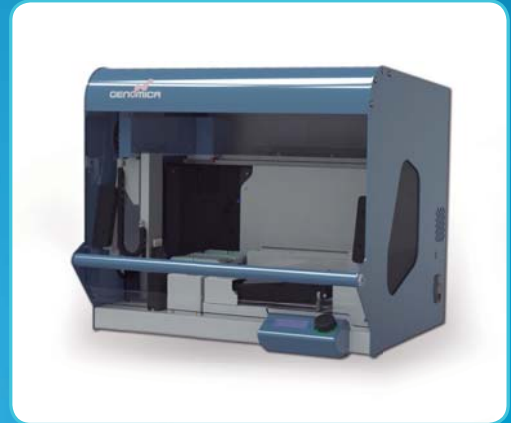
Its technical features makes it suitable for almost all molecular diagnostics laboratories throughput:

> Compact size: 60 x 60 x 65 cm.
> Plug and play system.
> Operator interface is via an integral control panel containing a knob and a LCD display screen.
> Microplate holder offers: heating and cooling under a peltier controlled system, giving precise temperature control during assay, but also shaking wells during incubations.

Autoclart main advantages:

> Notably reduces the hands-on time required for performing any CLART® assay.
> Minimizes the potential intra-assay variability, but also inter-laboratory variability.
> All consumables are housed inside the instrument, giving a very small footprint in the lab.
> Flexibility in number of samples per run, from 4 to 96 at once.

CLART® CMA
KRAS·BRAF·PI3K & NRAS·iKRAS

Specific detection of somatic mutations in oncogenes determining response therapy

MUTATIONS DETECTED

KRAS	BRAF	PI3K	NRAS	iKRAS
G12A	V600E	E542K	G12D	Q61H (A>C)
G12D	V600K	E545D	Q61R	A146V
G12R		E545K	Q61K	A146T
G12C		H1047R	Q61L	K117N (A>C)
G12S			Q61H (A>T)	K117N (A>T)
G12V				
G13D				
Q61H (A>T)				
G12A				

MAIN ADVANTAGES OF MULTIPLE DETECTION OF SOMATIC MUTATIONS

- Detects 20 of the most prevalent mutations on KRAS, BRAF, PI3K, NRAS and iKRAS.
- Reduces the amount of sample required
- All mutations included in one kit can be detected in a single array.
- Avoids unnecessary toxicity caused by improper selected antitumor therapy, as well as its associated costs.

FEATURES

- Both kits have been validated for automatic and manual DNA extraction from FFPE samples and cell lines.
- Mutational status can be detected for single or multiple genes just combining references.
- High sensitivity and specificity.
- Three internal quality controls included per sample:
  - **Genomic DNA control:** validates the extraction performance.
  - **Amplification control:** avoids false negative results.
  - **Biotin markers:** check the proper performance of the visualization reagents provided with the kit.
- Each mutation is detected in triplicate avoiding unspecific bindings.
- Results are obtained within a working day.

Data Management

- Automatic reading and interpretation of results (CAR®).
- User-friendly report format (html, bmp)
- Printable, exportable and storable files.

REPORTING RESULTS

> Report and image obtained by CAR® reader.
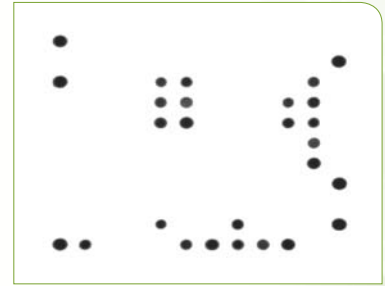
A1			
KRAS Analysis - Not tested			
Controls	Result	Controls	Result
Extraction	Not tested	Amplification	Not tested
Mutations			
Mutation	Result	Mutation	Result
KRAS 12 Ser	Not tested	KRAS 12 Arg	Not tested
KRAS 12 Asp	Not tested	KRAS 12 Cys	Not tested
KRAS 13 Asp	Not tested	KRAS 61 Leu	Not tested
KRAS 61 His (CAT)	Not tested	KRAS 12 Val	Not tested
KRAS 12 Ala	Not tested		
BRAF Analysis - Not tested			

ORDERING REFERENCES

CLART® CMA KRAS·BRAF·PI3K

CLART® CMA KRAS
Amplification 24 tests: CS-0412-24

CLART® CMA BRAF
Amplification 24 tests: CS-0512-24

CLART® CMA PI3K
Amplification 24 tests: CS-0612-24

CLART® CMA KBP Array
Visualization 24 tests: CS-0712-24

CLART® CMA NRAS·iKRAS

CLART® CMA NRAS·iKRAS
Amplification 24 tests: CS-0114-24
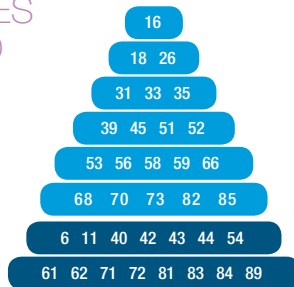
CLART® CMA NiK Array
Visualization 24 tests: CS-0214-24

> CLART® CMA KRAS·BRAF·PI3K: Essential features of CLART®CMA KRAS·BRAF·PI3K are protected by European Patent Application Nº EP11382397.5 and EP12382370.0

> CLART® CMA KRAS·BRAF·PI3K and CLART® CMA NRAS·iKRAS kits accomplish with all the normative described in EU 98/79/EC for IVD.

> CLART® CMA KRAS·BRAF·PI3K is included in the recommended methods for testing BRAF V600E mutation by the Danish Pathology Association". http://danskpatologi.dk/?pid=191

CLART® HPV2

Genotyping Human Papillomavirus

GENOTYPES DETECTED

16
18 26
31 33 35
39 45 51 52
53 56 58 59 66
68 70 73 82 85
6 11 40 42 43 44 54
61 62 71 72 81 83 84 89

> High risk & low risk distribution detected by GENOMICA according to Dunne, E. JAMA 2007;297 (8):813-81.

IMPORTANCE OF HPV GENOTYPING

- Genotyping allows simultaneous detection of single infections or co-infections.
- Provides information about HPV prevalences, specially among already vaccinated cohorts.
- Enables the early detection and patient follow up, essential for cancer prevention.
- Allows studies about HPV types and their distribution in rectal, pharyngeal and cervical cancer.

FEATURES

- Is the first genotyping assay used in HPV screening programs worldwide thanks to GENOMICA´s automated system (autoclart®).
- Detects and genotypes 35 different HPV types, including HR and LR in one assay.
- Kits are validated for automatic and manual extraction of LBC, Swabs and FFPE tissues.
- High sensitivity and specificity. Clinical validation performed.

- Three quality controls included per sample:
  - **Genomic DNA control:** validates the extraction performance.
  - **Amplification control:** avoids false negative results.
  - **Biotin markers:** check the proper performance of the visualization reagents provided with the kit.
- Each HPV genotype is detected in triplicate avoiding unspecific bindings.
- Results are obtained within a working day.

Data Management

- Automatic reading and interpretation of results (CAR®).
- User-friendly report format (html, bmp).
- Samples are processed individually and three complementary reports are generated.
- Printable, exportable and storable reports.

REPORTING RESULTS

> Report and image obtained by CAR® reader.
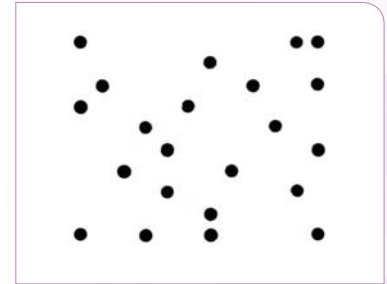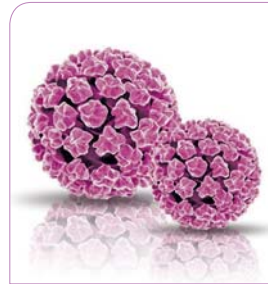
C3		

Result view
CLART® HPV2

Sample reference:	3
Array ID:	000000050516 (C1)
Analysis type:	tmb end point detection
Date and time:	Fri Jan 14 15:25:36 2011

Virus	Result	Controls
Type 6	Negative	Passed
Type 11	Negative	Passed
Type 16	Negative	Passed
Type 18	Positive	Passed

ORDERING REFERENCES

CLART® HPV2 Extraction

48 tests: AT-1105-48

CLART® HPV2 Amplification

48 tests: AT-1106-48-MT

CLART® HPV2 Visualization

48 tests: CS-0208-48

> CLART® HPV2: Essential features of CLART® HPV2 are protected by Patent Families of International PCT Patent applications WO2007017699 and WO2011116797.

> CLART® HPV2 kit, accomplish with all the normatives described in EU 98/79/EC for IVD.

CLART® STIs – A&B

Detecting microorganisms causing urogenital tract infections

MICROORGANISMS DETECTED

* Microorganism analyzed with CLART®STI A, remaining microorganism are analyzed with CLART®STI B

BACTERIA
- Chlamydia trachomatis*
- Neisseria gonorrhoeae*
- Mycoplasma genitalium*
- Mycoplasma hominis
- Ureaplasma parvum
- Ureaplasma urealiticum
- Treponema pallidum
- Haemophilus ducreyii

VIRUSES
- HSV1
- HSV2

PARASITE
- Trichomonas vaginalis*

FUNGI
- Candida albicans
- Candida glabrata
- Candida krusei
- Candida dubliniensis
- Candida guillermondi
- Candida parapsilosis
- Candida tropicalis

MAIN ADVANTAGES OF MOLECULAR DETECTION OF MICROORGANISMS CAUSING STI

Molecular diagnostic techniques provide greater sensitivity and standardize the multiple methodologies used so far for the detection of those microorganism causing urogenital tract infections.

Moreover, molecular diagnostics techniques reduce the drawbacks and limitations of conventional detection methods as:

- Low sensitivity shown by cultures.
- Antibody titers variations due to antiviral treatment.
- Dificulties in microscopy detection.

FEATURES

- Both kits have been validated for automatic DNA extraction from urine samples and swabs (vaginal, cervical, endocervical, urethral and rectal).
- High sensitivity and specificity.

- No previous culture required.
- Three quality controls included per sample:
  - **Genomic DNA control:** validates the extraction performance.
  - **Amplification control:** avoids false negative results.
  - **Biotin markers:** check the proper performance of the visualization reagents provided with the kit.
- Each target is detected in triplicate avoiding unspecific bindings.
- Results are obtained within a working day.
- Considerably reduction of turnaround time allowing the most effective therapy adjustment in the short term.

Data Management

- Automatic reading and interpretation of results (CAR®).
- User-friendly report format (html, bmp).
- Samples are analyzed individualy and three complementary reports are generated.
- Each report generated can be stored in the reader, exported or printed.

REPORTING RESULTS

> Report and image obtained by CAR® reader.

B4
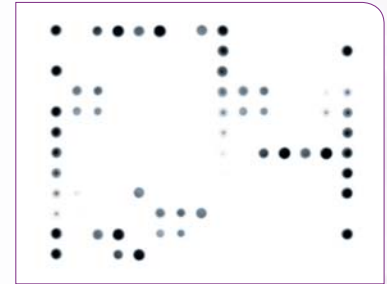
	A7 code: 506116 Rev: Mar.3
Result view	
CLART® STIs A	
Sample reference:	3
Array ID:	000000050516 (C1)
Analysis type:	tmb end point detection
Date and time:	Fri Jan 14 15:25:36 2011

Bacteria	Result	Controls
Chlamydia trachomatis	Negative	Passed
Neisseria ghonorroea	Positive	Passed
Treponema pallidum	Negative	Passed
Mycoplasma genitalium	Negative	Passed

ORDERING REFERENCES

CLART® STIs Amplification A

48 tests: CS-1112-48

CLART® STIs Amplification B

48 tests: CS-0213-48

CLART® STIs A / CLART® STIs B Visualization

48 tests: CS-1212-48

> CLART® STIs A&B for detection of microorganisms that cause infections of the urogenital tract fulfills the European Directive 98/79/EC for IVD products.

> CLART® STIs A: The analysis of Chlamydia trachomatis has been assented by the NB0318.

CLART® PneumoVir

Detection of respiratory viruses

VIRUSES DETECTED

Adenovirus	Bocavirus
Metapneumovirus A	Coronavirus 229E
Metapneumovirus B	Enterovirus
Parainfluenza 1	Influenza A, subtyping:
Parainfluenza 2	Seasonal H1N1
Parainfluenza 3	Seasonal H3N2
	New H1N1
Parainfluenza 4 subtyping:	
Parainfluenza 4 A	
Parainfluenza 4 B	
Rhinovirus	
RSV A	Influenza B
RSV B	Influenza C

MAIN ADVANTAGES OF RESPIRATORY VIRUS DETECTION

- Co-infections of several types and subtypes can be detected in the same assay.
- Avoids unnecessary treatments and long hospitalizations.
- Allows virus prevalence studies.

FEATURES

- Types an Influenza complete panel including: seasonal Influenza A H1N1 and H3N2, generic Influenza A and New Influenza A H1N1.
- The kit is validated for both, automatic and manual DNA/RNA extraction, of BAL, Nasopharyngeal washes and Nasopharyngeal swabs.
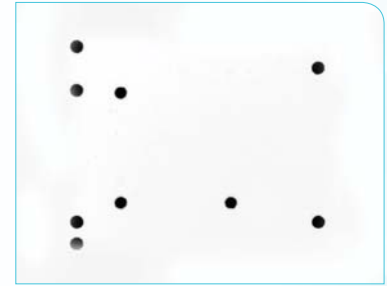- High sensitivity and specificity.

- Two quality controls included per sample:
  - **Amplification control:** avoids false negative results.
  - **Biotin markers:** check the proper performance of the visualization reagents provided with the kit.
- Each virus type is detected in triplicate avoiding unspecific bindings.
- Results are obtained within a working day.

Data Management

- Automatic reading and interpretation of results (CAR®).
- User-friendly report format (html, bmp).
- Samples are processed individually and three complementary reports are generated.
- Each report generated can be stored in the reader, exported or printed.

REPORTING RESULTS

> Report and image obtained by CAR® reader.

ORDERING REFERENCES

CLART® PneumoVir Extraction

48 tests: AT-0507-48

CLART® PneumoVir Amplification

48 tests: AT-0607-48-MT

CLART® PneumoVir Visualization
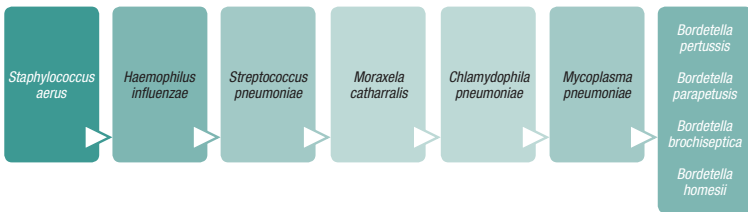
48 tests: CS-0408-48

> CLART® PneumoVir: Essential features of CLART® PneumoVir are protected by Patent Families of International PCT Patent application WO2009144497.

> CLART® PneumoVir kit, accomplish with all the normatives described in EU 98/79/CE for IVD.

PneumoCLART bacteria®

Detecting bacteria causing respiratory tract infections

| Staphylococcus aerus | Haemophilus influenzae | Streptococcus pneumoniae | Moraxela catharralis | Chlamydophila pneumoniae | Mycoplasma pneumoniae | Bordetella pertussis
Bordetella parapetusis
Bordetella brochiseptica
Bordetella homesii |

MAIN ADVANTAGES OF MULTIPLE MOLECULAR DETECTION OF RESPIRATORY BACTERIA

Co-infections with virus and bacteria represents more than 60% of all community acquired pneumonia. Multiplex MDx techniques allows the detection of such co-infections, providing greater sensitivity and standardizing the multiple methodologies used so far for the detection of those microorganism causing respiratory tract infections.

Moreover, Multiplex MDx techniques:

- Reduce the drawbacks and limitations of conventional detection methods.
- Allows pathogen-directed treatment.
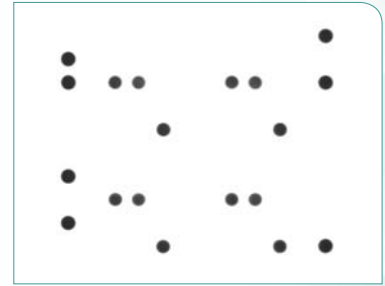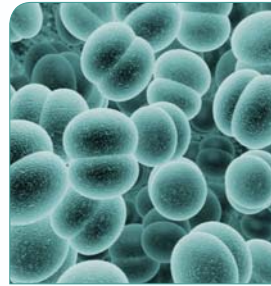- Anticipate illness potential complications.

FEATURES

- PneumoCLART bacteria® has been validated for automatic DNA extraction from sputum, nasopharyngeal lavages/exudates/aspirates, BAL and bronchial suction.
- Antibiotic resistance detection (Mec A genes).
- High sensitivity and specificity.
- Three quality controls included per sample:
  - **Genomic DNA control:** validates the extraction performance.
  - **Amplification control:** avoids false negative results.
  - **Biotin markers:** check the proper performance of the visualization reagents provided.
- Each target is detected in triplicate avoiding unspecific bindings.
- Results are obtained within a working day.
- Considerably reduction of turnaround time.

Data Management

- Automatic reading and interpretation of results (CAR®).
- User-friendly report format (html, bmp).

REPORTING RESULTS

> Report and image obtained by CAR® reader.

A2		
Result view		AT code: 60518
PneumoCLART bacteria		Rev. Mac.3
Sample reference:	3	
Array ID:	000000050516 (C1)	
Analysis type:	tmb end point detection	
Date and time:	Fri Jan 14 15:25:36 2011	

Bacteria	Result	Controls
Staphylococcus aureus	Negative	Passed
Haemophilus influenzae	Negative	Passed
Streptococcus pneumoniae	Negative	Passed
Moraxella catharralis	Negative	Passed

ORDERING REFERENCES

PneumoCLART bacteria® Amplification

48 tests: CS-1013-48

PneumoCLART bacteria® Visualization

48 tests: CS-1213-48

> PneumoCLART bacteria® accomplish with all the normatives described in EU98/79/EC for IVD.

CLART® ENTHERPEX

Detection of Human Herpesvirus and Enterovirus

VIRUSES DETECTED

Herpes Simplex Virus 1 (HSV1)
Herpes Simplex Virus 2 (HSV2)
Varicella Zoster Virus (VZV)
Epstein-Barr Virus (EBV)
Cytomegalovirus (CMV)
Human Herpes Virus 6 (HHV6)
Human Herpes Virus 7 (HHV7)
Human Herpes Virus 8 (HHV8)
Enterovirus (Coxsackievirus, Poliovirus and Enterovirus)

MAIN ADVANTAGES OF MULTIPLEX DETECTION

- Simultaneous detection of those virus causing a wide spectrum of diseases and infections.
- Single infections and co-infections can be detected.
- Best way to detect specific Enterovirus causing diseases, differentiating them from those sharing clinical and epidemiological characteristics.
- Reduced sample volume consuming obtaining the most accurate information.
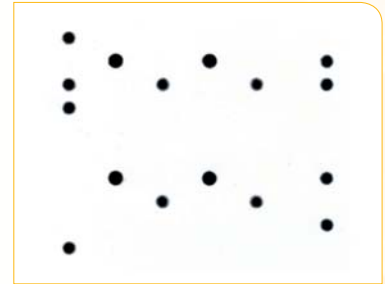
FEATURES

- The kit is validated for automatic and manual DNA/RNA extraction of CSF, Serum, Plasma, Swabs and FFPE samples.
- High sensitivity and specificity.
- Two quality controls included per sample:
  - **Amplification control:** avoids false negative results.
  - **Biotin markers:** check the proper performance of the visualization reagents provided with the kit.
- Each virus is detected in quadruplicate avoiding unspecific bindings.
- Results are obtained within a working day.

Data Management

- Automatic reading and interpretation of results (CAR®).
- User friendly report format (html, bmp).
- Samples are analyzed individually and three complementary reports are generated.
- Each report generated can be stored in the reader, exported or printed.

REPORTING RESULTS

> Report and image obtained by CAR® reader.

A5

Result view	AT code: 60518
CLART® ENTHERPEX	Rev. 10cc.3
Sample reference:	3
Array ID:	000000050516 (C1)
Analysis type:	tmb end point detection
Date and time:	Fri Jan 14 15:25:36 2011

Virus

Virus	Result	Controls
Herpes Simplex Virus 1	Negative	Passed
Herpes Simplex Virus 2	Negative	Passed
Varizella Zoster Virus	Negative	Passed
Epstein-Barr Virus	Negative	Passed

ORDERING REFERENCES

CLART® ENTHERPEX Extraction

48 tests: AT-0908-48

CLART® ENTHERPEX Amplification

48 tests: AT-1008-48-MT

CLART® ENTHERPEX Visualization

48 tests: CS-1108-48

> CLART® ENTHERPEX: Essential features of CLART® ENTHERPEX are protected by Patent Family of International PCT Patent application WO2009122201.

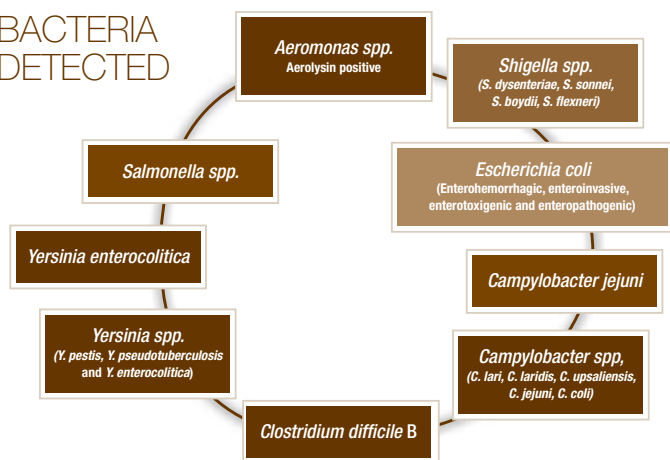> CLART® ENTHERPEX kit, accomplish with all the normatives described in EU 98/79/CE for IVD.

> CMV detection has been assented by the NB 0318.

CLART® EnteroBac

Detection of Bacteria causing Infectious Diarrhoea

BACTERIA DETECTED

Aeromonas spp.
Aerolysin positive

Shigella spp.
(S. dysenteriae, S. sonnei, S. boydii, S. flexneri)

Salmonella spp.

Escherichia coli
(Enterohemorrhagic, enteroinvasive, enterotoxigenic and enteropathogenic)

Yersinia enterocolitica

Campylobacter jejuni

Yersinia spp.
(Y. pestis, Y. pseudotuberculosis and Y. enterocolitica)

Campylobacter spp,
(C. lari, C. laridis, C. upsaliensis, C. jejuni, C. coli)

Clostridium difficile B

MAIN ADVANTAGES OF MOLECULAR METHODS IN GASTROENTERIC DISEASES

- Direct detection of a wide spectrum of bacteria causing infectious diarrhoea.
- Detection of single or multiple infections of the most prevalent bacteria causing infectious diarrhoea in one test.
- Early detection of common pathogens causing outbreaks, such as *Salmonella*.
- No stool culture required.
- Classical methods such as culturing or biochemical and phenotypic tests may not detect coinfections.

FEATURES

- The kit is validated for automatic DNA extraction directly from stool samples.
- High sensitivity and specificity.

- Three quality controls included per sample:
  - **Genomic DNA control:** validates the extraction performance.
  - **Amplification control:** avoids false negative results.
  - **Biotin markers:** check the proper performance of the visualization reagents provided with the kit.
- Each bacteria is detected in quadruplicate avoiding unspecific bindings.
- From sample to result in less than a working day.

Data Management

- Automatic reading and interpretation of results within 5 hours after sampling.
- User-friendly report format (html, bmp).
- Samples are analyzed individually and three complementary reports are generated.
- Each report generated can be stored in the reader, exported or printed.

REPORTING RESULTS

> Report and image obtained by CAR® reader.
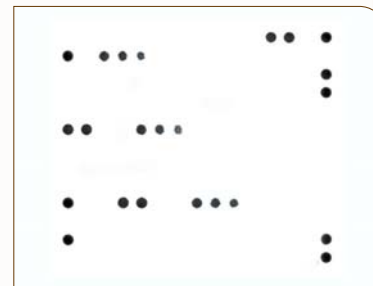
B4		
Result view		AT code: 60516
CLART® EnteroBac		Rev. 18cc.3
Sample reference:	3	
Array ID:	00000050516 (C1)	
Analysis type:	trmb end point detection	
Date and time:	Fri Jan 14 15:25:36 2011	

Bacteria	Result	Controls
Aeromonas spp.	Negative	Passed
Campylobacter coli	Positive	Passed
Campylobacter jejuni	Negative	Passed
Clostridium difficile	Negative	Passed

ORDERING REFERENCES

CLART® EnteroBac Amplification

48 tests: CS-0611-48

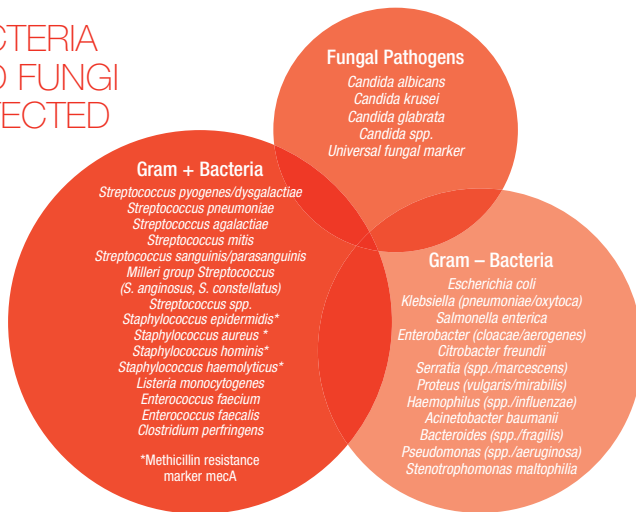**CLART® EnteroBac Visualization**

48 tests: CS-0711-48

> CLART® EnteroBac kit, accomplish with all the normative described in EU 98/79/EC for IVD.

CLART® SeptiBac

Sepsis Detection

BACTERIA AND FUNGI DETECTED

Fungal Pathogens

Candida albicans
Candida krusei
Candida glabrata
Candida spp.
Universal fungal marker

Gram + Bacteria

Streptococcus pyogenes/dysgalactiae
Streptococcus pneumoniae
Streptococcus agalactiae
Streptococcus mitis
Streptococcus sanguinis/parasanguinis
Milleri group Streptococcus
(S. anginosus, S. constellatus)
Streptococcus spp.
Staphylococcus epidermidis*
Staphylococcus aureus *
Staphylococcus hominis*
Staphylococcus haemolyticus*
Listeria monocytogenes
Enterococcus faecium
Enterococcus faecalis
Clostridium perfringens

*Methicillin resistance marker mecA

Gram – Bacteria

Escherichia coli
Klebsiella (pneumoniae/oxytoca)
Salmonella enterica
Enterobacter (cloacae/aerogenes)
Citrobacter freundii
Serratia (spp./marcescens)
Proteus (vulgaris/mirabilis)
Haemophilus (spp./influenzae)
Acinetobacter baumanii
Bacteroides (spp./fragilis)
Pseudomonas (spp./aeruginosa)
Stenotrophomonas maltophilia

MAIN ADVANTAGES OF MOLECULAR METHODS IN SEPSIS DIAGNOSTICS

Molecular methods reduce the limitations and drawbacks of conventional blood cultures:

- Blood/Sample volume.
- Turnaround time to definitive identification.
- Higher sensitivity to slow-growing and fastidious organisms.
- Co-infections detected
- Methicillin resistance marker included (*mecA* gene).

FEATURES

- The kit is validated for automatic DNA extraction from positive blood cultures.
- High sensitivity and specificity.

- Three quality controls included per sample:
  - **Genomic DNA control:** validates the extraction performance.
  - **Amplification control:** avoids false negative results.
  - **Biotin markers:** check the proper performance of the visualization reagents provided with the kit.
- Targets are detected in triplicate avoiding unspecific bindings.
- Results obtained within a working day (4 hrs).
- Reduces turnaround time, allowing therapy adjustments.

Data Management

- Automatic reading and interpretation of results.
- User-friendly report format (html, bmp).
- Samples are analyzed individually and three complementary reports are generated.
- Each report generated can be stored in the reader, exported or printed.

REPORTING RESULTS

> Report and image obtained by CAR® reader.

A2
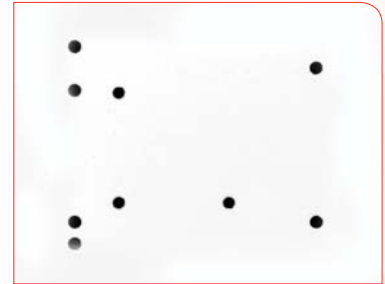
Result view	
CLART® SeptiBac	
Sample reference:	3
Array ID:	000000050516 (C1)
Analysis type:	trnb end point detection
Date and time:	Fri Jan 14 15:25:36 2011

Bacteria	Result	Controls
C. albicans	Positive	Passed
C. glabrata	Negative	Passed
C. krusei	Negative	Passed
C. perfingens	Negative	Passed

ORDERING REFERENCES

CLART® SeptiBac Amplification

48 tests: CS-0311-48

CLART® SeptiBac Visualization

48 tests: CS-0411-48

> CLART® SeptiBact kit accomplish with all the normative described in EU 98/79/EC for IVD.

BIBLIOGRAPHY

CLART® CMA KRAS·BRAF·PI3K & NRAS·IKRAS

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