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GENOMICA

CE
IVD

MULTIPLEX MICROARRAY MDX

GENOMICA

GENOMICA is a leading company in the biotech sector that designs, develops and commercializes *in vitro* diagnostics kits.

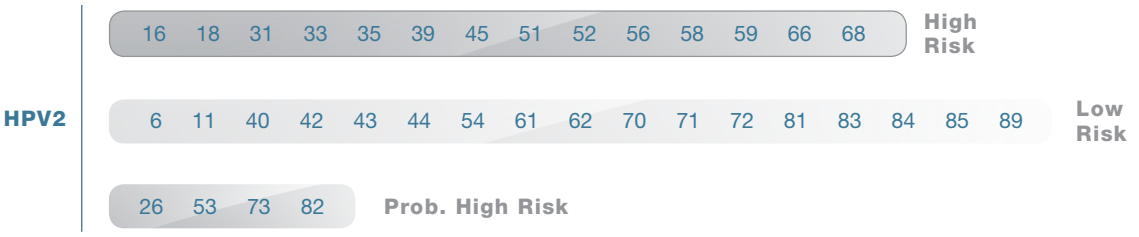
For more than 25 years GENOMICA has been relaying on two important values: innovation and reliability. The main mission of the company is to improve the current methods and technologies of molecular diagnostics with tools that meet the highest quality standards. Investing in research and development is the key to the constant growth and improvement of GENOMICA. The company is now present in over 40 countries worldwide and expanding globally.

Its proprietary **CLART®** technology is an easy and robust diagnostics platform that allows the simultaneous detection of multiple targets in a single assay. It has been designed and developed to provide detailed information and facilitate the decision-making process for the clinicians. GENOMICA provides several automation systems to optimize the diagnostics using **CLART®** kits.

CLART® HPV2

Genotyping Human Papillomavirus

GENOTYPES DETECTED :



Oncogenic risk clasification according to:
Bouvar d V, Baan R, Straif K, Grosse Y, Secretan B, El Ghissassi F et al.
A review of human carcinogens -Part B: biological agents. Lancet Oncol 2009:10(4):321 322

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.

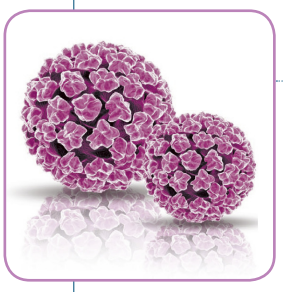
FEATURES :

- Is a full genotyping assay used in HPV screening programs worldwide thanks to GENOMICA´s automated system (autoclart® and autoclart® plus).
- 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:** check the proper performance of the visualization reagents provided with the kit.
  - **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.
- Compatible with any GENOMICA automation system.

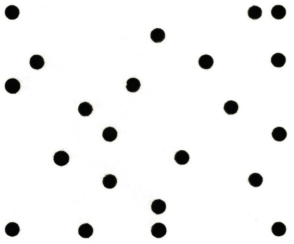
DATA MANAGEMENT :

- 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	AT code: 50516 Rev. 16sc.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	Result	Controls
Type 6	Negative	Passed
Type 11	Negative	Passed
Type 16	Negative	Passed
Type 18	Positive	Passed

ORDERING REFERENCES AND CONTACT DETAILS :

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

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BIBLIOGRAPHY :

1. "High frequency of multiple HPV types in cervical specimens from Danish women". APMIS 2009, 117: 108-114.
2. "External quality assessment for molecular detection of human papillomaviruses". Journal of Clinical Virology 48 (2010) 251-254.
3. "Human Papillomavirus 2 Assay Compared With the Hybrid Capture 2 Test". Journal of Medical Virology 2011 83:272-276 (2011).
4. "Identification of Multiple HPV Types on Spermatozoa from Human Sperm Donors". PLOS ONE. March 2011, Volume 6, Issue 3, e18095.
5. "Human papillomavirus genotype distribution among French women with and without cervical abnormalities". Intl J of Gynecol & Obstetrics 2011,Vol 114, Issue 2 , Pag116-119.
6. "Prevalence of Human Papillomavirus Infection in Women in Portugal. The CLEOPATRE Portugal Study". Int J Gynecol Cancer 2011;21: 1150Y1158.
7. "Detection and genotype distribution of human papillomavirus (HPV) DNA in Danish colorectal carcinoma patients". Poster presented at the 28th IPVC, Puerto Rico, 2012.
8. "Human Papillomavirus Type Distribution in Cervical Intraepithelial Neoplasia Grade 2/3 and Cervical Cancer in Portugal. A CLEOPATRE II Study". Int J Gynecol Cancer 2013;23: 500Y506.
9. "Patterns of cervical coinfection with multiple human papilloma virus types in a screening population in Denmark". Vaccine, Volume 31, Issue

- 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.

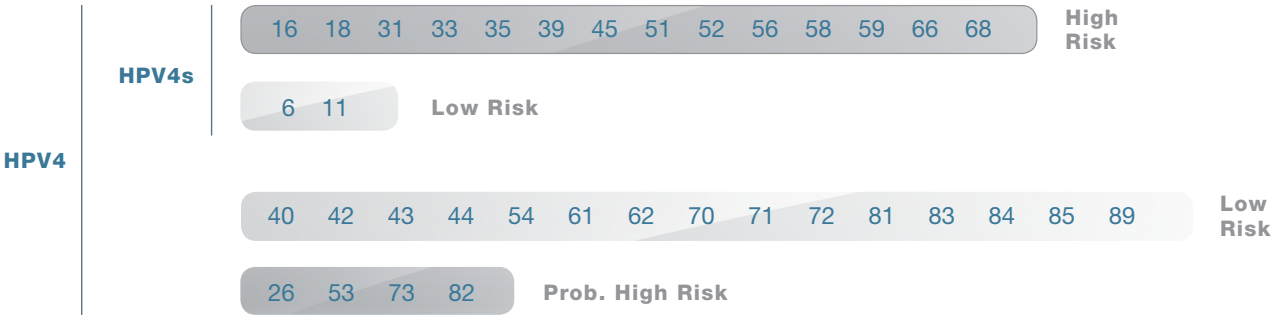
CE IVD

VERSION 4: **APRIL 2016**

CLART® HPV4 & HPV4s

Genotyping of Human Papillomavirus without DNA extraction from liquid cytology and swab.

GENOTYPES DETECTED :



▶ Oncogenic risk clasification according to:
Bouvar d V, Baan R, Straif K, Grosse Y, Secretan B, El Ghissassi F et al.
A review of human carcinogens -Part B: biological agents. Lancet Oncol 2009:10(4):321 322

GENOTYPING :

HPV4

- Full genotyping of HR and LR genotypes.

HPV4s

- Full gentopying of HR plus 6 and 11 genotypes.
- Aimed for HPV screening programs worldwide.

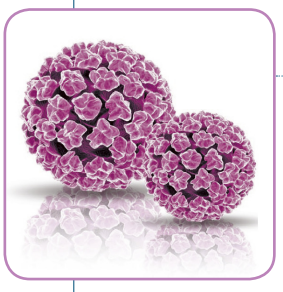
FEATURES :

- Detects and genotypes different HPV types, including HR and LR in one assay.
- Sample processing without any need of DNA extraction is validated for Dried Swab, Digene STM and Celular Suspension.
- 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 4 hours.
- Compatible with any GENOMICA automation system.

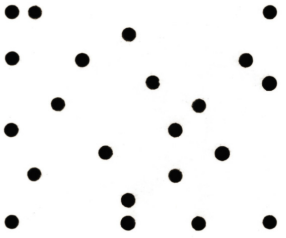
DATA MANAGEMENT :

- 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.



B1

Result view
CLART® HPV4

Assay ID: 50213
Rev. 13sc12

Sample reference:	2
Array ID:	00000000050213 (B1)
Date and time:	Thu Apr 07 14:07:37 2016

Virus

Virus	Result	Controls
6 (LR)	Negative	Passed
11 (LR)	POSITIVE	Passed
16 (HR)	Negative	Passed
18 (HR)	Negative	Passed
26 (PHR)	Negative	Passed

ORDERING REFERENCES AND CONTACT DETAILS :

CLART® HPV4

Amplification 48 tests: AT-0115-48

Genotyping 48 tests: CS-0215-48

CLART® HPV4s

Amplification 48 tests: CS-0116-48

Genotyping 48 tests: CS-1215-48

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BIBLIOGRAPHY :

1. Bosch, F.X., Lorincz, A., Muñoz, N., Maijer, C.J.L.M. and Shah K.V.: "The causal relation between human papillomavirus and cervical cancer". J. Clin. Pathl. 55, 244-265 (2002).
2. Calleja-Macías, I.E., Villa, L.L., Prado, J.C. et al. "Wordwide genomic diversity of the highrisk human papillomavirus types 31, 35, 52, 58, for close relatives of human papilloma virus type 16". Journal of Virology. 79, 13630-13640 (2005).
3. Chranioti A., Spathis A., Aga E., Merustoudis C. Pappas A., Panayiotides I. and Karakitsos P. "Comparison of two commercially available methods for HPV Genotyping: CLART HPV2 23 and Linear Arrays HPV Genotyping Test". Analytical and Quantitative Cytopathology and Histopathology. Volumen 34, number 5, October 2012.
4. De Villiers, E.M.: "Heterogeneity of the human papillomavirus group". J. Virol. 63, 4898-4903 (1989).
5. Dunne, E.F., Unger E.R., Sternberg m., McQuillan G., Swan D.C., Patel S.S., Markowitz L.E.: "Prevalence of VPH infection among females in the United States". JAMA, February 28, 2007-Vol 297, nº 8.

CE IVD

VERSION 4: **APRIL 2016**

CLART® PneumoVir 2

Detection of respiratory viruses

VIRUSES DETECTED :

Adenovirus	Bocavirus
Metapneumovirus A	Coronavirus 229E
Metapneumovirus B	Coronavirus OC43 *
Parainfluenza 1	Coronavirus NL63 *
Parainfluenza 2	Enterovirus
Parainfluenza 3	Influenza A, subtyping: H7N9 * H3N2 H1N1 H1N1/2009
Parainfluenza 4 subtyping: Parainfluenza 4 A Parainfluenza 4 B	
Rhinovirus	
RSV A	Influenza B
RSV B	Influenza C

* Amplification only available in Pneumovir 2 Amplification B.

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 :

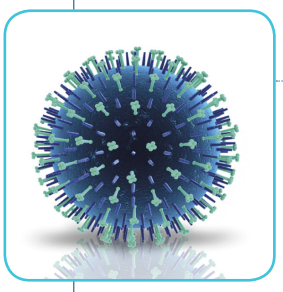
- Types an Influenza complete panel including: seasonal Influenza A H1N1 and H3N2, generic Influenza A, new Influenza A H1N1 and Influenza A H7N9.
- The kit is validated for both, automatic and manual DNA/RNA extraction, of BAL, Nasopharyngeal washes and Nasopharyngeal swabs.
- High sensitivity and specificity. 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 :

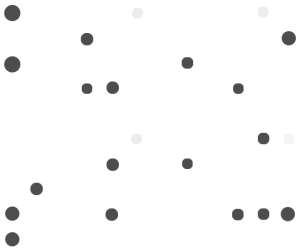
Automatic reading and interpretation of results (CAR®).

- User-friendly report format (html, bmp).
- Samples are processed individually and three complementary reports are generated.
- Printable, exportable and storable reports.

REPORTING RESULTS :



▶ Report and image obtained by CAR® reader.



A1

Resultados CLART ® PneumoVir2	Assay ID: 52501 Rev. 01sc.1
Referencia de la muestra:	focus_0
Array ID:	00000000052501 (A1)
Fecha y hora:	Thu Apr 28 05:25:21 2016

Virus

Virus	Resultado	Controles
Adenovirus	POSITIVO	Conforme
Bocavirus (HBoV)	POSITIVO	Conforme
Coronavirus (HCOV)	Negativo	Conforme
Enterovirus	Negativo	Conforme
Influenza A	Negativo	Conforme

ORDERING REFERENCES AND CONTACT DETAILS :

CLART® PneumoVir 2 Amplification A

2 amplification tubes - 48 tests: CS-0416-48

CLART® PneumoVir Amplification B

3 amplification tubes - 48 tests: CS-0516-48

CLART® PneumoVir 2 Visualization

48 tests: CS-0616-48

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BIBLIOGRAPHY :

1. Sha J1, Chen X2, Ren Y3, Chen H4, Wu Z5, Ying D6, Zhang Z7, Liu S8. Differences in the epidemiology and virology of mild, severe and fatal human infections with avian influenza A (H7N9) virus. Arch Virol. 2016 Feb 18. [Epub ahead of print]
2. Gerna G1, Campanini G, Rovida F, Percivalle E, Sarasini A, Marchi A, Baldanti F. Genetic variability of human coronavirus OC43-, 229E-, and NL63-like strains and their association with lower respiratory tract infections of hospitalized infants and immunocompromised patients. J Med Virol. 2006 Jul;78(7):938-49.
3. Heyman PVV, Carper HT, Murphy DD, Platss-Mills TA, Patrie J, McLaughlin AP. Viral infections in relation to age, atopy, and season of admission among children hospitalized for wheezing. J Allergy Clin Immunol. 2004;114: 239-47.
4. Spicuzza L, Spicuzza A, La Rosa M, Polosa R, Di Maria G. New and emerging infectious diseases. Allergy Asthma Proc. 2007; 28 (1):28-34.
5. Boschini A, Longo B, Caselli F, Begnini M, De Maria C, Ansaldi F, Durando P, Icardi G, Rezza G. An outbreak of influenza in a residential drug-rehabilitation community. J med Virol. 2006. 78 (9): 1218-22.

VERSION 4: **APRIL 2016**

PneumoCLART bacteria®

Detecting bacteria causing respiratory tract infections

Staphylococcus aureus

Haemophilus influenzae

Streptococcus pneumoniae

Moraxela catharralis

Chlamydophila pneumoniae

Mycoplasma pneumoniae

Bordetella pertussis

Bordetella parapertussis

Bordetella brochiseptica

Bordetella homesii

MAIN ADVANTAGES OF MULTIPLE MOLECULAR DETECTION OF RESPIRATORY BACTERIA :

Virus-bacteria co-infection 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.**

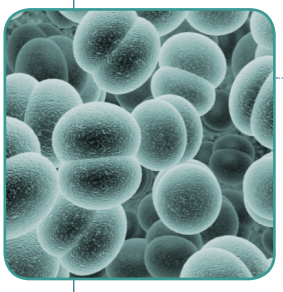
FEATURES :

- 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.
- Compatible with any GENOMICA automation system.

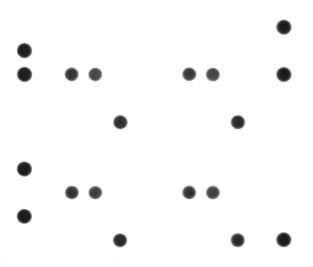
DATA MANAGEMENT :

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

REPORTING RESULTS :



- Report and image obtained by CAR® reader.



A2

Result view **PneumoCLART bacteria**	AT code: 50516 Rev. 16sc.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 AND CONTACT DETAILS :

PneumoCLART bacteria® Amplification

48 tests: CS-1013-48

PneumoCLART bacteria® Visualization

48 tests: CS-1213-48

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BIBLIOGRAPHY :

1. "Acute Respiratory Infection Due to Chlamydia pneumoniae:Current Status of Diagnostic Methods". Swati Kumar and Margaret R. Hammerschlag. Clinical Infectious Diseases 2007; 44:568– 76.
2. "Limited Utility of Culture for Mycoplasma pneumoniae and Chlamydophila pneumoniae for Diagnosis of Respiratory Tract Infections". Rosemary C. She, Andy Thurber, Weston C. Hymas, Jeffery Stevenson, Janine Langer, Christine M. Litwin and Cathy A. Petti. JOURNAL OF CLINICAL MICROBIOLOGY, Sept. 2010, p. 3380–3382
3. "Associations between Pathogens in the Upper Respiratory Tract of Young Children: Interplay between Viruses and Bacteria" Menno R. van den Bergh, Giske Biesbroek, John W. A. Rossen, Wouter A. A. de Steenhuijsen Piters, Astrid A. T. M. Bosch, Elske J. M. van Gils, Xinhui Wang, Chantal W. B. Boonacker, Reinier H. Veenhoven, Jacob P. Bruin, Debby Bogaert, Elisabeth A. M. Sanders. PLOS ONE, October 2012, 7,10 .
4. "Diagnóstico microbiológico de las infecciones bacterianas del tracto respiratorio inferior" Juana Begoña Cacho Calvo, María Antonia Meseguer Peinado, Antonio Oliver Palomo, Jorge Puig de la Bellacasa, Protocolos SEIMC 2007.

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

CE IVD

CLART® STIs - A&B

Detecting microorganisms causing urogenital tract infections

MICROORGANISMS DETECTED :

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

VIRUSES
- HSV1
- HSV2

PARASITE
- Trichomonas vaginalis*

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

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

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.**

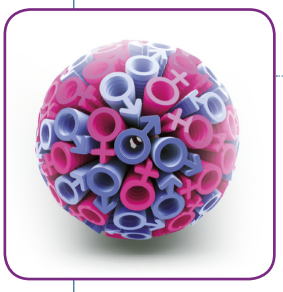
FEATURES :

- 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.
- Compatible with any GENOMICA automation system.

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.
- Every report generated can be stored, exported and printed.

REPORTING RESULTS :



- Report and image obtained by CAR® reader.

B4

Result view CLART® STIs A	AT code: 50516 Rev. 16sc.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
Chlamydia trachomatis	Negative	Passed
Neisseria ghonorroea	Positive	Passed
Treponema pallidum	Negative	Passed
Mycoplasma genitalium	Negative	Passed

ORDERING REFERENCES AND CONTACT DETAILS :

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

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BIBLIOGRAPHY :

1. "Gardnerella, Trichomonas vaginalis, Candida, Chlamydia trachomatis, Mycoplasma hominis and Ureaplasma urealyticum in the genital discharge of symptomatic fertile and asymptomatic infertile women". New Microbiologica, 33, 69-76, 2010.
2. "Global strategy for the prevention and control of sexually transmitted infections: 2006 -2015 : breaking the chain of transmission". WHO
3. "Sexually Transmitted Diseases in the United States, 2008 National Surveillance Data for Chlamydia, Gonorrhea, and Syphilis". CDC.
4. "Persistent increase in the incidence of acute male urethritis diagnosed in general practices in France". British Journal of General Practice 2006; 56: 110–114.
5. "Mycoplasma genitalium presence, resistance and epidemiology in Greenland". Int J Circumpolar Health 2012, 71:18203

- 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.

CE 0318

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 viruses 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 consuption obtaining the most accurate information.**

FEATURES :

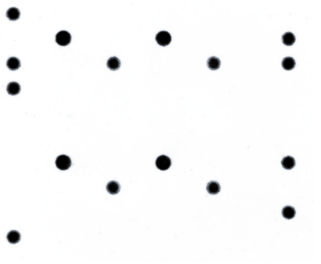
- The kit is validated for automatic and manual DNA/RNA extraction of CSF, Serum, Plasma, Swabs and FFPE samples.
- High sensitivity and specificity.
- Two quality controls included per sample:
  - **Amplification control:** avoids false negative results.
  - **Biotin markers:** check the proper performance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

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.
- Every report generated can be stored, exported and printed.

REPORTING RESULTS :

- Report and image obtained by CAR® reader.



A5

Result view CLART® ENTHERPEX	AT code: 50516 Rev. 16sc.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
Herpex Simplex Virus 1	Negative	Passed
Herpex Simplex Virus 2	Negative	Passed
Varizella Zoster Virus	Negative	Passed
Epstein-Barr Virus	Negative	Passed

ORDERING REFERENCES AND CONTACT DETAILS :

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

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BIBLIOGRAPHY :

1. "L´HHV7: co-facteur des infections méningées á entérovirus?". Poster presented at RICAI, December 2009.
2. "Evaluation of a new commercial PCR-DNA microarray for rapid and simultaneous detection of 9 viruses responsible for central nervous system infections". Poster presented at RICAI, December 2009.
3. "Combining Multiplex Reverse Transcription-PCR and a Diagnostic Microarray to Detect and Differentiate Enterovirus 71 and Coxsackievirus A16". Journal of Clinical Microbiology, 44(6), 2212-2219 (2006).
4. "DNA microarrays for virus detection in cases of central nervous system infection". Journal of Clinical Microbiology. 42(12), 5811-5818 (2004).
5. "Rapid Virological Diagnosis of Central Nervous System Infections by Use of a Multiplex Reverse Transcription-PCR DNA Microarray". Journal of Clinical Microbiology, Nov. 2011, p. 3874–3879 Vol. 49, No. 11.
6. "Human Herpesvirus-6A/B Binds to Spermatozoa Acrosome and Is the Most Prevalent Herpesvirus in Semen from Sperm Donors". PLOS ONE. November 2012, Vol. 7, Issue 11, e48810.

- 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.

CE 0318

VERSION 4: APRIL 2016

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*

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*

* Methicillin resistance marker mecA

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).**

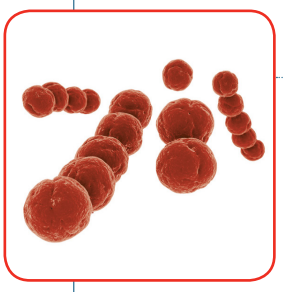
FEATURES :

- 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.
- Compatible with any GENOMICA automation system.

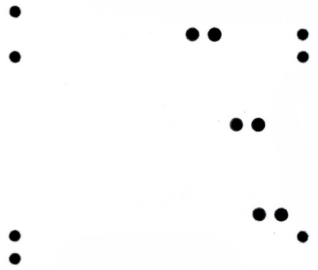
DATA MANAGEMENT :

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

REPORTING RESULTS :



- Report and image obtained by CAR® reader.



A2

Result view CLART® SeptiBac	AT code: 50516 Rev. 16sc.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
C. albicans	Positive	Passed
C. glabrata	Negative	Passed
C. kruseii	Negative	Passed
C. perfingens	Negative	Passed

ORDERING REFERENCES AND CONTACT DETAILS :

CLART® SeptiBac Amplification

48 tests: CS-0311-48

CLART® SeptiBac Visualization

48 tests: CS-0411-48

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BIBLIOGRAPHY :

1. "Hemocultivos". 2nd Ed. (3a). Eds. Cercenado E. and R. Canton. Procedimientos en Microbiología Clínica. Sociedad Española de Microbiología Clínica, SEIMC (2003).

2. "Diseño y optimización de un sistema de detección molecular por microarrays para la rápida identificación de bacterias gram positivas y hongos en hemocultivos positivos". Enfermedades Infecciosas y Microbiología Clínica. Vol 29, 33-34 (2011). 15th Congreso de la Sociedad. Española de Microbiología Clínica (SEIMC). Junio 2011.

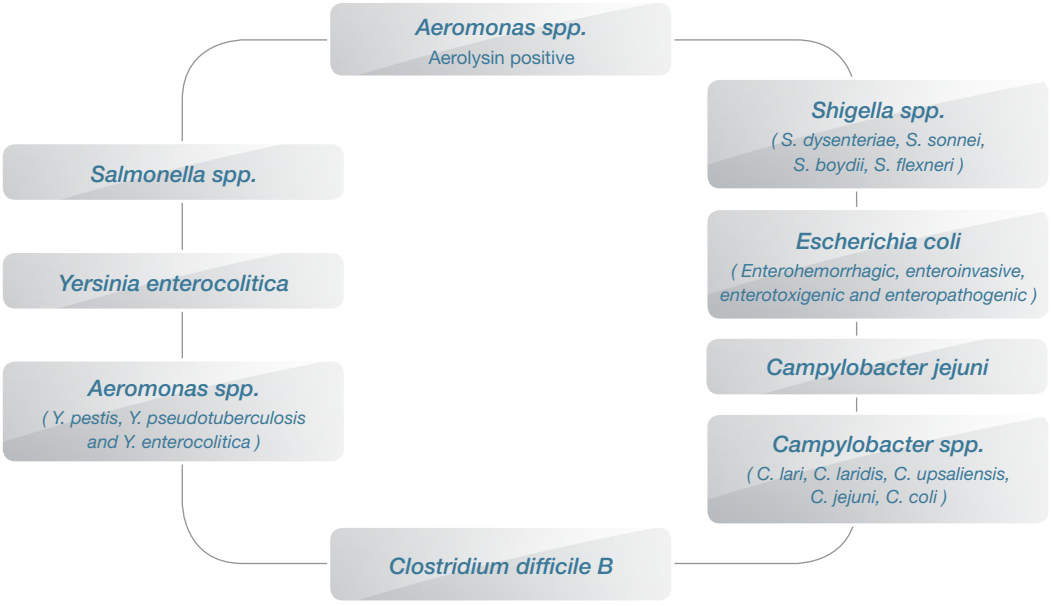
- CLART® SeptiBact kit accomplish with all the normative described in EU 98/79/EC for IVD.

CE IVD

CLART® EnteroBac

Detection of Bacteria causing Infectious Diarrhoea

BACTERIA DETECTED :



MAIN ADVANTAGES OF MOLECULAR METHODS IN GASTROENTERIC INFECTIONS :

- 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 co-infections.

FEATURES :

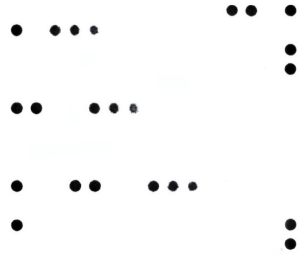
- The kit is validated for automatic DNA extraction directly from stool samples.
- High sensitivity and specificity.
- Three quality controls included per sample:
  - **Genomic DNA control:** validates the extraction performance.
  - **Amplification control:** avoids false negative results.
  - **Biotin markers:** check the proper performance of the visualization reagents provided with the kit.
- Each bacteria is detected in quadruplicate avoiding unspecific bindings.
- Short turnaround time.
- Compatible with any GENOMICA automation system.

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.
- Every report generated can be stored, exported and printed.

REPORTING RESULTS :

- Report and image obtained by CAR® reader.



B4

Result view CLART® EnteroBac	AT code: 50516 Rev. 16sc.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
Aeromonas spp.	Negative	Passed
Campylobacter coli	Positive	Passed
Campylobacter jejuni	Negative	Passed
Clostridium difficile	Negative	Passed

ORDERING REFERENCES AND CONTACT DETAILS :

CLART® EnteroBac Amplification

48 tests: CS-0611-48

CLART® EnteroBac Visualization

48 tests: CS-0711-48

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BIBLIOGRAPHY :

1. "Diagnóstico microbiológico de infecciones gastrointestinales". 2nd Ed. (24). Procedimientos en Microbiología Clínica. Sociedad Española de Microbiología Clínica, SEIMC (2007).
2. "Diseño y optimización de un sistema rápido por multiplex-PCR e hibridación en microarray para la detección e identificación de patógenos bacterianos en pacientes con diarrea. Enfermedades Infecciosas y Microbiología Clínica". Vol 29, 33-34 (2011). 15th Congreso de la Sociedad Española de Microbiología Clínica (SEIMC). Junio 2011

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

CE IVD

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CLART® CMA

CLART® CMA is an *in vitro* diagnostics test line of products for the detection of mutations in genes associated with response to therapy in cancer patients.

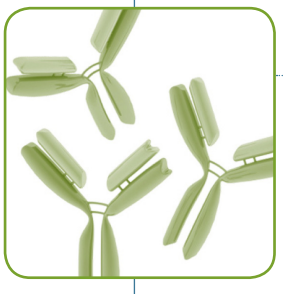
FEATURES OF CMA DIAGNOSTIC KITS :

- All 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.
- Avoids unnecessary toxicity caused by improper selected antitumor therapy, as well as its associated costs.
- Each mutation is detected in triplicate avoiding unspecific bindings.
- 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.
- Short turnaround time (5 hours).
- Reduces the amount of sample required. All mutations from any kit can be detected in a single array.
- Compatible with any GENOMICA automation system.

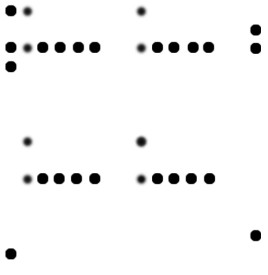
DATA MANAGEMENT :

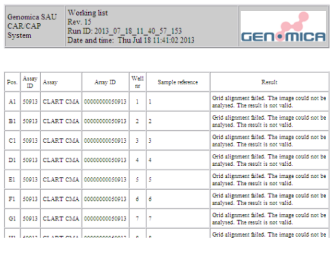
- Automatic reading and interpretation of results (CAR®).
- User-friendly report format (html, bmp).
- Printable, exportable and storable files.

REPORTING RESULTS :



- Report and image obtained by CAR® reader.





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

Specific detection of somatic mutations in oncogenes determining response to therapy in colorectal cancer patients.

KRAS
- G12A
- G12D
- G12R
- G12C
- G12S
- G12V
- G13D
- Q61H (A>T)
- Q61L

BRAF
- V600E
- V600K

PI3K
- E542K
- E545D
- E545K
- H1047R

NRAS
- G12D
- G16R
- G61K
- G61L
- Q61H (A>T)
- K117N (G>C)
- A146T (G>A)

iKRAS
- Q61H (A>C)
- A146V
- A146T
- K117N (A>C)

MAIN FEATURES :

KRAS · BRAF · PI3K :

- Diagnostic specifity close to 100% in all point mutations.
- Diagnostic sensitivity from 87% to 100% in BRAF and PI3K

iKRAS · NRAS :

- Detects the presence of the most prevalent mutations of NRAS and infrequent KRAS with a diagnostic sensitivity and specifity ≥98% .

ORDERING REFERENCES :

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
Genotyping 24 test: CS 0712-24

* Panels can be run and purchased separately.

NRAS · iKRAS :

CLART® CMA NRAS · iKRAS
Amplification 24 tests: CS-0114-24

CLART® CMA NiK Array
Genotyping 24 tests: CS-0214-24

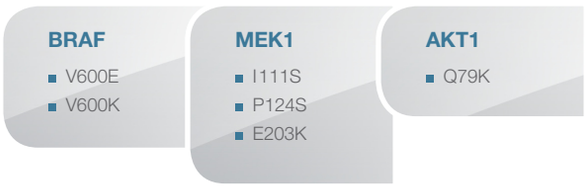
BIBLIOGRAPHY :

1. "Biomarkers Predicting Clinical Outcome of Epidermal Growth Factor Receptor-Targeted Therapy in Metastatic Colorectal Cancer". Review J Natl Cancer Inst 2009;101:1308–1324.
2. KRAS, BRAF, PIK3CA, and PTEN mutations: implications for targeted therapies in metastatic colorectal cancer". Lancet Oncol 2011; 12: 594–603
3. "NRAS and KRAS testing by a new diagnostic method to detect point mutations in colorectal cancer specimens: CLART NRAS·iKRAS. 2014 ASCO Anual Meeting Proceedings

CLART® CMA
BRAF · MEK1 · AKT1

GENOMICA . COM

Detection of specific somatic mutations in oncogenes determining response to therapy in melanoma patients.



MAIN FEATURES :

- Diagnostic sensitivity in BRAF > 93% .
- The obtained diagnostic specificity for all the mutations in the MEK1 and AKT1 genes is 100% .
- Specifity in BRAF is close to 100% .

ORDERING REFERENCES :

BRAF · MEK1 · AKT1 :

CLART® CMA BRAF

Amplification 24 tests: CS-0216-24

Genotyping 24 tests: CS-0716-24

CLART® CMA BRAF · MEK1 · AKT1

Amplification 24 tests: CS-0316-24

Genotyping 24 tests: CS-0716-24

BIBLIOGRAPHY :

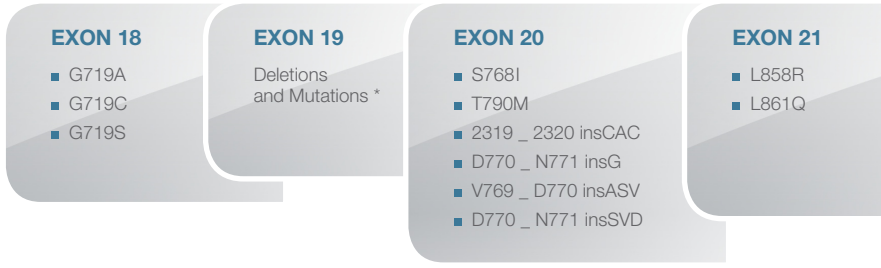
1. "Advances in personalized targeted treatment of metastatic melanoma and non-invasive tumor monito-ring." Klinac D, Gray ES, Millward M, Ziman M. Front Oncol. 2013 Mar 19;3:54. doi: 10.3389/fonc.2013.00054. eCollection 2013.
2. "Effects of AKT inhibitor therapy in response and resistance to BRAF inhibition in melanoma". Lassen A, Atefi M, Robert L, Wong DJ, Cerniglia M, Comin-Anduix B, Ribas A. Mol Cancer. 2014 Apr 16;13:83. doi: 10.1186/1476-4598-13-83.
3. Detection of BRAF V600 mutations in melanoma: evaluation of concordance between the Cobas® 4800 BRAF V600 mutation test and the methods used in French National Cancer Institute (INCa) platforms in a real-life setting.

CE IVD

VERSION 4: **APRIL 2016**

CLART® CMA EGFR

Specific detection of somatic mutations, deletions and insertions in EGFR determining response to therapy in non-small-cell lung cancer patients.



6223* E746_A750del (c.2235_2249 del 15), 12370* L747_P753>S (c. 2240_2257del18), 12369* L747_T751del (c.2240_2254del15), 6255* L747_S752del (c. 2239_2256del18), 12384* E746_S752>V (c.2237_2255>T), 12382* E747_A750>P (c.2239_2248TTAAGAGAAG>C), 6225*, 12678*, 6218*, 12728*, 6220*, 12419*, 6210*, 13556*, 12386*, 12385*, 18427*, 12403*, 12383*, 6254*, 13551*, 12367*, 12422*, 12387*, 26038*, 13552*, 12416*, 23571*

MAIN FEATURES :

- An average diagnostic sensitivity ≥92% in the most of the mutations.
- Diagnostic specifity close to 100% .

ORDERING REFERENCES :

CLART® CMA EGFR Amplification	CLART® CMA EGFR Genotyping
24 tests: CS-1014 –24	24 tests: CS-1114-24

BIBLIOGRAPHY :

1. ZHANG, Z., STIEGLER, A. L., BOGGON, T. J., KOBAYASHI, S. & HALMOS, B. (2010) EGFRmu-tated lung cancer: a paradigm of molecular oncology. Oncotarget, 1, 497-514. PAO, W., MILLER, V.A., POLITI, K.A., RIELY, G.J., SOMWAR, R.,
2. ZAKOWSKI, M.F., KRIS, M.G., VARMUS, H. (2005) Acquired resistance of lung adenocarci-nomas to gefitinib or erlotinib is associated with a second mutation in the EGFR kinase domain. PLoS Medicine, 2, 3, e73.
3. YASUDA, H., KOBAYASHI, S., COSTA, D.B. (2012) EGFR exon 20 insertion mutations in non-smallcell lung cancer: preclinical data and clinical implications. Lancet Oncol, 13: e23–31.
4. PEREZ-MORENO, P., BAMBRILLA E., THOMAS, R., SORIA, J.C. (2012) Squamous Cell Carci-noma of the Lung: Molecular Subtypes and Therapeutic Opportunities. Clin Cancer Res. 2012 May 1;18(9):2443-2451. ROSENZWEIG, S.A., ATREYA, H.S. (2010) Defining the pathway to insulin-like growth factor system targeting in cancer. Biochem Pharmacol, 15;80(8):1115-24.

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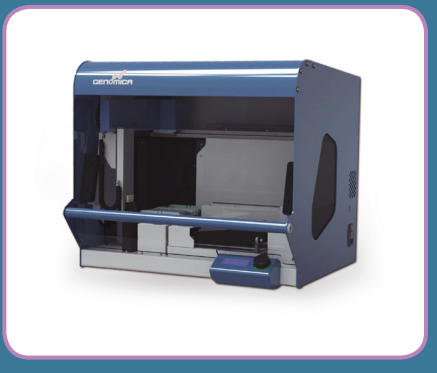
CLART® Technology

CLART® is a low density microarray-based platform for clinical use that allows the detection of multiple targets in a single test. Sample processing is straightforward and the analysis and interpretation of results are performed automatically by a reader (CAR® or CLINICAL ARRAY READER) running tailor-made software. Its simplicity makes this technology suitable for every molecular diagnostics laboratory.

CLART® provides fast, sensitive and accurate results that meet the highest quality standards, and allows the clinician to take the right decisions on time.

autoclart®

Autoclart is a GENOMICA automation system. It is designed for microplate processing and provides reagents addition, liquid handling, heating, cooling and microplate shaking. Its technical features make it suitable for almost all molecular diagnostics laboratories throughput:



AUTOCLART MAIN ADVANTAGES :

- Reduce significantly 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.

FEATURES :

- 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.

CAR®

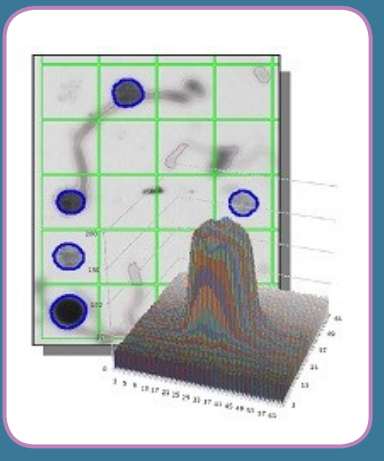
CAR® (Clinical Array Reader) is a colorimetric array reader unit, running our proprietary software, SAICLART®, for the analysis and interpretation of the array images. SAICLART® has been designed and validated for interpreting the arrays images turning them automatically into clinically relevant data.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

TECHNICAL CHARACTERISTICS :

- Integrated Computer.
- 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 microarrays analysis and interpretation. Originally developed for its diagnostic platform, SAICLART® can process microarrays in a wider range of formats like slides, tubes and microplates, spotted in a great variety of configurations.



- The image analysis is completely automated, avoiding the subjectivity that introduces user interaction, and providing fast, accurate and repeatable results.
- Its architecture allows easy and convenient customization for both R&D laboratories and *in vitro* diagnostics.

The SAICLART® recognition algorithm discerns spots from background signals using an advanced proprietary recognition algorithm:

- Identifies and segmentates the spots, validating them according to morphological criteria.
- Quantifies their signal considering all their effective area and offering up to 30 metrics per feature.

CE IVD

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autoclart® plus

- The latest GENOMICA automation system: It combines microplates processing for visualization and clinical array reading in the same device.
- The results from the visualization are automatically read and displayed on the integrated screen.
- Sample throughput flexibility: From 4 to 96 samples.
- Minimizes the potential variability: Both, intra-assay and inter-laboratory.

FEATURES :

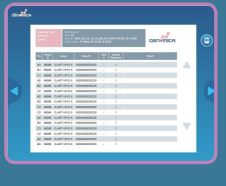
- Compact size. Benchtop device.
- Clinical Array Reader included.
- Full control of the equipmente from the touch screen.
- UV light for automatic decontamination.
- Microplate holder performs heating and cooling under a peltier controlled system but also shaking wells during incubations.
- 4 precision pumps for sample dispensing.

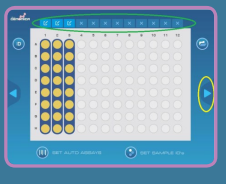
CLINICAL ARRAY READER FEATURES :

- Plug and play system.
- Patented CLEIS is an ituitive interface for an easy workflow.
- Different checklists are displayed during each run for an easy step by step tracking.
- Select three different ways of running samples:

  - Automatic Sample addition.
  - Manual Sample Addition.
  - Reading Only.

- Offers printable, storable or exportable reports.





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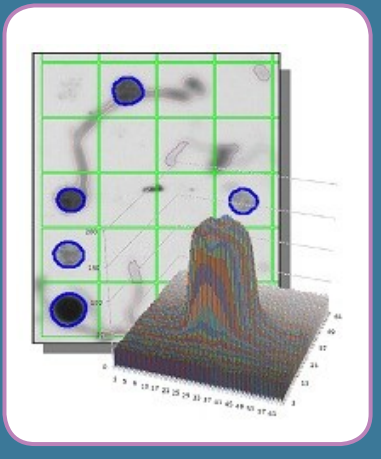
CLART® is a low density microarray-based platform for clinical use that allows the detection of multiple targets in a single test. Sample processing is straightforward and the analysis and interpretation of results are performed automatically by a reader (CAR® or CLINICAL ARRAY READER) running tailor-made software. Its simplicity makes this technology suitable for every molecular diagnostics laboratory.

CLART® provides fast, sensitive and accurate results that meet the highest quality standards, and allows the clinician to take the right decisions on time.

SAICLART®

SAICLART® is GENOMICA's proprietary image processing software for the analysis and interpretation of microarrays images. Originally developed for its diagnostic platform, SAICLART® can process microarrays in a wider range of formats like slides, tubes and microplates, spotted in a great variety of configurations.

- The image analysis is completely automated, avoiding the subjectivity that introduces user interaction, and providing fast, accurate and repeatable results.
- Its architecture allows easy and convenient customization for both R&D laboratories and *in vitro* diagnostics.



SAICLART®'s recognition algorithm discerns spots from background signals using an advanced proprietary recognition algorithm:

- Identifies and segmentates the spots, validating them according to morphological criteria.
- Quantifies their signal considering all their effective area and offering up to 30 metrics per feature.

CE IVD

VERSION 4: **APRIL 2016**