



**CLART**

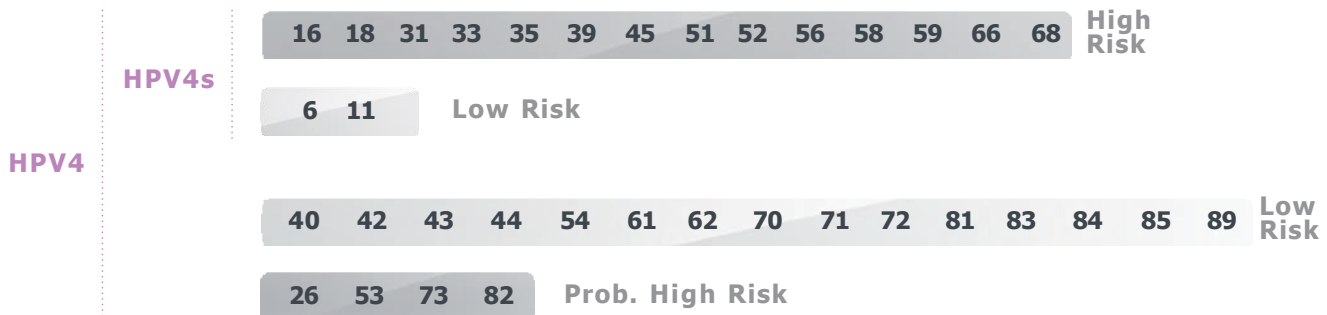
# MULTIPL X MICROARRAY MDX

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 clinicians. ARRAYTECH provides several automation systems to .optimize diagnostics using CLART® kits

# CLART® HPV 4 & HPV 4s

Genotyping Human Papillomavirus  
DNA extraction from liquid cytology and swab.

## GENOTYPES DETECTED :



- ▶ Oncogenic risk classification 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 genotyping of HR plus 6 and 11 genotypes.
- Aimed for HPV screening programs worldwide.

## Features:

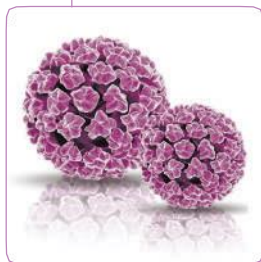
- ✓ Detects and genotypes different HPV types, including HR and LR in one assay.
- ✓ Sample processing without any need of DNA extraction is validated for Dried Swab, Digene STM and Cellular Suspension.
- ✓ High sensitivity and specificity.
- ✓ Clinical validation performed.
- ✓ Three quality controls 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 ARRAYTECH automation system.

## DATA MANAGEMENT :

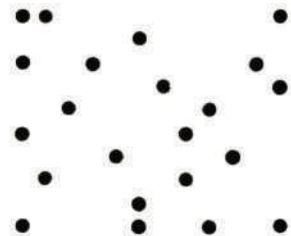
- ✓ Automatic reading and interpretation of results (CAR®).
- ✓ User-friendly report format (html, bmp).
- ✓ Samples are processed individually and three complementary reports are generated.
- ✓ Printable, exportable and storable reports.

# CLART® HPV 4

## REPORTING RESULTS :



► Report and image obtained by CAR® reader.



B1

Result view		Assay ID: 98213
CLART® HPV4		Rev. 13to 12
Sample reference:	2	
Array ID:	0000000050213 (B1)	
Date and time:	Thu Apr 07 14:07:37 2016	
Virus		
Virus	Result	Controls
6 (LR)	Negative	Passed
11 (LR)	<b>POSITIVE</b>	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: AT-0116-48

Genotyping 48 tests: CS-1215-48

## BIBLIOGRAPHY :

1. Bosch, F.X., Lorincz, A., Muñoz, N., Majjer, C.J.L.M. and Shah KV.: "The causal relation between human papillomavirus and cervical cancer". *J. Clin. Pathol.* 55, 244-265 (2002).
2. Calleja-Macías, I.E., Villa, L.L., Prado, J.C. et al. "Worldwide 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., Meroustoudis 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.

- CLART® HUMAN PAPILOMAVIRUS 4 or CLART® HPV4 is under protection of 2 patent families corresponding to International PCT Patent Applications WO2007017699 and WO2011116797, which comprise national and regional members in different territories, including granted patents in Spain, Germany, Denmark, France, Italy, Sweden, Russia, Mexico, China and Israel, and patent applications under prosecution in Brazil and Canada.

# CLART® Fast PneumoVir

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: H3N2 * H1N1 * H1N1/2009 *
Parainfluenza 4	
Coronavirus SARS-CoV-2	
Rhinovirus *	
RSV A	Influenza B *
RSV B *	Coronavirus HKU1

\*Amplification only available in Mix 2.

## IMPORTANCE OF HPV GENOTYPING :

- ▶ 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 :

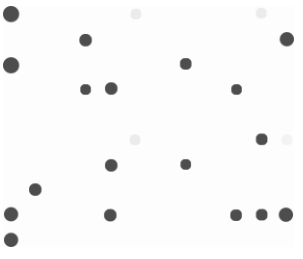
- ✓ Automatic reading and interpretation of results (CAR®).
- ✓ User-friendly report format (html, bmp).
- ✓ Samples are processed individually and three complementary reports are generated.
- ✓ Printable, exportable and storable reports.

# CLART® Fast PneumoVir

## REPORTING RESULTS :



► Report and image obtained by CAR® reader.



A1

Resultados		Assay ID: SC201
<b>CLART® PneumoVir2</b>		
Referencia de la muestra:	focus_0	Rev. 01sc.1
Array ID:	0000000052501 (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® Fast PneumoVir Amplification & Visualization**

48 tests: CS-0320-48

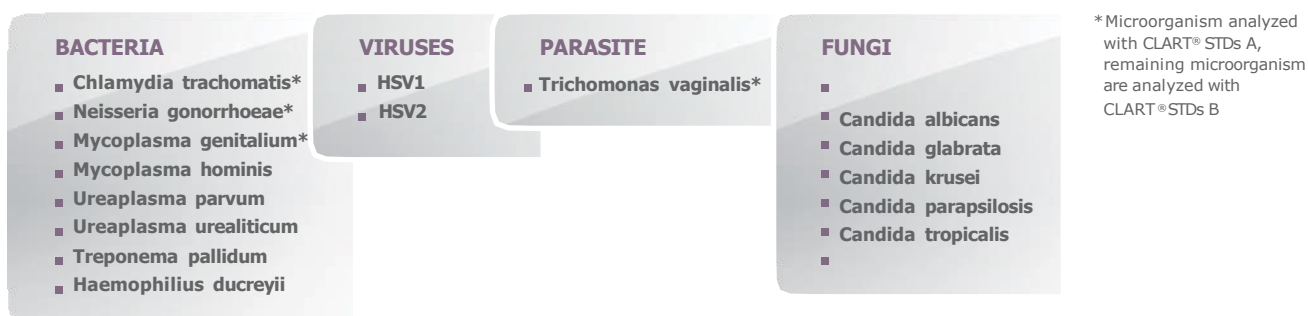
## BIBLIOGRAPHY :

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 PW, 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, Beghini M, De Maria C, Ansaldo 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.

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

# CLART® STDs - A&B

Detecting microorganisms causing urogenital tract infections



## 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 ARRAYTECH 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.

# CLART® STDs - A&B

## REPORTING RESULTS :



► Report and image obtained by CAR® reader.



Resultados CLART® STDs		Assay ID: S1027
Referencia del test:	0	
Assay ID:	0000000051027 (F1)	
Fecha y hora:	Wed Jan 28 11:23:41 2025	

Microorganism	Result
Chlamydia trachomatis LGV	<b>POSITIVE</b>
Chlamydia trachomatis NLGV	Negative
Chlamydia trachomatis	Negative

## ORDERING REFERENCES AND CONTACT DETAILS :

### CLART® STDs Amplification A

48 tests: CS-0417-48

### CLART® STDs Amplification A&B

48 tests: CS-0517-48

### CLART® STDs Visualization

48 tests: CS-0717-48

## 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® 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 consumption 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 ARRAYTECH automation system.

### DATA MANAGEMENT :

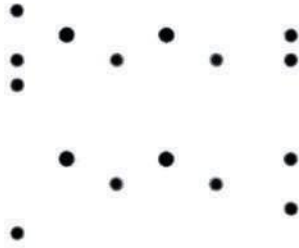
- ✓ Automatic reading and interpretation of results (CAR®).
- ✓ User-friendly report format (html, bmp).
- ✓ Samples are analyzed individually and three complementary reports are generated.
- ✓ Every report generated can be stored, exported and printed.

# CLART® ENTHERPEX

## REPORTING RESULTS :



► Report and image obtained by CAR® reader.



A5

Result view		AT code: 50516
<b>CLART® ENTHERPEX</b>		
Sample reference:	3	Rev. 10m.3
Array ID:	00000050516 (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
Varicella Zoster Virus	Negative	Passed
Epstein-Barr Virus	Negative	Passed

## ORDERING REFERENCES AND CONTACT DETAILS :

### CLART® ENTHERPEX Amplification

48 tests: AT-1008-48-MT

### CLART® ENTHERPEX Visualization

48 tests: CS-1108-48

## BIBLIOGRAPHY :

1. "L'HHV7: co-facteur des infections méningées à 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® Technology

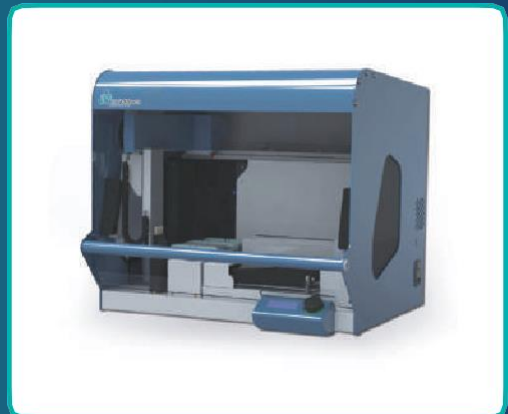
CLART® is a low density microarray-based platform for clinical use that allows the detection of multiple targets in a single test. Sample processing is straightforward and the analysis and interpretation of results are performed automatically by a reader (CAR® or CLINICAL ARRAY READER) running tailor-made 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 ARRAYTECH 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 CLAR®Tassay.
- ▶ 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.

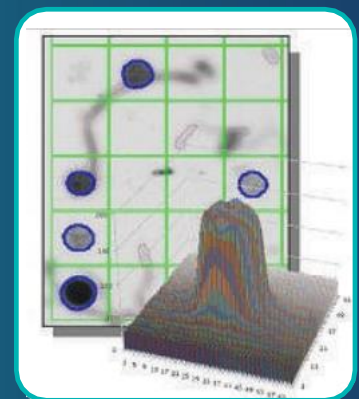
# SAICLART®

SAICLART® is ARRAYTECH's proprietary image processing software for microarrays analysis and interpretation. Originally developed for its diagnostic platform, SAICLAR® 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.



# autoclart® plus

- The latest ARRAYTECH 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 equipment 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 intuitive 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.



# CLART® Technology

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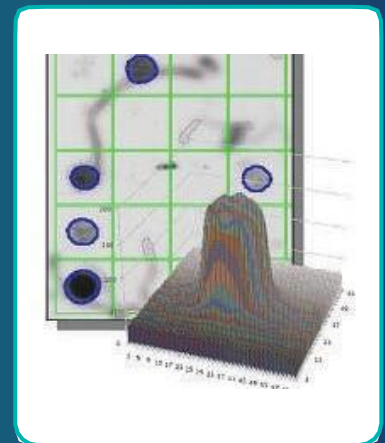
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- Quantifies their signal considering all their effective area and offering up to 30 metrics per feature.



# CLART



## Contact



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