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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.

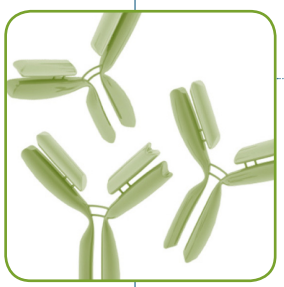
FEATURES OF CMA DIAGNOSTIC KITS :

- 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.

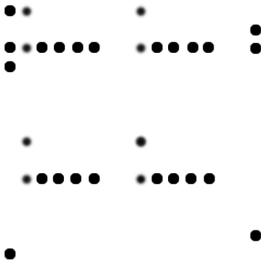
DATA MANAGEMENT :

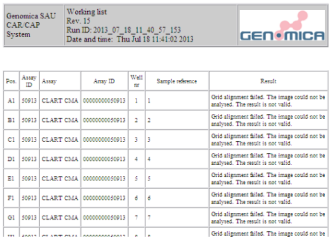
- Automatic reading and interpretation of results (CAR®).
- User-friendly report format (html, bmp).
- Printable, exportable and storable files.

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

NRAS · iKRAS :

- 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 EGFR

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

*6223, 12370, 12370, 6255, 12384, 12382, 6225, 12678, 6218, 12728, 6220, 12419, 6210, 13556, 12386, 12385, 18427, 12403, 12383, 6254, 13551, 12367, 12422, 12387, 26038, 13552, 12416, 23571. (According to COSMIC ID nomenclature).

MAIN FEATURES :

- An average diagnostic sensitivity ≥92% in the most of the mutations.
- Diagnostic specifity ≥99% .

ORDERING REFERENCES :

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

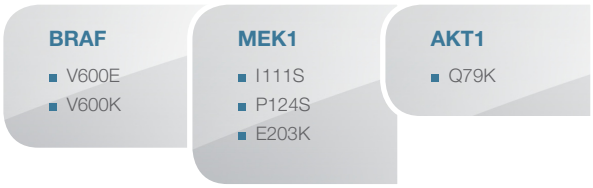
BIBLIOGRAPHY :

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.

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% .
- Diagnostic specifity ≥99% .

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**