CÖRE DIAGNOSTICS™

Case ID	: 24010006045
Patient Name	: Mr. W.M GUNADASA
Age/DOB/Sex	: 65 Years / / Male
Hospital Name	: Aegle Omics (Private) Limited, Colombo
Physician Name	: Dr. Jayantha Balawardana
Regn Date	: 11-Jul-2024 10:30
Collection On	: 08-Jul-2024 00:00
Reported On	: 17-Jul-2024 22:20
Process AT	: CORE-Gurugram
Ref no	:
Sample Type	: FFPE Block
Report Status	: Interim

MC-2256

UNIQUE PATIENT ID: 99687

TEST NAME

BRAF

SPECIMEN INFORMATION

Received 04 paraffin blocks labelled as 4262/24(A, B, C, D). Test performed on 4262/24-A.

CLINICAL HISTORY

Nodular melanoma

METHODOLOGY

Real Time Polymerase Chain Reaction (RT PCR)

DIAGNOSIS

MOLECULAR TEST	RESULT	INTERPRETATION
BRAF Mutation		
Exon 15 (Codon 600)	Wild Type	Negative

BRAF Molecular Mutation Tested	Result
V600E (c.1799T>A, C)	Wild Type
V600D (c.1799_1800TG>AT)	Wild Type
V600K (c.1798_1799GT>AA)	Wild Type
V600R (c.1798_1799GT>AG)	Wild Type

COMMENTS

1. There is absence of a BRAF mutation within this tumor specimen.
2. About 10-20% of the colon cancer patients harbor mutations of the BRAF gene.
3. Eighty percent of the mutations in the gene are attributed to the V600E (Exon 15) substitution.
4. The mutation is associated with proximal tumor location and microsatellite instability (MSI), with significant poor prognosis.
5. As per NNCN guidelines, BRAF V600E mutation should be tested in KRAS WT patients as it may contribute to resistance to antiEGFR therapy.
6. Studies have demonstrated that the response of patients to EGFR targeted therapies in colon cancer is limited to patients with tumors lacking KRAS and BRAF mutations.
7. The predictive value of BRAF testing applies to EGFR targeted therapies in colon cancer patients only and not to other therapeutic agents or cancers.
8. Correlation of these results with other clinicopathologic findings is required prior to use in any clinical management decisions.

CAP ACCREDITED
COLLEGE of AMERICAN PATHOLOGISTS
AU-ID-2010258

Dr. Shivani Sharma	Dr. Rahul Katara	Dr.Sanjay Kumar
DCP, DNB, DipRCPath.	Ph.D.	Ph.D
Reg. No. 1906		

Case ID	: 24010006045
Patient Name	: Mr. W.M GUNADASA
Age/DOB/Sex	: 65 Years / / Male
Hospital Name	: Aegle Omics (Private) Limited, Colombo
Physician Name	: Dr. Jayantha Balawardana
Regn Date	: 11-Jul-2024 10:30
Collection On	: 08-Jul-2024 00:00
Reported On	: 17-Jul-2024 22:20
Process AT	: CORE-Gurugram
Ref no	:
Sample Type	: FFPE Block
Report Status	: Interim

MC-2256

UNIQUE PATIENT ID: 99687

2. About 10-20% of the colon cancer patients harbor mutations of the BRAF gene.
3. Eighty percent of the mutations in the gene are attributed to the V600E (Exon 15) substitution.
4. The mutation is associated with proximal tumor location and microsatellite instability (MSI), with significant poor prognosis.
5. As per NNCN guidelines, BRAF V600E mutation should be tested in KRAS WT patients as it may contribute to resistance to antiEGFR therapy.
6. Studies have demonstrated that the response of patients to EGFR targeted therapies in colon cancer is limited to patients with tumors lacking KRAS and BRAF mutations.
7. The predictive value of BRAF testing applies to EGFR targeted therapies in colon cancer patients only and not to other therapeutic agents or cancers.
8. Correlation of these results with other clinicopathologic findings is required prior to use in any clinical management decisions.

TEST ATTRIBUTES

Assay Description and Methodology

Formalin-fixed, paraffin-embedded tumour tissue sections are deparaffinized and DNA is extracted using the Tissue Kit (Qiagen, Valencia, CA). BRAF Codon 600X is detected using an in-house developed and validated test, which identifies somatic mutations using mutation-specific amplification followed by Taqman Based Real Time PCR with an analytical sensitivity of 1.85 ng/uL mutant DNA in a background of wild-type genomic DNA and analytical specificity of 100%

Intended Use:

This laboratory-developed test is intended to be used and be interpreted in conjunction with all other available clinical and laboratory information when evaluating prognosis and resistance to anti-EGFR therapy in colon cancer patients. The BRAF gene encodes a protein belonging to the RAF family of serine/threonine protein kinases.

This protein plays a role in regulating the MAP kinase/ERK signaling pathway, which affects cell division, differentiation, and secretion. Mutations in this gene, most commonly the V600E mutation, are the most frequently identified cancer-causing mutations in melanoma, and have been identified in various other cancers as well, including non-Hodgkin lymphoma, colorectal cancer, thyroid carcinoma, non-small cell lung carcinoma, hairy cell leukemia and adenocarcinoma of lung.

Disclaimer:

This test is performed using in-house developed assay for BRAF (Codon 600). The assay is designed to perform the reactions at the specified analytical sensitivity given that the template DNA is not heavily fragmented and does not contain materials that could inhibit the amplification reaction.

REFERENCES:

1. Cetuximab Therapy and RAS and BRAF Genotype Laura Dean, MD and Megan Kane, PhD. Medical Genetics Summaries 2020

2. Are KRAS/BRAF Mutations Potent Prognostic and/or Predictive Biomarkers in Colorectal Cancers? Tomoya Yokota Anti-Cancer Agents in Medicinal Chemistry, 2012, 12, 163-171

3. Molecular targeted therapy of BRAF-mutant colorectal cancer Michel Ducreux, Ali Chamseddine Therapeutic Advances in Medical Oncology Ther Adv Med Oncol 2019, Vol. 11: 1–15

4. Comprehensive review of targeted therapy for colorectal cancer Yuan-Hong Xie, Ying-Xuan Chenet al. Signal Transduction and Targeted Therapy 20 March 2020

CAP ACCREDITED
COLLEGE of AMERICAN PATHOLOGISTS
AU-ID-2010258

Dr. Shivani Sharma	Dr. Rahul Katara	Dr.Sanjay Kumar
DCP, DNB, DipRCPath.	Ph.D.	Ph.D
Reg. No. 1906		

Case ID	: 24010006045
Patient Name	: Mr. W.M GUNADASA
Age/DOB/Sex	: 65 Years / / Male
Hospital Name	: Aegle Omics (Private) Limited, Colombo
Physician Name	: Dr. Jayantha Balawardana
Regn Date	: 11-Jul-2024 10:30
Collection On	: 08-Jul-2024 00:00
Reported On	: 17-Jul-2024 22:20
Process AT	: CORE-Gurugram
Ref no	:
Sample Type	: FFPE Block
Report Status	: Interim

MC-2256

UNIQUE PATIENT ID: 99687

5. Meta-analysis of BRAF mutation as a predictive biomarker of benefit from anti-EGFR monoclonal antibody therapy for RAS wildtype metastatic colorectal cancer A Rowland et al. British Journal of Cancer (2015) 112, 1888–1894

6. Kang X, Zeng Y, Liang J, et al. Aberrations and clinical significance of BRAF in malignant melanoma: a series of 60 cases in Chinese Uyghur. Medicine (Baltimore) 2018;97:e9509.

7. Sharma K, Mohanti BK, Rath GK. Malignant melanoma: A retrospective series from a regional cancer center in India. J Can Res Ther 2009;5:173–80.

8. Byrd-Miles K, Toombs EL, Peck GL. Skin cancer in individuals of African, Asian, Latin-American, and American-Indian descent: differences in incidence, clinical presentation, and survival compared to Caucasians. J Drugs Dermatol 2007;6:10–16.

9. Ishihara K, Saida T, Otsuka F, et al. Statistical profiles of malignant melanoma and other skin cancers in Japan: 2007 update. Int J Clin Oncol 2008;13:33–41.

10. Goel VK, Lazar AJ, Warneke CL, et al. Examination of mutations in BRAF, NRAS, and PTEN in primary cutaneous melanoma. J Invest Dermatol 2006;126:154–60.

Pending Services

c- KIT Mutation Analysis (GIST)

Scan to Connect

If you have any questions about this report or would like to have a conversation about the test results, please feel free to reach out to us at

+91 88828 99999 or **info@corediagnostics.in**

CONDITIONS OF REPORTING

1. The tests are carried out in the lab with the presumption that the specimen belongs to the patient named or identified in the bill/test request form.
2. The test results relate specifically to the sample received in the lab and are presumed to have been generated and transported per specific instructions given by the physicians/laboratory.
3. The reported results are for information and are subject to confirmation and interpretation by the referring doctor.
4. Some tests are referred to other laboratories to provide a wider test menu to the customer.
5. CORE Diagnostics Pvt. Ltd. shall in no event be liable for accidental damage, loss, or destruction of specimen, which is not attributable to any direct and mala fide act or omission of CORE Diagnostics Pvt. Ltd. or its employees. Liability of CORE Diagnostics Pvt. Ltd. for deficiency of services, or other errors and omissions shall be limited to fee paid by the patient for the relevant laboratory services.

CŌRE Diagnostics (Central Reference Lab) - Gurugram
406, Udyog Vihar, Phase III, Gurugram, Haryana - 122016

CŌRE Diagnostics Satellite Lab - New Delhi
C-13, 1st Floor, Green Park Extension, New Delhi - 110016
67, Hargobind Enclave, New Delhi - 110092
H64, Block H, Bali Nagar, New Delhi - 110015

CŌRE Diagnostics Satellite Lab - Bhubaneswar
Plot No. - 249, Near Police Academy, AIIMS Nagar, Patrapada, Bhubaneswar - 751019

CŌRE Diagnostics Satellite Lab - Bangalore
1st Floor, KMK Tower, 142 KH Road, Bangalore - 560027

CŌRE Diagnostics Satellite Lab - Lucknow
J.S. Tower, Plot No. - K-702, Sector K, Ashiyana, Near Raj Luxmi Sweets, Lucknow, Uttar Pradesh - 226012

CŌRE Diagnostics Satellite Lab - Guwahati
Ground Floor, Honuram Boro Path, Shubham Velocity, GS Road, Dispur, Kamrup Metropolitan, Guwahati, Assam - 781005

CŌRE Diagnostics Satellite Lab -Hyderabad
S. No.155, Mahalakshmi Trade Center, 2nd Floor, Thokatta -Village, Diamond Point Road, Bowenpally, Secunderabad,Telangana-500009