## DATAR <u>CANCER GENETICS</u>

TRF01

### **CONSENT STATEMENT**

I, the undersigned (Patient / Relative of Patient) request that the Genetic Diagnostic test as specified in the Test Request Form be performed. I have read and understood the following.

- 1. I understand that Genetics is a rapidly evolving science and that the test report made available to me will contain results / inferences which are based on present knowledge, scientific information and publication.
- 2. I have been informed about the purpose of this genetic test and I understand the limitations of the same.
- 3. I have discussed the benefits and risks of this genetic test with my Physician and/or other health care professional. I understand some genetic tests can involve possible Medical and Psychological issues. I understand that some significant incidental finding may be detected during genetic testing and I will be informed about it.
- 4. I will not act on basis of the Genetic Analysis report alone without consulting a Medical professional / Doctor.
- 5. All personal data entered in the Registration Form and/or otherwise submitted to the Company is true and the collected sample is mine and doesn't belong to a third party and / or is not in any way contaminated by human / animal / plant material. I am aware that inadequately collected genetic material may lead to a lack of data about analyzed genetic variations.
- 6. I understand and agree that the company may retain and utilize the de-identified sample and / or data generated from the processing for future analysis, research and anonymous publication.
- 7. My questions have been answered to my satisfaction.
- 8. I have been informed about the test purpose, procedures, possible risks and have received a copy of the consent statement.
- 9. I understand that the sample may be rejected/recollected due to inadequate quantity / quality of Bio-Markers to be analysed.
- 10. In Exacta<sup>®</sup> analysis I am aware that the Therapy Recommendation provided pursuant to the Exacta<sup>®</sup> investigation / analysis may include drugs that are FDA approved, however these drugs may be in use for other cancers or other non-cancerous disease conditions.
- 11. Courts in Mumbai will have exclusive jurisdiction over any claims or disputes arising out of or in connection with the Terms /Testing /Analysis /Reports in respect of sample submitted by me.
- 12. I understand that the test report is not a prescription and my treating physician / clinician may not take clinical decision only based on this report.
- 13. I hereby certify that the information furnished in the form is true and correct to the best of my knowledge. I further certify that the Sample furnished by me is my own / of my ward and is submitted as per the instructions / directions furnished to me. I hereby undertake to pay the total amount payable as aforesaid.
- 14. I understand and accept that my details supplied at the time of collection of sample(s), will be shared with the laboratory personnel for the purpose of personal data analysis and generation of reports. I understand that this laboratory may be situated beyond the UK / Europe jurisdiction. If I want my personal data and/or the raw data deleted from the laboratory records, I am aware that I can write to the laboratory and within 7 days the laboratory will destroy all my personal data except as required to be stored under the regulatory requirements.
- 15. I understand and accept that the data shared by me shall be transferred to DCG Laboratory in India for the purpose of sample processing and report preparation.

Specimen Retention: I authorize "Datar Cancer Genetics" to store and use my de-identified sample and test data as described above.

 I confirm that I am not pregnant at the time of giving this sample. (applicable for women patients only)
 Name of the Patient :

| Signature of the Patient / Guardian :                          | ]   |
|--|-----|
| Date:  |     |
|  |     |
| Name of Guardian:  |     |
| Name of Guardian:  | 600 |
| ······································                         | 070 |
| NOTE . We do not account blood complete first another any test | 4   |

NOTE :- We do not accept blood sample of pregnant women for any test. We do not conduct any test for determination of sex of the fetus.

# **Test Requisition Form**



(Oncology)

| Test Name:  | Test Code:                                      |
|---|---|
| Name: Dr./ Mr./ Ms./ Mrs. First Name Middle Name  | Surname   |
| Address for report dispatch:  |   |
|   | Pincode   |
| Mobile No.: E-mail:   |   |
| Patient's Age:       Gender: Male       Female:       Date of Birth:       D       M       Y  | E A R   |
| Occupation: Nationality:  | Ethnicity:                                      |
| Date and Time of Collection: Sample Collected by  | :   |
| Sample type: Blood EDTA Tube ml DCG Tube  | ml  |
| FFPE Block Slides Fresh Tissue Block No. / Slide No. / Site of Biopsy:  |   |
| *Refer DCG Directory of Services for sample type and volume<br>Name of Fixative*: Formalin Media Preservative solution Fixation time (h<br>* Mandatory Information.   | ours)*:   |
| Referring Doctor: Contact No.:  |   |
| E-mail ID (Mandatory):  |   |
| NOTE : 1. Complete analysis will be carried on primary sample received (Blood / Tissue). 2. I am submitting all the FFPE blocks / fresh tissue sample available with me for the test. I am fully aware that the test analysis will be performed entirely on the provided <u>blood sample</u> in case FFPE blocks / fresh tissue sample submitted is insufficient / does not meet our Quality criteria. 3. I Authorise Datar Cancer Genetics to send copy of my reports to my doctor and / or his assistant. | Sign. of Patient / Relative / Guardian          |
| PERSONAL MEDICAL DETAILS  |   |
| Type of Cancer: When detected:  |   |
| Operated: Yes No If Yes, When:  |   |
| FFPE Blocks Available: Yes No If Yes, please send to DCG (Optional)   |   |
| Histo-pathology report Date: D D M M Y E A R Present Status: R  | elapse / Recurrence / Metastasis / Other        |
| Whether on chemotherapy: Yes       No       Name of Chemotherapy Drugs:   |   |
| Date of last Chemotherapy:       D       D       M       M       Y       E       A       R       No. of Cycles:   |   |
| Name of other Drugs:  |   |
| Whether on Radiation Therapy : Yes   No   No. of Cycles:  |   |
| Date of last Radiation Therapy:       D       D       M       M       Y       E       A       R       Date of last PET/ CT/   | MRI ** D D M M Y E A R                          |
| History of recent blood transfusion: Yes No If Yes, Date: D D M M Y H   | E A R   |
| History of previous bone marrow transplant: Yes No If Yes, Date: D D M  | M Y E A R                                       |
| Have you been recently tested for any Infectious disease / Viral disease / COVID-19 : $\gamma_{\text{es}}$  | s No  |
| If Yes, Date of test D D M M Y E A R Result of test :   | Please attach copy of the report<br>(Mandatory) |
| For female patients only - Date of Last Menstrual Period: D D M M Y E A R   |   |
| Family history (Cancer related):  |   |
| Other medical history:  | Signature of Doctor and Date                    |
|   | IMP : PLEASE SIGN OVERLEAF P.T.O.               |

NOTE :- Copies of all available reports must be sent along with the sample and TRF in order to avoid any delays in receipt of DCG reports. \*\* A gap of at least two weeks is preferred between date of sample collection and date of last PET / CT / MRI / Radiation therapy / blood transfusion.

## DATAR **CANCER GENETICS**

#### **PERSONAL HISTORY**

| Diabetes Hyperte            | ension      | CAD               |  |
|-----------------------------|-------------|-------------------|--|
| Hypercholesterolemia        | Any other   |                   |  |
| 1) Smoking :                | Yes         | No If Yes (years) |  |
| 2) Alcohol :                | Yes         | No If Yes (years) |  |
| 3) Diet Vegetarian :        | Yes         | No If Yes (years) |  |
| 4) Abnormal Vitamin level : | Yes         | No If Yes (years) |  |
|                             | Vit D Vit E | B12 Vit B6        |  |

5) Others :

| CONSENT FOR MINORS |  |
|--------------------|--|
|                    |  |

(CHILDREN BELOW 18 YEARS OF AGE)

| ļ | ,                         |         |         |       |      |    |         |       | ,  | INOU | ier / Faui | er / |
|---|---------------------------|---------|---------|-------|------|----|---------|-------|----|------|------------|------|
|   | Legal Guardian of (name o | f the m | inor) _ |       |      |    |         |       |    |      |            |      |
|   | (Age of minor)            | state   | that I  | would | like | to | conduct | (name | of | the  | genetic    | test |

genetic test on my child / ward. I have been made aware of the nature of this genetic test. I have also been made aware that the said test may reveal presence or absence of certain genetic mutations or variations which may increase the predisposition for certain diseases like cancers, I am aware that such disclosure may have medical as well as psychosocial implications for the child as well as parents and I am willing to take responsibility for the same.

I will not hold DCG responsible for any psychosocial consequences that may arise from the interpretations of this report. I will seek genetic counselling on our own accord to understand the implications of the test results.

I would like to go ahead with the above mentioned genetic test for my child / ward. I have also signed Consent on the DCG Test Requisition Form (TRF)

| )ate: | / |
|-------|---|
|       |   |

| Place: |
|--------|
| Flate. |

Signature of the Parent / Guardian

#### YOUR OBSERVATIONS

#### Dear Sir/Madam.

Thank you for giving us the opportunity to serve you. Kindly spare a few minutes and let us know your observations to help us improve our services.

| 1) Did you receive clear and complete information on the test you requested for? |           |                   |  |  |  |  |  |  |  |  |
|--|-----------|-------------------|--|--|--|--|--|--|--|--|
| Satisfactory 😳   | Neutral 😑 | Dissatisfactory © |  |  |  |  |  |  |  |  |

2) Was the whole process from sample collection to reporting sufficiently explained to you?

| Yes | ) |  | Inco | mplet | e 😑 |  | No | ;; |
|-----|---|--|------|-------|-----|--|----|----|
|     |   |  |      |       |     |  |    |    |

3) How neat, clean and punctual was the Phlebotomist?

Satisfactory 😊 Neutral 😑 Dissatisfactory 😣 4) How smooth and comfortable was the sample collection process?

Satisfactory 

Neutral 

Dissatisfactory

5) Is there anything else you would like to share with us?

| Signature of the Patient:                            |
|--|
| PAYMENT DETAILS                                      |
| Name:  |
| Test Amount:   |
| Mode of Payment : Cash / Cheque / DD / NEFT / Online |
| Online Transaction Ref.:                             |
| Bank Name :  |
| Cheque No. and Date :                                |



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Specimen Retention: I authorize "Datar Cancer Genetics" to store and use my de-identified sample and test data as described above.

|  | Please tic | k if y | ou do | not want | the sample | to be | retained | by | DCG |
|--|------------|--------|-------|----------|------------|-------|----------|----|-----|
|--|------------|--------|-------|----------|------------|-------|----------|----|-----|

| I confirm that I am not pregnant at the time of giving this sample |
|--|
| (applicable for women patients only)                               |

Name of the Patient : .....

| ignature of the Patient / Guardian : |  |
|--------------------------------------|--|
|                                      |  |
| ate:                                 |  |
|                                      |  |
|                                      |  |

Name of Guardian:

| Relationship with the patient:   |
|--|
| NOTE :- We do not accept blood sample of pregnant women for any test.<br>We do not conduct any test for determination of sex of the fetus. |

## DATAR **CANCER GENETICS**

| Test Name:         |             |         |
|--------------------|-------------|---------|
| Test Code:         |             |         |
| Name: Dr./ Mr./ Ms | s./ Mrs.    |         |
| First Name         | Middle Name | Surname |
| Date and Time of C | ollection : |         |

### **INFORMATION TO PATIENT**

Please read the following information carefully before signing the consent.

- 1. Datar Cancer Genetics (herein after referred to as "DCG") has taken all reasonable efforts to ensure a quality report for the genetic testing. However, as genetics is all a rapidly evolving science, no medical and personal decisions can be made based on the report without consultation with an appropriate professional for advise for your specific results.
- 2. With the complexity of information reported in the genetic test report, a pretest and post-test counseling can be offered by DCG to help you understand the test and the result.
- 3. <u>Negative Results</u> A negative result for a particular condition is an indication that no known genetic variant / abnormality was identified during the analysis as on that date.
- 4. Limitations of the test You will understand that DCG employs latest technology and knowledge to the best of its ability to perform the test. However, with the evolving nature of genetics, the results are based on current scientific research and publication available in the public domain and cannot be considered as confirmatory diagnosis and the liability of DCG is limited to that extent. Interpretations are provided based on current scientific evidence and knowledge which is evolving, and therefore the nonactionable finding such as driver mutations with unknown clinical significance or inherited (germline) mutations with Variants of Unknown Significance (VUS) may in future become actionable and therefore such reports may be communicated to the patients in future by the laboratory.
- 5. If for any reason you choose to cancel the testing and analysis of your sample after the sample has been collected, please note that the payment made may be refunded after certain deduction, depending on the time of cancellation

|  | PAYMENT DETAILS |  |  |  |  |
|--|-----------------|--|--|--|--|
| Name:  |                 |  |  |  |  |
| Test Am  | unt:            |  |  |  |  |
| Mode of Payment : Cash / Cheque / DD / NEFT / Online |                 |  |  |  |  |
| Online Transaction Ref.:                             |                 |  |  |  |  |
| Bank Na  | ne :            |  |  |  |  |
| Cheque No. and Date :                                |                 |  |  |  |  |