CONSENT FORMS

MUTATION ANALYSIS PROGRAM † ENROLLMENT FORM

Patient Identification Information

The Johns Hopkins Genomics DNA Diagnostic Laboratory (JHGDDL)

†Funded by the Cystic Fibrosis Foundation

Fax completed forms to 410-367-3266. For questions, call the JHGDDL at 410-614-2750.
All fields must be complete and legible. Provider and patient stamps or stickers are not valid.
Information must be typed or handwritten.

Shipping address:
Johns Hopkins Genomics - DDL
1812 Ashland Ave
Sample Intake, Room 245
Baltimore, MD 21205

***MAP Authorization#:** ______________________ **Date:** ______________________ *For JHGDDL Use Only*

Indicate whether this is the patient's first enrollment, or whether the patient is eligible for re-enrollment.
Please visit the Program website for eligibility requirements.

☐ First-Time Enrollment ☐ Qualified Re-Enrollment, CFFMAP Genetic ID:______________________

Referrer Information

Referring Provider:______________________ NPI:______________________

Nurse/Genetic Counselor/Social Worker:______________________ Email:______________________

CF Care Center Name:______________________ CF Care Center ID #:______________________

Address:______________________

City:______________________ State:______________________ Zip:______________________

Phone Number:______________________ Fax number for results:______________________

Institution/Reference Lab/Sendout Lab Fax # (if applicable):______________________

Patient Information **Two or more of these identifiers must appear on the sample.*

Patient Name: Last ______________________ First______________________ Middle ______________________

Date of Birth (mm/dd/yyyy):______________________ Sex assigned at birth:____________ Gender identity:______________________

Address:______________________

City:______________________ State:______________________ Zip:______________________

Sample Accession # or Patient's Medical Record (MRN) #:______________________

Clinical Information *Please attach a copy of the patient's most recent clinic note.*

Lowest sweat chloride concentration(s):____________ (mmol/L)

Notes:______________________

Genetic Testing Information *Please attach a copy of the patient's prior genetic testing results.*

Has this individual ever received *CFTR* genetic testing? ☐ No (Prior testing is required for enrollment) ☐ Yes

Were any variants identified by prior testing? ☐ No ☐ Yes, variants identified:______________________

____

Transfusion/Transplant Information *Please contact the lab to coordinate submission of alternate sample types.*

Blood and saliva samples are not acceptable if the patient has:

- Received blood products <2 weeks before specimen collection. Exceptions are made for pRBC-only transfusions.
- Received a bone marrow or allogenic stem cell transplant. Cultured skin fibroblasts are the only accepted specimen type in this case.
- Active hematologic malignancy; cultured skin fibroblasts are the recommended sample type.

For Internal Use Only		
Accession #:	Date Received:	ID #:
Notes:		

https://www.hopkinsmedicine.org/dnadiagnostic/mutation-analysis-program

Original - Medical Record

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Sample Collection Please select the type of sample to be submitted for testing.

☐ Venous blood	☐ Saliva	☐ Previously Submitted Specimen
To be completed by provider after approval. Do not collect sample without prior approval.	Not suitable for patients under 5 years of age. Do not use non-CFFMAP collection kits.	For patients qualified for re-enrollment, the lab will determine whether there is sufficient DNA remaining for processing.
Date blood sample collected: ______________________	**A CFFMAP saliva kit will be sent to patient for approval.** *Note: The lab is unable to ship to a PO Box. Please provide a residential address.*	**If a new sample is required, the lab will contact the provider.**

Mutation Analysis Program Informed Consent

Provider Consent: Read and Sign

I certify that I am the referring provider for the patient identified above, and have assisted the patient in completing this form. I certify that the patient identified above has a confirmed or strongly suspected CF diagnosis. I also understand that the Mutation Analysis Program (MAP) is not intended to be used to diagnose patients with CF, but rather used to identify the patient's unknown genetic variants(s). I certify that I have discussed the purpose of this genetic testing with the patient and explained to the patient that the testing may take up to three months to complete.

✘ ____

Signature of Provider (Required) **Signature Date/Time (Required)**

Patient Consent: Read and Sign

I understand that my physician is requesting the Johns Hopkins Genomics DNA Diagnostic Laboratory (JHGDDL) to perform the Mutation Analysis Protocol on me/my dependent, and that my physician may provide a limited amount of health information with the request. The purpose and accuracy of this testing have been reviewed by my health care provider and my questions about these issues have been answered. I understand that in most cases, a negative test result does not necessarily rule out a hereditary condition. Results of DNA testing should be considered with the results of other types of testing and clinical evaluation. Test results may disclose non-paternity or other genetic conditions. No clinical tests other than those authorized will be performed; however, any remaining sample may be used for quality control purposes or research after de-identification. My physician will receive a clinical report, but the laboratory cannot guarantee turn-around time or that a result will be obtained on any sample. Release to other parties requires written consent of the patient.

I have read and agree to the Program Informed Consent section above.

____

Patient Name (Printed) **Date of Birth (MM/DD/YYYY)**

✘ ____

Signature of Patient/Parent/Guardian (Required) **Signature Date/Time (Required)**

____

Parent/Guardian Name (Printed) Relationship to patient if not self

I would describe my race/ethnicity as (please select all that apply):

- ☐ Black, African American, or of African descent
- ☐ East Asian
- ☐ Middle Eastern, Southwest Asian, North African
- ☐ Hispanic, Latino/Latina/Latinx
- ☐ Native American, Alaska Native, First Nations
- ☐ Native Hawaiian, Pacific Islander
- ☐ South Asian
- ☐ Southeast Asian
- ☐ White
- ☐ Other: ______________________
- ☐ Prefer not to respond