

**GENETIC DIAGNOSTIC LABORATORY  
UNIVERSITY OF PENNSYLVANIA SCHOOL OF MEDICINE  
DEPARTMENT OF GENETICS  
Tel: (215) 573-9161 • Fax: (215) 573-5940  
CLIA ID: 39D0893887**

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## **FAP (Familial Adenomatous Polyposis)**

**Background:** Familial Adenomatous Polyposis (FAP) is a genetic disorder which typically presents with colorectal cancer in early adult life secondary to extensive adenomatous polyps of the colon. Polyps also develop in the upper gastrointestinal track and malignancies may occur in other sites, including the brain and the thyroid. Helpful diagnostic features include pigmented retinal lesions known as congenital hypertrophy of the retinal pigment (CHRPE), jaw cysts, sebaceous cysts, and osteomata.

Screening for a mutation in the coding region of the APC gene is offered to individuals who have multiple colonic polyps. A pedigree demonstrating all cancers in the family must be submitted with the sample. At-risk family members related to individuals in whom a mutation has been identified can be studied to determine if they have inherited the familial mutation. APC mutations are inherited in an autosomal dominant pattern.

Screening for mutations in the MYH gene is offered to individuals with multiple polyps who have a negative family history and who are APC mutation negative. Mutations in the MYH gene have recently been shown to cause FAP when two copies of the MYH gene with a mutation are inherited (autosomal recessive pattern). MYH is more likely to be the gene involved when there is no prior family history of colorectal cancer. Testing is done first for two common mutations (Y165C and G382D). If neither of these two mutations is present, full sequencing of the MYH gene can be done. There is no tendency for other extracolonic tumors associated with MYH.

**Assay:** Direct mutation analysis by sequencing.

**Utility:** To identify individuals at very high risk of developing colon cancer so that they can be targeted for aggressive prevention programs and to reassure individuals in families with a known mutation that they are not at any higher risk for colorectal cancer than individuals in the general population (1-25 lifetime risk) if they have not inherited the familial mutation.

**Sensitivity:** Molecular genetic testing will detect a mutation in the APC gene in approximately 70% of affected individuals. Mutations in non-coding sequences, insertions, deletions or other rearrangements will not be detected by sequencing. A substantial proportion of people with multiple polyps in the colon, perhaps as many as 30% who have 15 to 100 polyps, have biallelic MYH mutations.

**Turn around:** 10 weeks for APC screening, 6 weeks for MYH screening, 3 weeks for familial/targeted mutation, 1-3 weeks for prenatal diagnosis

**Fees:** APC = \$1360 for Sequencing      MYH = \$600 for Sequencing  
APC/MYH = \$340 for Familial Mutation(s)    APC/MYH = \$340 for Prenatal Diagnosis

**CPT Codes:** APC Screening: 83891, 83894x10, 83898x27, 83904x24, 83909x2, 83912  
MYH Screening: 83891, 83894x8, 83898x15, 83909x2, 83912  
Familial/Targeted Mutation: 83891, 83898x6, 83904x6, 83912  
Prenatal Diagnosis: 83891x2, 83898x4, 83904x5, 83912

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**Mutation Analysis for Familial Adenomatous Polyposis (FAP)  
INSTRUCTIONS FOR SAMPLE SUBMISSION**

**Documentation:** Each sample must be accompanied by:

1. A requisition for DNA analysis completed by the physician, nurse, or genetic counselor requesting screening. ***Please note: ICD-9 code is required for billing purposes. If ICD-9 code is unknown, please provide patient's clinical symptom(s) or family history that prompted testing.***
2. The patient's pedigree including three generations, if possible.
3. An informed consent signed by the patient (if under 18 years of age, the parent or guardian should sign) and the professional obtaining the consent. Please have the patient initial at the top of each page and send **all** pages of the consent.
4. A verification of blood tubes form signed by the patient, parent or guardian. The form should be signed at the time of the blood draw.
5. A completed registration form with check, money order, credit card authorization or information for billing the referring institution.

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**IN THE EVENT THAT ALL PROPERLY COMPLETED FORMS DO NOT ACCOMPANY  
THE SPECIMEN, YOU WILL BE NOTIFIED, AND TESTING WILL BE HELD UNTIL  
PAPERWORK IS COMPLETE.**

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**Preparing Sample:**

- Obtain 2 EDTA tubes (lavender top) of blood - approx. 4 mL per tube
- Label each tube with the patient's name and date sample was obtained
- We accept banked or recently extracted DNA; please include the concentration.
  
- For prenatal testing: cultured amniotic fluid or CVS cells, 2 confluent T-25 flasks. Please call the lab prior to sending a prenatal sample. We are often able to offer testing on a direct villi or amnio sample, and we can discuss the requirements with you. 5mL of whole blood from each parent should accompany the prenatal sample.

**Shipping Sample:** Ship at room temperature via Federal Express or other overnight courier that guarantees AM delivery to arrive Monday-Friday. There is no one in the laboratory evenings and weekends to receive samples. If sample is drawn on a Friday, please refrigerate it until shipment on the following business day.

**Shipping Address:** Genetic Diagnostic Laboratory  
University of Pennsylvania  
415 Anatomy-Chemistry Building  
3620 Hamilton Walk  
Philadelphia, PA 19104

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**REQUEST FOR FAMILIAL ADENOMATOUS POLYPOSIS (APC/MYH) TESTING**

PATIENT FIRST NAME \_\_\_\_\_ PATIENT LAST NAME \_\_\_\_\_

BIRTH DATE \_\_\_\_\_ SEX \_\_\_\_\_ RACE \_\_\_\_\_ ETHNICITY \_\_\_\_\_

STREET ADDRESS \_\_\_\_\_

CITY \_\_\_\_\_ STATE \_\_\_\_\_ ZIP \_\_\_\_\_ HOME PHONE \_\_\_\_\_

Has the patient had any type of cancer or polyps? \_\_\_\_\_  
If yes, indicate what types of tumors/polyps and age of onset.

Is there any family history of colon cancer or polyps? \_\_\_\_\_  
If yes, indicate how the individual is related to the proband, what types of tumors/polyps and age of onset.

**Please include a family pedigree with three generations.**

Has anyone in the patient's family ever had DNA testing for FAP? \_\_\_\_\_ If yes, what was the result?

**Please include a copy of the affected relative's genetic test result.**

REFERRING PHYSICIAN \_\_\_\_\_ PHONE \_\_\_\_\_ FAX \_\_\_\_\_

GENETIC COUNSELOR \_\_\_\_\_ PHONE \_\_\_\_\_ FAX \_\_\_\_\_

EMAIL ADDRESS FOR COUNSELOR OR PHYSICIAN \_\_\_\_\_  
INSTITUTION and  
DEPARTMENT \_\_\_\_\_

STREET ADDRESS \_\_\_\_\_

CITY \_\_\_\_\_ STATE \_\_\_\_\_ ZIP \_\_\_\_\_ COUNTRY \_\_\_\_\_

**ICD-9 CODE (or patient's clinical symptoms)** \_\_\_\_\_

**TEST REQUESTED**

- \_\_\_\_ Sequencing of the coding regions of the APC gene (exons 1-15)  
\_\_\_\_ APC familial sequencing mutation (attach copy of report)      \_\_\_\_ MYH Familial mutations(s) (attach copy of report)  
\_\_\_\_ Screening for Y165C & G382D in the MYH gene      \_\_\_\_ Sequencing of the entire coding regions in the MYH gene  
\_\_\_\_ Prenatal diagnosis of known familial mutation (please call the lab before sending sample to discuss fetal sample requirements; 5mL of whole blood from both parents is required for MCC studies)

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**CONSENT FORM: PROBAND GENETIC TESTING  
FOR MUTATIONS IN APC AND MYH GENES**

**BACKGROUND:**

Most colon cancer is sporadic. However, in 5-10% of present cases, the cancer may be due to an alteration in a gene inherited from the parent/parents. These alterations are called mutations. Familial Adenomatous Polyposis (FAP) is a condition in which polyps are inherited. Polyps are abnormal, mushroom-like growths which most commonly occur inside the colon and less often in the stomach and small intestine. The danger of FAP is the very strong likelihood that the polyps will eventually become cancerous. FAP is estimated to affect nearly 1 in 5000 people. A large fraction of FAP families carry mutations in the Adenomatous Polyposis Coli (APC) gene. FAP can also arise in the absence of any family history due to a de novo mutation in the APC gene or biallelic mutations in the MYH gene.

**PURPOSE:**

I will be tested for alterations in the APC and/or MYH genes. The purpose of this genetic testing is to determine whether I have an alteration of my APC/MYH genes that is involved in the development of multiple colonic polyps and colorectal cancer that runs in families. Individuals who inherit an altered APC/MYH gene are at greatly increased risk of colorectal cancer when compared to individuals who do not have the altered gene/genes. Both men and women with an altered APC/MYH gene/genes are at a highly increased risk of developing adenomatous polyposis and colon cancer. I have had the opportunity to discuss the benefits and drawbacks of APC/MYH testing for myself.

I also understand that the testing may not detect all of the alterations in these genes. I know that this means I may have an alteration that will not be detected by the screening. No information pertaining to my genetic test results will be provided to any of my relatives or anyone else without my written consent.

**TESTING PROCEDURE:**

Genetic testing requires several teaspoons (2 tubes) of blood. Before my blood is drawn, I will watch as my name is written correctly on empty blood tubes and after my blood is drawn I will sign a form indicating that I have positively identified the tubes containing my blood. I have been told that the blood sent to the laboratory will be divided into two separate samples. The first sample will be used to complete the genetic testing. The second sample will be tested to confirm the result if the first sample identifies an alteration.

**RISKS AND DISCOMFORTS:**

I understand that there is usually a minimal amount of risk involved in drawing a blood sample. These include pain at the blood drawing site, bleeding, bruising and infection.

**Initials** \_\_\_\_\_

*PROBAND SEQUENCING*

The risks of disclosure of information regarding my genetic susceptibility to colorectal cancer include depression, anxiety, anger, and fear of the future. This result could affect my relationships with family members and loved ones. I understand that if I learn that I have an altered APC/MYH gene, my health and life insurance rates, my ability to obtain health, disability or life insurance and my employability could be affected. Certain health, disability and life insurance companies may consider an inherited APC/MYH alteration to be a "pre-existing condition," and I may be responsible for disclosing this prior to obtaining new health or life insurance.

Some individuals may experience feelings of guilt or other forms of anxiety if they are found not to have an altered gene, while other family members did inherit an altered gene.

I may learn that my results are inconclusive at the present time and that the laboratory was unable to determine whether I have a clinically significant alteration. Therefore, I may have gone through the testing process and not have any more information at present about my personal risk to develop cancer in the future.

**ALTERNATIVE TO GENETIC TESTING:**

I understand that my participation in this testing is completely voluntary and will not affect my medical treatment now or in the future. The alternative is not to undergo testing; in which case I will not learn whether I have an altered form of the APC/MYH gene. This decision is perfectly acceptable.

**RESULTS:**

I understand that there are three possible results to this testing:

1. I may learn that I have a clinically significant altered APC/MYH gene. I understand that this means that I have a high risk to develop polyps and eventually some of these polyps can become cancerous.
2. I may learn that the testing did not detect an altered APC/MYH gene. I know that the methods currently in use are unable to detect all mutations and I may still have a mutation that was not detected.
3. The laboratory may detect an alteration in my APC/MYH gene of currently unknown significance.

**BENEFITS OF RECEIVING INFORMATION:**

This study may provide information about whether my relatives, including my children, are at high risk of developing colorectal cancer. If I am found to have a clinically significant alteration, I may choose to advise my relatives of this. They can have counseling and decide whether or not they wish to be tested to see if they inherited the same alteration. This study may also provide me with the information currently available regarding my genetic predisposition and may enable me to make better choices about planning my career, my family and children and my health care needs. If I do have an altered gene/genes, I will be able to initiate a comprehensive surveillance plan for the early detection of polyps and colorectal cancer. It is the opinion of acknowledged experts in the field that enhanced surveillance will be of benefit.

Initials \_\_\_\_\_

PROBAND SEQUENCING

**LIMITATIONS OF DNA TESTING FOR FAP:**

In addition, I understand that there are limitations as to what these test results can tell me. This testing is intended to provide me with an accurate estimate about my lifetime chance of developing colon cancer with the help of computer risk prediction models available to my physician. If an alteration is detected in me, there is a 50% chance the alteration has been passed on to each of my children. I understand that this test will not provide me with any new information about the current status of my health. This DNA testing is highly accurate for detection of the majority of disease causing mutations. However, a small fraction of mutations may be missed by the current technology. Occasionally, there may be a result that cannot be interpreted.

**USE OF SPECIMENS:**

I understand that any blood or tissue specimens obtained for the purposes of this genetic testing become the exclusive property of the Genetic Diagnostic Laboratory. After the specific tests requested have been completed and reported, the Laboratory may dispose of, retain, or preserve these specimens and may use these specimens for research. I understand that my identity will be protected and that research results will not be provided to me or to any other party. If there are new developments in the field, my physician/genetic counselor may be contacted by the Genetic Diagnostic Laboratory staff to offer me the opportunity to have additional clinical testing. If use of this genetic material results in a scientific publication, it will not contain any identifying information.

**REQUEST FOR MORE INFORMATION:**

I have been assured that my results will not be released to any relative or any other third party without my express written consent. I understand that I may ask more questions about this testing and my results at any time. Susan Walther, MS, CGC (215-573-9161) and Arupa Ganguly, PhD, FACMG (215-898-3122) will be available to answer questions as they arise. I will be given a copy of this consent form to keep.

**CONSENT OF PATIENT**

I have explained to \_\_\_\_\_ the purpose of this genetic testing, the procedures required and the possible risks and benefits to the best of my ability.

Signature of Professional Obtaining Consent: \_\_\_\_\_

Print Name: \_\_\_\_\_ Date: \_\_\_\_\_

I have read and received a copy of this consent form. I agree to have genetic testing and accept the risks. I understand the information provided in this document, and I have had the opportunity to ask questions I might have about the testing, the procedure, the associate risks and the alternatives.

*PROBAND SEQUENCING*

Signature of Patient: \_\_\_\_\_ Date: \_\_\_\_\_

Print Name: \_\_\_\_\_ Patient Date of Birth: \_\_\_\_\_

**CONSENT OF PARENT OR GUARDIAN**

I have explained to \_\_\_\_\_ the purpose of this genetic testing, the procedures required and the possible risks and benefits to the best of my ability.

Signature of Professional Obtaining Consent: \_\_\_\_\_

Print Name: \_\_\_\_\_ Date: \_\_\_\_\_

I have read and received a copy of this consent form. I agree to have genetic testing performed for my child and accept the risks. I understand the information provided in this document and I have had the opportunity to ask questions I have about the testing, the procedure, the associate risks and the alternatives.

Signature of Parent/Guardian: \_\_\_\_\_ Date: \_\_\_\_\_

Relationship to Child: \_\_\_\_\_

Print Name of Child: \_\_\_\_\_

Child's Date of Birth: \_\_\_\_\_

Initials \_\_\_\_\_

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**CONSENT FORM: GENETIC TESTING  
FOR FAMILIAL ADENOMATOUS POLYPOSIS (FAP) KNOWN MUTATION**

**BACKGROUND:**

Most colon cancer is sporadic. However, in 5-10% of cases, the cancer may be due to an alteration or change in a gene inherited from a parent. These changes are called mutations. Familial Adenomatous Polyposis (FAP) is a condition in which polyps are inherited. Polyps are abnormal, mushroom-like growths that most commonly occur inside the colon and less often in the stomach and small intestine. The danger of FAP is the very strong likelihood that the polyps will eventually become cancerous. FAP is estimated to affect nearly 1 in 5000 people. A large fraction of FAP families carry mutations in the Adenomatous Polyposis Coli (APC) gene. A smaller percentage of affected individuals have mutations in the MYH gene.

**PURPOSE:**

I will be tested for the alterations in the APC or MYH gene, which has been identified in one of my family members. I understand that the testing will take approximately 3 weeks to complete. The purpose of this genetic testing is to determine whether I have an altered APC/MYH gene/s that is involved in the development of multiple colonic polyps and colorectal cancer that runs in families. Individuals who inherit an altered APC/MYH gene/s are at greatly increased risk of colorectal cancer when compared to individuals who do not have an altered gene/s. Both men and women with an alteration in APC/MYH gene/s are at a highly increased risk of developing adenomatous polyposis and colon cancer. I have had the opportunity to discuss the benefits and drawbacks of APC/MYH testing for myself. No information pertaining to my genetic test results will be provided to any of my relatives without my written consent.

**TESTING PROCEDURE:**

Genetic testing requires several teaspoons (2 tubes) of blood. Before my blood is drawn, I will watch as my name is written correctly on empty blood tubes and after my blood is drawn I will sign a form indicating that I have positively identified the tubes containing my blood.

**RISKS AND DISCOMFORTS:**

I understand that there is usually a minimal amount of risk involved in drawing a blood sample. These include pain at the blood drawing site, bleeding, bruising and infection. The risks of disclosure of information regarding my genetic susceptibility to colorectal cancer include depression, anxiety, anger, and fear of the future. This result could affect my relationships with family members and loved ones. I understand that if I learn that I have an altered APC/MYH gene/s, my health and life insurance rates, my ability to obtain health, disability or life insurance and my employability could be affected. Certain health, disability and life insurance companies may consider an inherited APC/MYH alteration/s to be a "pre-existing condition," and I may be responsible for disclosing this prior to obtaining new health or life insurance.

Some individuals may experience feelings of guilt or other forms of anxiety if they are found not to have an altered gene when other family members did inherit an altered gene.

Initials \_\_\_\_\_

*FAMILIAL MUTATION*

**ALTERNATIVE TO GENETIC TESTING:**

I understand that my participation in this testing is completely voluntary and will not affect my medical treatment now or in the future. The alternative is not to undergo testing; in which case I will not learn whether I have an altered form of the APC or MYH gene/s. This decision is perfectly acceptable.

**RESULTS:**

I understand that there are two possible results to this testing:

1. I may learn that I have a clinically significant altered APC/MYH gene/s. I understand that this means that I have a high risk to develop polyps and eventually some of these polyps can become cancerous.
2. I may learn that the testing did not detect the altered APC or MYH gene/s.

**BENEFITS OF RECEIVING INFORMATION:**

This study may provide information about whether my relatives, including my children, are at high risk of developing colorectal cancer. If I am found to have a clinically significant alteration, I may choose to advise my relatives of this result. They can have counseling and decide whether or not they wish to be tested to see if they inherited the same alteration. If a gene alteration is not detected, I may experience some sense of relief as a result. This study will provide me with the information currently available regarding my genetic predisposition and may enable me to make better choices about planning my career, my family and children and my health care needs.

If I do have an altered gene/s, I will be able to initiate a comprehensive surveillance plan for the early detection of polyps and colorectal cancer. It is the opinion of acknowledged experts in the field that enhanced surveillance will be of benefit.

**USE OF SPECIMENS:**

I understand that any blood or tissue specimens obtained for the purposes of this genetic testing become the exclusive property of the Genetic Diagnostic Laboratory. After the specific tests requested have been completed and reported, the Laboratory may dispose of, retain, or preserve these specimens and may use these specimens for research. I understand that my identity will be protected and that research results will not be provided to me or to any other party. If there are new developments in the field, my physician/genetic counselor may be contacted by the Genetic Diagnostic Laboratory staff to offer me the opportunity to have additional clinical testing.

**REQUEST FOR MORE INFORMATION:**

I understand that I may ask more questions about this testing and my results at any time. Susan Walther, MS, CGC (215-573-9161) and Arupa Ganguly, PhD, FACMG (215-898-3122) will be available to answer questions as they arise. I will be given a copy of this consent form to keep.

**CONSENT OF PATIENT**

I have explained to \_\_\_\_\_ the purpose of this genetic testing, the procedures required and the possible risks and benefits to the best of my ability.

Signature of Professional Obtaining Consent: \_\_\_\_\_

Print Name: \_\_\_\_\_ Date: \_\_\_\_\_

*FAMILIAL MUTATION*

I have read and received a copy of this consent form. I agree to have genetic testing and accept the risks. I understand the information provided in this document and I have had the opportunity to ask questions I might have about the testing, the procedure, the associate risks and the alternatives.

Signature of Patient: \_\_\_\_\_ Date: \_\_\_\_\_

Print Name: \_\_\_\_\_

**CONSENT OF PARENT OR GUARDIAN**

I have explained to \_\_\_\_\_ the purpose of this genetic testing, the procedures required and the possible risks and benefits to the best of my ability.

Signature of Professional Obtaining Consent: \_\_\_\_\_

Print Name: \_\_\_\_\_ Date: \_\_\_\_\_

I have read and received a copy of this consent form. I agree to have genetic testing performed for my child and accept the risks. I understand the information provided in this document and I have had the opportunity to ask questions I have about the testing, the procedure, the associate risks and the alternatives.

Signature of Parent/Guardian: \_\_\_\_\_ Date: \_\_\_\_\_

Relationship to Child: \_\_\_\_\_

Print Name of Child: \_\_\_\_\_

Child's Date of Birth: \_\_\_\_\_

***Verification of Correctly Identified Blood Tubes***

I am a participant in genetic DNA testing.

I have been shown the tubes containing my blood for this genetic testing and my name has been correctly placed on each one of these tubes.

I have signed a copy of the consent form regarding this genetic testing to be sent along with my blood samples. I have been given a copy of the consent form to keep.

Participant Name: \_\_\_\_\_

Participant/Parent Signature: \_\_\_\_\_

Date: \_\_\_\_\_

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***Patient Registration Form***

*Please provide the following information. We cannot perform your test without ALL of this information. PLEASE PRINT ALL ANSWERS*

**PATIENT INFORMATION**

\_\_\_\_\_  
LAST FIRST MI PATINET'S MAIDEN NAME IF PREVIOUS TESTING WAS PERFORMED

*Date of Birth:* \_\_\_\_\_ *Gender:* \_\_\_ Male \_\_\_ Female

*Patient Address:* \_\_\_\_\_  
STREET/APT NO.

\_\_\_\_\_  
CITY, STATE, ZIP COUNTRY IF OUTSIDE UNITED STATES HOME TELEPHONE

**REFERRING PHYSICIAN**

\_\_\_\_\_  
NAME MD DO OTHER INSTITUTION

\_\_\_\_\_  
STREET ADDRESS CITY, STATE, ZIP

\_\_\_\_\_  
TELEPHONE FAX

**PAYMENT OPTIONS (must choose one) [a receipt will be mailed to the patient for self-pay options]**

\_\_\_\_\_ I have enclosed a check payable to the "Genetic Diagnostic Laboratory" for \$ \_\_\_\_\_

\_\_\_\_\_ Please charge my credit card for the amount of \$ \_\_\_\_\_  
\_\_\_ VISA \_\_\_ Master Card \_\_\_ Discover \_\_\_ American Express

Card Number: \_\_\_\_\_ Exp date: \_\_\_\_\_

Name as it appears on card: \_\_\_\_\_

\_\_\_\_\_ I have Pennsylvania Medicaid. A copy of my Medicaid card is attached.

\_\_\_\_\_ INSTITUTIONAL BILLING: The Institution where my testing originated has agreed to pay all charges for the testing. INCLUDE Billing Address, Person Authorizing Payment, Telephone, and Fax below:

\_\_\_\_\_  
BILLING ADDRESS

\_\_\_\_\_  
BILLING ADDRESS

\_\_\_\_\_  
PERSON AUTHORIZING PAYMENT PHONE FAX

