

Inclusion criteria for the CRC cases was:

- a) Subject is diagnosed with colorectal cancer
- b) Subject is between 45 and 85 years of age at the time of the blood draw.
- c) Subject has had no other cancer
- d) If the subject has other GI conditions these should be recorded on the case report form.
- e) Consent has been given.

Exclusion criteria for CRC cases was

- a) Subject has been diagnosed with any other type of cancers
- b) Subject is younger than 45 or older than 85 years old at the time of the blood draw.
- c) Subject received neoadjuvant treatment prior to sample collection .
- d) Subject has diagnosis or personal history of any of the following high-risk conditions for colorectal cancer:
 - ≥ 2 first-degree relatives who have been diagnosed with colon cancer (Note: first-degree relatives include parents, siblings and offspring).
 - One first-degree relative with CRC diagnosed before the age of 60.
 - Familial adenomatous polyposis (also referred to as “FAP”, including attenuated FAP)
 - Hereditary non-polyposis colorectal cancer syndrome (also referred to a “HNPCC” or “Lynch Syndrome”).
 - Other hereditary cancer syndromes including but are not limited to Peutz-Jeghers Syndrome, MYH-Associated Polyposis (MAP), Gardner’s Syndrome, Turcot’s (or Crail’s) Syndrome, Cowden’s Syndrome, Juvenile Polyposis, Cronkhite-Canada Syndrome, Neurofibromatosis and Familial Hyperplastic Polyposis.
- e) Subject has family history of
 - Familial adenomatous polyposis (also referred to as “FAP”).
 - Hereditary non-polyposis colorectal cancer syndrome (also referred to as “HNPCC” or “Lynch Syndrome”).

Inclusion criteria for Adenoma cases

- a) Subject is diagnosed with Advanced or Non-advanced colorectal adenoma(s).
- b) Subject is between 45 and 85 years of age at the time of the blood draw.
- c) Subject has never been diagnosed with any cancer.
- d) Consent has been given.

Exclusion criteria for Adenoma cases

- a) Subject is younger than 45 or older than 85 years old at the time of the blood draw.
- b) Subject has a history of colorectal cancer.
- c) Subject has been diagnosed or has a history of any cancer.
- d) Subject had prior colorectal resection for any reason other than sigmoid diverticular disease.
- e) Subject had overt rectal bleeding, e.g. hematochezia or melena, within the previous 30 days.
- f) Subject has diagnosis or personal history of any of the following high-risk conditions for colorectal cancer:
 - ≥ 2 first-degree relatives who have been diagnosed with colon cancer (Note: first-degree relatives include parents, siblings and offspring).
 - One first-degree relative with CRC diagnosed before the age of 60.

- Familial adenomatous polyposis (also referred to as “FAP”, including attenuated FAP)
 - Hereditary non-polyposis colorectal cancer syndrome (also referred to a “HNPCC” or “Lynch Syndrome”).
 - Other hereditary cancer syndromes including but are not limited to Peutz-Jeghers Syndrome, MYH-Associated Polyposis (MAP), Gardner’s Syndrome, Turcot’s (or Crail’s) Syndrome, Cowden’s Syndrome, Juvenile Polyposis, Cronkhite-Canada Syndrome, Neurofibromatosis and Familial Hyperplastic Polyposis.
- g) Subject has family history of
- Familial adenomatous polyposis (also referred to as “FAP”).
 - Hereditary non-polyposis colorectal cancer syndrome (also referred to as “HNPCC” or “Lynch Syndrome”).

Inclusion criteria of the Controls

- a) Subject has average risk for development of colorectal cancer (as defined by the exclusion criteria below).
- b) Subject is between 45 and 85 years of age at the time of the blood draw.
- c) Subject has no history of colorectal cancer and has no adenomas, as determined by colonoscopy.
- d) If the subject has attended colonoscopy for any other reason other than routine screening only then this must be recorded on the case report form.
- e) If the subject has other GI conditions these should be recoded on the case report form.
- f) Consent has been given.

Exclusion criteria for Controls

- a) Subject is younger than 45 or older than 85 years old at the time of the blood draw.
- b) Subject has a history of colorectal cancer or adenoma as determined by colonoscopy.
- c) Subject has been diagnosed or has a history of any cancer.
- d) Subject had a positive fecal occult blood test or FIT within the previous 12 months.
- e) Subject had prior colorectal resection for any reason other than sigmoid diverticular disease.
- f) Subject had overt rectal bleeding, e.g. hematochezia or melena, within the previous 30 days.
- g) Subject has diagnosis or personal history of any of the following high-risk conditions for colorectal cancer:
 - ≥ 2 first-degree relatives who have been diagnoses with colon cancer (Note: first-degree relatives include parents, siblings and offspring).
 - One first-degree relative with CRC diagnosed before the age of 60.
 - Familial adenomatous polyposis (also referred to as “FAP”, including attenuated FAP)
 - Hereditary non-polyposis colorectal cancer syndrome (also referred to a “HNPCC” or “Lynch Syndrome”).
 - Other hereditary cancer syndromes including but are not limited to Peutz-Jeghers Syndrome, MYH-Associated Polyposis (MAP), Gardner’s Syndrome, Turcot’s (or Crail’s) Syndrome, Cowden’s Syndrome, Juvenile Polyposis, Cronkhite-Canada Syndrome, Neurofibromatosis and Familial Hyperplastic Polyposis.
- h) Subject has family history of

- Familial adenomatous polyposis (also referred to as “FAP”).
 - Hereditary non-polyposis colorectal cancer syndrome (also referred to as “HNPCC” or “Lynch Syndrome”).
- i) Subject is having a colonoscopy to diagnose unexplained rectal bleeding or intestinal blockage, or other symptoms suggestive of colorectal cancer. Subjects that are receiving colonoscopies to aid diagnosis of IBD or other, non-malignant, diseases should not be excluded.
 - j) No more than 10% of controls can have received a diagnosis of inflammatory bowel disease.