Hereditary Cancer Panel

Consultation Kit

IntelligeneDx
Cancer Genomics

IntelligeneDx's Genetic Tests Consultation Kit.

IntelligeneDx™ Integrated Genetics is a laboratory specialized in molecular genetics and pathologic analysis related to cancer.

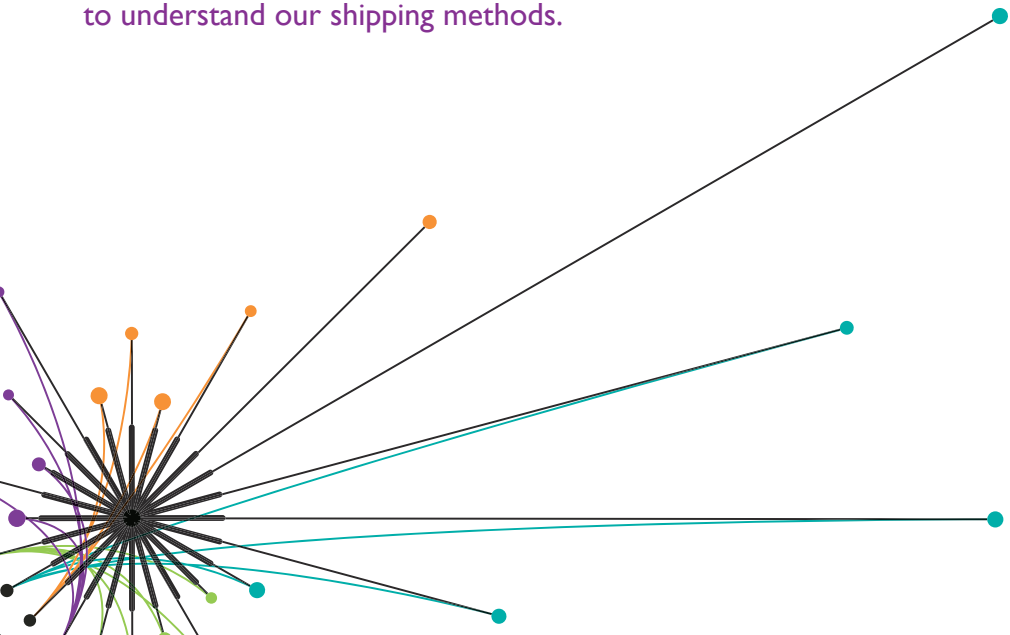
We offer the most advanced techniques in genetic testing for hereditary cancer risk and the analysis of solid tumors. We provide detailed reports and assist medical teams to help create the most efficient and effective custom oncology treatment for their patients.

What sets IntelligeneDx apart is that we offer pre/post genetic counseling for doctors, clear and detailed medical reports, and patient support for each test. We also provide guidance regarding the health insurance claim process.

We integrate technical, scientific and logistic expertise with specialized treatment formed by professional and well-prepared geneticists to clarify any questions regarding the genetic and pathological analysis.

Through our Consultation Kit you can get to know **IntelligeneDx`s** genetic test portfolio and always have access to quick and specific information. The Kit also contains instructions on how to request the correct test for a specific diagnosis or prognosis.

- Check our webpage: www.intelligenedx.com, in order to understand our shipping methods.



Hereditary Cancer Panel - Colorectal Cancer - Extended I

This panel analyzes the main genes that are associated with Colorectal Cancer **(MSH2, MSH6, MLH1, APC, and PMS2)**, including large deletions and insertions.

Hereditary Cancer Panel - Colorectal Cancer Extended II

This panel covers **15 genes** that are associated with predisposition to CRC. Among them: **MSH2, MSH6, MLH1**, and **PMS2** (related to Lynch syndrome), **MUTYH** (associated with **MAP** Syndrome - MYH-Associated Polyposis) and **APC** (for Adenomatous Polyps Familial).

The panel also analyzes the following genes: **BUB1B, CHEK2, EPCAM, FLCN, PMS1, TP53, SDHD and SMAD4**, including large deletions and insertions.

Hereditary Cancer Panel - Breast and Ovarian Cancer - Extended II

This panel covers **31 genes** that are associated with a predisposition to **HBOC**. In addition to the genes **BRCA1** and **BRCA2**, we also analyze the genes: **ATM, BRIP1, CDH1, CHEK2, MLH1, MSH2, MSH6, PALB2, PMS2, RAD51C, RAD51D, TP53, and PTEN**, including large deletions and insertions.

Hereditary Cancer Panel
Breast and Ovarian Cancer - BRCA1, BRCA2 - NGS

This panel analyzes the genes **BRCA1** and **BRCA2** through a complete sequencing, including large deletions and insertions.

Hereditary Cancer Panel - Li Fraumeni Syndrome

This panel covers the main genes that are associated with Li-Fraumeni syndrome: **CHEK2** and **TP53**, including large deletions and insertions.

Hereditary Cancer Panel - Familial Melanoma

This panel analyzes the genes that are associated with familial melanoma: **CDKN2A, CDK4, BAP1, BRCA2, RB1, NF1, TP53, VHL, XPA, and XPC**, including large deletions and insertions.

Hereditary Cancer Panel - Endocrine gland neoplasm

This panel analyzes the genes that are associated with neoplasms of the endocrine system including multiple endocrine neoplasms of the types 1 and 2: **RET, MEN1, PRKAR1A, PTEN, CDC73, HRAS,** and **VHL,** including large deletions and insertions.

Hereditary Cancer Panel - Familial gastric cancer

This panel analyzes the genes that are associated with hereditary gastric cancer: **APC, CDH1, MUTYH, BRCA1, BRCA2, MLH1, MSH2, MSH6, PMS2, EPCAM, TP53, SMAD4, BMPR1A, SDHB, SDHC, SDHD, and KIT,** including large deletions and insertions.

Hereditary Cancer Panel - Familial Pancreatic Cancer

This panel analyzes the genes that are associated with hereditary pancreatic cancer which are: **CDKN2A, CDK4, BRAC1, BRCA2, TP53, MLH1, MSH2, APC, PALB2 , and ATM,** including large deletions and insertions.

Hereditary Cancer Panel - Bladder and Renal Cancers

This panel analyzes the genes that are associated with hereditary bladder and renal cancers: **VHL, SDHD, SDHC, SDHB, FH, FLCN, MET, CDC73, MSH2, MLH1, PMS2, PMS1, MSH6, TSC1, and TSC2**, including large deletions and insertions.

Hereditary Cancer Panel - Prostate Cancer

This panel analyzes the genes associated with the development of hereditary prostate cancer: **BRCA2, CDH1, CHK2** and **PTEN,** including large deletions and insertions.

You can request your kits easily and quickly!

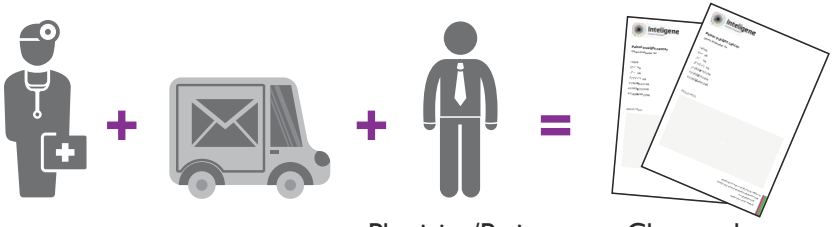
For hereditary cancer:

1. Request your saliva collection kit through telephone or email:
   (913) 258 2300 / info@intelligenedx.com

2. Pre-paid FedEx mailing supplies are included in each kit.
   Simply schedule FedEx pickup or drop off at a FedEx location.
   (at room temperature)

3. Reports are guaranteed to be available within 45 days

4. Results are made available through a secure Physician Portal and/or secure fax



Order Test | Ship to Lab | Physician/Patient Assistance | Clear and complete reports

Why IntelligeneDx differs?

- We have higher quality scores and therefore lower error rates.

- We sequence homopolymers accurately, while others have an inherent problem in sequencing those regions.

- We measure the accuracy of every base, while others rely on stacks of reads and a reference.

- Our sequencing approach is more sensitive and produces higher fidelity data.

- In summary, our results are at least 10 times more reliable in comparison with other companies' results.

Application	Tests	Platforms
Hereditary Cancer	94 genes TruSight Panel	NGS
Tumor Analysis	up to 400 genes Oncomine / EGFR, BRAF & KRAS / Prosigna	NGS / Cobas / nCounter
HPV/Cystic Fibrosis	Virus / Pulmonary Disease	Cobas / NGS
Rare Diseases / Unidentified Syndromes	4,813 genes TruSight One Panel	NGS


Pre and post genetic
counseling for doctors,
clear and
complete reports.

Competitors - Overall Comparison

Criteria	IntelligeneDx	Most of Competitors
Multiple Technologies	●	—
Broader Tests Availability	●	—
Short TAT	●	●
Focused Cancer Knowledge	●	—
non NGS complementary tests (FISH/HCI)	●	—
CLIA / CAP Certified	●	●
Hereditary Cancer Panel	●	●
Tumor Panel	●	●
Comprehensive Report	●	●
Customized Tests	●	—
R&D	●	—
Physician & Patient Support	●	—
Breast Cancer Prognosis	●	—
Genetic Counseling	●	●

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Cancer Genomics

Number of Genes sequenced in full panel?
94.

Using the correct platform for Hereditary tests?
YES,
IntelligeneDx uses the Illumina platform for Hereditary tests which is 10 times more accurate than other NGS platforms.

Meet our advertised turnaround time?
YES,
we like to under promise and over deliver.
We use realistic timelines and do a thorough analysis on each sample. With IntelligeneDx there are never any unpleasant surprises.

Less likely to generate false positives?
YES,
by using the correct system (Illumina) for hereditary tests IntelligeneDx is less likely to amplify errors.

INDELS & Sanger Sequencing offered?
YES,
All analyses include insertions and deletions (INDELS) which are paramount to a proper diagnosis. Also, Sanger Sequencing (the gold standard) is done as a confirmation/check on all dubious mutations found through the Illumina process.

Test	Possible indications for testing
Hereditary - Bladder and Renal Cancer Panel	Renal Carcinoma with clear cell histology, if any of the following criteria are met: • Diagnosed under age 50; • Bilateral or multifocal tumors; • One or more close relatives with clear cell renal carcinoma; • Renal carcinoma with papillary type 1 histology, papillary type 2 histology, collecting duct histology, tubulopapillary histology or BHD-related histology (chromophobe, oncocytoma, oncocytic hybrid); • Urothelial carcinoma (or transitional cell carcinoma) and 2 additional cases of any Lynch Syndrome -associated cancer in the same person or in relatives; • Renal carcinoma and 2 additional Cowden syndrome criteria in the same person; • Angiomyolipomas of the kidney and one additional tuberous sclerosis complex criterion in the same person.
Hereditary - Breast and Ovarian Cancer Panel	• Patient with bilateral breast cancer; • Young triple negative patients; • Patients with a family member with a known gene mutation with susceptibility to developing breast cancer (could have variant testing for known mutation or panel); • Patients who have at least one relative with bilateral breast cancer; • Patients with at least two first-degree relatives diagnosed with breast cancer, ovarian cancer and/or prostate cancer, younger than 50 years old; • Patients with male breast cancer; • One or more family members on the same side (maternal or paternal) with a combination of breast cancer and one or more of the following types of cancer: pancreatic, aggressive prostate, sarcoma, adrenocortical carcinoma, brain tumor, endometrial tumor, leukemia/ lymphoma, thyroid, skin manifestations, and/or macrocephaly, hamartomatous polyps of the gastrointestinal tract, and diffuse gastric cancer. • Member of a population at an increased risk (example: Ashkenazi Jewish).

Test	Possible indications for testing
Hereditary - Colorectal Cancer (CRC) Panel	Using the Bethesda criteria: • CRC diagnosed in patients younger than 50 years old; • Presence of synchronous or metachronous CRC, or other extracolonic tumor associated with the syndrome, regardless of the age; • CRC with histology, suggesting the presence of lymphocytes infiltrating the tumor, Crohnlike lymphocytic reaction, mucinous differentiation or in signet ring cell or spinal growth pattern diagnosed in patients younger than 60 years old; • CRC present in one or more 1st degree relatives with any tumor related to the syndrome, with one of the tumors being diagnosed before the age of 50; • CRC diagnosed in one or more relatives of 1st or 2nd degree with tumors related to this syndrome, regardless of the age.
Hereditary - Endocrine Neoplasia Panel	• Patient has at least one of the three main manifestations of the syndrome and at least one relative who was diagnosed with Multiple Endocrine Neoplasia type 1 (MEN1).
Hereditary - Gastric Cancer Panel	In accordance to the International Gastric Cancer Linkage Consortium 2010: • Two cases of gastric cancer in the patient's family: one confirmed diffuse type, one diagnosed under the age of 50 years; • Three cases of gastric cancer diagnosed in 1st and 2nd degree relatives, regardless of the age; • Diffuse gastric cancer diagnosed in patients under the age of 40 years (with no history of cancer in the family); • Diffuse gastric cancer and lobular breast cancer diagnosed in the patient or in a patient's relative (1st or 2nd degree) under the age of 50 years.

Test	Possible indications for testing
Hereditary - Li-Fraumeni Syndrome Cancer Panel	• Recommended by the National Comprehensive Cancer in accordance to the Chompret criteria; • In any patient with breast cancer who is younger than 30 years old, showing negative results for BRCA1 and BRCA2.
Hereditary - Melanoma Cancer Panel	• Two first-degree relatives affected with melanoma and/or pancreatic cancer; • At least three family members with melanoma and/or pancreatic cancer; • Multiple primary melanomas in an individual, especially if at a young age and in areas not exposed to the sun, regardless of family history.
Hereditary - Pancreatic Cancer Panel	• Two or more first-degree relatives who are affected by Pancreatic Ductal Adenocarcinoma without any identification of the syndrome in the patient's family.
Hereditary - Prostate Cancer Panel	Patients with two or more 1st degree relatives who had prostate cancer have an increased risk of developing this disease and, if the relatives had had this cancer before they were 65 years old, this risk is even greater.
Hereditary - Variant Testing	There is a known familial mutation(s) determined by other family member's testing.
Exome	Patient cases whose common analysis of genes and other different approaches were inconclusive.
Solid Tumor Panels	Patient has one of the following types of tumors: • Metastatic Breast Cancer • Metastatic Colorectal Cancer • Metastatic Lung Cancer • Metastatic Melanoma • Metastatic Ovarian Cancer • Gastrointestinal Stroma Tumor (GIST)

Test	Possible indications for testing
Prosigna	Female breast cancer patients who have undergone surgery in conjunction with locoregional treatment consistent with standard of care, either as: • Post-menopausal women with Hormone Receptor Positive (HR+), lymph node-negative, Stage I or II breast cancer to be treated with adjuvant endocrine therapy alone, when used in conjunction with other clinicopathological factors; or • Post-menopausal women with Hormone Receptor-Positive (HR+), lymph node-positive (1–3 positive nodes), Stage II breast cancer to be treated with adjuvant endocrine therapy alone, when used in conjunction with other clinicopathological factors.
HPV	• Women aged 25 years and older can be tested for HPV alone (without a Pap test). Known as primary screening. • Women aged 30 years and older can be tested for HPV at the same time as the Pap test. Known as co-testing.

Visit our website and try our genetic risk calculator.
www.intelligenedx.com

Prosigna™

Prosigna is a genetic signature test capable of identifying the individual risk of late recurrence in postmenopausal women diagnosed with breast cancer at an early stage.

The gene expression profile of a patient's tumor is compared with each of the four **PAM50** prototypical molecular profiles to determine the degree of similarity. The results, in combination with a proliferation score and tumor size, produce an individualized Prosigna Score.

Prosigna is indicated for use in postmenopausal women with HER2-positive, node-negative (Stage I or II), or node-positive (Stage II) breast cancer to be treated with adjuvant endocrine therapy.

IntelligeneDx
Cancer Genomics

Clinical Management Guideline

Gene	Syndrome	Maximun Lifetime Cancer Risk								
		BR	OV	CO	EN	ME	PA	GA	PR	OC
BRCA1	Hereditary Breast and Ovarian Cancer Syndrome (HBOC)	● 87	● 44				○ E		○ 16	
BRCA2		● 84	● 27			○ E	● 7		○ 20	
MLH1			● 12	● 82	● 60		○ 6	● 13		● 9
MSH2			● 12	● 82	● 60		○ 6	● 13		● 9
MSH6	Lynch Syndrome / Hereditary Non-Polyposis Colorectal Cancer (HNPCC)		○ E	● 69	● 71		○ E	○ E		○ E
PMS2			○ E	● 20	● 15		○ E	○ E		○ E
EPCAM			● 12	● 82	● 60		○ 6	● 13		● 9
APC	Familial Adenomatous Polyposis (FAP)/ Attenuated FAP (AFAP)			● 99			○ PE	○ E		● 12
MUTYH *(2 copies)*	MUTYH-Associated Polyposis (MAP) Cancer Risk			● 100						● 5
CDKN2A *(p16INK40)*	Melanoma-Pancreatic Cancer Syndrome (M-PCS)					● 76	● 17			
CDKN2A *(p14ARF)*	Melanoma Cancer Syndrome (MCS)					● 76	○ E			
CDK4	Melanoma Cancer Syndrome (MCS)					● 76	○ E			
TP53	Li-Fraumeni Syndrome (LFS)	● EYA	○ EYA	○ EYA	○ EYA	○ EYA	○ EYA	○ EYA	○ EYA	● EYA
PTEN	PTEN Hamartoma Tumor Syndrome (PHTS)	● 85		● 16	● 28	● 6				● 38

E = Elevated Risk **P =** Possibly Elevated Risk **R,E =** Rare but Elevated Risk **EYA =** Elevated Risk, Young Age of Diagnosis
I = Increased Risk **HHT =** Hereditary Hemorrhagic Telangiectasia ● High Risk ○ Elevated Risk

Summary of Medical Management (age to begin)[34]

Management could include any of the following. Please refer to published guidelines for complete management recomendations.

breast awareness (18), clinical exams (25), breast MRI (25), mammogram (30), mastectomy, salpingo-oophorectomy (35-40), male breast surveillance (35), CA-125 and transvaginal ultrasound (30), breast/ovarian chemoprevention, prostate screening (40)[1]

pancreatic surveillance endoscopic ultrasound/magnetic resonance cholangiopancreatography (EUS/MRCP) and/or other clinical trials for screening, consider whole-body skin exams (BRCA2 only) [1]

colonoscopy (20-25, or 25-30 for MSH6/PMS2), hysterectomy, salpingo-oophorectomy, endometrial sampling, CA-125 and transvaginal ultrasound, EGD (30-35), urinalysis (25-30)[2] (excluding PMS2 & MSH) pancreatic surveillance (EUS/MRCP)and/or other clinical trials for screening[3]

colonoscopy/sigmoidoscopy (10-15), colectomy, chemoprevention, upper endoscopy and MRI/CT (25-30), thyroid exam/ultrasound (late teens)abdominal palpation[2]

colonoscopy (25-30), colectomy, chemoprevention, upper endoscopy (30-35)[2]

skin protection, skin exams (10),[4,5] pancreatic surveillance (EUS/MRCP) and/or other clinical trial screening [3]

skin protection, skin exams (10),[4,5]

breast awareness (18), clinical exams (20), breast MRI (20) mammography (30), mastectomy, colonoscopy (25), skin exams, physical/neurological exams, individualized additional other organ-targeted surveillance[1]

breast awareness (18), clinical exams (20), breast MRI (30-35) mammography (30-35), mastectomy, endometrial biopsy/ultrasound (30-35), hysterectomy, thyroid ultrasound (18), colonoscopy (35), renal ultrasound (40)[1]

Information listed in this table is subject to change per guideline updates.

Clinical Management Guideline

Gene	Syndrome	Maximun Lifetime Cancer Risk								
		BR	OV	CO	EN	ME	PA	GA	PR	OC
STK11	Peutz-Jeghers Syndrome (PJS)	● 50	● 21	● 39	● 9		● 36	● 29		● 17
CDH1	Hereditary Diffuse Gastric Cancer (HDGC)	● 52		○ PE				● 80		
BMPR1A	Juvenile Polyposis Syndrome (JPS)			● 50			○ R,E	● 21		○ R,E
SMAD4	Juvenile Polyposis Syndrome (JPS) & Hereditary Hemorrahgic Telangiectasia (HHT)			● 50			○ R,E	● 21		○ HHT
PALB2	PALB2-Associated Cancer Risk	● 40					○ E			
CHEK2	*CHEK2*-Associated Cancer Risk	● 48		○ 9.5					○ 44	
ATM	*ATM*-Associated Cancer Risk	● 52					○ E			
NBN	*NBN*-Associated Cancer Risk	○ 30							○ I	
BARD1	*BARD1*-Associated Cancer Risk	○ E								
BRIP1	*BRIP1*-Associated Cancer Risk	○ 20	● 8.3							
RAD51C	*RAD51C*-Associated Cancer Risk	○ PE	○ 6.5							
RAD51D	*RAD51D*-Associated Cancer Risk		○ 7							

E = Elevated Risk **P =** Possibly Elevated Risk **R,E =** Rare but Elevated Risk **EYA =** Elevated Risk, Young Age of Diagnosis
I = Increased Risk **HHT =** Hereditary Hemorrhagic Telangiectasia ● High Risk ○ Elevated Risk

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Summary of Medical Management (age to begin)[34]

Management could include any of the following. Please refer to published guidelines for complete management recomendations.

mammography and breast MRI (25), colonoscopy and upper endoscopy (late teens), CT or MRI enterography (8-10), pancreatic surveillance (EUS/MRCP) and/or other clinical trials for screening (30-35), pelvic exam/pap smear/transvaginal ultrasound (18-20), testicular exams (10)[2,3]

mammography and breast MRI (35), endoscopy with biopsy (16), gastrectomy (20), colonoscopy (40) treat for Helicobacter pylori infection if present[6]

colonoscopy and upper endoscopy (15), monitor for rectal bleeding and/or anemia[2,7]

colonoscopy and upper endoscopy (15), monitor for rectal bleeding and/or anemia[2,7] brain MRI, contrast echocardiogram, and chest CT may be recommended[8]

mammography and breast MRI (30),[9,11] male breast screening,[1,11] pancreatic surveillance (EUS/MRCP) and/or other clinical trials for screening[3,12]

mammography and breast MRI (30),[9,13] individualized colorectal screening,[14,30] prostate screening (40),[10,15,29] male breast screening[1,16]

mammography and breast MRI (30),[9,17] pancreatic surveillance (EUS/MRCP), and/or other clinical trials for screening[3,18]

individualized breast and prostate screening/rik reduction,[9,19] prostate screening (40)[10,20,29]

individualized breast and screening/rik reduction,[1,9,21]

individualized breast and ovarian screening/rik reduction,[1,9,21]

individualized breast and ovarian screening/rik reduction,[1,9,24,25]

individualized ovarian screening/rik reduction,[1,26]

Information listed in this table is subject to change per guideline updates.

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34. In many cases, the ages to begin an intervention should be younger if indicated by the patient's family history

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