

Module: molecular

Module Contents

msi

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1	CENTER_NO	number (2,0)	Required:true
	Center identification number.		

Allowable Values

11	Sinai Health Systems (formerly Cancer Care Ontario)
12	University of Southern California Consortium (USCC)
13	University of Melbourne
14	University of Hawaii Cancer Center
15	Mayo Clinic
16	Fred Hutch, Seattle
17	University of California at San Francisco (UCSF) (formerly CPIC, originally Northern California (NCCC))

2	PERSON_ID	string (12)	Required:true
	Number that Uniquely Identifies an Individual.		

3	MSI_TEST_LAB	number (1,0)	Required:true						
Code for type of lab that did the MSI testing.									
<table border="1"> <tr> <td colspan="2">Allowable Values</td> </tr> <tr> <td>1</td> <td>CFR Lab</td> </tr> <tr> <td>2</td> <td>Clinical Lab</td> </tr> </table>				Allowable Values		1	CFR Lab	2	Clinical Lab
Allowable Values									
1	CFR Lab								
2	Clinical Lab								

4	COLLECTION_CID	string (30)	Required:true
Identifier used internally by centers to denote a unique surgical event.			

5	TEST_TISSUE	number (1,0)	Required:true												
Tissue on which test was performed.															
<table border="1"> <tr> <td colspan="2">Allowable Values</td> </tr> <tr> <td>1</td> <td>Cancer</td> </tr> <tr> <td>2</td> <td>Contiguous (Adjacent) adenoma</td> </tr> <tr> <td>3</td> <td>Colon Polyp</td> </tr> <tr> <td>4</td> <td>Gastric polyp</td> </tr> <tr> <td>5</td> <td>Sebaceous adenoma</td> </tr> </table>				Allowable Values		1	Cancer	2	Contiguous (Adjacent) adenoma	3	Colon Polyp	4	Gastric polyp	5	Sebaceous adenoma
Allowable Values															
1	Cancer														
2	Contiguous (Adjacent) adenoma														
3	Colon Polyp														
4	Gastric polyp														
5	Sebaceous adenoma														

6	TUMOR_NO	number (2,0)	Required:true
Numbers labeling tumors of the individual. Numbers are not necessarily sequential.			
Allowable Values			
1 to 99	Range		
-9	NA/Out of scope: Tissue does not currently have a TUMOR_NO and is not cancer or contiguous adenoma		
-15	Information Unknown		

7	POLYP_NO	number (2,0)	Required:true
Sequential number over range of 1 to 99 to distinguish a polyp removed on a particular date. The tuple PERSON_ID, DATE_COLLECTED, and POLYP_NO uniquely identify a physical polyp globally within the CFR database.			
Allowable Values			

1 to 99 or -9, -1	Range
-9	NA/Out of scope. Tissue is not a polyp.
-1	Polyp has IHC/MSI result but center is currently unable to locate polyp pathology information. Center review to obtain this information is currently underway.

8	BLOCK_SPEC_CID	string (40)	Required:true
Unique local identifier used at a center to uniquely identify a block tissue specimen.			

9	NUC_ACID_CID_TUMOR	string (40)	Required:true
Center's unique identifier for the tumor DNA used in this MSI test. Each DNA extraction has a unique identifier.			

10	NUC_ACID_CID_NORMAL	string (40)	Required:true
Center's unique identifier for the normal DNA used in this MSI test. Each DNA extraction has a unique identifier.			

11	METASTASIS	number (1,0)	Required:true
Primary or metastatic tumor.			

Allowable Values	
1	Primary
2	Metastasis
-9	Test is not performed on cancerous tissue

12	MSI_DETECTION_METHOD	number (2,0)	Required:true
MSI Testing method.			

Allowable Values	
1	PCR non-radiolabeled
2	PCR radiolabeled
3	Fluorescent PCR capillary electrophoresis
4	Fluorescent PCR slab gel electrophoresis
5	Silver-stained gel electrophoresis

-13	Not tested: Quantity of DNA or tissue not sufficient
-----	--

-15	Method not specified
-----	----------------------

13

MSI_ACTC

number (2,0)

Required:true

MSI test result at ACTC locus

Allowable Values

1	Stable
---	--------

2	Unstable
---	----------

6	Equivocal (Inconclusive)
---	--------------------------

7	Stable - Normal DNA not used in test
---	--------------------------------------

8	Unstable - Normal DNA not used in test
---	--

9	Equivocal (Inconclusive) - Normal DNA not used in test
---	--

-11	No Amplification
-----	------------------

-12	Not tested, reason not specified
-----	----------------------------------

-13	Quantity of DNA or tissue not sufficient
-----	--

-14	Tested, outcome not specified
-----	-------------------------------

-15	Unknown if tested
-----	-------------------

14

MSI_BAT25

number (2,0)

Required:true

MSI test result at BAT25 locus

Allowable Values

1	Stable
---	--------

2	Unstable
---	----------

6	Equivocal (Inconclusive)
---	--------------------------

7	Stable - Normal DNA not used in test
---	--------------------------------------

8	Unstable - Normal DNA not used in test
---	--

9	Equivocal (Inconclusive) - Normal DNA not used in test
---	--

-11	No Amplification
-----	------------------

-12	Not tested, reason not specified
-----	----------------------------------

-13	Quantity of DNA or tissue not sufficient
-----	--

-14	Tested, outcome not specified
-----	-------------------------------

-15	Unknown if tested
-----	-------------------

15	MSI_BAT26	number (2,0)	Required:true
MSI test result at BAT26 locus			

Allowable Values	
1	Stable
2	Unstable
6	Equivocal (Inconclusive)
7	Stable - Normal DNA not used in test
8	Unstable - Normal DNA not used in test
9	Equivocal (Inconclusive) - Normal DNA not used in test
-11	No Amplification
-12	Not tested, reason not specified
-13	Quantity of DNA or tissue not sufficient
-14	Tested, outcome not specified
-15	Unknown if tested

16	MSI_BAT34C4	number (2,0)	Required:true
MSI test result at BATC34C4 locus			

Allowable Values	
1	Stable
2	Unstable
6	Equivocal (Inconclusive)
7	Stable - Normal DNA not used in test
8	Unstable - Normal DNA not used in test
9	Equivocal (Inconclusive) - Normal DNA not used in test
-11	No Amplification
-12	Not tested, reason not specified
-13	Quantity of DNA or tissue not sufficient
-14	Tested, outcome not specified
-15	Unknown if tested

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17	MSI_BAT40	number (2,0)	Required:true
MSI test result at BAT40 locus			

Allowable Values	
1	Stable
2	Unstable
6	Equivocal (Inconclusive)
7	Stable - Normal DNA not used in test
8	Unstable - Normal DNA not used in test
9	Equivocal (Inconclusive) - Normal DNA not used in test
-11	No Amplification
-12	Not tested, reason not specified
-13	Quantity of DNA or tissue not sufficient
-14	Tested, outcome not specified
-15	Unknown if tested

18	MSI_D5S346	number (2,0)	Required:true
MSI test result at D5S346 locus			

Allowable Values	
1	Stable
2	Unstable
6	Equivocal (Inconclusive)
7	Stable - Normal DNA not used in test
8	Unstable - Normal DNA not used in test
9	Equivocal (Inconclusive) - Normal DNA not used in test
-11	No Amplification
-12	Not tested, reason not specified
-13	Quantity of DNA or tissue not sufficient
-14	Tested, outcome not specified
-15	Unknown if tested

19	MSI_D10S197	number (2,0)	Required:true
MSI test result at D10S197 locus			

Allowable Values	
1	Stable
2	Unstable
6	Equivocal (Inconclusive)
7	Stable - Normal DNA not used in test
8	Unstable - Normal DNA not used in test
9	Equivocal (Inconclusive) - Normal DNA not used in test
-11	No Amplification
-12	Not tested, reason not specified
-13	Quantity of DNA or tissue not sufficient
-14	Tested, outcome not specified
-15	Unknown if tested

20	MSI_D17S250	number (2,0)	Required:true
	MSI test result at D17S250 locus		

Allowable Values	
1	Stable
2	Unstable
6	Equivocal (Inconclusive)
7	Stable - Normal DNA not used in test
8	Unstable - Normal DNA not used in test
9	Equivocal (Inconclusive) - Normal DNA not used in test
-11	No Amplification
-12	Not tested, reason not specified
-13	Quantity of DNA or tissue not sufficient
-14	Tested, outcome not specified
-15	Unknown if tested

21	MSI_D18S55	number (2,0)	Required:true
	MSI test result at D18S55 locus		

Allowable Values	
1	Stable

2	Unstable
6	Equivocal (Inconclusive)
7	Stable - Normal DNA not used in test
8	Unstable - Normal DNA not used in test
9	Equivocal (Inconclusive) - Normal DNA not used in test
-11	No Amplification
-12	Not tested, reason not specified
-13	Quantity of DNA or tissue not sufficient
-14	Tested, outcome not specified
-15	Unknown if tested

22	MSI_D2S123	number (2,0)	Required:true
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MSI test result at D2S123 locus

Allowable Values	
1	Stable
2	Unstable
6	Equivocal (Inconclusive)
7	Stable - Normal DNA not used in test
8	Unstable - Normal DNA not used in test
9	Equivocal (Inconclusive) - Normal DNA not used in test
-11	No Amplification
-12	Not tested, reason not specified
-13	Quantity of DNA or tissue not sufficient
-14	Tested, outcome not specified
-15	Unknown if tested

23	MSI_MYCL	number (2,0)	Required:true
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MSI test result at MyCL locus

Allowable Values	
1	Stable
2	Unstable
6	Equivocal (Inconclusive)

7	Stable - Normal DNA not used in test
8	Unstable - Normal DNA not used in test
9	Equivocal (Inconclusive) - Normal DNA not used in test
-11	No Amplification
-12	Not tested, reason not specified
-13	Quantity of DNA or tissue not sufficient
-14	Tested, outcome not specified
-15	Unknown if tested

Module: molecular

Module Contents

ihc

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12. [IHC_MSH6](#)
13. [IHC_PMS2](#)

1	CENTER_NO	number (2,0)	Required:true
Center identification number.			

Allowable Values

11	Sinai Health Systems (formerly Cancer Care Ontario)
12	University of Southern California Consortium (USCC)
13	University of Melbourne
14	University of Hawaii Cancer Center
15	Mayo Clinic
16	Fred Hutch, Seattle
17	University of California at San Francisco (UCSF) (formerly CPIC, originally Northern California (NCCC))

2	PERSON_ID	string (12)	Required:true
Number that Uniquely Identifies an Individual.			

3	IHC_TEST_LAB	number (1,0)	Required:true
Lab that conducted the results			

Allowable Values

1	CFR lab
2	Clinical lab

4	COLLECTION_CID	string (40)	Required:true
The label assigned by the center to all tissue associated with a single surgical event - resection or biopsy/endoscopy procedure.			

Allowable Values	
8888	No BLOCK_SPEC_CID available due to external lab testing

5	TEST_TISSUE	number (1,0)	Required:true
Type of tissue tested.			

Allowable Values	
1	Cancer
2	Contiguous (Adjacent) adenoma
3	Colon Polyp
4	Gastric polyp
5	Sebaceous adenoma

6	TUMOR_NO	number (2,0)	Required:true
Numbers labeling tumors of the individual. Numbers are not necessarily sequential.			

Allowable Values	
1 to 99 or -9, -15	Range
-9	NA/Out of scope: Tissue does not currently have a TUMOR_NO and is not cancer or contiguous adenoma
-15	Information Unknown

7	POLYP_NO	number (2,0)	Required:true
Sequential number over range of 1 to 99 to distinguish a polyp removed on a particular date. The tuple PERSON_ID, DATE_COLLECTED, and POLYP_NO uniquely identify a physical polyp globally within the CFR database.			

Allowable Values	
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1 to 99 or -1, -9	Range
-9	NA/Out of scope. Tissue is not a polyp.
-1	Polyp has IHC/MSI result but center is currently unable to locate polyp pathology information. Center review to obtain this information is currently underway.

8	BLOCK_SPEC_CID	string (40)	Required:true				
Unique local identifier used at a center to uniquely identify a block tissue specimen.							
<table border="1"> <tr> <td colspan="2">Allowable Values</td> </tr> <tr> <td>8888</td> <td>No BLOCK_SPEC_CID available due to external lab testing</td> </tr> </table>				Allowable Values		8888	No BLOCK_SPEC_CID available due to external lab testing
Allowable Values							
8888	No BLOCK_SPEC_CID available due to external lab testing						

9	METASTASIS	number (1,0)	Required:true								
Primary or metastatic tumor.											
<table border="1"> <tr> <td colspan="2">Allowable Values</td> </tr> <tr> <td>1</td> <td>Primary</td> </tr> <tr> <td>2</td> <td>Metastasis</td> </tr> <tr> <td>-9</td> <td>Test is not performed on cancerous tissue</td> </tr> </table>				Allowable Values		1	Primary	2	Metastasis	-9	Test is not performed on cancerous tissue
Allowable Values											
1	Primary										
2	Metastasis										
-9	Test is not performed on cancerous tissue										

10	IHC_MLH1	number (2,0)	Required:true																				
IHC result for MSI test at locus MLH1																							
<table border="1"> <tr> <td colspan="2">Allowable Values</td> </tr> <tr> <td>0</td> <td>Negative - Expression absent and abnormal</td> </tr> <tr> <td>1</td> <td>Positive - Expression present and normal</td> </tr> <tr> <td>2</td> <td>Positive - Technically poor, probably positive</td> </tr> <tr> <td>3</td> <td>Positive - Technically equivocal, not truly interpretable but if forced would be positive</td> </tr> <tr> <td>4</td> <td>Negative - Technically poor, probably negative</td> </tr> <tr> <td>5</td> <td>Negative - Technically equivocal, not truly interpretable but if forced would be negative</td> </tr> <tr> <td>7</td> <td>Heterogeneous tumor - some areas lack expression and some have expression</td> </tr> <tr> <td>8</td> <td>Reduced - expression reduced but not absent</td> </tr> <tr> <td>-11</td> <td>Technical failure</td> </tr> </table>				Allowable Values		0	Negative - Expression absent and abnormal	1	Positive - Expression present and normal	2	Positive - Technically poor, probably positive	3	Positive - Technically equivocal, not truly interpretable but if forced would be positive	4	Negative - Technically poor, probably negative	5	Negative - Technically equivocal, not truly interpretable but if forced would be negative	7	Heterogeneous tumor - some areas lack expression and some have expression	8	Reduced - expression reduced but not absent	-11	Technical failure
Allowable Values																							
0	Negative - Expression absent and abnormal																						
1	Positive - Expression present and normal																						
2	Positive - Technically poor, probably positive																						
3	Positive - Technically equivocal, not truly interpretable but if forced would be positive																						
4	Negative - Technically poor, probably negative																						
5	Negative - Technically equivocal, not truly interpretable but if forced would be negative																						
7	Heterogeneous tumor - some areas lack expression and some have expression																						
8	Reduced - expression reduced but not absent																						
-11	Technical failure																						

-12	Not tested
-13	Quantity of tissue not sufficient

11	IHC_MSH2	number (2,0)	Required:true
IHC result for MSI test at locus MSH2			

Allowable Values	
0	Negative - Expression absent and abnormal
1	Positive - Expression present and normal
2	Positive - Technically poor, probably positive
3	Positive - Technically equivocal, not truly interpretable but if forced would be positive
4	Negative - Technically poor, probably negative
5	Negative - Technically equivocal, not truly interpretable but if forced would be negative
7	Heterogeneous tumor - some areas lack expression and some have expression
8	Reduced - expression reduced but not absent
-11	Technical failure
-12	Not tested
-13	Quantity of tissue not sufficient

12	IHC_MSH6	number (2,0)	Required:true
IHC result for MSI test at locus MSH6			

Allowable Values	
0	Negative - Expression absent and abnormal
1	Positive - Expression present and normal
2	Positive - Technically poor, probably positive
3	Positive - Technically equivocal, not truly interpretable but if forced would be positive
4	Negative - Technically poor, probably negative
5	Negative - Technically equivocal, not truly interpretable but if forced would be negative
7	Heterogeneous tumor - some areas lack expression and some have expression
8	Reduced - expression reduced but not absent
-11	Technical failure
-12	Not tested
-13	Quantity of tissue not sufficient

13	IHC_PMS2	number (2,0)	Required:true
IHC result for MSI test at locus PMS2			

Allowable Values

0	Negative - Expression absent and abnormal
1	Positive - Expression present and normal
2	Positive - Technically poor, probably positive
3	Positive - Technically equivocal, not truly interpretable but if forced would be positive
4	Negative - Technically poor, probably negative
5	Negative - Technically equivocal, not truly interpretable but if forced would be negative
7	Heterogeneous tumor - some areas lack expression and some have expression
8	Reduced - expression reduced but not absent
-11	Technical failure
-12	Not tested
-13	Quantity of tissue not sufficient

Module: molecular

Module Contents

mlpa

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14. [VARIANT_NAME](#)

1	CENTER_NO (*PK)	number (2,0)	Required:true
Center identification number. *CENTER_NO & NUC_ACID_CID are the primary key for the table.			

Allowable Values

11	Sinai Health Systems (formerly Cancer Care Ontario)
12	University of Southern California Consortium (USCC)
13	University of Melbourne
14	University of Hawaii Cancer Center
15	Mayo Clinic
16	Fred Hutch, Seattle
17	University of California at San Francisco (UCSF) (formerly CPIC, originally Northern California (NCCC))

2	PERSON_ID	string (12)	Required:true
Number that Uniquely Identifies an Individual.			

3	GENE	string (20)	Required:true
Gene on which testing has been performed.			

4	NUC_ACID_CID (*PK)	string (40)	Required:true
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Identifier used internally by centers for a nucleic acid sample from a single extraction.
*CENTER_NO & NUC_ACID_CID are the primary key for the table.

5	MLPA_DATE_TESTED	string (8)	Required:true
Date of test.			

Date Value Check

The date must follow to the following format:

Format YYYYMMDD. Must consist of valid date.

Components of date should be right justified and zero filled.

MM = 01 - 12, 88, 99

DD = 01 - 31, 88, 99

YYYY = **Minimum year** - system date year, 8888, 9999

Use 88, 8888 for not currently known, in progress to obtain information.

Use 99, 9999 for not known.

If century is known, but year is unknown then give an estimate of year or code YYYY = 9999.

If MM = 99 then DD must = 99.

If century is known, but year is unknown then give an estimate of year or code YYYY = 9999.

If YYYY = 9999 then MM and DD must = 99.

The following special parameters are used:

1700	Minimum year
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6	MLPA_INVEST_ID	number (1,0)	Required:true
Laboratory investigator conducting the tests on samples.			

Allowable Values

1	Dr. Steve Thibodeau
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2	Dr. Melissa Southey
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3	GMP Genetics (Corporation)
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4	Joanne Young
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5	Clinical Laboratory
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6	Dan Buchanan
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7	MLPA_DETECTION_METHOD	number (1,0)	Required:false
Testing method.			

Allowable Values

1	Multiplex ligation-dependent probe amplification (MLPA)
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2	Conversion analysis
----------	---------------------

8	MLPA_RESULT	number (1,0)	Required:true
Summary of test findings.			

Allowable Values	
0	Failed test
1	Negative (no deletion or duplication)
2	Deletion
3	Duplication
4	Equivocal
5	Inversion

9	MLPA_RESULT_SUB	number (2,0)	Required:false
Additional specific findings of test.			

Allowable Values	
0	Failed test
1	Confirmed by second MLPA test only
2	Confirmed by Southern blot
3	Confirmatory test not done for positive result
4	Confirmed by other method or other information
5	Deletion artifact. DNA sequence change under primer found by sequencing (scored as negative)
6	Deletion artifact. Results not consistent, normal on repeat (scored as negative)
7	Deletion artifact. Southern did not confirm deletion
8	Deletion artifact. Sequencing and/or Southern not done to determine cause for discordant result (assumed to be negative based on analysis of other similar cases)
9	Deletion artifact, Other
10	Duplication artifact. Results not consistent, normal on MLPA repeat (scored as negative)
11	Duplication artifact. Southern did not confirm duplication
12	Duplication artifact. Sequencing and/or Southern not done to determine cause for discordant result (assumed to be negative based on analysis of other similar cases)
13	Duplication artifact, Other
14	Equivocal. Single exon deletion, unclear whether artifact; Southern could not be performed
15	Equivocal. Multiple exons deleted, not enough sample to repeat test
16	Equivocal. Single exon duplication, unclear whether artifact; Southern could not be performed

17	Equivocal. Multiple exons duplicated, not enough sample to repeat test
-7	NA One assay only for negative result

10	MLPA_EXON_FROM	number (10,0)	Required:false
	Starting exon in range.		
	Allowable Values		
	1 to 9999999999 or -7	Range	
	-7	NA: Negative result or failed test Otherwise number of starting exon.	

11	MLPA_EXON_TO	number (10,0)	Required:false
	Ending exon in range.		
	Allowable Values		
	1 to 9999999999 or -7	Range	
	-7	NA: Negative result or failed test Otherwise number of starting exon.	

12	MLPA_OTHER_TEST_COMMENT	string (400)	Required:false
	Text field containing comments regarding other test findings.		

13	GENOMIC_REGION_TESTED	string (100)	Required:false
	Indicates what part(s) of the gene or other genomic region(s) was tested.		

14	VARIANT_NAME	string (100)	Required:false
	Proper variant name using HGVS nomenclature.		

Module: molecular

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genomics

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1	CENTER_NO (*PK)	number (2,0)	Required:true
Center identification number. * CENTER_NO & GENOMIC_CID are the primary key for the table.			

Allowable Values

11	Sinai Health Systems (formerly Cancer Care Ontario)
12	University of Southern California Consortium (USCC)
13	University of Melbourne
14	University of Hawaii Cancer Center
15	Mayo Clinic
16	Fred Hutch, Seattle

17 University of California at San Francisco (UCSF) (formerly CPIC, originally Northern California (NCCC))

2 **PERSON_ID** string (12) Required:true
Number that Uniquely Identifies an Individual.

3 **GENOMIC_CID (*PK)** string (40) Required:true
Center identifier for the test. *CENTER_NO & GENOMIC_CID are the primary key for the table.

4 **GENE** number (1,0) Required:true
Gene on which testing has been performed.

Allowable Values

1	MLH1
2	MSH2
3	MSH6
4	MUTYH
5	PMS2
8	EPCAM
10	APC
11	TP53

5 **VARIANT_ORIGIN** number (1,0) Required:true
Describes if the variant was tested as an acquired or a germline variant.

Allowable Values

1	Presumed somatic
2	Known somatic
3	Germline

6 **SOURCE_NUC_ACID** number (1,0) Required:true
Specifies source of tissue used for testing

Allowable Values

1	blood

2	Mouth wash/saliva
3	lymphoblastoid cells
4	normal fresh frozen tissue
5	other non-tumour tissue
6	polyp
7	tumour (paraffin embedded tumour- PET)
8	tumor- fresh frozen
9	unknown/private lab

7	NUC_ACID_CID	string (12)	Required:true
	Identifier used internally by centers for a single extraction on which the test was carried out		

8	DETECTION_METHOD	number (2,0)	Required:true
	Germline or somatic DNA testing method. (Mass Spec = Sequenom MassARRAY system, MALDI-TOF)		

Allowable Values	
1	DNA Sequencing
10	DHPLC (Denaturing High Performance Liquid Chromatography)
11	Phase 1 protocol DHPLC+SEQ (MLH1 and MSH2)
12	12 SNP panel genotyping by Mass Spec
13	12 SNP panel genotyping, dHPLC with sequencing (MUTYH)
14	9 SNP panel genotyping by Mass Spec
15	9 SNP panel genotyping with sequencing (MUTYH)
16	PTT
17	SSCP
18	Fluorescent ASP (BRAF)
19	HRM with sequencing (KRAS)
33	Sequencing from Conversion Analysis
50	whole exome sequencing
60	whole genome sequencing
70	targeted panel sequencing
99	Unknown/private genetic test results

9	GENOMIC_REGION_TESTED	string (100)	Required:true
Indicates what part(s) of the gene or specific mutation or other genomic region(s) was TESTED			

10	TEST_RESULT	number (1,0)	Required:true
Result of the test carried out and this is at the test level (e.g. entire gene sequencing or MSH2 exon 2 etc.). This is NOT at person level or at variant level.			

Allowable Values											
<table border="1"> <tr> <td>1</td> <td>Change detected</td> </tr> <tr> <td>2</td> <td>No change detected</td> </tr> <tr> <td>3</td> <td>Test failed</td> </tr> <tr> <td>9</td> <td>Equivocal</td> </tr> </table>				1	Change detected	2	No change detected	3	Test failed	9	Equivocal
1	Change detected										
2	No change detected										
3	Test failed										
9	Equivocal										

11	VARIANT_NAME_RESULT	string (100)	Required:false
Proper variant name using Human Genomic Variant Society (HGVS) nomenclature.			

12	EXON_NO	number (2,0)	Required:false
Number of exon containing variant. In the case the variant spans more than one exon, then this field should indicate the first exon affected by the variant.			

13	INTRON_NO	number (2,0)	Required:false
Number of intron containing variant. In the case the variant spans more than one intron, then this field should indicate the first intron affected by the variant			

14	OTHER_REGION	number (1,0)	Required:false
Region, other than coding exon and intron, containing the variant.			

Allowable Values									
<table border="1"> <tr> <td>1</td> <td>5 UTR</td> </tr> <tr> <td>2</td> <td>3 UTR</td> </tr> <tr> <td>3</td> <td>Other</td> </tr> </table>				1	5 UTR	2	3 UTR	3	Other
1	5 UTR								
2	3 UTR								
3	Other								

15	NUC_POS_START	string (20)	Required:false
For exonic mutations, the numeric value of the nucleotide first affected by the mutation relative to the reference sequence. For intronic mutations, the numeric value of the first affected nucleotide			

relative to the exon number; a (-) indicates the number of nucleotides upstream (5) of the exon, and a (+) indicates the number of nucleotides downstream (3) from the exon. The 5 UTR and 3 UTR are considered to be part of the first and Last Exon respectively but have special notation here. Positions in the 5-UTR have (-) sign. Positions in the 3-UTR have (*) sign.

16	NUC_POS_END	string (20)	Required:false
<p>For exonic mutations, the numeric value of the nucleotide last affected by the mutation relative to the reference sequence. For intronic mutations, the numeric value of the first affected nucleotide relative to the exon number; a (-) indicates the number of nucleotides upstream (5) of the exon, and a (+) indicates the number of nucleotides downstream (3) from the exon. The 5 UTR and 3 UTR are considered to be part of the first and Last Exon respectively but have special notation here. Positions in the 5-UTR have (-) sign. Positions in the 3-UTR have (*) sign</p>			

17	NUCLEOTIDE_FROM	string (1)	Required:false
<p>Expected nucleotide with respect to the reference sequence.</p>			

Allowable Values	
A	Adenine
C	Cytosine
G	Guanine
T	Thymidine

18	NUCLEOTIDE_TO	string (1)	Required:false
<p>Observed (mutated) nucleotide.</p>			

Allowable Values	
A	Adenine
C	Cytosine
G	Guanine
T	Thymidine

19	DELETE_SEQ	string (50)	Required:false
<p>Deletion nucleotide sequence</p>			

20	INSERT_SEQ	string (50)	Required:false
<p>Insertion nucleotide sequence</p>			

21	TYPE_VARIANT	number (1,0)	Required:false
----	---------------------	--------------	----------------

Type of genetic change

Allowable Values

- | | |
|---|-----------------------|
| 1 | Deletion |
| 2 | Insertion |
| 3 | Substitution |
| 4 | Duplication |
| 5 | Translocation |
| 6 | Inversion |
| 7 | Complex Rearrangement |
| 9 | Uncertain |

22	CODON	number (4,0)	Required:false
----	--------------	--------------	----------------

Numeric location of first mutated amino acid of reference sequence. A numeric value of 1 to the total number of codons on the reference sequence

23	AA_FROM	string (1)	Required:false
----	----------------	------------	----------------

Wild type amino acid value of first affected amino acid on reference sequence

Allowable Values

- | | |
|---|-----|
| A | Ala |
| C | Cys |
| D | Asp |
| E | Glu |
| F | Phe |
| G | Gly |
| H | His |
| I | Ile |
| K | Lys |
| L | Leu |
| M | Met |
| N | Asn |
| P | Pro |
| Q | Gln |

R	Arg
S	Ser
T	Thr
V	Val
W	Trp
Y	Tyr
X	Stop

24	AA_TO	string (1)	Required:false
Expressed amino acid value of last affected amino acid on reference sequence			

Allowable Values	
A	Ala
C	Cys
D	Asp
E	Glu
F	Phe
G	Gly
H	His
I	Ile
K	Lys
L	Leu
M	Met
N	Asn
P	Pro
Q	Gln
R	Arg
S	Ser
T	Thr
V	Val
W	Trp
Y	Tyr
X	Stop

25	CONSEQUENCE	number (2,0)	Required:false														
Category of mutation- defining outcome of the variant																	
<table border="1"> <tr> <td colspan="2" data-bbox="614 257 981 313">Allowable Values</td> </tr> <tr> <td data-bbox="614 313 670 369">1</td> <td data-bbox="670 313 981 369">Missense</td> </tr> <tr> <td data-bbox="614 369 670 425">2</td> <td data-bbox="670 369 981 425">Premature termination</td> </tr> <tr> <td data-bbox="614 425 670 481">4</td> <td data-bbox="670 425 981 481">Aberrant splicing</td> </tr> <tr> <td data-bbox="614 481 670 537">7</td> <td data-bbox="670 481 981 537">Nonstop</td> </tr> <tr> <td data-bbox="614 537 670 593">8</td> <td data-bbox="670 537 981 593">Other</td> </tr> <tr> <td data-bbox="614 593 670 649">99</td> <td data-bbox="670 593 981 649">Uncertain</td> </tr> </table>				Allowable Values		1	Missense	2	Premature termination	4	Aberrant splicing	7	Nonstop	8	Other	99	Uncertain
Allowable Values																	
1	Missense																
2	Premature termination																
4	Aberrant splicing																
7	Nonstop																
8	Other																
99	Uncertain																

26	ZYGOSITY	number (1,0)	Required:false										
Indicates the heterozygote/homozygote state of a variation, regardless of whether it is a polymorphism, unclassified variant or well established mutation.													
<table border="1"> <tr> <td colspan="2" data-bbox="590 963 1005 1019">Allowable Values</td> </tr> <tr> <td data-bbox="590 1019 630 1075">1</td> <td data-bbox="630 1019 1005 1075">Homozygous wildtype (-/-)</td> </tr> <tr> <td data-bbox="590 1075 630 1131">2</td> <td data-bbox="630 1075 1005 1131">Heterozygous change (+/-)</td> </tr> <tr> <td data-bbox="590 1131 630 1187">3</td> <td data-bbox="630 1131 1005 1187">Homozygous change (+/+)</td> </tr> <tr> <td data-bbox="590 1187 630 1243">9</td> <td data-bbox="630 1187 1005 1243">Unknown</td> </tr> </table>				Allowable Values		1	Homozygous wildtype (-/-)	2	Heterozygous change (+/-)	3	Homozygous change (+/+)	9	Unknown
Allowable Values													
1	Homozygous wildtype (-/-)												
2	Heterozygous change (+/-)												
3	Homozygous change (+/+)												
9	Unknown												

27	SEVERITY	number (1,0)	Required:false										
Type of mutation													
<table border="1"> <tr> <td colspan="2" data-bbox="119 1500 1476 1556">Allowable Values</td> </tr> <tr> <td data-bbox="119 1556 183 1624">1</td> <td data-bbox="183 1556 1476 1624">Deleterious</td> </tr> <tr> <td data-bbox="119 1624 183 1680">2</td> <td data-bbox="183 1624 1476 1680">Polymorphism, assumed neutral</td> </tr> <tr> <td data-bbox="119 1680 183 1747">3</td> <td data-bbox="183 1680 1476 1747">Unclassified variant</td> </tr> <tr> <td data-bbox="119 1747 183 1870">4</td> <td data-bbox="183 1747 1476 1870">Unclassified variant, possibly pathogenic. DNA missense alteration with corresponding loss of expression by tumor IHC; alternatively, missense alteration that cosegregates with the disease in family.</td> </tr> </table>				Allowable Values		1	Deleterious	2	Polymorphism, assumed neutral	3	Unclassified variant	4	Unclassified variant, possibly pathogenic. DNA missense alteration with corresponding loss of expression by tumor IHC; alternatively, missense alteration that cosegregates with the disease in family.
Allowable Values													
1	Deleterious												
2	Polymorphism, assumed neutral												
3	Unclassified variant												
4	Unclassified variant, possibly pathogenic. DNA missense alteration with corresponding loss of expression by tumor IHC; alternatively, missense alteration that cosegregates with the disease in family.												

28	INSIGHT_SEVERITY	number (1,0)	Required:false	
This will be the 5-point severity code which InSiGHT use.				
<table border="1"> <tr> <td data-bbox="646 2116 949 2163"></td> </tr> </table>				

Allowable Values	
5	Pathogenic
4	Likely Pathogenic
3	Unclassified
2	Likely Neutral
1	Neutral
9	Unknown

29	LAB_ID	number (3,0)	Required:true
	Lab or individual who performed the testing.		

Allowable Values	
119	Graham Casey
125	Steve Gallinger
128	Peter Laird
129	Joanne Young
141	Steve Thibodeau
228	Robert Haile
300	Dan Buchanan
301	Karen Makar
998	Other (specify, free text)
999	Unknown

30	LAB_OTHER_TEXT	string (50)	Required:false
	Name of other/private lab		

31	DATE_TEST	string (8)	Required:false
	Date on which test was performed. Format: YYYYMMDD		

Date Value Check

The date must follow to the following format:

Format YYYYMMDD. Must consist of valid date.

Components of date should be right justified and zero filled.

MM = 01 - 12, 88, 99

DD = 01 - 31, 88, 99

YYYY = **Minimum year** - system date year, 8888, 9999

Use 88, 8888 for not currently known, in progress to obtain information.

Use 99, 9999 for not known.

If century is known, but year is unknown then give an estimate of year or code YYYY = 9999.

If MM = 99 then DD must = 99.

If century is known, but year is unknown then give an estimate of year or code YYYY = 9999.

If YYYY = 9999 then MM and DD must = 99.

The following special parameters are used:

2002	Minimum year
-------------	--------------

Module: molecular

Module Contents

braf_kras

- 1.[CENTER_NO \(*PK\)](#)
- 2.[SOMATIC_CID\(*PK\)](#)
- 3.[PERSON_ID](#)
- 4.[TUMOR_NO](#)
- 5.[POLYP_NO](#)
- 6.[GENE](#)
- 7.[VARIANT_ORIGIN](#)
- 8.[SOURCE_NUC_ACID](#)
- 9.[NUC_ACID_CID](#)
- 10.[DETECTION_METHOD](#)
- 11.[GENOMIC_REGION_TESTED](#)
- 12.[TEST_RESULT](#)
- 13.[VARIANT_NAME_RESULT](#)
- 14.[EXON_NO](#)
- 15.[NUC_POS_START](#)
- 16.[NUC_POS_END](#)
- 17.[NUCLEOTIDE_FROM](#)
- 18.[NUCLEOTIDE_TO](#)
- 19.[TYPE_VARIANT](#)
- 20.[CODON](#)
- 21.[AA_FROM](#)
- 22.[AA_TO](#)
- 23.[CONSEQUENCE](#)
- 24.[LAB_ID](#)
- 25.[LAB_OTHER_TEXT](#)
- 26.[DATE_TEST](#)

1	CENTER_NO (*PK)	number(2,0)	Required:TRUE
Center identification number. *CENTER_NO & SOMATIC_CID are the primary key for the table.			

Allowable Values

11	Sinai Health Systems (formerly Cancer Care Ontario)
12	University of Southern California Consortium (USCC)
13	University of Melbourne
14	University of Hawaii Cancer Center
15	Mayo Clinic
16	Fred Hutch, Seattle
17	University of California at San Francisco (UCSF) (formerly CPIC, originally Northern California (NCCC))

2	SOMATIC_CID (*PK)	String (40)	Required:TRUE
Centre identifier for the test. *CENTER_NO & SOMATIC_CID are the primary key for the table.			

3	PERSON_ID	string (12)	Required:TRUE
Number that uniquely identifies an individual.			

4	TUMOR_NO	number (2,0)	Required:TRUE
Number labelling the tumor of the individual. Numbers are not necessarily sequential.			

Allowable Values	
-9	NA/Out of scope: Tissue is not cancer or contiguous adenoma.
-15	Information Unknown

5	POLYP_NO	number (2,0)	Required:TRUE
Sequential number over range of 1 to 99 to distinguish a polyp removed on a particular date.			

Allowable Values	
-9	NA/Out of scope: Tissue is not a polyp.
-1	Polyp has MSI/IHC result but center is currently unable to locate polyp pathology information

6	GENE	number (1,0)	Required:TRUE
Gene on which testing has been performed.			

Allowable Values	
6	BRAF
7	KRAS

7	VARIANT_ORIGIN	number (1,0)	Required:TRUE
Describes if the variant was tested as an acquired or a germline variant.			

Allowable Values	
1	Presumed somatic
2	Known somatic
3	Germline

8	SOURCE_NUC_ACID	number (1,0)	Required:TRUE
	Specifies source of tissue used for testing		

Allowable Values	
4	normal fresh frozen tissue
5	other non-tumour tissue
6	polyp
7	tumour (paraffin embedded tumour- PET)
8	tumor- fresh frozen
9	unknown/private lab

9	NUC_ACID_CID	string (15)	Required:TRUE
	Identifier used internally by centers for a single extraction on which the test was carried out		

Allowable Values	
-9	unknown

10	DETECTION_METHOD	number (2,0)	Required:TRUE
	Somatic DNA testing method. (Mass Spec = Sequenom MassARRAY system, MALDI-TOF)		

Allowable Values	
1	DNA Sequencing
18	Fluorescent ASP (BRAF)
19	HRM with sequencing (KRAS)
40	SYBR real time PCR assay
99	Unknown/private genetic test results

11	GENOMIC_REGION_TESTED	string (30)	Required:TRUE
	Indicates what part(s) of the gene or specific mutation or other genomic region(s) was TESTED		

12	TEST_RESULT	number (1,0)	Required:TRUE
	Result of the test carried out at the tumor level. This is NOT at person level.		

Allowable Values	

1	Change detected
2	No change detected
3	Test failed
9	Equivocal

13	VARIANT_NAME_RESULT	string (30)	Required:FALSE
Proper variant name using Human Genomic Variant Society (HGVS) nomenclature.			

14	EXON_NO	number (2,0)	Required:false
Number of exon containing variant. In the case the variant spans more than one exon, then this field should indicate the first exon affected by the variant.			

Allowable Values

2	KRAS
15	BRAF

15	NUC_POS_START	string (20)	Required:false
For exonic mutations, the numeric value of the nucleotide first affected by the mutation relative to the reference sequence.			

16	NUC_POS_END	string (20)	Required:false
For exonic mutations, the numeric value of the nucleotide last affected by the mutation relative to the reference sequence.			

17	NUCLEOTIDE_FROM	string (1)	Required:false
Expected nucleotide with respect to the reference sequence.			

Allowable Values

A	Adenine
C	Cytosine
G	Guanine
T	Thymidine

18	NUCLEOTIDE_TO	string (1)	Required:FALSE
Observed (mutated) nucleotide.			

Allowable Values	
------------------	--

A	Adenine
----------	---------

C	Cytosine
----------	----------

G	Guanine
----------	---------

T	Thymidine
----------	-----------

19

TYPE_VARIANT

number (1,0)

Required:false

Type of genetic change

Allowable Values	
------------------	--

3	Substitution
----------	--------------

9	Uncertain
----------	-----------

20

CODON

number (4,0)

Required:false

Numeric location of first mutated amino acid of reference sequence. A numeric value of 1 to the total number of codons on the reference sequence

21

AA_FROM

string (1)

Required:FALSE

Wild type amino acid value of first affected amino acid on reference sequence

Allowable Values	
------------------	--

A	Ala
----------	-----

C	Cys
----------	-----

D	Asp
----------	-----

E	Glu
----------	-----

F	Phe
----------	-----

G	Gly
----------	-----

H	His
----------	-----

I	Ile
----------	-----

K	Lys
----------	-----

L	Leu
----------	-----

M	Met
----------	-----

N	Asn
----------	-----

P	Pro
----------	-----

Q	Gln
R	Arg
S	Ser
T	Thr
V	Val
W	Trp
Y	Tyr
X	Stop

22	AA_TO	string (1)	Required:FALSE
Expressed amino acid value of last affected amino acid on reference sequence			

Allowable Values	
A	Ala
C	Cys
D	Asp
E	Glu
F	Phe
G	Gly
H	His
I	Ile
K	Lys
L	Leu
M	Met
N	Asn
P	Pro
Q	Gln
R	Arg
S	Ser
T	Thr
V	Val
W	Trp
Y	Tyr
X	Stop

23	CONSEQUENCE	number (1,0)	Required:FALSE
	Category of mutation- defining outcome of the variant		

Allowable Values	
1	Missense
2	Premature termination
9	Uncertain

24	LAB_ID	number (3,0)	Required:TRUE
	Lab or individual who performed the testing.		

Allowable Values	
119	Graham Casey
125	Steve Gallinger
128	Peter Laird
129	Joanne Young
141	Steve Thibodeau
228	Robert Haile
300	Dan Buchanan
301	Karen Makar
998	Other (specify, free text)
999	Unknown

25	LAB_OTHER_TEXT	string (30)	Required:false
	Name of other/private lab		

26	DATE_TEST	string (8)	Required:TRUE
	Date on which test was performed. Format: YYYYMMDD		

Date Value Check

The date must follow to the following format:

Format YYYYMMDD. Must consist of valid date.
Components of date should be right justified and zero filled.
MM = 01 - 12, 88, 99
DD = 01 - 31, 88, 99
YYYY = **Minimum year** - system date year, 8888, 9999

Use 88, 8888 for not currently known, in progress to obtain information.

Use 99, 9999 for not known.

If century is known, but year is unknown then give an estimate of year or code YYYY = 9999.

If MM = 99 then DD must = 99.

If century is known, but year is unknown then give an estimate of year or code YYYY = 9999.

If YYYY = 9999 then MM and DD must = 99.

The following special parameters are used:

MM	01 - 12, 88, 99
DD	01 - 31, 88, 99
YYYY	2002 - system year, 8888, 9999

Module: derived

Module Contents

d_MSI_IHC_STATUS_TISSUE

- 1.[CENTER_NO](#)
- 2.[PERSON_ID](#)
- 3.[COLLECTION_CID](#)
- 4.[TEST_TISSUE](#)
- 5.[TUMOR_NO](#)
- 6.[IHC_STATUS_TISSUE](#)
- 7.[MSI_STATUS_TISSUE](#)
- 8.[MSIHC_STATUS_TISSUE](#)

1	CENTER_NO	number (2,0)	Required:true
	Center Identification Number.		

Allowable Values

11	Sinai Health Systems (formerly Cancer Care Ontario)
12	University of Southern California Consortium (USCC)
13	University of Melbourne
14	University of Hawaii Cancer Center
15	Mayo Clinic
16	Fred Hutch, Seattle
17	University of California at San Francisco (UCSF) (formerly CPIC, originally Northern California (NCCC))

2	PERSON_ID	string (12)	Required:true
	Number that Uniquely Identifies an Individual.		

3	COLLECTION_CID	string (40)	Required:true
	The label assigned by the center to all tissue associated with a single surgical event - resection or biopsy/endoscopy procedure. This data element is typically used to allow aggregation of all materials, such as blocks, from a single surgery.		

4	TEST_TISSUE	number (1,0)	Required:true
	Type of tissue tested. Only values of 1,2,3 link to pathology information. Although values 2 and 3 may represent the same tissue type, their pathology information is stored in different database tables. Adjacent adenomas are recorded on the Colorect_Malig table and so are associated with a cancer; Colorectal polyps are recorded on the Polyps table. As a result, the pathology information for each will differ somewhat. There may be cases where TEST_TISSUE variable has value 2 but the		

ADJ_ADEN variable of Colorect_Malig table indicates no adjacent adenoma present. In these cases, the TEST_TISSUE value takes precedence and the adjacent adenoma is considered to have been overlooked.

Allowable Values	
1	Cancer
2	Contiguous (Adjacent) adenoma
3	Colon Polyp
4	Gastric polyp
5	Sebaceous adenoma

TUMOR_NO

number (2,0)

Required:true

5

Numbers labeling tumors of the individual. Numbers are not necessarily sequential. No adjustment is made when a tumor is deleted from the system. Tumor numbers are never reused. PERSON_NO plus TUMOR_NO uniquely identifies each tumor in the central database. The same tumor number from different tables (including tables outside of the biospecimen module) must always refer to the same physical tumor.

Allowable Values

1 to 99 or -9, -15	Range
-9	NA/Out of scope: Tissue does not currently have a TUMOR_NO and is not cancer or contiguous adenoma
-15	Information Unknown

IHC_STATUS_TISSUE

number(1,0)

Required:true

6

IHC status of tissue from tested block. Multiple blocks from the same tumor may be tested. Expression is ABSENT if any of IHC_MLH1, IHC_MSH2, IHC_MSH6, IHC_PMS2 equal either 0 or 4. Expression is NORMAL if at least one of them equals 1 or 2 and none equal 0 or 4.

Allowable Values

-8	No data transmitted from centers
-7	NA/Out of scope - None of IHC_MLH1, IHC_MSH2, IHC_MSH6, IHC_PMS2 recorded values 0,1,2,4. Test failed or result was equivocal.
1	Normal MMR protein expression
2	Absence of MMR protein expression

7	MSI_STATUS_TISSUE	number(1,0)	Required:true
	MSI status of tissue from tested block. Multiple blocks from the same tumor may be tested. For each set of scores (MSI_ACTC, _BAT25, _BAT26, _BAT34C4, _BAT40, _D5S346, _D10S197, _D17S250, _D18S55, _MYCL (excluding D2S123) (with a minimum of 4 out of 10 markers that are either stable or unstable - Options 1 and 2 only), the percent unstable among stable and unstable markers is calculated and compared to cutpoints to determine if the results are stable, low or high. If only 3 markers are scored but they are all unstable then the status is scored as high.		

Allowable Values	
-8	No data transmitted from centers
-7	NA/Out of scope - Less than 4 marker scores stable or unstable
1	Stable - 0% unstable
2	Low - More than 0% but less than 30% unstable
3	High - At least 30% unstable

8	MSIIHC_STATUS_TISSUE	number(1,0)	Required:true
	MMR status considering the MSI and IHC results from the same collection block.		

Allowable Values	
-8	No data transmitted from centers for MSI_STATUS_TISSUE -AND- IHC_STATUS_TISSUE
-7	NA/Out of Scope - MSI_STATUS_TISSUE and IHC_STATUS_TISSUE are -7; -OR-, one of them is -7 and the other is -8.
1	Proficient MMR 1 - MSI_STATUS_TISSUE is Stable (1) or Low (2) -OR- IHC_STATUS_TISSUE is Normal (1), but not both
2	Proficient MMR 2 - MSI_STATUS_TISSUE is Stable (1) or Low (2) -AND- IHC_STATUS_TISSUE is Normal (1) (both are true)
3	Defective MMR 1 - MSI_STATUS_TISSUE is High (3) -OR- IHC_STATUS_TISSUE is Absent (2), but not both
4	Defective MMR 2 - MSI_STATUS_TISSUE is High (3) -AND- IHC_STATUS_TISSUE is Absent (2) (both are true)

Module: derived

Module Contents

d_MSI_IHC_STATUS_PERSON

1. [CENTER_NO](#)
2. [PERSON_ID](#)
3. [IHC_STATUS_PERSON](#)
4. [MSI_STATUS_PERSON](#)
5. [MSIIHC_STATUS_PERSON](#)

1	CENTER_NO	number (2,0)	Required:true
Center Identification Number.			

Allowable Values	
11	Sinai Health Systems (formerly Cancer Care Ontario)
12	University of Southern California Consortium (USCC)
13	University of Melbourne
14	University of Hawaii Cancer Center
15	Mayo Clinic
16	Fred Hutch, Seattle
17	University of California at San Francisco (UCSF) (formerly CPIC, originally Northern California (NCCC))

2	PERSON_ID	string (12)	Required:true
Number that Uniquely Identifies an Individual.			

3	IHC_STATUS_PERSON	number (1,0)	Required:true
IHC status of person tested. It considers IHC results for ALL colorectal cancer tumor types and excludes all non-colorectal malignancies, adenomas, metastases and in situ carcinomas. It does not restrict to qualifying tumors. Colorectal cancer is defined by ICDO3 site codes C180, C181, C182, C183, C184, C185, C186, C187, C188, C189, C199, C209, C218, C260 and a malignant tumor (BEHAV=3).			

Allowable Values	
-8	No data transmitted
-7	NA/Out of scope: Individual has IHC record, but no markers having values 0,1,2, or 4.
1	NORMAL MMR protein expression

2	ABSENCE of MMR protein expression
---	-----------------------------------

4	MSI_STATUS_PERSON	number (1,0)	Required:true
	MSI status of person tested. It considers MSI results for ALL colorectal cancer tumor types and excludes all non-colorectal malignancies, adenomas, metastases and in situ carcinomas. It does not restrict to qualifying tumors. Colon cancer is defined by ICDO3 site codes C180, C181, C182, C183, C184, C185, C186, C187, C188, C189, C199, C209, C218, C260 and a malignant tumor (BEHAV=3).		

Allowable Values

-8	No data transmitted
-7	NA/Out of scope: An MSI record, but no Stable, Low, or High tissue-level result recorded.
1	STABLE: No High or Low tissue-level results, but at least one Stable.
2	LOW: No High tissue-level results, but at least one Low.
3	HIGH: At least one High tissue-level result

5	MSIIHC_STATUS_PERSON	number (1,0)	Required:true
	MMR status for person tested. An overall MMR status is derived per person by collating MSI and IHC results for ALL colorectal cancer tumor types and excluding all non-colorectal malignancies, adenomas, metastases and in situ carcinomas. It does not restrict to qualifying tumors.		

Allowable Values

-8	No data transmitted from centers for MSI_STATUS_TISSUE -AND- IHC_STATUS_TISSUE
-7	NA/Out of Scope - MSI_STATUS_TISSUE and IHC_STATUS_TISSUE are -7; -OR-, one of them is -7 and the other is -8.
1	Proficient MMR 1 - MSI_STATUS_TISSUE is Stable (1) or Low (2) -OR- IHC_STATUS_TISSUE is Normal (1), but not both
2	Proficient MMR 2 - MSI_STATUS_TISSUE is Stable (1) or Low (2) -AND- IHC_STATUS_TISSUE is Normal (1) (both are true)
3	Defective MMR 1 - MSI_STATUS_TISSUE is High (3) -OR- IHC_STATUS_TISSUE is Absent (2), but not both
4	Defective MMR 2 - MSI_STATUS_TISSUE is High (3) -AND- IHC_STATUS_TISSUE is Absent (2) (both are true)

Module: derived

Module Contents

d_GENOMIC

- 1.[CENTER_NO](#)
- 2.[PERSON_ID](#)
- 3.[C_DEL_MMR](#)
- 4.[C_MLH1](#)
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- 8.[C_EPCAM](#)
- 9.[C_MUTYH](#)

1	CENTER_NO	number (2,0)	Required:true
	Center Identification Number.		

Allowable Values

11	Sinai Health Systems (formerly Cancer Care Ontario)
12	University of Southern California Consortium (USCC)
13	University of Melbourne
14	University of Hawaii Cancer Center
15	Mayo Clinic
16	Fred Hutch, Seattle
17	University of California at San Francisco (UCSF) (formerly CPIC, originally Northern California (NCCC))

2	PERSON_ID	string (12)	Required:true
	Number that uniquely identifies an individual.		

3	C_DEL_MMR	number (1,0)	Required:true
	Presence of deleterious mutation in one or more MMR gene (MLH1, MSH2, MSH6, PMS2, EPCAM) by sequencing (genomic and /or MLPA)		

Allowable Values

-8	No data transmitted from centers
-9	Failed or equivocal MLPA result or failed sequencing result
1	One or more MMR gene (MLH1, MSH2, MSH6, PMS2, EPCAM) has been tested for a germline mutation (by any method) and no deleterious/pathogenic mutation was found

2	One or more MMR gene (MLH1, MSH2, MSH6, PMS2, EPCAM) has been tested for a germline mutation (by any method) and one or more deleterious/pathogenic mutation was found (positive for Lynch syndrome)
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4	C_MLH1	number (1,0)	Required:true
Presence of deleterious mutation or unclassified variant in MLH1 gene			

Allowable Values	
-8	No data transmitted from centers
-9	Failed or equivocal MLPA result or failed sequencing result
-1	One of the tests (Genomic or MLPA) has been run, and no deleterious variant or unclassified variant detected
1	Both of the tests (Genomics and MLPA) have been run and no deleterious variant or unclassified variant detected
2	One or more deleterious variants detected (Genomic or MLPA) (If 1 should be homozygous)
3	One or more unclassified variants detected (Genomic or MLPA)
4	One or more deleterious AND one or more unclassified variants detected (Genomic or MLPA)

5	C_MSH2	number (1,0)	Required:true
Presence of deleterious mutation or unclassified variant in MSH2 gene			

Allowable Values	
-8	No data transmitted from centers
-9	Failed or equivocal MLPA result or failed sequencing result
-1	One of the tests (Genomic or MLPA) has been run, and no deleterious variant or unclassified variant detected
1	Both of the tests (Genomics and MLPA) have been run and no deleterious variant or unclassified variant detected
2	One or more deleterious variants detected (Genomic or MLPA) (If 1 should be homozygous)
3	One or more unclassified variants detected (Genomic or MLPA)
4	One or more deleterious AND one or more unclassified variants detected (Genomic or MLPA)

6	C_MSH6	number (1,0)	Required:true
Presence of deleterious mutation or unclassified variant in MSH6 gene			

Allowable Values	
-8	No data transmitted from centers

-9	Failed or equivocal MLPA result or failed sequencing result
-1	One of the tests (Genomic or MLPA) has been run, and no deleterious variant or unclassified variant detected
1	Both of the tests (Genomics and MLPA) have been run and no deleterious variant or unclassified variant detected
2	One or more deleterious variants detected (Genomic or MLPA) (If 1 should be homozygous)
3	One or more unclassified variants detected (Genomic or MLPA)
4	One or more deleterious AND one or more unclassified variants detected (Genomic or MLPA)

7	C_PMS2	number (1,0)	Required:true
Presence of deleterious mutation or unclassified variant in PMS2 gene			

Allowable Values	
-8	No data transmitted from centers
-9	Failed or equivocal MLPA result or failed sequencing result
-1	One of the tests (Genomic or MLPA) has been run, and no deleterious variant or unclassified variant detected
1	Both of the tests (Genomics and MLPA) have been run and no deleterious variant or unclassified variant detected
2	One or more deleterious variants detected (Genomic or MLPA) (If 1 should be homozygous)
3	One or more unclassified variants detected (Genomic or MLPA)
4	One or more deleterious AND one or more unclassified variants detected (Genomic or MLPA)

8	C_EPCAM	number (1,0)	Required:true
Presence of deleterious mutation or unclassified variant in EPCAM gene			

Allowable Values	
-8	No data transmitted from centers
-9	Failed or equivocal MLPA result
-1	MLPA test has been run, and no deleterious variant or unclassified variant detected
2	One or more deleterious variants detected (If 1 should be homozygous)
3	One or more unclassified variants detected
4	One or more deleterious AND one or more unclassified variants detected

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9	C_MUTYH	number (1,0)	Required:true
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Presence of deleterious mutation or unclassified variant in MUTYH gene

Allowable Values

-8	No data transmitted from centers
-9	Failed or equivocal sequencing result
-1	Genomic test has been run, and no deleterious variant or unclassified variant detected
2	One or more deleterious variants detected (If 1 should be homozygous)
3	One or more unclassified variants detected
4	One or more deleterious AND one or more unclassified variants detected