

**Colorectal Cancer Control Program (CRCCP)  
Colorectal Cancer Clinical Data Elements (CCDE) Data Definition Table**

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Public reporting burden of this collection of information is estimated to average 15 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Reports Clearance Officer, 1600 Clifton Road, MS-24, Atlanta, GA 30333

## Colorectal Cancer Control Program (CRCCP) Colorectal Cancer Clinical Data Elements (CCDE) Data Definition Table

### 1. Client and Record Identification – Complete for each CCDE record

Item #	Variable Name	Column			Codes / Format / Comments	Edit Checks / Skip Patterns
		Length	Begin	End		
1.1	<b>Program</b>	3	1	3	State FIPS code or program code assigned to tribal and territorial programs. Right justify and include leading zeroes (i.e. California = 006).	Valid code for your program.
1.2	<b>Client identifier</b>	15	4	18	If Social Security Number (SSN) is used, it must be encoded. The ID number must be unique for each client and used consistently across all records for an individual client in order to track the client over time. This field should not contain any identifiable information, including partial names or dates.  <b>Alphanumeric (no special symbols), left justify</b>  <b>Alphabetic characters must be entered consistently in uppercase or lowercase, and include leading zeroes as applicable.</b>	
1.3	<b>Record identifier</b>	6	19	24	This field will be used to uniquely identify one record among many for a unique Client ID. This can be a visit date or a sequential record number.  <b>Numeric, right justify</b>	

### 2. Demographic Information – Complete for each CCDE record

Item #	Variable Name	Column			Codes / Format / Comments	Edit Checks / Skip Patterns
		Length	Begin	End		
2.1	<b>Date of birth</b>	8	25	32	MMDDYYYY  <i>If just the year is known, blank fill the month and day. If just the year and month are known, blank fill the day (e.g. 04 1950).</i>	"MMDDYYYY", "MM YYYY" or "YYYY", but not blank.
2.2	<b>Gender</b> <i>(self-reported)</i>	1	33	33	1 = Male 2 = Female 9 = Other/unknown	Range check.
2.3	<b>Hispanic or Latino origin</b> <i>(self-reported)</i>	1	34	34	1 = Yes 2 = No 9 = Unknown/missing	Range check.

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Item #	Variable Name	Column			Codes / Format / Comments	Edit Checks / Skip Patterns
		Length	Begin	End		
2.4.1	<b>Race 1</b> <i>(self-reported)</i>	1	35	35	1 = White 2 = Black or African American 3 = Asian 4 = Native Hawaiian or Other Pacific Islander 5 = American Indian or Alaska Native 9 = Unknown  <i>Note: Racial groups are OMB-defined. No primary race is collected. Race 1 has no significance over Race 2-5, and may simply be the first race mentioned.</i>	Range check.  This field should be populated first. If a client self-identifies more than one race, then each race identified should be reported in a separate race field.
2.4.2	<b>Race 2</b> <i>(self-reported)</i>	1	36	36	1 = White 2 = Black or African American 3 = Asian 4 = Native Hawaiian or Other Pacific Islander 5 = American Indian or Alaska Native	Range check.  Item 2.4.2 should be left blank, unless the client reports more than one race.
2.4.3	<b>Race 3</b> <i>(self-reported)</i>	1	37	37	1 = White 2 = Black or African American 3 = Asian 4 = Native Hawaiian or Other Pacific Islander 5 = American Indian or Alaska Native	Range check.  Item 2.4.3 should be left blank, unless the client reports more than two races.
2.4.4	<b>Race 4</b> <i>(self-reported)</i>	1	38	38	1 = White 2 = Black or African American 3 = Asian 4 = Native Hawaiian or Other Pacific Islander 5 = American Indian or Alaska Native	Range check.  Item 2.4.4 should be left blank, unless the client reports more than three races.
2.4.5	<b>Race 5</b> <i>(self-reported)</i>	1	39	39	1 = White 2 = Black or African American 3 = Asian 4 = Native Hawaiian or Other Pacific Islander 5 = American Indian or Alaska Native	Range check.  Item 2.4.5 should be left blank, unless the client reports more than four races.
2.5	<b>State of residence</b>	2	40	41	2-digit FIPS code  <b>Right justify</b>	Valid FIPS code for state.
2.6	<b>County of residence</b>	3	42	44	3-digit FIPS code  <b>Right justify</b>	Valid FIPS county code for state in 2.5.

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**3. Screening History-Complete for each CCDE record. This information can be self-reported, or can come from information documented in the client's medical record (preferred).**

Item #	Variable Name	Column			Codes / Format / Comments	Edit Checks / Skip Patterns
		Length	Begin	End		
3.1	Has client ever had a colorectal screening test?	1	45	45	1 = Yes 2 = No 9 = Unknown	Range check. A CRC screening test is limited to one of the following: Take-home FOBT Take-home FIT Sigmoidoscopy Colonoscopy DCBE CTC Stool DNA

**4. Assessed Risk- Complete for each CCDE record. This information can be self-reported, or can come from information documented in the client's medical record (preferred).**

Item #	Variable Name	Column			Codes / Format / Comments	Edit Checks / Skip Patterns
		Length	Begin	End		
4.1	Personal history of CRC or precancerous polyps	1	46	46	1 = Yes 2 = No 9 = Unknown	Range check. If Item 4.1 = 1, then Item 6.0 should <u>not</u> = 1. If Item 4.1 = 2, then Item 6.0 should <u>not</u> = 2.
4.2	Family history of CRC	1	47	47	1 = Yes 2 = No 9 = Unknown	Range check.
4.3	Currently experiencing CRC symptoms	1	48	48	1 = Yes 2 = No 9 = Unknown	Range check. Clients currently experiencing CRC symptoms are clinically ineligible for CRCCP funded testing and will need to be referred out of the program for the appropriate medical care or evaluation. Each grantee and their Medical Advisory Board will define their list of symptoms requiring medical evaluation and may include rectal bleeding, lower abdominal pain, bloody stools or marked change in bowel habits such as diarrhea or constipation, and significant unexplained weight loss.

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### 5. Screening Adherence – Complete for each CCDE record

Item #	Variable Name	Column			Codes / Format / Comments	Edit Checks / Skip Patterns
		Length	Begin	End		
5.1	Initial test appointment date, or date fecal kit distributed	8	49	56	MMDDYYYY	
5.2	Screening adherence	1	57	57	1 = Test performed 2 = Test pending 3 = No test performed, FOBT/FIT card not returned* 4 = No test performed, appointment not kept*  <i>*Guidelines should be established to determine when a fecal kit is deemed unreturned, or how much time can elapse before a client is considered an appointment no show.</i>	Range check.  If Item 5.2 = 1, then Section 6 must be completed to report at least one test performed, and Item 9.01 must be completed.  If Item 5.2 is not = 1, then Sections 6 through 11 should be left blank. Section 12 must be completed for each record.

### 6. Screening and Diagnostic Tests Performed – Complete for each CCDE record in which Item 5.2 = 1 (Test performed)

Item #	Variable Name	Column			Codes / Format / Comments	Edit Checks / Skip Patterns
		Length	Begin	End		
6.0	Indication for test 1	1	58	58	1 = Screening 2 = Surveillance 3 = Diagnostic 9 = Unknown	Range check.  If 4.1 = 1, then Item 6.0 should <u>not</u> = 1.  If Item 4.1 = 2, then Item 6.0 should <u>not</u> = 2.  If Item 5.2 = 1, then Item 6.0 should be completed.
6.1.01	Test 1 performed	1	59	59	1 = Take-home FOBT 2 = Take-home FIT 3 = Sigmoidoscopy 4 = Colonoscopy 5 = DCBE 7 = Other	Range check.  If Item 5.2 = 1, then 6.1.01 should be completed.  If 6.0 = 1 then 6.1.01 should not = 5 (DCBE).  If 6.0 = 2 then 6.1.01 should not = 1 or 2.  If 6.0 = 3 then 6.1.01 should = 4 or 5.
6.1.02	Test 1 performed – other specify	40	60	99	Free text	If 6.1.01 = 7 (Other), then 6.1.02 should be completed; otherwise, leave blank.

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Item #	Variable Name	Column			Codes / Format / Comments	Edit Checks / Skip Patterns
		Length	Begin	End		
6.1.03	Date of test 1	8	100	107	MMDDYYYY  <i>If 6.1.01 is 1 or 2, please report the date of the lab result.</i>  <i>If just the year is known, blank fill the month and day. If just the year and month are known, blank fill the day (e.g. 04 2010).</i>	"MMDDYYYY", "MM YYYY" or "YYYY", but not blank.  If Item 5.2 = 1, then 6.1.03 should be completed.
6.1.04	Provider specialty	2	108	109	1 = General practitioner 2 = Internist 3 = Family practitioner 4 = Gastroenterologist 5 = General surgeon 6 = Colorectal surgeon 7 = Licensed practical nurse 8 = Registered nurse 9 = Nurse practitioner 10 = Physician assistant 11 = Administrator, if FOBT/FIT mailed by non-clinician 12 = Radiologist 13 = Obstetrician / Gynecologist (OB/GYN) 99 = Unknown  <b>Right Justify</b>	Range check.  If Item 5.2 = 1, then 6.1.04 should be completed.

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Item #	Variable Name	Column			Codes / Format / Comments	Edit Checks / Skip Patterns
		Length	Begin	End		
6.1.05	<b>Result of test 1</b>	1	110	110	1 = Normal/Negative/Diverticulosis/Hemorrhoids 2 = Other finding not suggestive of cancer or polyp(s) 3 = Polyp(s), or Lesion(s) suspicious for cancer 4 = Inadequate/Incomplete test with no findings 5 = FOBT/FIT/Other Test Performed Negative 6 = FOBT/FIT/Other Test Performed Positive 7 = Pending 9 = Unknown	Range check.  If Item 5.2 = 1, then 6.1.05 should be completed.  If 6.1.01 = 1 or 2 then 6.1.05 should = 5, 6, 7 or 9.  If 6.1.01 = 3-5, then 6.1.05 should = 1-4, 7 or 9.  If 6.1.01 = 7, then 6.1.05 must be completed as appropriate for test performed.  If 6.1.05 = 1, then 6.1.06 should not = 1.  If 6.1.05 = 1, then 6.1.07 and 6.1.08 should not = 2.  If 6.1.05 = 1, then 6.1.09 should = 1.
6.1.06	<b>Was a biopsy/polypectomy performed during the endoscopy?</b>	1	111	111	1 = Yes 2 = No 9 = Unknown	Range check.  If 6.1.06 = 1, then 7.1 must be completed.  If 6.1.05 = 1, then 6.1.06 should not = 1.  Leave blank if 6.1.01 = 1, 2, 5 or 7.
6.1.07	<b>Was the bowel preparation considered adequate by the clinician performing the endoscopy or DCBE?</b>	1	112	112	1 = Yes* 2 = No 9 = Unknown  <i>Adequacy will be determined by the clinician performing the test.</i>  <i>*Procedure report must explicitly state that the bowel prep was adequate; otherwise, report 9 (Unknown). See Field Description for guidance about the clarification of vague endoscopy report descriptions.</i>	Range check.  If 6.1.01 = 3, 4, 5 or 7, then 6.1.07 must be completed; otherwise, leave blank.  If 6.1.05 = 1, then 6.1.07 should not = 2.

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Item #	Variable Name	Column			Codes / Format / Comments	Edit Checks / Skip Patterns
		Length	Begin	End		
6.1.08	Was the cecum reached during the colonoscopy?	1	113	113	1 = Yes 2 = No 9 = Unknown	Range check.  If 6.1.01 does not = 4, then 6.1.08 should be blank.  If 6.1.05 = 1, then 6.1.08 should not = 2.
6.1.09	Test 1 outcome	1	114	114	1 = Complete 2 = Incomplete/Inadequate	Range check.  If Item 5.2 = 1, then 6.1.09 should be completed.  If 6.1.05 = 1, 5 or 6, then 6.1.09 should = 1 (Complete).  If 6.1.05 = 4, then 6.1.09 should = 2 (Incomplete/Inadequate).  If 6.1.07 = 2, then 6.1.09 should = 2 (Incomplete/Inadequate).  If 6.1.08 = 2, then 6.1.09 should = 2 (Incomplete/Inadequate).
6.1.10	Recommended next follow-up procedure within this cycle	1	115	115	1 = Sigmoidoscopy 2 = Colonoscopy 3 = DCBE 4 = Surgery to complete diagnosis* 7 = Other 8 = None (cycle is complete)  <i>* Diagnosis Information for Surgeries Performed to Complete Diagnosis section must be completed if surgery is recommended.</i>	Range check.  If Item 5.2 = 1, then 6.1.10 should be completed.  If 6.1.10 = 4 or 8, then 6.2.01, 6.3.01 and 6.4.01 should = 0 (None).  If 6.1.10 = 4, then 8.1 must be completed.
6.1.11	Other recommended test, specify	40	116	155	Free text	If 6.1.10 = 7 (Other), then 6.1.11 should be completed; otherwise, leave blank.

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Item #	Variable Name	Column			Codes / Format / Comments	Edit Checks / Skip Patterns
		Length	Begin	End		
6.2.01	Test 2 performed	1	156	156	0 = None 1 = Take-home Fecal Occult Blood Test (FOBT) 2 = Take-home Fecal Immunochemical Test (FIT) 3 = Sigmoidoscopy 4 = Colonoscopy 5 = DCBE 7 = Other	Range check.  If 6.2.01 = 0 (None), then 6.2.02 through 6.2.11 should be blank.
6.2.02	Test 2 performed – other specify	40	157	196	Free text	If 6.2.01 = 7 (Other), then 6.2.02 should be completed; otherwise, leave blank.
6.2.03	Date of test 2	8	197	204	MMDDYYYY  <i>If just the year is known, blank fill the month and day. If just the year and month are known, blank fill the day (e.g. 04 2010).</i>	"MMDDYYYY", "MM YYYY" or "YYYY", but not blank.
6.2.04	Provider specialty	2	205	206	1 = General practitioner 2 = Internist 3 = Family practitioner 4 = Gastroenterologist 5 = General surgeon 6 = Colorectal surgeon 7 = Licensed practical nurse 8 = Registered nurse 9 = Nurse practitioner 10 = Physician assistant 12 = Radiologist 13 = Obstetrician / Gynecologist (OB/GYN) 99 = Unknown  <b>Right justify</b>	Range check.

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Item #	Variable Name	Column			Codes / Format / Comments	Edit Checks / Skip Patterns
		Length	Begin	End		
6.2.05	Result of test 2	1	207	207	1 = Normal/Negative/Diverticulosis/Hemorrhoids 2 = Other finding not suggestive of cancer or polyp(s) 3 = Polyp(s), or Lesion(s) suspicious for cancer 4 = Inadequate/Incomplete test with no findings 5 = FOBT/FIT/Other Test Performed Negative 6 = FOBT/FIT/Other Test Performed Positive 7 = Pending 9 = Unknown	Range check.  If 6.2.01 = 1 or 2 then 6.2.05 should = 5, 6, 7 or 9.  If 6.2.01 = 3-5, then 6.2.05 should = 1-4, 7 or 9.  If 6.2.01 = 7, then 6.2.05 must be completed as appropriate for test performed.  If 6.2.05 = 1, then 6.2.06 should not = 1.  If 6.2.05 = 1, then 6.2.07 and 6.2.08 should not = 2.  If 6.2.05 = 1, then 6.2.09 should = 1.
6.2.06	Was a biopsy/polypectomy performed during the endoscopy?	1	208	208	1 = Yes 2 = No 9 = Unknown	Range check.  If 6.2.05 = 1, then 6.2.06 should not = 1.  If 6.2.06 = 1, then 7.1 must be completed.  Leave blank if 6.2.01 = 0, 1, 2, 5 or 7.
6.2.07	Was the bowel preparation considered adequate by the clinician performing the endoscopy or DCBE?	1	209	209	1 = Yes* 2 = No 9 = Unknown  <i>Adequacy will be determined by the clinician performing the test.</i>  <i>*Procedure report must explicitly state that the bowel prep was adequate; otherwise, report 9 (Unknown).</i>	Range check.  If 6.2.01 = 3, 4, 5 or 7, then 6.2.07 must be completed; otherwise, leave blank.  If 6.2.05 = 1, then 6.2.07 should not = 2.
6.2.08	Was the cecum reached during the colonoscopy?	1	210	210	1 = Yes 2 = No 9 = Unknown	Range check.  If 6.2.01 does not = 4, then 6.2.08 should be blank.  If 6.2.05 = 1, then 6.2.08 should not = 2.

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Item #	Variable Name	Column			Codes / Format / Comments	Edit Checks / Skip Patterns
		Length	Begin	End		
6.2.09	Test 2 outcome	1	211	211	1 = Complete 2 = Incomplete/Inadequate	Range check.  If 6.2.05 = 1, 5 or 6, then 6.2.09 should = 1 (Complete).  If 6.2.05 = 4, then 6.2.09 should = 2 (Incomplete/Inadequate).  If 6.2.07 = 2, then 6.2.09 should = 2 (Incomplete/Inadequate).  If 6.2.08 = 2, then 6.2.09 should = 2 (Incomplete/Inadequate).
6.2.10	Recommended next follow-up procedure within this cycle after test 2	1	212	212	1 = Sigmoidoscopy 2 = Colonoscopy 3 = DCBE 4 = Surgery to complete diagnosis* 7 = Other 8 = None (cycle is complete)  <i>* Diagnosis Information for Surgeries Performed to Complete Diagnosis section must be completed if surgery is recommended.</i>	Range check.  If 6.2.10 = 4 or 8, then 6.3.01 and 6.4.01 should = 0 (None).  If 6.2.10 = 4, then 8.1 must be completed.
6.2.11	Other recommended test, specify	40	213	252	Free text	If 6.2.10 = 7 (Other), then 6.2.11 should be completed; otherwise, leave blank.
6.3.01	Test 3 performed	1	253	253	0 = None 1 = Take-home Fecal Occult Blood Test (FOBT) 2 = Take-home Fecal Immunochemical Test (FIT) 3 = Sigmoidoscopy 4 = Colonoscopy 5 = DCBE 7 = Other	Range check.  If 6.3.01 = 0 (None), then 6.3.02 through 6.3.11 should be blank.
6.3.02	Test 3 performed – other specify	40	254	293	Free text	If 6.3.01 = 7 (Other), then 6.3.02 should be completed; otherwise, leave blank.
6.3.03	Date of test 3	8	294	301	MMDDYYYY  <i>If just the year is known, blank fill the month and day. If just the year and month are known, blank fill the day (e.g. 04 2010).</i>	"MMDDYYYY", "MM YYYY" or "YYYY", but not blank.

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Item #	Variable Name	Column			Codes / Format / Comments	Edit Checks / Skip Patterns
		Length	Begin	End		
6.3.04	Provider specialty	2	302	303	1 = General practitioner 2 = Internist 3 = Family practitioner 4 = Gastroenterologist 5 = General surgeon 6 = Colorectal surgeon 7 = Licensed practical nurse 8 = Registered nurse 9 = Nurse practitioner 10 = Physician assistant 12 = Radiologist 13 = Obstetrician / Gynecologist (OB/GYN) 99 = Unknown  <b>Right justify</b>	Range check.
6.3.05	Result of test 3	1	304	304	1 = Normal/Negative/Diverticulosis/Hemorrhoids 2 = Other finding not suggestive of cancer or polyp(s) 3 = Polyp(s), or Lesion(s) suspicious for cancer 4 = Inadequate/Incomplete test with no findings 5 = FOBT/FIT/Other Test Performed Negative 6 = FOBT/FIT/Other Test Performed Positive 7 = Pending 9 = Unknown	Range check.  If 6.3.01 = 1 or 2 then 6.3.05 should = 5, 6, 7 or 9.  If 6.3.01 = 3-5, then 6.3.05 should = 1-4, 7 or 9.  If 6.3.01 = 7, then 6.3.05 must be completed as appropriate for test performed.  If 6.3.05 = 1, then 6.3.06 should not = 1.  If 6.3.05 = 1, then 6.3.07 and 6.3.08 should not = 2.  If 6.3.05 = 1, then 6.3.09 should = 1.
6.3.06	Was a biopsy/polypectomy performed during the endoscopy?	1	305	305	1 = Yes 2 = No 9 = Unknown	Range check.  If 6.3.05 = 1, then 6.3.06 should not = 1.  If 6.3.06 = 1, then 7.1 must be completed.  Leave blank if 6.3.01 = 0, 1, 2, 5 or 7.

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Item #	Variable Name	Column			Codes / Format / Comments	Edit Checks / Skip Patterns
		Length	Begin	End		
6.3.07	Was the bowel preparation considered adequate by the clinician performing the endoscopy or DCBE?	1	306	306	1 = Yes* 2 = No 9 = Unknown  <i>Adequacy will be determined by the clinician performing the test.</i>  <i>*Procedure report must explicitly state that the bowel prep was adequate; otherwise, report 9 (Unknown).</i>	Range check.  If 6.3.01 = 3, 4, 5 or 7, then 6.3.07 must be completed; otherwise, leave blank.  If 6.3.05 = 1, then 6.3.07 should not = 2.
6.3.08	Was the cecum reached during the colonoscopy?	1	307	307	1 = Yes 2 = No 9 = Unknown	Range check.  If 6.3.01 does not = 4, then 6.3.08 should be blank.  If 6.3.05 = 1, then 6.3.08 should not = 2.
6.3.09	Test 3 outcome	1	308	308	1 = Complete 2 = Incomplete/Inadequate	Range check.  If 6.3.05 = 1, 5 or 6, then 6.3.09 should = 1 (Complete).  If 6.3.05 = 4, then 6.3.09 should = 2 (Incomplete/Inadequate).  If 6.3.07 = 2, then 6.3.09 should = 2 (Incomplete/Inadequate).  If 6.3.08 = 2, then 6.3.09 should = 2 (Incomplete/Inadequate).
6.3.10	Recommended next follow-up procedure within this cycle after test 3	1	309	309	1 = Sigmoidoscopy 2 = Colonoscopy 3 = DCBE 4 = Surgery to complete diagnosis* 7 = Other 8 = None (cycle is complete)  <i>* Diagnosis Information for Surgeries Performed to Complete Diagnosis section must be completed if surgery is recommended.</i>	Range check.  If 6.3.10 = 4 or 8, then 6.4.01 should = 0 (None).  If 6.3.10 = 4, then 8.1 must be completed.
6.3.11	Other recommended test, specify	40	310	349	Free text	If 6.3.10 = 7 (Other), then 6.3.11 should be completed; otherwise, leave blank.

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		Length	Begin	End		
6.4.01	Test 4 performed	1	350	350	0 = None 1 = Take-home Fecal Occult Blood Test (FOBT) 2 = Take-home Fecal Immunochemical Test (FIT) 3 = Sigmoidoscopy 4 = Colonoscopy 5 = DCBE 7 = Other	Range check.  If 6.4.01 = 0 (None), then 6.4.02 through 6.4.10 should be blank.
6.4.02	Test 4 performed – other specify	40	351	390	Free text	If 6.4.01 = 7 (Other), then 6.4.02 should be completed; otherwise, leave blank.
6.4.03	Date of test 4	8	391	398	MMDDYYYY  <i>If just the year is known, blank fill the month and day. If just the year and month are known, blank fill the day (e.g. 04 2010).</i>	“MMDDYYYY”, “MM YYYY” or “YYYY”, but not blank.
6.4.04	Provider specialty	2	399	400	1 = General practitioner 2 = Internist 3 = Family practitioner 4 = Gastroenterologist 5 = General surgeon 6 = Colorectal surgeon 7 = Licensed practical nurse 8 = Registered nurse 9 = Nurse practitioner 10 = Physician assistant 12 = Radiologist 13 = Obstetrician / Gynecologist (OB/GYN) 99 = Unknown  <b>Right justify</b>	Range check.

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Item #	Variable Name	Column			Codes / Format / Comments	Edit Checks / Skip Patterns
		Length	Begin	End		
6.4.05	Result of test 4	1	401	401	1 = Normal/Negative/Diverticulosis/Hemorrhoids 2 = Other finding not suggestive of cancer or polyp(s) 3 = Polyp(s), or Lesion(s) suspicious for cancer 4 = Inadequate/Incomplete test with no findings 5 = FOBT/FIT/Other Test Performed Negative 6 = FOBT/FIT/Other Test Performed Positive 7 = Pending 9 = Unknown	Range check.  If 6.4.01 = 1 or 2 then 6.4.05 should = 5, 6, 7 or 9.  If 6.4.01 = 3-5, then 6.4.05 should = 1-4, 7 or 9.  If 6.4.01 = 7, then 6.4.05 must be completed as appropriate for test performed.  If 6.4.05 = 1, then 6.4.06 should not = 1.  If 6.4.05 = 1, then 6.4.07 and 6.4.08 should not = 2.  If 6.4.05 = 1, then 6.4.09 should = 1.
6.4.06	Was a biopsy/polypectomy performed during the endoscopy?	1	402	402	1 = Yes 2 = No 9 = Unknown	Range check.  If 6.4.05 = 1, then 6.4.06 should not = 1.  If 6.4.06 = 1, then 7.1 must be completed.  Leave blank if 6.4.01 = 0, 1, 2, 5 or 7.
6.4.07	Was the bowel preparation considered adequate by the clinician performing the endoscopy or DCBE?	1	403	403	1 = Yes* 2 = No 9 = Unknown  <i>Adequacy will be determined by the clinician performing the test.</i>  <i>*Procedure report must explicitly state that the bowel prep was adequate; otherwise, report 9 (Unknown).</i>	Range check.  If 6.4.01 = 3, 4, 5 or 7, then 6.4.07 must be completed; otherwise, leave blank.  If 6.4.05 = 1, then 6.4.07 should not = 2.
6.4.08	Was the cecum reached during the colonoscopy?	1	404	404	1 = Yes 2 = No 9 = Unknown	Range check.  If 6.4.01 does not = 4, then 6.4.08 should be blank.  If 6.4.05 = 1, then 6.4.08 should not = 2.

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Item #	Variable Name	Column			Codes / Format / Comments	Edit Checks / Skip Patterns
		Length	Begin	End		
6.4.09	<b>Test 4 outcome</b>	1	405	405	1 = Complete 2 = Incomplete/Inadequate	Range check.  If 6.4.05 = 1, 5 or 6, then 6.4.09 should = 1 (Complete).  If 6.4.05 = 4, then 6.4.09 should = 2 (Incomplete/Inadequate).  If 6.4.07 = 2, then 6.4.09 should = 2 (Incomplete/Inadequate).  If 6.4.08 = 2, then 6.4.09 should = 2 (Incomplete/Inadequate).
6.4.10	<b>Recommended next follow-up procedure within this cycle after test 4</b>	1	406	406	4 = Surgery to complete diagnosis* 8 = None (cycle is complete)  <i>* Diagnosis Information for Surgeries Performed to Complete Diagnosis section must be completed if surgery is recommended.</i>	Range check.  If 6.4.10 = 4, then 8.1 must be completed.

**7. Pathology From All Endoscopy Tests Performed - Complete if a biopsy or polypectomy was performed during any of Test 1-4 [if 6.x.06 = 1(Yes)]**

Item #	Variable Name	Column			Codes / Format / Comments	Edit Checks / Skip Patterns
		Length	Begin	End		
7.1	<b>Histology of most severe polyp/lesion</b>	2	407	408	1 = Normal or other non-polyp histology 2 = Non-adenomatous polyp (inflammatory, hamartomatous, etc.) 3 = Hyperplastic polyp 4 = Adenoma, NOS (no high grade dysplasia noted) 5 = Adenoma, tubular (no high grade dysplasia noted) 6 = Adenoma, mixed tubular villous (no high grade dysplasia noted) 7 = Adenoma, villous (no high grade dysplasia noted) 8 = Adenoma, serrated (no high grade dysplasia noted) 9 = Adenoma with high grade dysplasia (includes in situ carcinoma) 10 = Adenocarcinoma, invasive 11 = Cancer, other 99 = Unknown/other lesions ablated, not retrieved or confirmed  <b>Right justify</b>  <i>Do not include information from surgical resections in this section.</i>	Range check.  Do not update/change this variable if polyp with high grade dysplasia is determined to be cancer during a subsequent surgery.  If 7.1 = 4-11, then 7.2 and 7.3 must be completed.

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Item #	Variable Name	Column			Codes / Format / Comments	Edit Checks / Skip Patterns
		Length	Begin	End		
7.2	<b>Total number of adenomatous polyps/lesions</b>	2	409	410	01 – 96 = Number of adenomatous polyps/lesions removed or biopsied 97 = ≥ 97 adenomatous polyps/lesions removed or biopsied 98 = At least one adenomatous polyp/lesion removed, exact number removed or biopsied not known 99 = Unknown  <i>Do not include information from surgical resections in this section.</i>  <b>Right justify</b>	Range Check.  If 7.1 = 4-11, then 7.2 must be completed; otherwise, leave blank.
7.3	<b>Size of largest adenomatous polyp/lesion</b>	1	411	411	1 = < 1 cm 2 = ≥ 1 cm 9 = Unknown  <i>Do not include information from surgical resections in this section.</i>	Range check.  If 7.1 = 4-11, then 7.3 must be completed; otherwise, leave blank.

**8. Diagnosis Information for Surgeries Performed to Complete Diagnosis**

Item #	Variable Name	Column			Codes / Format / Comments	Edit Checks / Skip Patterns
		Length	Begin	End		
8.1	<b>Histology from surgical resection</b>	2	412	413	0 = Surgery recommended but not performed 1 = Normal or other non-polyp histology 2 = Non-adenomatous polyp (inflammatory, hamartomatous, etc.) 3 = Hyperplastic polyp 4 = Adenoma, NOS (no high grade dysplasia noted) 5 = Adenoma, tubular (no high grade dysplasia noted) 6 = Adenoma, mixed tubular villous (no high grade dysplasia noted) 7 = Adenoma, villous (no high grade dysplasia noted) 8 = Adenoma, serrated (no high grade dysplasia noted) 9 = Adenoma with high grade dysplasia (includes in situ carcinoma) 10 = Adenocarcinoma, invasive 11 = Cancer, other 99 = Unknown/other lesions ablated, not retrieved or confirmed  <i>Use histology from surgical resection in conjunction with histology of the most severe polyp/lesion reported in Item 7.1, to report the “Final diagnosis” (Item 9.02).</i>  <b>Right justify</b>	Range check.  If 6.1.10, 6.2.10, 6.3.10 or 6.4.10 = 4, then complete 8.2; otherwise, leave blank.  If surgery was recommended (6.1.10, 6.2.10, 6.3.10 or 6.4.10 = 4) but was not performed, then 8.1 should = 0 (Surgery recommended but not performed).  If no surgery was recommended (6.1.10, 6.2.10, 6.3.10 and 6.4.10 not = 4), then leave blank.
8.2	<b>Date surgery performed</b>	8	414	421	MMDDYYYY  <i>If just the year is known, blank fill the month and day. If just the year and month are known, blank fill the day (e.g. 04 2010).</i>	“MMDDYYYY”, “MM YYYY”, or “YYYY”.  If 8.1 = 1-11, 99, then complete 8.2; otherwise, leave blank.

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### 9. Final Diagnosis – Complete for all CCDE records with at least one test performed

Item #	Variable Name	Column			Codes / Format / Comments	Edit Checks / Skip Patterns
		Length	Begin	End		
9.01	Status of final diagnosis	1	422	422	<p>1 = Complete (final diagnosis determined)                      2 = Pending final diagnosis                      3 = Client refused diagnostic follow-up<sup>1,2</sup>                      4 = Client lost to follow-up before final diagnosis was made<sup>1,2</sup>                      5 = Irreconcilable<sup>2</sup></p> <p><sup>1</sup>Programs must have a policy in place to define how much time can elapse before the client is deemed refused or lost to follow-up.</p> <p><sup>2</sup>These items should have an administrative close-out date reported in 9.03 "Date of final diagnosis".</p> <p>A response of 5 will be used for those records where, after clinical review, it was determined that there was no sufficient way to translate the clinical scenario into the CCDE data record.</p>	<p>Range check.</p> <p>If 5.2 = 1, then complete 9.01; otherwise, leave blank.</p>
9.02	Final diagnosis	1	423	423	<p>1 = Normal/Negative                      2 = Hyperplastic polyps                      3 = Adenomatous polyp, no high grade dysplasia                      4 = Adenomatous polyp with high grade dysplasia                      5 = Cancer</p> <p><b>Registry Information for Cancer/High Grade Dysplasia section must be completed if 9.02 (Final diagnosis) = 5.</b></p>	<p>Range check.</p> <p>If the only test performed in the cycle was either FOBT or FIT, then complete 9.02 as 1 (Normal/Negative).</p> <p>If 9.01 = 1, then complete 9.02; otherwise, leave blank.</p> <p>If 9.02 = 5, then 11.01 (Registry linkage status) must be completed.</p>
9.03	Date of final diagnosis	8	424	431	<p>MMDDYYYY</p> <p><i>If just the year is known, blank fill the month and day. If just the year and month are known, blank fill the day (e.g. 04 2010).</i></p>	<p>If 9.01 = 1, 3, 4 or 5, then "MMDDYYYY", "MM YYYY" or "YYYY".</p> <p>If 9.01 = 3, 4 or 5, then an administrative close-out date will be necessary.</p> <p>Leave blank if 9.01 = 2</p>

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Item #	Variable Name	Column			Codes / Format / Comments	Edit Checks / Skip Patterns
		Length	Begin	End		
9.04	<b>Recommended screening or surveillance test for next cycle</b>	1	432	432	1 = Take-home FOBT 2 = Take-home FIT 3 = Sigmoidoscopy 4 = Colonoscopy 5 = DCBE 8 = None 9 = Unknown	Range check.  If client is terminally ill or for other reasons no further tests are recommended, then code this as 8 (None).  Leave blank if 9.01 does not = 1
9.05	<b>Indication for screening or surveillance test for next cycle</b>	1	433	433	1 = Screening 2 = Surveillance after a positive colonoscopy and/or surgery	Range check.  Leave blank if 9.01 does not = 1  Leave blank if 9.04 = 8, 9
9.06	<b>Number of months before screening or surveillance test for next cycle</b>	3	434	436	1 – 120 = Actual number of months 999 = Unknown  <b>Right Justify</b>	Range check.  Leave blank if 9.01 does not = 1  Leave blank if 9.04 = 8, 9
9.07	<b>Complications (1) of endoscopy or DCBE requiring observation or treatment</b>	2	437	438	0 = No complications reported 1 = Bleeding requiring transfusion 2 = Bleeding not requiring transfusion 3 = Cardiopulmonary events (hypotension, hypoxia, arrhythmia, etc) 4 = Complications related to anesthesia 5 = Bowel perforation 6 = Post-polypectomy syndrome/excessive abdominal pain 7 = Death 8 = Other 99 = Unknown  <b>Right justify</b>	Range check.  If 6.1.01, 6.2.01, 6.3.01 or 6.4.01 = 3, 4, 5 or 7, then 9.07 must be completed; otherwise, leave blank.  Report the worst of up to 2 distinct serious complications of CRC testing occurring within 30 days of the test date and resulting in an emergency room visit, hospitalization or death.  Report only one complication in each of 9.07 and 9.08.

## Colorectal Cancer Control Program (CRCCP) Colorectal Cancer Clinical Data Elements (CCDE) Data Definition Table

Item #	Variable Name	Column			Codes / Format / Comments	Edit Checks / Skip Patterns
		Length	Begin	End		
9.08	<b>Complications (2) of endoscopy or DCBE requiring observation or treatment</b>	2	439	440	0 = N/A – no 2nd complication reported 1 = Bleeding requiring transfusion 2 = Bleeding not requiring transfusion 3 = Cardiopulmonary events (hypotension, hypoxia, arrhythmia, etc) 4 = Complications related to anesthesia 5 = Bowel perforation 6 = Post-polypectomy syndrome/excessive abdominal pain 7 = Death 8 = Other 99 = Unknown  <b>Right justify</b>	Range check.  If 6.1.01, 6.2.01, 6.3.01 or 6.4.01 = 3, 4, 5 or 7, then 9.08 must be completed; otherwise, leave blank.  Report the worst of up to 2 distinct serious complications of CRC testing occurring within 30 days of the test date and resulting in an emergency room visit, hospitalization or death.  Report only one complication in each of 9.07 and 9.08.
9.09	<b>Complications of endoscopy or DCBE – other specify</b>	40	441	480	Free text	If 9.07 or 9.08 = 8, then 9.09 must be completed; otherwise, leave blank.
9.10	<b>CRCCP funds used for any screening/diagnostic test?</b>	1	481	481	1 = Yes 2 = No 9 = Unknown	Range check.

**10. Treatment Information - Complete this section when Final Diagnosis (9.02) = 5. This section may be completed when Final Diagnosis (9.02) = 4.**

Item #	Variable Name	Column			Codes / Format / Comments	Edit Checks / Skip Patterns
		Length	Begin	End		
10.1	<b>Recurrent cancers</b>	1	482	482	1 = New CRC primary 2 = Recurrent CRC 3 = Non-CRC primary (metastasis from another organ) 9 = Unknown	Range check.  If 9.02 = 5, then 10.1 must be completed; otherwise, leave blank.
10.2	<b>Status of treatment</b>	1	483	483	1 = Treatment started and/or completed 2 = Treatment pending 3 = Treatment not indicated due to polypectomy (or surgery to complete diagnosis) <sup>2</sup> 4 = Treatment not recommended <sup>2</sup> 5 = Treatment refused <sup>1,2</sup> 6 = Lost to follow-up <sup>1,2</sup> 9 = Unknown  <sup>1</sup> Programs must have a policy in place to define how much time can elapse before the client is deemed refused or lost to follow-up. <sup>2</sup> These items must have an administrative close-out date reported in 10.3 "Date of treatment".	Range check.  If 9.02 = 5, then 10.2 must be completed.  If 9.02 = 4, then 10.2 may be completed; however, 10.2 may not = 3, 4 or 9.  Leave blank if 9.02 = 1, 2 or 3.

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Item #	Variable Name	Column			Codes / Format / Comments	Edit Checks / Skip Patterns
		Length	Begin	End		
10.3	<b>Date of treatment</b>	8	484	491	MMDDYYYY  <i>If just the year is known, blank fill the month and day. If just the year and month are known, blank fill the day (e.g. 04 2010).</i>	If 10.2 = 1, 3-6, then "MMDDYYYY", "MM YYYY" or "YYYY".  If 10.2 = 3-6, then an administrative close-out date is required.  Leave blank if 10.2 = 2 or 9.

**11. Registry Information for Cancer – Complete this section when Final Diagnosis (9.02) = 5**

*Refer to the CCDE Cancer Registry Resource Document (Appendix E) in the Data User's Manual for additional information about the Registry data items.*

Item #	Variable Name	Column			Codes / Format / Comments	Edit Checks / Skip Patterns
		Length	Begin	End		
11.01	<b>Registry linkage status</b>  <i>Has this record been linked to the state cancer registry?</i>	1	492	492	1 = Pending linkage 2 = Linked, matched 3 = Linked, not matched	Range check.  Leave blank if 9.01 is not = 5.
11.02	<b>Registry date of diagnosis</b>  <i>[NAACCR data item #390]</i>	8	493	500	MMDDYYYY	Leave blank if 11.01 = 1, 3.  If not blank, must be a valid date.
11.03	<b>Registry histologic type</b>  <i>[NAACCR data item #522]</i>	4	501	504	Range: 8000-9975	Range check.  Leave blank if 11.01 = 1, 3.
11.04	<b>Registry behavior</b>  <i>[NAACCR data item #523]</i>	1	505	505	0 = Benign 1 = Uncertain whether benign or malignant/Borderline malignancy 2 = Carcinoma In Situ 3 = Malignant	Range check.  Leave blank if 11.01 = 1, 3.
11.05	<b>Registry primary site</b>  <i>[NAACCR data item #400]</i>	4	506	509	C000-C999  <i>NOTE: The 'C' must be included as part of the variable response in the CCDE file. For example Cecum = C180.</i>  <b>Alphanumeric, left justify</b>	Range check.  Leave blank if 11.01 = 1, 3

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Item #	Variable Name	Column			Codes / Format / Comments	Edit Checks / Skip Patterns
		Length	Begin	End		
11.06	<b>Registry Summary Stage</b> <i>[NAACCR data item #3020 or #759]</i>	1	510	510	0 = In situ 1 = Localized 2 = Regional, direct extension only 3 = Regional, regional lymph nodes only 4 = Regional, extension and nodes 5 = Regional, NOS 7 = Distant 8 = Not applicable 9 = Unknown/unstaged  <i>NAACCR item #3020 is preferred. In the absence of NAACCR item #3020, NAACCR item #759 may be reported.</i>	Range check.  Leave blank if 11.01 = 1, 3
11.07	<b>Registry CS-derived AJCC stage group</b> <i>[NAACCR data item #3000]</i>	3	511	513	Range: 000-999  <b>Numeric, right justify with leading zeroes.</b>	Range check.  Leave blank if 11.01 = 1, 3
11.08	<b>Registry CS extension</b> <i>[NAACCR data item #2810]</i>	3	514	516	Range: 000-999  <b>Numeric, right justify with leading zeroes.</b>	Range check.  Leave blank if 11.01 = 1, 3
11.09	<b>Registry CS lymph nodes</b> <i>[NAACCR data item #2830]</i>	3	517	519	Range: 000-999  <b>Numeric, right justify with leading zeroes.</b>	Range check.  Leave blank if 11.01 = 1, 3
11.10	<b>Registry CS mets at diagnosis</b> <i>[NAACCR data item #2850]</i>	2	520	521	Range: 00-99  <b>Numeric, right justify with leading zeroes.</b>	Range check.  Leave blank if 11.01 = 1, 3
11.11	<b>Registry CS tumor size</b> <i>[NAACCR data item #2800]</i>	3	522	524	001-988 Exact size in millimeters 989 = ≥ 989 millimeters 990 = Microscopic focus or foci only; no size of focus is given 991 = Described as less than 1 cm 992 = Described as between 1 cm and 2 cm 993 = Described as between 2 cm and 3 cm 994 = Described as between 3 cm and 4 cm 995 = Described as between 4 cm and 5 cm 998 = Familial/Multiple polyposis 999 = Unknown; size not stated  <b>Numeric, right justify with leading zeroes.</b>	Range check and skip pattern check.  Leave blank if 11.01 = 1, 3.

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**12. Record Information – Completed for each CCDE record**

Item #	Variable Name	Column			Codes / Format / Comments	Edit Checks / Skip Patterns
		Length	Begin	End		
12.1	CCDE version	3	525	527	100 = Data collected beginning 10/01/2009	Range check.
	End of record mark	1	528	528	Character that ends the current record and begins a new line of text.	Example: Carriage Return – Line Feed (CR-LF)



