ACRIN 6664

NATIONAL CT COLONOGRAPHY TRIAL
Case Report Form Set
American College of Radiology Imaging Network
CT Colonography
Forms Index

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<td>08-03-06</td>
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<td>01-26-05</td>
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</table>

See next page for Cost Effectiveness Forms

1. The "person responsible for the data" refers to the individual who has collated the data on this specific data form.

2. The "person entering data" is the individual who enters the data from the specific form into the web data form.

3. The "data form completed" is the date the worksheet, 'paper' CRF, etc. is completed, not the date it is entered into the web form. However, in most instances, the date form completed will be the same as the date of web data entry.

* Submission date* - This column is intended as a tracking tool for forms submission on individual cases. It is recommended that the RA maintain a printed copy within each case file as a tool to document form submission.
<table>
<thead>
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**Image Quality Control**

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<td>03-17-05</td>
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<tr>
<td>QA</td>
<td>07-12-05</td>
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APPENDIX II
Eligibility Checklist

ACRIN Institution # _______
ACRIN 6664 Case#_______

ELIGIBILITY CHECK

Eligibility Requirements: Inclusion Criteria (a response coded other than that prompted renders a participant ineligible for enrollment).

________ (Y) 1. Participant is scheduled for a screening colonoscopy exam.

________(Y) 2. Scheduled date of Colonoscopy exam.

________(Y) 3. Participant is aged 50 years or older.

Eligibility Requirements: Exclusion Criteria (a response coded other than that prompted renders a participant ineligible for enrollment).

________(N) 4. Serious medical condition that would increase the risk associated with colonoscopy or is so severe that screening would not benefit the participant.

________(N) 5. Lower GI Symptoms related to melanotic stools and or hematochezia (on more than one occasion within previous 6 months)


________(N) 7. Personal history (participant) of adenomatous familial polyposis (genetic syndrome).

________(N) 8. Personal (participant) history of inflammatory bowel disease.


________(N) 10. Anemia (hemoglobin less than 10gm/dl).

________(N) 11. Prior colonoscopy in the past 5 years.


The following questions will be asked at Study Registration:

___________ 1. Name of institutional person registering this case?

___________(Y) 2. Has the Eligibility Checklist (above) been completed?

___________(Y) 3. Is the participant eligible for this study?
4. Date the study-specific Consent Form was signed? (must be signed prior to any study procedure)

5. Participant’s Initials (Last, First) (L, F)(numerics may be used other than the case number, NNNN)

6. Verifying Physician

7. Participant ID # (optional: this is an institution’s method of internally tracking a participant to a protocol case number; may code a series of 9s)

8. Date of Birth (mm/dd/yyyy)

9. Ethnicity
   1 Hispanic or Latino
   2 Not Hispanic or Latino
   9 Unknown

10. Race (check all that apply)
   - American Indian or Alaskan Native
   - Asian
   - Black or African American
   - Native Hawaiian or other Pacific Islander
   - White
   - Unknown

11. Gender
   1 Male
   2 Female

12. Participant’s Country of Residence (if country of residence is other, complete Q18)
   1 United States
   2 Canada
   3 Other
   9 unknown

13. Zip Code (5 digit code, US residents only)

14. Participant’s Insurance Status
   0 Other
   1 Private insurance
   2 Medicare
   3 Medicare and Private insurance
   4 Medicaid
   5 Medicaid and Medicare
   6 Military or Veteran Administration
   7 Self-pay
   8 No means of payment
   9 Unknown/declined to answer

18. Other country, specify (completed only if Q12 is coded other)
15. Will any component of the participant’s care be given at a military or VA facility?
   1  No
   2  Yes
   9  Unknown

___/___/____  16. Scheduled date of CTC exam (mm/dd/yyyy)

          17. Registration Date

Completed by ___________________________    Date form completed: ___/___/____

Participant signature: ______________________________________________________
  (If information is obtained through direct interview with the participant, participant signature and date MUST appear on document)

________________________
Signature of person entering data onto the web
I. **GENERAL** (Colonoscopy must take place within 30 days after CTC)

1. **Date of Screening Colonoscopy exam**  
   mm dd yyyy

2. **Date of CTC exam**  
   mm dd yyyy

II. **LOWER GI TRACT MEDICAL HISTORY** (participant history)

3. **Indication(s) prompting colonoscopy exam:**  
   (Check all that apply)
   - Screening, no symptoms
   - Follow-up to test(s)
     - FOBT
     - Barium enema
     - Proctosigmoidoscopy
     - Colonoscopy, Date of last exam mm-yyyy  
     (If date is unknown, code as 12-2100)
   - Personal history of polyps or cancer
   - Irritable bowel syndrome
   - Family history of colon cancer
     - Mother
     - Father
     - Sister(s)
     - Brother(s)
     - Other, specify: ____________________________

III. **BOWEL PREPARATION ASSESSMENT**

4. **Type of colon preparation utilized** (check one)
   - Go-Lytely lavage preparation plus bisacodyl tablets
   - Phosphosoda, plus bisacodyl tablets
   - Magnesium citrate, plus bisacodyl tablets
   - Other, specify: ____________________________

5. **Was the cathartic laxative (Go-Lytely, Phosphosoda or Magnesium Citrate) taken as directed**  
   - No (Answer Q5a, and continue with form)
   - Yes (Continue with form)

   5a. % provide percent consumed

6. **Were 10mg (2 tablets) of bisacodyl taken?**  
   - No (Answer Q6a, and continue with form)
   - Yes (Continue with form)

   6a. number of tablets taken

7. **Was the barium sulfate taken as directed?**  
   - No (Answer Q7a and Q7b, then continue with form)
   - Yes (Continue with form)

   7a. % estimate percentage consumed

   7b. **Specify when barium sulfate was consumed**  
     (A check equals a "yes" response)
     - Breakfast
     - Lunch
     - Dinner

8. **Was the iodinated oral contrast taken as directed?**  
   - No (Answer Q8a and Q8b, then continue with form)
   - Yes (Continue with form)

   8a. % estimate percentage consumed

   8b. **Specify when iodinated oral contrast was consumed**  
     (A check equals a "yes" response)
     - Bed time
     - Morning of exam

IV. **Medical History**

9. **Other known medical conditions?** (record only "yes" responses from the participant completed questionnaire.)  
   - No (sign and date form)
   - Yes (proceed to Q9a and Q9b)
   - Unknown (sign and date form)

Continued on page 2
9a. Check all applicable medical history events:
(A ✔ equals a yes response)
☑ Lung cancer or nodule
☒ Kidney cancer or cyst
☒ Kidney stones
☒ Abdominal Aortic Aneurysm
☒ Liver disease/Cirrhosis
☒ Hernia
☒ Gallbladder disease
   (not including cholecystectomy)
☒ Cyst or cancer of the ovary

9b. List any other significant abdominal medical problems:
1. ____________________________________________
2. ____________________________________________
3. ____________________________________________
4. ____________________________________________
5. ____________________________________________

If information reported directly on the form has been obtained through participant interview only, signature of the participant must appear below.

__________________________________________________________________________  __________
Participant's signature  Date

COMMENTS:
__________________________________________________________________________
__________________________________________________________________________
__________________________________________________________________________

__________________________________________________________________________  __________
Name of person responsible for data 1  Date form completed

__________________________________________________________________________
Name of person entering data into web 2
I. General

1. Date of CTC exam __________ mm-dd-yyyy

2. Person performing colon insufflation (check one)
   - Research associate
   - Technologist
   - Nurse
   - Physician
   - Other

2a. Was a physician immediately available during exam? (e.g. adjacent room or within radiology department)
   - No
   - Yes
   - Unknown

2b. Record time patient enters room ________ (military time; e.g. 9am = 0900, 3pm = 1500)

2c. Record time patient leaves room ________ (military time; e.g. 9am = 0900, 3pm = 1500)

II. Procedure Preparation

3. Method performed for insufflation of colon (check one)
   - Mechanical insufflation
   - Manual insufflation
   - Mechanical and manual insufflation

4. Gas used for insufflation (check one)
   - Room air
   - CO₂
   - Room air and CO₂
   - Venting to room air
   - Other, specify __________________________

5. Glucagon administered (check one)
   - No (complete Q5a only)
   - Yes (complete Q5b, 5c, and 5d)

5a. If glucagon not administered: check one
   - Brittle diabetic
   - Pheochromocytoma
   - Patient request
   - Other, specify __________________________

5b. If glucagon administered: route of administration
   - Subcutaneous
   - Other, specify __________________________

5c. ______ mg/ml

5d. Elapsed time from glucagon injection to beginning of insufflation _______ (minutes)

6. Are there any reportable complications / adverse events per protocol Sec. 17.4?
   - No
   - Yes, Complete Adverse Event Reporting Form (AE)

III. CT Acquisition Parameters

7. Specify scanner type (check one and complete Q7a)
   - GE (complete chart 1)
   - Siemens (complete chart 2)
   - Philips (complete chart 3)
   - Toshiba (complete chart 4)
7a. Complete parameters based on Scanner type used:

<table>
<thead>
<tr>
<th>Algorithm</th>
<th>Thickness (mm)</th>
<th>Interval (mm)</th>
<th>Rotation Time (s)</th>
<th>Detector Configuration</th>
<th>Pitch</th>
<th>kVp</th>
<th>mA</th>
<th>Feed (mm/rot)</th>
<th>DFOV (cm)</th>
<th>CTDI mGy</th>
</tr>
</thead>
<tbody>
<tr>
<td>GE</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>SIEMENS</td>
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<tr>
<td>TOSHIBA</td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Comments:__________________________________________________________________________

Name of person completing the form: ________________________

Name of person entering data into web: ________________________

Date form completed: ________________________

"Copyright 2005"
I. GENERAL INFORMATION

1. Did study commence?
   - No* (complete Q1a)
   - Yes (proceed to Q2)

   1a. If no, give reason (then skip to Signature Page) [In all instances other than patient refusal, the exam should be rescheduled]
   - Scheduling problems
   - Equipment failure
   - Patient refusal
   - Medical reasons
   - Other, specify ______________________
   - Unknown

2. Study completed?
   - No* (complete Q2a and Q3, then sign and date form)
   - Yes (proceed to Q3)

   2a. Reason not completed (check one) [In all instances other than patient refusal, the exam should be rescheduled]
   - Equipment failure
   - Patient refusal
   - Medical reasons
   - Other, specify ______________________
   - Unknown

3. Date of CTC exam ______-____-_______ (mm-dd-yyyy)

4. Date of CTC interpretation ______-____-_______ (mm-dd-yyyy)

5. Reader ID # ____________

   5a. Primary image review method: (primary image review method is designated at time of participant registration)
   - 2D conventional (with 3D problem solving)
   - 3D endoluminal fly-through (with 2D problem solving)

6. Machine Software:
   - Siemens
   - GE
   - Philips
   - Viatronix
   - Vital Images
   - Other, specify ______________________
II. COLONOGRAPHY PREPARATION ASSESSMENT

7. Interpretation start time (military time, e.g. 9:00 a.m. = 0900, 3:00 p.m. = 1500)
8. Interpretation end time (military time, e.g. 9:00 a.m. = 0900, 3:00 p.m. = 1500)

9. Colon Assessment:

<table>
<thead>
<tr>
<th>Preparation Assessment</th>
<th>Residual Fluid</th>
<th>Residual Stool</th>
<th>Bowel Distention</th>
<th>Breathhold Artifacts</th>
<th>Confidence of polyp</th>
<th>Confidence of polyp</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1 No luminal fluid present 0%</td>
<td>1 No stool</td>
<td>1 Entire segment visualized and well distended</td>
<td>1 No breathhold artifacts</td>
<td>0 No lesions identified of the designated size</td>
<td></td>
</tr>
<tr>
<td></td>
<td>2 Minimal fluid present 1-25%</td>
<td>2 Small particles present (did not compromise study)</td>
<td>2 Entire segment visualized but under distended</td>
<td>2 Moderate</td>
<td>1 Low confidence</td>
<td></td>
</tr>
<tr>
<td></td>
<td>3 Moderate amount 25-50%</td>
<td>3 Moderate amount of solid stool, diagnostic</td>
<td>3 Poorly visualized</td>
<td>3 Severe, non-diagnostic</td>
<td>2 Possible</td>
<td></td>
</tr>
<tr>
<td></td>
<td>4 More than 50% full</td>
<td>4 Lumen full of liquid stool, non-diagnostic</td>
<td>4 Collapsed</td>
<td>4 Probable</td>
<td>3 Indeterminate</td>
<td></td>
</tr>
<tr>
<td>Rectum</td>
<td>1 No stool</td>
<td>1 No luminal fluid present 0%</td>
<td>1 Entire segment visualized and well distended</td>
<td>1 No breathhold artifacts</td>
<td>0 No lesions identified of the designated size</td>
<td></td>
</tr>
<tr>
<td>Sigmoid</td>
<td>2 Small particles present (did not compromise study)</td>
<td>2 Minimal fluid present 1-25%</td>
<td>2 Entire segment visualized but under distended</td>
<td>2 Moderate</td>
<td>1 Low confidence</td>
<td></td>
</tr>
<tr>
<td>Descending</td>
<td>3 Moderate amount of solid stool, diagnostic</td>
<td>3 Moderate amount of solid stool, diagnostic</td>
<td>3 Poorly visualized</td>
<td>3 Severe, non-diagnostic</td>
<td>2 Possible</td>
<td></td>
</tr>
<tr>
<td>Transverse</td>
<td>4 Lumen full of liquid stool, non-diagnostic</td>
<td>4 Lumen full of liquid stool, non-diagnostic</td>
<td>4 Collapsed</td>
<td>4 Probable</td>
<td>3 Indeterminate</td>
<td></td>
</tr>
<tr>
<td>Ascending</td>
<td>Entire segment visualized and well distended</td>
<td>Entire segment visualized and well distended</td>
<td>Entire segment visualized and well distended</td>
<td>Entire segment visualized and well distended</td>
<td>Entire segment visualized and well distended</td>
<td></td>
</tr>
<tr>
<td>Cecum</td>
<td>Entire segment visualized and well distended</td>
<td>Entire segment visualized and well distended</td>
<td>Entire segment visualized and well distended</td>
<td>Entire segment visualized and well distended</td>
<td>Entire segment visualized and well distended</td>
<td></td>
</tr>
</tbody>
</table>

10. Does this patient have any significant findings ≥ 5 mm in largest diameter?
   - No (proceed to Q12)
   - Yes (complete Q10a and 10b and continue with form)

10a. What is your confidence that this patient has at least one lesion ≥ 5 mm in largest diameter that would be classified as a polyp? (check one)
   - Low confidence
   - Possible
   - Indeterminate
   - Probable
   - High confidence

10b. % What is the estimated probability that at least one finding ≥ 5 mm is a polyp? (0-100%)

11. Does this patient have any significant findings ≥ 10 mm in largest diameter?
   - No (proceed to Q12)
   - Yes (complete Q11a and Q11b and continue with form)

11a. What is your confidence that this patient has at least one lesion ≥ 10 mm in largest diameter that would be classified as a polyp? (check one)
   - Low confidence
   - Possible
   - Indeterminate
   - Probable
   - High confidence

11b. % What is the estimated probability that at least one finding ≥ 10 mm is a polyp? (0-100%)

12. Are there any Extracolonic findings to report?
   - No
   - Yes (complete form FX-Extracolonic Findings)

COMMENTS:

Name of person responsible for data 1
Name of person entering data into web 2

ACRIN Study 6664 Case #
Revised by C2 02-28-05 2 of 2
I. General Information:

1. Date of CTC exam ______ - ______ - ______
   mm   dd   yyyy

2. Date of interpretation ______ - ______ - ______
   mm     dd      yyyy

3. Reader ID #

4. Machine Software
   o Siemens
   o GE
   o Philips
   o Viatronix
   o Vital Images
   o Other, specify: ______________________

II. CTC Interpretation:

5. Interpretation start time [Exclude load time] (military time, e.g., 9:00a.m.=0900, 3:00p.m. =1500)

6. Interpretation end time

7. Are there any colonic findings to report?
   o No (proceed to comments, page 3)
   o Yes (continue with form, pages 2 and 3)

Continued on page 2
8. **Colon Assessment**: Complete all columns associated with each finding ≥5mm in diameter.

**Measurements should be made of the maximum diameter of the polyp, excluding the stalk, in any plane, whichever shows optimally.**

For softwares reporting x, y + z coordinates as row, column and slice #, please follow instructions. If coordinate is not applicable, code as “998”

<table>
<thead>
<tr>
<th>CTC Findings #</th>
<th>Segment</th>
<th>Seen on:</th>
<th>Supine Axial Slice #</th>
<th>Prone Axial Slice #</th>
<th><strong>X,Y,Z</strong> Coordinate Supine #</th>
<th><strong>X,Y,Z</strong> Coordinate Prone #</th>
<th><strong>CTC Size (mm)</strong></th>
<th>Confidence level that finding identified is a polyp:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1 Rectum</td>
<td>1 Supine only</td>
<td>x = column y = row z = slice #</td>
<td>x = column y = row z = slice #</td>
<td>1 Rectum</td>
<td>1 Supine only</td>
<td>x = column y = row z = slice #</td>
<td>x = column y = row z = slice #</td>
</tr>
<tr>
<td>2</td>
<td>2 Sigmoid 2 Prone only</td>
<td>2 Sigmoid 2 Prone only</td>
<td>x = column y = row z = slice #</td>
<td>x = column y = row z = slice #</td>
<td>2 Sigmoid 2 Prone only</td>
<td>2 Sigmoid 2 Prone only</td>
<td>x = column y = row z = slice #</td>
<td>x = column y = row z = slice #</td>
</tr>
<tr>
<td>3</td>
<td>3 Ascending 3 Both supine and prone</td>
<td>3 Ascending 3 Both supine and prone</td>
<td>x = column y = row z = slice #</td>
<td>x = column y = row z = slice #</td>
<td>3 Ascending 3 Both supine and prone</td>
<td>3 Ascending 3 Both supine and prone</td>
<td>x = column y = row z = slice #</td>
<td>x = column y = row z = slice #</td>
</tr>
<tr>
<td>4</td>
<td>4 Transverse</td>
<td>4 Transverse</td>
<td>x = column y = row z = slice #</td>
<td>x = column y = row z = slice #</td>
<td>4 Transverse</td>
<td>4 Transverse</td>
<td>x = column y = row z = slice #</td>
<td>x = column y = row z = slice #</td>
</tr>
<tr>
<td>5</td>
<td>5 Ascending</td>
<td>5 Ascending</td>
<td>x = column y = row z = slice #</td>
<td>x = column y = row z = slice #</td>
<td>5 Ascending</td>
<td>5 Ascending</td>
<td>x = column y = row z = slice #</td>
<td>x = column y = row z = slice #</td>
</tr>
</tbody>
</table>

*Continued on page 3*
9. **Colon Assessment continued**: Complete all columns associated with each finding >5mm in diameter. Measurements should be made of the maximum diameter of the polyp, excluding the stalk, in any plane, whichever shows optimally.

For softwares reporting x, y + z coordinates as row, column and slice #, please follow instructions. If coordinate is not applicable, code as “998”.

<table>
<thead>
<tr>
<th>CTC Findings #</th>
<th>Segment</th>
<th>Seen on:</th>
<th>Supine Axial Slice #</th>
<th><strong>X,Y,Z Coordinate Supine #</strong></th>
<th>Prone Axial Slice #</th>
<th><strong>X,Y,Z Coordinate Prone #</strong></th>
<th><strong>CTC Size (mm)</strong></th>
<th>Confidence level that finding identified is a polyp:</th>
<th>Polyp Morphology</th>
<th>Polyp location</th>
<th>Orientation of colon at polyp site:</th>
<th>Location of polyp relative to colonic bend</th>
<th>Additional findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>6</td>
<td>Rectum</td>
<td>1 Supine</td>
<td>x=column y=row z=slice #</td>
<td>x ______ y ______ z ______</td>
<td>x ______ y ______ z ______</td>
<td></td>
<td></td>
<td>0 Not a polyp 1 Low confidence 2 Possible 3 Indeterminate 4 Probable 5 High confidence</td>
<td>1 Polypoid 2 Flat*</td>
<td>1 Between folds 2 On folds</td>
<td>1 Straight 2 Bend</td>
<td>1 Inside curve 2 Outside curve</td>
<td>1 No 2 Yes</td>
</tr>
<tr>
<td>7</td>
<td>Sigmoid</td>
<td>2 Prone</td>
<td></td>
<td></td>
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<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>8</td>
<td>Descending</td>
<td>3 Both supine and prone</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
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</tr>
<tr>
<td>9</td>
<td>Transverse</td>
<td>4 Ascending</td>
<td></td>
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<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>Ascending</td>
<td>5 Ascending</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Comments:**

Name of person responsible for data

Name of person entering data into web

Date form completed (mm-dd-yyyy)
I. General Information:

1. Date of CTC exam ______ - ______ - ______
   mm   dd     yyyy

2. Date of interpretation ______ - ______ - ______
   mm    dd     yyyy

3. Reader ID # _______________________

4. Machine Software _______________________
   o Siemens _______________________
   o GE _______________________
   o Philips _______________________
   o Viatronix _______________________
   o Vital Images _______________________
   o Other, specify: _______________________

II. CTC Interpretation:

5. Interpretation start time [Exclude load time] (military time, e.g., 9:00a.m. =0900, 3:00p.m. =1500)

6. Interpretation end time

7. Are there any colonic findings to report?
   o No (proceed to comments, page 3)
   o Yes (continue with form, pages 2 and 3)

Continued on page 2
8. **Colon Assessment:** Complete all columns associated with each finding ≥5mm in diameter.

**Measurements should be made of the maximum diameter of the polyp, excluding the stalk, in any plane, whichever shows optimally.**

For softwares reporting x, y + z coordinates as row, column and slice #, please follow instructions. If coordinate is not applicable, code as “998”

<table>
<thead>
<tr>
<th>CTC Findings #</th>
<th>Segment</th>
<th>Seen on:</th>
<th>Supine Axial Slice #</th>
<th>Prone Axial Slice #</th>
<th><strong>CTC Size (mm)</strong></th>
<th>Confidence level that finding identified is a polyp:</th>
<th>Polyp location</th>
<th>Polyp Morphology</th>
<th>Orientation of colon at polyp site:</th>
<th>Location of polyp relative to colonic bend</th>
<th>Additional findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>11</td>
<td>1 Rectum</td>
<td>1 Supine only</td>
<td>x = column</td>
<td>x</td>
<td>y = row</td>
<td>z = slice #</td>
<td>0 Not a polyp</td>
<td>1 Between folds</td>
<td>1 Inside curve</td>
<td>1 No</td>
<td></td>
</tr>
<tr>
<td>12</td>
<td>2 Sigmoid</td>
<td>2 Prone only</td>
<td>y</td>
<td>y</td>
<td>z</td>
<td>z = slice #</td>
<td>1 Low confidence</td>
<td>2 On folds</td>
<td>2 Straight</td>
<td>2 Yes</td>
<td></td>
</tr>
<tr>
<td>13</td>
<td>3 Descending</td>
<td>Both supine and prone</td>
<td>x</td>
<td>x</td>
<td>y</td>
<td>y = row</td>
<td>2 Possible</td>
<td>3 Outside curve</td>
<td>3 Outside curve</td>
<td>3 If yes complete next row</td>
<td></td>
</tr>
<tr>
<td>14</td>
<td>4 Transverse</td>
<td></td>
<td>z</td>
<td>z</td>
<td>z</td>
<td>z = slice #</td>
<td>3 Indeterminate</td>
<td>4 Inside curve</td>
<td>4 Inside curve</td>
<td></td>
<td></td>
</tr>
<tr>
<td>15</td>
<td>5 Ascending</td>
<td></td>
<td>x</td>
<td>x</td>
<td>y</td>
<td>y = row</td>
<td>4 Probable</td>
<td>5 Inside curve</td>
<td>5 Inside curve</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>6 Cecum</td>
<td></td>
<td>z</td>
<td>z</td>
<td>z</td>
<td>z = slice #</td>
<td>5 High confidence</td>
<td>6 Outside curve</td>
<td>6 Outside curve</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Continued on page 3
9. Colon Assessment continued: Complete all columns associated with each finding ≥5mm in diameter. **Measurements should be made of the maximum diameter of the polyp, excluding the stalk, in any plane, whichever shows optimally.

For softwares reporting x, y + z coordinates as row, column and slice #, please follow instructions. If coordinate is not applicable, code as "998"

<table>
<thead>
<tr>
<th>CTC Findings #</th>
<th>Segment</th>
<th>Seen on:</th>
<th>Supine Axial Slice #</th>
<th>Prone Axial Slice #</th>
<th><strong>CTC Size (mm)</strong></th>
<th>Confidence level that finding identified is a polyp:</th>
</tr>
</thead>
<tbody>
<tr>
<td>16</td>
<td>Rectum</td>
<td>1 Supine</td>
<td>x=column y=row z=slice #</td>
<td>x=column y=row z=slice #</td>
<td></td>
<td>0 Not a polyp 1 Low confidence 2 Possible 3 Indeterminate 4 Probable 5 High confidence</td>
</tr>
<tr>
<td>17</td>
<td>Sigmoid</td>
<td>2 Prone only</td>
<td>x=column y=row z=slice #</td>
<td>x=column y=row z=slice #</td>
<td></td>
<td></td>
</tr>
<tr>
<td>18</td>
<td>Descending</td>
<td>3 Both supine and prone</td>
<td>x=column y=row z=slice #</td>
<td>x=column y=row z=slice #</td>
<td></td>
<td></td>
</tr>
<tr>
<td>19</td>
<td>Transverse</td>
<td>x=column y=row z=slice #</td>
<td>x=column y=row z=slice #</td>
<td>x=column y=row z=slice #</td>
<td></td>
<td></td>
</tr>
<tr>
<td>20</td>
<td>Ascending</td>
<td>x=column y=row z=slice #</td>
<td>x=column y=row z=slice #</td>
<td>x=column y=row z=slice #</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Comments: ___________________________________________________________

**Copyright 2005**
Instructions: This form is completed by the participating (6664 Radiologist), based on the Local Colonoscopy and Pathology interpretations. The radiologist must complete Forms C2 and WX while blinded to the colonoscopy results and prior to completing the PL Form. Record the time the PL Form is started in military format.

NOTE: On page 2 (question 7) Lesion size(s): ONLY LESION(s) 5mm or greater will need pathology submission to the central pathology laboratory at the Mayo Clinic. The following forms, reports will be sent: (P4 with the left half completed by the RA, PC, P1, C3, and S2 if applicable) - See protocol for descriptions.

Enter time form is started here □□□ : □□□

I. Colonoscopy

1. Was colonoscopy completed or attempted?
   - o No, exam not attempted (Complete Q1a, sign and date form)
   - o No, exam not completed, no findings (Complete Q1a, Q2, Q3, and Q5, then proceed to comments and sign and date form)
   - o Yes (Proceed to Q2)
     - o Yes, No findings to report (Answer Q2, Q3, Q4, Q5, Q6, then proceed to comments and sign and date form)
     - o Incomplete exam with findings (Complete Q1a, Q2, Q3, Q4, Q5 and Q6)

   1a. o Contraindications
       - o Scheduling problem
       - o Equipment failure
       - o Patient refusal
       - o Medical reason
       - o Other, specify ________________
       - o Unknown

2. Date of colonoscopy exam ________ mm dd yyyy

3. Segment to which colonoscopy reached:
   - o Rectum
   - o Sigmoid
   - o Descending
   - o Transverse
   - o Ascending
   - o Cecum

4. Is there indication of prior colon resection?
   - o No (Proceed to Q5)
   - o Yes (Complete Q4a, and continue)

   4a. Indicate most proximal section remaining:
       - o Rectum
       - o Sigmoid
       - o Descending
       - o Transverse
       - o Ascending
       - o Cecum

5. Are there any reportable complications / adverse events from Colonoscopy per protocol Sec. 17.4?
   - o No
   - o Yes, [Complete Adverse Event Reporting Form (AE)]

II. Surgery

6. Was surgery performed post colonoscopy?
   - o No (continue with form)
   - o Yes (Provide date of surgery in Q6a, and continue)
   - o Unknown

   6a. Date of surgery ____________ mm dd yyyy
### Colonoscopy/Pathology Results

*Record lesion size based on pathology for all instances except when the lesion is removed in pieces; if lesion is removed in pieces, record the estimated size from the colonoscopy report.*

<table>
<thead>
<tr>
<th>Lesion #</th>
<th>Segment</th>
<th>Size (mm)</th>
<th>Specimen removed in pieces</th>
<th>Histology (1-17, 88, 98)</th>
<th><strong>Other Histology Specified (write in)</strong></th>
<th>Morphology (1-4, 8)</th>
<th><strong>Other Morphology Specified (write in)</strong></th>
<th>Treatment (0-4)</th>
<th>Additional Findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1 Rectum</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0 Not detected, at colonoscopy</td>
<td>1 No</td>
</tr>
<tr>
<td>2</td>
<td>2 Sigmoid</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1 Detected, no RX, not removed</td>
<td>2 Yes</td>
</tr>
<tr>
<td>3</td>
<td>3 Descending</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>2 Biopsy removal</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>4 Transverse</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>3 Fulguration (burnt off)</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>5 Ascending</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>4 Surgical removal</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>6 Cecum</td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>5 Histology continued:</td>
<td></td>
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<td></td>
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<td></td>
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<td></td>
<td>6 Small cell carcinoma</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>7 Undifferentiated carcinoma</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>8 Carcinoma, NOS</td>
<td></td>
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<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td>9 Hyperplastic</td>
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<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>10 Lipomatous</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>11 Adenomatous</td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>12 Medullary carcinoma</td>
<td></td>
</tr>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>13 Mucinous carcinoma (colloid type) (greater than 50% mucinous carcinoma)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>14 Signet ring cell carcinoma (greater than 50% signet ring cell)</td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>15 Squamous cell (epidermoid) carcinoma</td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>16 Adenosquamous carcinoma</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>17 Small cell carcinoma</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>18 Undifferentiated carcinoma</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>19 Carcinoma, NOS</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>20 Hyperplastic</td>
<td></td>
</tr>
</tbody>
</table>

**Histology continued:**

- 12 Adenomatous
- 13 Tubular adenoma
- 14 Tubulovillous adenoma
- 15 Villous adenoma
- 16 Tubulovillous adenoma with dysplasia
- 17 Normal mucosa
- 88 Other, specify**
- 98 Not applicable

**Note:** "Flat" polyp is defined as any lesion > 5mm with less than 3mm of elevation from flush.
III. TNM Stage [AJCC Cancer Staging Manual, 6th edition]

8. Has specimen histology yielded a diagnosis of cancer? (stage is based on worst finding)
   o No (sign and date form)
   o Yes (complete Q8a, 8b, and 8c)

8a. Primary Tumor (T)
   o TX Primary tumor cannot be assessed
   o T0 No evidence of primary tumor
   o Tis Carcinoma in situ: intraepithelial or invasion of lamina propria
   o T1 Tumor invades submucosa
   o T2 Tumor invades muscularis propria
   o T3 Tumor invades through the muscularis propria into the subserosa, or into non-peritonealized pericolic or perirectal tissues
   o T4 Tumor directly invades other organs or structures, and/or perforates visceral peritoneum

8b. Regional Lymph Nodes (N)
   o NX Regional lymph nodes cannot be assessed
   o N0 No regional lymph node metastasis
   o N1 Metastasis in 1 to 3 regional lymph nodes
   o N2 Metastasis in 4 or more regional lymph nodes

8c. Distant Metastasis (M)
   o MX Distant metastasis cannot be assessed
   o M0 No distant metastasis
   o M1 Distant metastasis

Comments: ________________________________________________________________

__________________________________________________________________________

__________________________________________________________________________

__________________________________________________________________________

Name of person responsible for data

Name of person entering data into web

Date form completed (mm-dd-yyyy)
ACRIN 6664
CT Colonography
Lesion Photograph Transmittal

Instructions: This form is used to submit photographs of all lesions removed during colonoscopy as well as a photograph documenting the completed colon examination (either the appendiceal orifice or ileocecal valve). Label photograph underneath image if not labeled on image already. Use as many pages as necessary to submit all photographs.

Total # of images ____  Total # of pages ____

Name of individual submitting photographs ____________________________ Date (mm - dd - yyyy) __________

Name of person submitting form ____________________________
INSTRUCTIONS: Part A is to be completed by the Research Associate. After completion of Part A, the form is sent to the Core Pathologist for completion of Part B. Part B will be completed by the Core Pathologist based on the pathologic material available. Part C will be completed by the Alternate Core Pathologist if a second opinion is needed. At the time of slide submission a copy of the PC form, the P4 form and the P1 (pathology report) should be mailed to ACRIN 6664 Data Management, 1818 Market Street, Suite 16, Philadelphia, PA 19103. A separate form is submitted for each lesion.

**Part A** (completed by site Research Associate)

1. Date of procedure ______-______-______(mm-dd-yyyy)
2. Date specimen sent to core lab ______-______-______(mm-dd-yyyy)
3. Number of slides submitted on this specimen
4. Finding # ______ of # ______ as identified on Colonoscopy. To maintain consistency in reporting of lesions, the "Finding #" is column 1 on the PL form.
5. Segment (check one)
   - Rectum
   - Sigmoid
   - Descending
   - Transverse
   - Ascending
   - Cecum

   Completed by (Site RA) ____________________________

**Part B** (completed by Core Pathologist)

1. Core Pathology Reviewer
   - 1 Lawrence Burgart M.D.
   - 2 Other________________________

2. Histology of Index Lesion
   (Check all that apply; A ☑ indicates a "yes" response)
   
   **Histopathological Type**
   - Adenocarcinoma
   - Medullary carcinoma
   - Mucinous carcinoma (colloid type)
     (greater than 50% mucinous carcinoma)
   - Signet ring cell carcinoma (greater than 50% signet ring cell)
   - Squamous cell (epidermoid) carcinoma
   - Adenosquamous carcinoma
   - Small cell carcinoma
   - Undifferentiated carcinoma
   - Carcinoma, NOS
   - Other, specify ____________________________
   
   **Benign**
   - Hyperplastic
   - Lipomatous
   - Adenomatous
     - Tubular adenoma
     - Tubulovillous adenoma
     - Villous adenoma
     - Tubulovillous adenoma with dysplasia
   - Normal mucosa
   - Other, specify ____________________________

3. Specimen size (largest diameter in mm) ____________ mm

4. Histologic grade (G)
   - 1 GX Grade cannot be assessed
   - 2 G1 Well differentiated
   - 3 G2 Moderately differentiated
   - 4 G3 Poorly differentiated
   - 5 G4 Undifferentiated

   **Histologic grade (G)**
   
   **Adenomas**
   - 1 G1A low grade
   - 2 G2A high grade
   - 3 Not applicable

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Part B (continued)

Complete Q6, Q7 and Q8 if histology of index lesion (Q2) is not benign. If histology of index lesion is benign proceed to Q9.

6. Primary Tumor (T)
   1. TX Primary tumor cannot be assessed
   2. T0 No evidence of primary tumor
   3. Tis Carcinoma in situ: intraepithelial or invasion of lamina propria
   4. T1 Tumor invades submucosa
   5. T2 Tumor invades muscularis propria
   6. T3 Tumor invades through muscularis propria into the subserosa, or into non-peritonealized pericolic or perirectal tissues
   7. T4 Tumor directly invades other organs or structures, and/or perforates visceral peritoneum

7. Regional Lymph Nodes (N)
   1. NX Regional lymph nodes cannot be assessed
   2. N0 No regional lymph nodes metastasis
   3. N1 Metastasis in 1 to 3 regional lymph nodes
   4. N2 Metastasis in 4 or more regional lymph nodes

8. Distant Metastasis (M)
   1. MX Distant metastasis cannot be assessed
   2. M0 No distant metastasis
   3. M1 Distant metastasis

9. Agree with local diagnosis
   o No (complete 9a)
   o Yes

9a. Second opinion needed
   (If Core Pathologist disagrees with local read)
   o No
   o Yes

Part C (completed by the Alternate Core Pathologist)

1. Agree with
   o Local diagnosis
   o Core Pathologist

Name of Pathologist completing Section C

Date of second opinion (mm-dd-yyyy)

Comments: _________________________________________________________________
___________________________________________________________________________
___________________________________________________________________________

Name of Pathologist completing the form ___________________________ Date form completed (mm-dd-yyyy)
### INSTRUCTIONS:
This form must be completed and mailed with the Pathology Specimens whenever slides are sent. All slides must be sent with the [Pathology Transmittal Form (PC)](https://www.acrin.org/). At the time of shipment, a copy of the PC and P4 forms and the P1 (pathology report) should also be mailed to ACRIN 6664 Data Management Associate at 1818 Market Street, Suite 16, Philadelphia, PA 19103. Refer to Pathology Section of protocol.

*Specimens need to be labeled with the ACRIN Study and Case Number.*

### Lesion Number
<table>
<thead>
<tr>
<th>Procedure Date</th>
<th>Number of Slides</th>
<th>Slide ID</th>
<th>Pathology Specimen #</th>
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</thead>
<tbody>
<tr>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**REQUIRED ENCLOSURES:**
- Pathology Report(s) (to ACR)
- Slides (see Protocol Sec. 13)

* Fax to ACR copy of this form and Pathology reports.

**SEND TO:**
- Rebecca Chavez
- Mayo Clinic
- Department of Pathology
- Hilton 11
- 200 First Street, S.W.
- Rochester, MN 55905

---

"Copyright 2005"
**ACRIN 6664 Extracolonic Findings**

**Instructions:** This form is completed by the Radiologist who interprets the CTC exam. Report all extracolonic findings found at the time of CTC exam. Submit this form via the ACRIN website. A paper form is submitted only in the event of a revised or corrected form by mail to ACRIN: Data Management.

*Note:* Check all findings that apply within an overall location. Each checked location requires at least one diagnosis code. If a code (067) "other" or code (076) "Hernia (list type)" is used, detail in question 6.

### Location

#### Part I

1. GI

   - Liver
   - Bile Duct
   - Gall Bladder
   - Pancreas
   - Stomach
   - Small Bowel
   - Colon
   - Appendix
   - Spleen
   - Peritoneum/Mesentery
   - Retroperitoneum

#### Part II

2. Chest

   - Lung Parenchyma
   - Pleura
   - Chest Wall
   - Mediastinum

#### Part III

3. GU

   - Adrenal
   - Kidney
   - Ureter
   - Bladder
   - Prostate
   - Uterus
   - Ovary/Adnexal

---

**KEY DIAGNOSIS CODES**

<table>
<thead>
<tr>
<th>Category</th>
<th>Codes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Congenital</strong></td>
<td></td>
</tr>
<tr>
<td>Absence</td>
<td>011</td>
</tr>
<tr>
<td>Normal variant</td>
<td>012</td>
</tr>
<tr>
<td>Anomaly</td>
<td>013</td>
</tr>
<tr>
<td><strong>Inflammatory/Parenchyma</strong></td>
<td></td>
</tr>
<tr>
<td>Inflammation</td>
<td>021</td>
</tr>
<tr>
<td>Infection</td>
<td>022</td>
</tr>
<tr>
<td>(including Diverticulitis)</td>
<td></td>
</tr>
<tr>
<td>Abscess</td>
<td>023</td>
</tr>
<tr>
<td>Granuloma</td>
<td>024</td>
</tr>
<tr>
<td><strong>Indeterminate Mass/Nodule</strong></td>
<td>030</td>
</tr>
<tr>
<td><strong>Benign Mass</strong></td>
<td></td>
</tr>
<tr>
<td>Simple cyst</td>
<td>310</td>
</tr>
<tr>
<td>Fibroid</td>
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</tr>
<tr>
<td>Lipoma</td>
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<td>Adenoma</td>
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<tr>
<td>Hemangioma</td>
<td>314</td>
</tr>
<tr>
<td>Other Benign Tumor</td>
<td>315</td>
</tr>
<tr>
<td><strong>Malignant Mass</strong></td>
<td></td>
</tr>
<tr>
<td>Malignant Tumor</td>
<td>320</td>
</tr>
<tr>
<td>Lymphoma</td>
<td>321</td>
</tr>
<tr>
<td>Metastases</td>
<td>330</td>
</tr>
<tr>
<td><strong>Vascular</strong></td>
<td></td>
</tr>
<tr>
<td>Aneurysm</td>
<td>050</td>
</tr>
<tr>
<td>Atherosclerosis/Vascular</td>
<td>051</td>
</tr>
<tr>
<td>Ca++</td>
<td>052</td>
</tr>
<tr>
<td>Thrombosis</td>
<td>053</td>
</tr>
<tr>
<td><strong>Fluid</strong></td>
<td></td>
</tr>
<tr>
<td>Effusion/Ascites</td>
<td>060</td>
</tr>
<tr>
<td><strong>Miscellaneous</strong></td>
<td></td>
</tr>
<tr>
<td>Calcification</td>
<td>071</td>
</tr>
<tr>
<td>Stone</td>
<td>072</td>
</tr>
<tr>
<td>Degenerative</td>
<td>073</td>
</tr>
<tr>
<td>Diverticulum (osis)</td>
<td>074</td>
</tr>
<tr>
<td>Dilatation/Obstruction</td>
<td>075</td>
</tr>
<tr>
<td>Hemia (list type)</td>
<td>076</td>
</tr>
<tr>
<td><strong>Parenchymal Disease</strong></td>
<td></td>
</tr>
<tr>
<td>Atrophy</td>
<td>061</td>
</tr>
<tr>
<td>Focal Scarring/Infarct</td>
<td>062</td>
</tr>
<tr>
<td>Cirrhosis</td>
<td>063</td>
</tr>
<tr>
<td>Fibrosis</td>
<td>064</td>
</tr>
<tr>
<td>Emphysema</td>
<td>065</td>
</tr>
<tr>
<td>Organomegaly</td>
<td>066</td>
</tr>
<tr>
<td>Other</td>
<td>067</td>
</tr>
</tbody>
</table>
**Part IV**

4. **Vascular**
   - [ ] Aorta 
     - Aneurysm max size [ ] cm Location [ ]
   - [ ] Heart/Pericardium
   - [ ] Other artery
   - [ ] Vein

5. **Musculoskeletal**
   - [ ] Bones
   - [ ] Joint

6. **Other (detail)**: (Question 6 is completed only if a code "067" or "076" is used in Q1-5: The location coded in 6a - 6c is at location from Q1-5 coding "067" or "076").
   - 6a. Location [ ] description: __________________________
   - 6b. Location [ ] description: __________________________
   - 6c. Location [ ] description: __________________________

7. In your practice, would you recommend additional evaluation of findings?
   - [ ] No (proceed to Q8)
   - [ ] Yes (complete Q7a)
   - 7a. Code findings for follow-up: [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ]

8. In clinical practice, would you recommend urgent care regarding highly significant clinical findings?
   - [ ] No (form complete, Sign and date)
   - [ ] Yes (complete Q8a)
   - 8a. Code findings requiring urgent treatment: [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ]

**COMMENTS:**

________________________________________

________________________________________

________________________________________

________________________________________

Name of person responsible for data 1 __________________________ Date form completed ____________________

Name of person entering data into web 2 __________________________
I. GENERAL INFORMATION

1. Date of CTC exam ______-____-______ (mm-dd-yyyy)
2. Date of CTC interpretation ______-____-______ (mm-dd-yyyy)
3. Reader ID # ______ ______ ______ ______ ______
   3a. Primary image review method: (as assigned for the case by ACRIN)
      o 2D conventional (with 3D problem solving)
      o 3D endoluminal fly-through (with 2D problem solving)
   o Siemens __________
   o GE __________
   o Philips __________
   o Viatronix __________
   o Vital Images __________
   o Other, specify __________

II. COLONOGRAPHY ASSESSMENT

5. Does this patient have any significant findings ≥ 5 mm in largest diameter?
   o No (proceed to comments, then sign and date form)
   o Yes (complete Q5a and 5b and continue with form)
   5a. What is your confidence that this patient has at least one lesion ≥ 5 mm in largest diameter that would be classified as a polyp?
      o Low confidence
      o Possible
      o Indeterminate
      o Probable
      o High confidence
   5b. ______% What is the estimated probability of at least one finding ≥ 5 mm is a polyp? (0-100%)

6. Does this patient have any significant findings ≥ 10 mm in largest diameter?
   o No (proceed to comments then sign and date form)
   o Yes (complete Q6a and Q6b)
   6a. What is your confidence that this patient has at least one lesion ≥ 10 mm in largest diameter that would be classified as a polyp?
      o Low confidence
      o Possible
      o Indeterminate
      o Probable
      o High confidence
   6b. ______% What is the estimated probability of at least one finding ≥ 10 mm is a polyp? (0-100%)

COMMENTS: __________________________________________

__________________________________________
Date form completed

Name of person responsible for data ¹

Name of person entering data into web ²

"Copyright 2005"
I. General Information:

1. Date of CTC exam ______ - ______ - ______
   mm   dd   yyyy

2. Date of interpretation ______ - ______ - ______
   mm    dd     yyyy

3. Reader ID # ______

4. Machine Software
   - o Siemens
   - o GE
   - o Philips
   - o Viatronix
   - o Vital Images
   - o Other, specify: ______________________

   Software Version

   ______________________
   ______________________
   ______________________
   ______________________
   ______________________

II. CTC Interpretation:

5. Interpretation start time [Exclude load time] (military time, e.g., 9:00a.m.=0900, 3:00p.m. =1500)

6. Interpretation end time

7. Are there any colonic findings to report?
   - o No (proceed to comments, page 3)
   - o Yes (continue with form, pages 2 and 3)

Continued on page 2
8. **Colon Assessment**: Complete all columns associated with each finding ≥5mm in diameter.

**Measurements should be made of the maximum diameter of the polyp, excluding the stalk, in any plane, whichever shows optimally.**

For softwares reporting x, y + z coordinates as row, column and slice #, please follow instructions. If coordinate is not applicable, code as “998”

<table>
<thead>
<tr>
<th>CTC Findings #</th>
<th>Segment</th>
<th>Seen on:</th>
<th>Supine Axial Slice #</th>
<th>X.Y.Z Coordinate Supine #</th>
<th>X.Y.Z Coordinate Prone #</th>
<th>Polyp Morphology</th>
<th>Polyp location</th>
<th>Orientation of colon at polyp site:</th>
<th>Polyp relative to colonic bend:</th>
<th>Location of polyp location to relative</th>
<th>Additional findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Rectum 1</td>
<td>Supine only</td>
<td>1</td>
<td>x=column y=row z=slice #</td>
<td>x=column y=row z=slice #</td>
<td>1 Polypoid</td>
<td>1 Between folds</td>
<td>1 Straight</td>
<td>1 Inside curve</td>
<td>1 No</td>
<td>1 No</td>
</tr>
<tr>
<td>2</td>
<td>Sigmoid 2</td>
<td>Prone only</td>
<td>2</td>
<td></td>
<td></td>
<td>2 Flat</td>
<td>2 On folds</td>
<td>2 Bend</td>
<td>2 Outside curve</td>
<td>2 Yes</td>
<td>2 Yes</td>
</tr>
<tr>
<td>3</td>
<td>Descending 3</td>
<td>Both supine and prone</td>
<td>3</td>
<td></td>
<td></td>
<td>&quot;A &quot;flat&quot; polyp is defined as any lesion &gt;5mm with less than 3mm of elevation from flush.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>3 Indeterminate</td>
</tr>
<tr>
<td>4</td>
<td>Transverse 4</td>
<td>Both supine and prone</td>
<td>4</td>
<td></td>
<td></td>
<td>Polypoid</td>
<td></td>
<td>4 Probable</td>
<td></td>
<td>4 Probable</td>
<td>4 Probable</td>
</tr>
<tr>
<td>5</td>
<td>Ascending 5</td>
<td>Both supine and prone</td>
<td>5</td>
<td></td>
<td></td>
<td>Flat</td>
<td></td>
<td>5 High confidence</td>
<td></td>
<td>5 High confidence</td>
<td>5 High confidence</td>
</tr>
</tbody>
</table>

Continued on page 3
Colon Assessment continued: Complete all columns associated with each finding >5mm in diameter.

**Measurements should be made of the maximum diameter of the polyp, excluding the stalk, in any plane, whichever shows optimally.

For softwares reporting x, y + z coordinates as row, column and slice #, please follow instructions. If coordinate is not applicable, code as “998”

<table>
<thead>
<tr>
<th>CTC Findings #</th>
<th>Segment</th>
<th>Seen on:</th>
<th>Supine Axial Slice #</th>
<th>Prone Axial Slice #</th>
<th><strong>CTC Size (mm)</strong></th>
<th>Confidence level that finding identified is a polyp:</th>
<th>Polyp location</th>
<th>Orientation of colon at polyp site:</th>
<th>Location of polyp relative to colonic bend</th>
<th>Additional findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>6</td>
<td>1 Rectum 2 Sigmoid 3 Descending 4 Transverse 5 Ascending 6 Cecum</td>
<td>x ____</td>
<td>x ____</td>
<td>y ____</td>
<td>y ____</td>
<td>z ____</td>
<td><strong>CTC Size (mm)</strong></td>
<td>Polyp location</td>
<td>Polyp size</td>
<td>Polyp relative to colonic bend</td>
</tr>
<tr>
<td>7</td>
<td>x ____</td>
<td>x ____</td>
<td>y ____</td>
<td>y ____</td>
<td>z ____</td>
<td><strong>CTC Size (mm)</strong></td>
<td>Confidence level that finding identified is a polyp:</td>
<td>Polyp location</td>
<td>Orientation of colon at polyp site:</td>
<td>Location of polyp relative to colonic bend</td>
</tr>
<tr>
<td>8</td>
<td>x ____</td>
<td>x ____</td>
<td>y ____</td>
<td>y ____</td>
<td>z ____</td>
<td><strong>CTC Size (mm)</strong></td>
<td>Confidence level that finding identified is a polyp:</td>
<td>Polyp location</td>
<td>Orientation of colon at polyp site:</td>
<td>Location of polyp relative to colonic bend</td>
</tr>
<tr>
<td>9</td>
<td>x ____</td>
<td>x ____</td>
<td>y ____</td>
<td>y ____</td>
<td>z ____</td>
<td><strong>CTC Size (mm)</strong></td>
<td>Confidence level that finding identified is a polyp:</td>
<td>Polyp location</td>
<td>Orientation of colon at polyp site:</td>
<td>Location of polyp relative to colonic bend</td>
</tr>
<tr>
<td>10</td>
<td>x ____</td>
<td>x ____</td>
<td>y ____</td>
<td>y ____</td>
<td>z ____</td>
<td><strong>CTC Size (mm)</strong></td>
<td>Confidence level that finding identified is a polyp:</td>
<td>Polyp location</td>
<td>Orientation of colon at polyp site:</td>
<td>Location of polyp relative to colonic bend</td>
</tr>
</tbody>
</table>

Comments: ________________________________________________

Name of person responsible for data: ________________________
Name of person entering data into web: ____________________
Date form completed (mm-dd-yyyy): ________________________

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**INSTRUCTIONS:** Part A is to be completed by the Research Associate. After completion of Part A, the form is sent to the Core Pathologist for completion of Part B. Part B will be completed by the Core Pathologist based on the pathologic material available. Part C will be completed by the Alternate Core Pathologist if a second opinion is needed. At the time of slide submission a copy of the PC form, the P4 form and the P1 (pathology report) should be mailed to ACRIN 6664 Data Management, 1818 Market Street, Suite 16, Philadelphia, PA 19103. A separate form is submitted for each lesion.

### Part A (completed by site Research Associate)

1. Date of procedure __________-________-________ (mm-dd-yyyy)
2. Date specimen sent to core lab __________-________-________ (mm-dd-yyyy)
3. Number of slides submitted on this specimen
4. Finding # ______of # ______as identified on Colonoscopy. To maintain consistency in reporting of lesions, the "Finding #" is column 1 on the PL form.
5. Segment (check one)
   - Rectum
   - Sigmoid
   - Descending
   - Transverse
   - Ascending
   - Cecum

Completed by (Site RA) ________________________________

### Part B (completed by Core Pathologist)

1. [ ] Core Pathology Reviewer
   - 1 Lawrence Burgart M.D.
   - 2 Other ____________________________

2. Histology of Index Lesion
   (Check all that apply;  a checked box indicates a "yes" response)
   - Histopathological Type
     - Adenocarcinoma
     - Medullary carcinoma
     - Mucinous carcinoma (colloid type) (greater than 50% mucinous carcinoma)
     - Signet ring cell carcinoma (greater than 50% signet ring cell)
     - Squamous cell (epidermoid) carcinoma
     - Adenosquamous carcinoma
     - Small cell carcinoma
     - Undifferentiated carcinoma
     - Carcinoma, NOS
     - Other, specify ____________________________
   - Benign
     - Hyperplastic
     - Lipomatous
     - Adenomatous
     - Tubular adenoma
     - Tubulovillous adenoma
     - Villous adenoma
     - Tubulovillous adenoma with dysplasia
     - Normal mucosa
     - Other, specify ____________________________

3. Specimen size (largest diameter in mm) __________ mm

4. [ ] Histologic grade (G)
   - 1 GX Grade cannot be assessed
   - 2 G1 Well differentiated
   - 3 G2 Moderately differentiated
   - 4 G3 Poorly differentiated
   - 5 G4 Undifferentiated

   Histologic grade (G)

5. [ ] Adenomas
   - 1 G1A low grade
   - 2 G2A high grade
   - 3 Not applicable

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### Part B (continued)

Complete Q6, Q7 and Q8 if histology of index lesion (Q2) is not benign. If histology of index lesion is benign proceed to Q9.

6. **Primary Tumor (T)**
   - 1 TX Primary tumor cannot be assessed
   - 2 T0 No evidence of primary tumor
   - 3 Tis Carcinoma in situ: intraepithelial or invasion of lamina propria
   - 4 T1 Tumor invades submucosa
   - 5 T2 Tumor invades muscularis propria
   - 6 T3 Tumor invades through muscularis propria into the subserosa, or into non-peritonealized pericolic or perirectal tissues
   - 7 T4 Tumor directly invades other organs or structures, and/or perforates visceral peritoneum

7. **Regional Lymph Nodes (N)**
   - 1 NX Regional lymph nodes cannot be assessed
   - 2 N0 No regional lymph nodes metastasis
   - 3 N1 Metastasis in 1 to 3 regional lymph nodes
   - 4 N2 Metastasis in 4 or more regional lymph nodes

8. **Distant Metastasis (M)**
   - 1 MX Distant metastasis cannot be assessed
   - 2 M0 No distant metastasis
   - 3 M1 Distant metastasis

9. **Agree with local diagnosis**
   - o No (complete 9a)
   - o Yes

9a. **Second opinion needed**
   (If Core Pathologist disagrees with local read)
   - o No
   - o Yes

---

**Comments:**

---

Name of Pathologist completing the form: ____________________________

Date form completed (mm-dd-yyyy): ________________________________

---

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**ACRIN 6664**  
Pathology Submission Form

**Study # 6664**  
**Case #**

If this is a revised or corrected form, please √ box.

### Institution

### Institution #

### Participant

### Participant I.D.

**INSTRUCTIONS:** This form must be completed and mailed with the Pathology Specimens whenever slides are sent. All slides must be sent with the Pathology Transmittal Form (PC). At the time of shipment, a copy of the PC and P4 forms and the P1 (pathology report) should also be mailed to ACRIN 6664 Data Management Associate at **1818 Market Street, Suite 16, Philadelphia, PA 19103**. Refer to Pathology Section of protocol. *Specimens need to be labeled with the ACRIN Study and Case Number.*

<table>
<thead>
<tr>
<th>Lesion Number</th>
<th>Procedure Date</th>
<th>Number of Slides</th>
<th>Slide ID</th>
<th>Pathology Specimen #</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tr>
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<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**REQUIRED ENCLOSURES:**

- Pathology Report(s) (to ACR)
- Slides (see Protocol Sec. 13)

* Fax to ACR copy of this form and Pathology reports.

**SEND TO:**

- **Rebecca Chavez**  
  Mayo Clinic  
  Department of Pathology  
  Hilton 11  
  200 First Street, S.W.  
  Rochester, MN 55905

**SUBMITTED BY:** ________________________________

**DATE:** ______-______-______

**TELEPHONE NO:** (_______)________________________

*Copyright 2005*
### Instructions:
This form is completed by the Radiologist who interprets the CTC exam. Report all extracolonic findings found at the time of CTC exam. Submit this form via the ACRIN website. A paper form is submitted only in the event of a revised or corrected form by mail to ACRIN: Data Management.

**Note:** Check all findings that apply within an overall location. Each checked location requires at least one diagnosis code. If a code (067) "other" or code (076) "Hernia (list type)" is used, detail in question 6.

<table>
<thead>
<tr>
<th>Location</th>
<th>Diagnosis Code</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Part I</strong></td>
<td></td>
</tr>
<tr>
<td>1. GI</td>
<td></td>
</tr>
<tr>
<td>□ Liver</td>
<td></td>
</tr>
<tr>
<td>□ Bile Duct</td>
<td></td>
</tr>
<tr>
<td>□ Gall Bladder</td>
<td></td>
</tr>
<tr>
<td>□ Pancreas</td>
<td></td>
</tr>
<tr>
<td>□ Stomach</td>
<td></td>
</tr>
<tr>
<td>□ Small Bowel</td>
<td></td>
</tr>
<tr>
<td>□ Colon</td>
<td></td>
</tr>
<tr>
<td>□ Appendix</td>
<td></td>
</tr>
<tr>
<td>□ Spleen</td>
<td></td>
</tr>
<tr>
<td>□ Peritoneum/Mesentery</td>
<td></td>
</tr>
<tr>
<td>□ Retroperitoneum</td>
<td></td>
</tr>
<tr>
<td><strong>Part II</strong></td>
<td></td>
</tr>
<tr>
<td>2. Chest</td>
<td></td>
</tr>
<tr>
<td>□ Lung Parenchyma</td>
<td></td>
</tr>
<tr>
<td>□ Pleura</td>
<td></td>
</tr>
<tr>
<td>□ Chest Wall</td>
<td></td>
</tr>
<tr>
<td>□ Mediastinum</td>
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<td><strong>Part III</strong></td>
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<tr>
<td>3. GU</td>
<td></td>
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<tr>
<td>□ Adrenal</td>
<td></td>
</tr>
<tr>
<td>□ Kidney</td>
<td></td>
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<tr>
<td>□ Ureter</td>
<td></td>
</tr>
<tr>
<td>□ Bladder</td>
<td></td>
</tr>
<tr>
<td>□ Prostate</td>
<td></td>
</tr>
<tr>
<td>□ Uterus</td>
<td></td>
</tr>
<tr>
<td>□ Ovary/Adnexal</td>
<td></td>
</tr>
</tbody>
</table>

**KEY DIAGNOSIS CODES**

1. **Congenital**
   - Absence 011
   - Normal variant 012
   - Anomaly 013

2. **Inflammatory/Parenchyma**
   - Inflammation 021
   - Infection 022
   - (including Diverticulitis) 023
   - Abscess 023
   - Granuloma 024

3. **Indeterminate Mass/Nodule** 030

4. **Benign Mass**
   - Simple cyst 310
   - Fibroid 311
   - Lipoma 312
   - Adenoma 313
   - Hemangioma 314
   - Other Benign Tumor 315

5. **Malignant Mass**
   - Malignant Tumor 320
   - Lymphoma 321
   - Metastases 330

6. **Vascular**
   - Aneurysm 050
   - Atherosclerosis/Vascular 051
   - Ca++ 052
   - Thrombosis 053

7. **Fluid**
   - Effusion/Ascites 060

8. **Miscellaneous**
   - Calcification 071
   - Stone 072
   - Degenerative 073
   - Diverticulum (osis) 074
   - Dilatation/Obstruction 075
   - Hernia (list type) 076

9. **Parenchymal Disease**
   - Atrophy 061
   - Focal Scarring/Infarct 062
   - Cirrhosis 063
   - Fibrosis 064
   - Emphysema 065
   - Organomegaly 066
   - Other 067

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4. **Vascular**

- [ ] Aorta
  - Aneurysm max size [ ] cm
  - Location
- [ ] Heart/Pericardium
- [ ] Other artery
  - Location
- [ ] Vein
  - Location

5. **Musculoskeletal**

- [ ] Bones
  - Location
- [ ] Joint
  - Location

6. **Other (detail):** (Question 6 is completed only if a code "067" or "076" is used in Q1-5: The location coded in 6a - 6c is at location from Q1-5 coding "067" or "076").

   **Code Table to Complete Question 6 (Location)**
   - 1 Liver
   - 2 Bile Duct
   - 3 Gall Bladder
   - 4 Pancreas
   - 5 Stomach
   - 6 Small Bowel
   - 7 Colon
   - 8 Appendix
   - 9 Spleen
   - 10 Peritoneum/Mesentery
   - 11 Retroperitoneum
   - 12 Lung Parenchyma
   - 13 Pleura
   - 14 Chest Wall
   - 15 Mediastinum
   - 16 Adrenal
   - 17 Kidney
   - 18 Ureter
   - 19 Bladder
   - 20 Prostate
   - 21 Uterus
   - 22 Ovary/Adnexal
   - 23 Aorta
   - 24 Heart/Pericardium
   - 25 Other Artery
   - 26 Vein
   - 27 Bones
   - 28 Joint

6a. Location __________ description: __________________________________________

6b. Location __________ description: __________________________________________

6c. Location __________ description: __________________________________________

7. In your practice, would you recommend additional evaluation of findings?
   - [ ] No (proceed to Q8)
   - [ ] Yes (complete Q7a)

   **7a. Code findings for follow-up:** [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ]

8. In clinical practice, would you recommend urgent care regarding highly significant clinical findings?
   - [ ] No (form complete, Sign and date)
   - [ ] Yes (complete Q8a)

   **8a. Code findings requiring urgent treatment:** [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ]

**COMMENTS:**

______________________________________________________________________________
______________________________________________________________________________
______________________________________________________________________________
______________________________________________________________________________

Name of person responsible for data: ____________________________ Date form completed ____________

Name of person entering data into web: ____________________________
I. GENERAL INFORMATION

1. Date of CTC exam _____-_____--_______ (mm-dd-yyyy)

2. Date of CTC interpretation _____-_____--_______ (mm-dd-yyyy)

3. Reader ID # [ ] [ ] [ ] [ ] [ ]
   3a. Primary image review method: (as assigned for the case by ACRIN)
       o 2D conventional (with 3D problem solving)
       o 3D endoluminal fly-through (with 2D problem solving)

   o Siemens [ ] [ ]
   o GE [ ] [ ]
   o Philips [ ] [ ]
   o Viatronix [ ] [ ]
   o Vital Images [ ] [ ]
   o Other, specify [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ]

II. COLONOGRAPHY ASSESSMENT

5. Does this patient have any significant findings > 5 mm in largest diameter?
   o No (proceed to comments, then sign and date form)
   o Yes (complete Q5a and 5b and continue with form)

   5a. What is your confidence that this patient has at least one lesion > 5 mm in largest diameter that would be classified as a polyp?
       o Low confidence
       o Possible
       o Indeterminate
       o Probable
       o High confidence

   5b. [ ] [ ] % What is the estimated probability that at least one finding > 5 mm is a polyp? (0-100%)

6. Does this patient have any significant findings > 10 mm in largest diameter?
   o No (proceed to comments then sign and date form)
   o Yes (complete Q6a and Q6b)

   6a. What is your confidence that this patient has at least one lesion > 10 mm in largest diameter that would be classified as a polyp?
       o Low confidence
       o Possible
       o Indeterminate
       o Probable
       o High confidence

   6b. [ ] [ ] % What is the estimated probability that at least one finding > 10 mm is a polyp? (0-100%)

COMMENTS:

__________________________
Name of person responsible for data

__________________________
Date form completed

__________________________
Name of person entering data into web

"Copyright 2005"
1. Check The Protocol Event Being Reported (report only one per form)

Provide a description of the event (see page 2)

- Inclusion/exclusion criteria not met at time of registration/randomization (complete 1a)
- Imaging-related deviation (complete 1b)
- Duplicate case registration, duplicate case #__________
- Unapproved radiologist read CTC exam
- Assigned 2D/3D reading did not follow randomization
- CTC workstation not per protocol requirements
- Lesion pathology unavailable/lost, other issue
- Lesion photographs lost/unavailable
- Participant cost and acceptance questionnaire not completed
- Colonoscopy occurred greater than 30 days from CT Colonography
- No Follow-up colonoscopy performed within 90 days for false positives greater than 1 cm
- Participant rescheduled due to poor prep
- Colonoscopy incomplete
- Incorrect bowel prep/non-protocol approved bowel prep
- Colonoscopy performed by Fellow
  - Colonoscopy was performed with limited or no oversight by a GI physician
  - Colonoscopy was performed with close oversight by a GI physician
- Other, specify: ____________________________________________

1a. Inclusion/exclusion criteria not met:

- Aged 50 years or older (at study entry)
- Inflammatory bowel disease and/or familial polyposis syndrome (Personal history)
- Pregnancy
- Previous colonoscopy within the past five years
- Anemia (hemoglobin less than 10 gm/dl)
- Positive fecal occult blood test (FOBT)
- Melanotic stools and/or hematochezia on more than one occasion in the previous six months
- Lower abdominal pain that would normally require medical evaluation
- Serious medical conditions that would increase risk associated with colonoscopy or are so severe that screening would have no benefit
- Other, specify: ____________________________________________
1b. Imaging Deviation

- CTC Images lost, unable to archive
- Image data not available for CAD database
- CT Scanner used was not per protocol
- Supine image data set not performed
- Prone image data set not performed
- Incorrect KV utilized
- Incorrect Gantry Rotation Time utilized
- Incorrect MA utilized
- Incorrect Reconstructed Slice Width utilized
- Incorrect Reconstructed Interval utilized
- Incorrect Reconstructed Algorithm utilized
- Incorrect Number of Slices for a specific Algorithm
- Incorrect Pitch utilized
- Incorrect DFOV utilized
- Other, specify: __________________________

2. Date Protocol Deviation Occurred: ______-____-____ (mm-dd-yyyy)

3. Date Protocol Deviation Was Discovered: ______-____-____ (mm-dd-yyyy)

4. Describe the Protocol Deviation:

   _______________________________________________________________
   _______________________________________________________________
   _______________________________________________________________
   _______________________________________________________________

5. What was done to rectify the situation and/or prevent future occurrence:

   _______________________________________________________________
   _______________________________________________________________
   _______________________________________________________________
   _______________________________________________________________

Person responsible for data (RA, study staff) __________________________

Investigator Signature __________________________

Date form completed (mm-dd-yyyy) 20
I. GENERAL REVIEWER/SOFTWARE INFORMATION:

Date of review ____-____-______ (mm/dd/yyyy)

1. Reader I.D.#

1a. Reviewer Name: ____________________________

2. Reviewer ACRIN Institution # : ________________

2a. Institution Name: ____________________________

☐ No change in my evaluation method since the previous questionnaire.

(Check box if there are no changes since completion of previous form, then skip to page 4, sign and date form).

4. Reviewer experience (approximate number of CTC exams with colonoscopy correlation evaluated):

○ < 50
○ 50-100
○ 100-200
○ >200

5. Specify CT scanner type used for (CTC) exams (check one)

○ GE
○ Toshiba
○ Philips
○ Siemens
○ Other ____________________________

5a. Number of detectors __________

6. CTC software type (check one)

○ Siemens
○ GE
○ Philips
○ Viatronix
○ Vital images
○ Other, specify ____________________________

7. CTC workstation version #: ________________

8. Monitor size: (check one)

○ 17 inch
○ 20 inch
○ 25 inch
○ Other, specify ____________________________

9. # of Monitors: (e.g., 1, 2)
10. When doing clinical CTC cases (non-study) do you prefer:
   - Primary 2D Evaluation
   - Primary 3D Evaluation
   - Both - Complete 2D and 3D Evaluation
   - Other, specify: ______________________________

II. WHEN EVALUATING AXIAL IMAGES FOR POLYPS

11. Do you evaluate the axial images for polyps so that the axial image is the only one displayed on your monitor?
   (see image A, page 4)
   - No (proceed to Q12)
   - Yes (complete Q11A)

11a. If yes, select one of the following responses:
   - Do you evaluate the axial images using the large field of view (FOV) (see image A, page 4)
     OR
   - Do you decrease the FOV (i.e., zoom) on a specific colon segment (see image B, page 4)

12. Do you evaluate the axial images for polyps when the axial image is displayed with coronal/sagittal images on the same monitor (see image C, page 4)
   - No (proceed Q13)
   - Yes (complete Q12A)

12a. If yes, select one of the following responses:
   - Do you evaluate the axial images using the large FOV (see image C, page 4)
     OR
   - Do you decrease the field of view (FOV, i.e., zoom) on a specific colon segment (see image D, page 4)

13. How do you evaluate SUPINE images: (select one of the following responses)
   - Axial supine: rectum to cecum (or vice-versa) and reverse
     OR
   - Axial supine: rectum to cecum (or vice-versa) only
     OR
   - Other specify, ______________________________

14. How do you evaluate PRONE images: (select one of the following responses)
   - Axial prone: only used to confirm supine findings
     OR
   - Axial prone: rectum to cecum (or vice-versa) and reverse
     OR
   - Axial prone: rectum to cecum (or vice-versa) only
     OR
   - Other specify, ______________________________
15. SUPINE AND PRONE IMAGES:  
(select one of the following responses)  
  ○ Synchronized supine and prone images on different monitors  
  OR  
  ○ Synchronized supine and prone images on same monitor  
  OR  
  ○ Non-Synchronized supine and prone images on different monitors  
  OR  
  ○ Non-Synchronized supine and prone images on same monitor  
  OR  
  ○ Other specify, ________________________________________________  

16. EVALUATION OF ABNORMAL INTRACOLONIC FINDINGS:  (select one of the following responses) 
  ○ Evaluate each abnormal axial finding immediately with multiplanar and/or 3D imaging  
  OR  
  ○ Evaluate the entire colon, mark abnormal findings and evaluate lesions after completely evaluating the colon  
  OR  
  ○ Other specify, ________________________________________________  

III. REVIEW ORIENTATION / SETTINGS  

17. MULTIPLANAR 2D IMAGES: (check all that apply)  
   □ Used only to further evaluate abnormalities on axial CT  
   □ Reformatted coronal images evaluated routinely  
   □ Reformatted sagittal images evaluated routinely  
   □ Other specify, ________________________________________________  

18. WINDOW SETTINGS: (check all that apply)  
   □ Soft tissue window settings: routinely used to evaluate the colon  
   □ Soft tissue window settings: routinely used for extracolonic findings  
   □ Soft tissue window settings: routinely used to evaluate colonic polyps/masses  
   □ Other specify, ________________________________________________  

COMMENTS:  
______________________________________________________________  
______________________________________________________________  

______________________________________________________________  

Name of person responsible for data 1 ______________________________  
Date form completed  
(mm-dd-yyyy)  

Name of person entering data into web 2 _____________________________  

"Copyright 2005"
Images for reference when completing Section II

A. Large FOV axial image (occupies entire monitor)

B. Small FOV axial image (occupies entire monitor)

C. Multiplanar 2D images all on one monitor with LARGE FOV axial

D. Multiplanar 2D images on one monitor with SMALL FOV axial
Instructions: This coversheet represents the first page of the Cost and Acceptance questionnaire. This form is not sent to the Participant. It is completed by the RA who administers the PQ. This form is submitted via the ACRIN website. Submit paper form only in the event of a revised or corrected form via fax to ACRIN Data Management.

Questionnaire Compliance

1. Did participant answer any questionnaire items?
   1  No (complete Q2, Sign and date form)
   2  Yes, date questionnaire completed: ___________ Skip to Q3

2. If no, please state reason:
   1  Participant refused
   2  Participant ill or hospitalized
   3  Participant deceased
   4  Participant out of the country
   5  Incorrect contact information
   6  Telephone disconnected
   7  Participant unable to be contacted
   8  Other, specify: __________________________

3. Specify method of completion:
   1  At appointment
   2  By mail (include mailed questionnaire brought to the site completed)
   3  By telephone
   99  Unknown

COMMENTS: ________________________________________________________________

__________________________________________________________________________

__________________________________________________________________________

__________________________________________________________________________

Name of person responsible for data 1 ________________________________ Date form completed ___________

Name of person entering data into web 2 ________________________________
Instructions: Thank you for completing the PQ Cost and Acceptance questionnaire. We would now like to ask you some questions to help us understand when and how people get the results of their colon screening test, and to understand whether someone helped you with completing these forms. Your cooperation in providing this additional information is very important to the success of this trial and we appreciate your time.

1. Have you received both the CT Colonography and colonoscopy screening tests?
   - No (go to Q4)
   - Yes (complete Q2)
   - Not sure

2. Have you received any results from your screening test?
   - No (go to Q4)
   - Yes (complete Q2a)

   2a. If yes, do you remember the date on which you first received these results?
   - No
   - Yes - Date you received the results: _____-_____ - 20 ____(mm-dd-yy)

3. How were the results first given to you?
   - Phone call from doctor’s office
   - Letter from doctor’s office
   - Nurse told me during office visit
   - Doctor's told me during office visit
   - Other (please tell us how): ______________________________

4. Did you require any assistance to complete the PQ Cost and Acceptance Questionnaire?
   - No (go to signature and date)
   - Yes (complete Q4a and Q4b)

   4a. Please specify the person who assisted you in completing PQ Cost and Acceptance Questionnaire
   - Family
   - Friend
   - Other, specify ______________________________

   4b. What assistance did this person provide to you?
   - Read items to you
   - Marked items on the questionnaire in the way that you asked them to
   - Interpreted items into another language for you
   - Helped explain items in English for you

Participant: Please Initial ____________________________  Today’s date: _____ - _____ - 20 ____ (mm-dd-yy)

Thank You!
# ACRIN 6664 Time-Motion Study Form

**If this is a revised or corrected form, indicate by checking box □**

---

## Task Description

<table>
<thead>
<tr>
<th>Task No.</th>
<th>Start Military Time</th>
<th>Stop Military Time</th>
<th>Skipped</th>
<th>Task Description</th>
<th>If present during task</th>
<th>CT Tech #1</th>
<th>CT Tech #2</th>
<th>CT Tech Asst</th>
<th>Res/Fellow</th>
<th>Radiologist</th>
<th>LPN</th>
<th>Nurse Asst</th>
<th>Transport</th>
<th>Other</th>
</tr>
</thead>
</table>
| 1        |                     |                    |         | Patient Arrival and Preparation  
Note: Begins when patient leaves changing area and ends when patient sits on exam table. | | | | | | | | | | |
| 2        |                     |                    |         | Glucagon Administration  
Note: May begin and/or end within task 1. | | | | | | | | | | |
| 3        |                     |                    |         | Pre-Examination Room Preparation  
Note: May begin and/or end within task 1 or 2. | | | | | | | | | | |
| 4        |                     |                    |         | 1st Image Acquisition (Circle: Supine Prone Other)  
Note: Begins when patient sits on exam table and ends when final image acquisition and image checking is complete. Includes positioning, insufflation, scout scan, re-positioning and reinsufflation (if necessary) and image acquisition. | | | | | | | | | |
| 5        |                     |                    |         | 2nd Image Acquisition (Circle: Supine Prone Other)  
Note: Begins when patient is repositioned from first acquisition and ends when final image acquisition and image checking is complete. Includes positioning, insufflation, scout scan, re-positioning and reinsufflation (if necessary) and image acquisition. | | | | | | | | | |
| 6        |                     |                    |         | Administration of IV Contrast (if necessary)  
Note: Begins with ordering of IV contrast and ends when patient is ready for scans to resume. | | | | | | | | | |
| 7        |                     |                    |         | Further Image Acquisition (Circle: Supine Prone Other)  
Note: Begins when patient is repositioned from second acquisition and ends when all additional images are acquired. Includes positioning, insufflation, scout scan, re-positioning and reinsufflation (if necessary) and image acquisition. | | | | | | | | | |
| 8        |                     |                    |         | Post-Examination Patient Care  
Note: Begins when enema tip is withdrawn and ends when patient is returned to changing area. | | | | | | | | | |
| 9        |                     |                    |         | Post-Examination Room Cleanup  
Note: Begins when patient returns to changing area and ends when room is ready to be prepared for next patient. Do not include activities also included in Task 3 for the next patient. | | | | | | | | | |

---

**List Other Personnel Present and Associated Task Number**

---

**Signature of person responsible for the data 1**

**Signature of person entering data onto the web 2**

**Date form completed 3 (mm-dd-yyyy)**

---

---

---

---

---

---

---
1. Reader ID

2. This read was:
   - □ Primary 2D with 3D Problem Solving
   - □ Primary 3D with 2D Problem Solving

3. __ : __ Time Radiologist begins to prepare workspace and loads images (record in military time)

4. __ : __ Time Interpretation stops (Read completed) (record in military time)

5. __ hours __ minutes Stopwatch Time (Time on task)

Interruption checkbox:

6. ______ Number of Interruptions

7. Is the Radiologist completing ACRIN Forms during the interpretation time?
   - □ No
   - □ Yes

8. Radiologist used digital subtraction on this case?
   - □ No
   - □ Yes

Signature of person responsible for data  
Date form completed 
Signature of person entering data onto the web

*Copyright 2005*
1. Date of study _______ - _______ - _______ (mm-dd-yyyy)

2. Technical Parameter Checklist for **Supine** series

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Inspection findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Slice collimation</td>
<td></td>
</tr>
<tr>
<td>Pitch</td>
<td></td>
</tr>
<tr>
<td>MA or Effective mAs</td>
<td></td>
</tr>
<tr>
<td>Recon interval</td>
<td></td>
</tr>
<tr>
<td>Rotation time</td>
<td></td>
</tr>
<tr>
<td>DFOV</td>
<td></td>
</tr>
</tbody>
</table>

3. Technical Parameter Checklist for **Prone** series

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Inspection findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Slice collimation</td>
<td></td>
</tr>
<tr>
<td>Pitch</td>
<td></td>
</tr>
<tr>
<td>MA or Effective mAs</td>
<td></td>
</tr>
<tr>
<td>Recon interval</td>
<td></td>
</tr>
<tr>
<td>Rotation time</td>
<td></td>
</tr>
<tr>
<td>DFOV</td>
<td></td>
</tr>
</tbody>
</table>

4. Indicated data sets sent

<table>
<thead>
<tr>
<th></th>
<th># Images sent</th>
<th># Images received</th>
</tr>
</thead>
<tbody>
<tr>
<td>Supine</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prone</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
5. [ ] Scanner type
   1 GE
   2 Siemens
   3 Other ________________________________

Contact Person completing form

Name: ____________________________________

Phone: ____________________________________

COMMENTS: ____________________________________

__________________________________________

__________________________________________

__________________________________________

__________________________________________

Signature of person responsible for the data 1

Signature of person entering data onto the web 2

Date form completed 3: ___ - ___ - ______ (mm-dd-yyyy)
1. Technical Parameter Checklist

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Required</th>
<th>Inspection findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Slice collimation</td>
<td>1.0 - 1.25</td>
<td></td>
</tr>
<tr>
<td>Pitch</td>
<td>.9 - 1.4</td>
<td></td>
</tr>
<tr>
<td>MA or Effective mAs</td>
<td>50 - 140</td>
<td></td>
</tr>
<tr>
<td>Recon interval</td>
<td>0.8</td>
<td></td>
</tr>
<tr>
<td>Rotation time</td>
<td>≤ 0.5</td>
<td></td>
</tr>
<tr>
<td>DFOV</td>
<td></td>
<td>To fit patient</td>
</tr>
</tbody>
</table>

2. Does imaging parameters meet protocol specification of:
   1 No*
   2 Yes

   * If No, provide explanation

3. Is the entire colon included on both the prone and supine images?
   1 No
   2 Yes

4. Supine and prone series present?
   1 No
   2 Yes

5. Indicated data sets sent and received

<table>
<thead>
<tr>
<th></th>
<th># Images sent</th>
<th># Images received</th>
</tr>
</thead>
<tbody>
<tr>
<td>Supine</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prone</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

6. Overall Images Quality
   1 Excellent
   2 Good
   3 Average
   4 Below average, acceptable
   5 Unacceptable

7. Are there substantial artifacts (motion, barium, metallic) that degrade image quality?
   1 No
   2 Yes
8. **Reason unacceptable or below average**

   (check all that apply)

   [ ] 1 Incorrect Algorithm
   [ ] 2 Incorrect Slice Thickness
   [ ] 3 Incorrect Slice Interval
   [ ] 4 Incorrect Pitch
   [ ] 5 Incorrect KVP
   [ ] 6 Incorrect Effective mAs
   [ ] 7 Incorrect DFOV
   [ ] 8 Other ________________________________

9. [ ] Imaging Site Contacted?
   1 No
   2 Yes

10. **Contact Date _____-_____ -_____ (mm-dd-yyyy)**

11. Imaging site contact person: ________________________________

12. **Reader ID# [ ] [ ] [ ] [ ] [ ]**

13. **Date of study _____-_____ -_____ (mm-dd-yyyy)**

14. [ ] **Scanner Type**

   1 GE
   2 Siemens
   3 Toshiba
   4 Other ________________________________

15. [ ] **Is there adequate destination with minimal stool?**

   1 No
   2 Yes

---

**COMMENTS:**

________________________________________

________________________________________

__________________________

Signature of person responsible for the data  

__________________________

Signature of person entering data onto the web

__________________________

Date form completed  

____-____-____ (mm-dd-yyyy)
Instructions: The appointed Radiologist will review the colonoscopy and pathology reports for each individual case and match the lesions reported within the reports with findings from CTC using the algorithm included within this form on page 5. For a lesion to be considered a match, the lesion must be reported at colonoscopy and CTC to be within the same or adjacent segment. If the lesion matches by location then it will be assessed by size. If the lesion is reported to be within 50% in diameter of the size at colonoscopy and CTC will be considered a match. If the lesion does not match by location but is within two colon segments the colonoscopic photograph will be compared with its CTC image. If the lesion size reported is variant greater than 50% or if the lesion location is more than 2 segments apart, matching will be determined by consensus. Lesions that match by morphology and by their position on a haustral fold or colon wall will be considered to be a match. Lesions matching by location but not by size will be reviewed in a similar manner.

A False positive is a "finding" seen on CTC but not seen on Pathology and a False negative is a "finding" seen on Pathology but not found on CTC.

- Column I: record the Lesion # on the WX form (column I) matching the Lesion # from the PL form. All unmatched lesions found on either CTC or Pathology are to be recorded within the form and identified as "88".
- Column II: the lesion # is abstracted from the case specific PL form (column I) for consistent numbering of identified lesions.
- Column III and V: completed from data abstracted from the colonoscopy and pathology reports (reference standard).
- Column IV and VI: completed from data abstracted from the CTC report.
- Column I-VII: completed for all findings.
- Column VII-VIII: completed in the instance when lesion matching will be determined by consensus: a size variance of more than 50% or more than 2 segments apart in location
- Column IX: completed for all findings.
- Column X: completed for all unmatched lesions recorded in Column I or Column II.
- The CT Colonography (CTC) and Colonoscopy Lesion Matching Algorithm may be referenced on page 5 of this form.

1. Date of lesion matching review   _____ - _____ - _____
   mm   dd   yyyy

2. Reviewer ID: ____________

3. Name of reviewer ____________________________
4. Lesion Matching

<table>
<thead>
<tr>
<th>Column I</th>
<th>Column II</th>
<th>Column III</th>
<th>Column IV</th>
<th>Column V</th>
<th>Column VI</th>
<th>Column VII</th>
<th>Column VIII</th>
<th>Column IX</th>
<th>Column X</th>
<th>Column XI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lesion # (from the WX form)</td>
<td>Lesion # (from the PL form)</td>
<td>Colonoscopy/Pathology Size (mm)</td>
<td>CTC Segment (1-6)</td>
<td>Colonoscopy/Pathology Size (mm)</td>
<td>CTC Size (mm)</td>
<td>2 member team review (0-2)</td>
<td>3 Member team review</td>
<td>Match Status (0-2)</td>
<td>False Negative (1-4)</td>
<td>Missed lesion coordinates</td>
</tr>
<tr>
<td>1</td>
<td></td>
<td>Rectum 1</td>
<td>Rectum 1</td>
<td>Lesion 1</td>
<td>2</td>
<td>0 not required</td>
<td>1 performed with consensus</td>
<td>2 false negative</td>
<td>1 seen retrospectively on 2D</td>
<td>x _____ y _____ z _____</td>
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<tr>
<td>2</td>
<td></td>
<td>Sigmoid 2</td>
<td>Sigmoid 2</td>
<td>Lesion 2</td>
<td>3</td>
<td>1 performed without consensus</td>
<td>3 performed with 2 to 1 vote</td>
<td>1 true positive</td>
<td>2 seen retrospectively on 3D</td>
<td>x _____ y _____ z _____</td>
</tr>
<tr>
<td>3</td>
<td></td>
<td>Ascending 4</td>
<td>Descending 4</td>
<td>Lesion 3</td>
<td>5</td>
<td>0 not required</td>
<td>3 performed with 2 to 1 vote</td>
<td>2 false positive</td>
<td>3 seen on both 2D and 3D</td>
<td>x _____ y _____ z _____</td>
</tr>
<tr>
<td>4</td>
<td></td>
<td>Transverse 5</td>
<td>Transverse 5</td>
<td>Lesion 4</td>
<td>6</td>
<td></td>
<td></td>
<td>4 not seen in retrospect on 2D or 3D</td>
<td>x _____ y _____ z _____</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td></td>
<td>Cecum 6</td>
<td>Cecum 6</td>
<td>Lesion 5</td>
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<td></td>
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<td>x _____ y _____ z _____</td>
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<td>Lesion 6</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>x _____ y _____ z _____</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td></td>
<td></td>
<td></td>
<td>Lesion 7</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>x _____ y _____ z _____</td>
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4. Lesion Matching (continued)

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"Copyright 2005"
4. Lesion Matching (continued)

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</table>
CT Colonography (CTC) and Colonoscopy Lesion Matching Algorithm

5. Name of First Consensus Reviewer ___________________________ (completed only if 2 member consensus review is required)

6. Date of First Consensus Review ______ - ______ - ______
   mm    dd       yyyy

7. Name of Consensus Gastroenterologist ___________________________ (completed only if 3 member consensus review is required)

8. Date of Gastroenterologist Consensus review ______ - ______ - ______
   mm    dd       yyyy

Lesion Size at CTC > 1 cm

No

CTC/Colonoscopy Same/Adj. Location

Within 2 Segments

No

CTC/Colonoscopy Same/Adj. Location

Yes

Size +/- 50%

No

Review Endoscopic Photo and CTC Images

No Morphology Match

False Pos

Morphology/Fold-Wall Location Match

True Pos

Yes

Repeat Colonoscopy in 90 Days

No

False Pos

Yes

False Pos

True Pos
Instructions: The appointed Radiologist will review the colonoscopy and pathology reports for each individual case and match the lesions reported within the reports with findings from CTC using the algorithm included within this form on page 5. For a lesion to be considered a match, the lesion must be reported at colonoscopy and CTC to be within the same or adjacent segment. If the lesion matches by location then it will be assessed by size. If the lesion is reported to be within 50% in diameter of the size at colonoscopy and CTC will be considered a match. If the lesion does not match by location but is within two colon segments the colonoscopic photograph will be compared with its CTC image. If the lesion size reported is variant greater than 50% or if the lesion location is more than 2 segments apart, matching will be determined by consensus. Lesions that match by morphology and by their position on a haustral fold or colon wall will be considered to be a match. Lesions matching by location but not by size will be reviewed in a similar manner.

**False positive** is a “finding” seen on CTC but not seen on Pathology and a **False negative** is a “finding” seen on Pathology but not found on CTC.

---

<table>
<thead>
<tr>
<th>Column I: record the Lesion # on the W2 form (column I) matching the Lesion # from the PL form. All unmatched lesions found on either CTC or Pathology are to be recorded within the form and identified as “88.”</th>
</tr>
</thead>
<tbody>
<tr>
<td>Column II: the lesion # is abstracted from the case specific PL form (column I) for consistent numbering of identified lesions.</td>
</tr>
<tr>
<td>Column III and V: completed from data abstracted from the colonoscopy and pathology reports (reference standard).</td>
</tr>
<tr>
<td>Column IV and VI: completed from data abstracted from the CTC report.</td>
</tr>
<tr>
<td>Column I-VII: completed for all findings.</td>
</tr>
<tr>
<td>Column VII-VIII: completed in the instance when lesion matching will be determined by consensus: a size variance of more than 50% or more than 2 segments apart in location</td>
</tr>
<tr>
<td>Column IX: completed for all findings.</td>
</tr>
<tr>
<td>Column X: completed for all unmatched lesions recorded in Column I or Column II.</td>
</tr>
<tr>
<td>The CT Colonography (CTC) and Colonoscopy Lesion Matching Algorithm may be referenced on page 5 of this form.</td>
</tr>
</tbody>
</table>

---

1. **Date of lesion matching review**
   - **mm**
   - **dd**
   - **yyyy**

2. **Reviewer ID:**
   - [2]

3. **Name of reviewer**
   - [3]

4. **Re-read Institution**
   - [281]
   - o 4204 Clinical Radiologists S.C.
   - o 4205 Washington University Medical
   - o 4214 UT M.D. Anderson Cancer Center
   - o 4218 Mayo Clinic
   - o 4240 UCSD Medical Center
   - o 4277 VCU Health System
   - o 4303 Scottsdale Medical Imaging, LTD
   - o 4320 Radiology Imaging Associates
   - o 4342 Mayo Clinic Arizona
   - o 4470 Yale University-New Haven Hospital
   - o 4486 SF VA
   - o 4487 BI Medical Center
   - o 4492 University of Chicago
   - o 4494 UCLA Medical Center
   - o 4499 John Hopkins University

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## 5. Lesion Matching

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### ACRIN National CT Colonography Lesion Matching Form for Re-Read Cases

**Revision**

**Institution**

**Institution No.**

**Participant Initials**

**Case No.**

#### 5. Lesion Matching (continued)

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CT Colonography (CTC) and Colonoscopy Lesion Matching Algorithm

6. Name of First Consensus Reviewer ____________________________ [277] (completed only if 2 member consensus review is required)
7. Date of First Consensus Review mm - dd - yyyy [280]
8. Name of Second Consensus Reviewer ____________________________ [278] (completed only if 3 member consensus review is required)
9. Date of Second Consensus Review mm - dd - yyyy [279]

Lesion Size at CTC ≥ 1 cm

- No
  - False Pos
  - Repeat Colonoscopy in 90 Days

- Yes
  - Negative
  - Colonoscopy

C/Colonscopic Same/Adj. Location

- No
  - Within 2 Segments
    - No
      - False Pos
    - Yes
      - Review Endoscopic Photo and CTC Images

- Yes
  - Size +/− 50%
    - No
      - False Pos
    - Yes
      - True Pos

No Morphology Match

- False Pos
- True Pos

Morphology/Fold-Wall Location Match

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