

CA209-7DXLS – Required Laboratory Tests

Version # 4 Date: 04-FEB-2022

Protocol v #2

Subject Number _ _ _ _ _

**** If a test result is delayed, hold off on sending report until all lab results are received.
DO NOT upload this page to iSite, please use as a checklist to ensure
all required laboratory tests are present. ****

**** If a protocol required test was not performed, please indicate the test(s) in the TEST
COMMENT section of the requisition form ****

Chemistry Panel

- ☐ **AST (SGOT)**
 - ☐ **ALT (SGPT)**
 - ☐ **Total Bilirubin**
 - ☐ Alkaline Phosphatase
 - ☐ LDH
 - ☐ Creatinine
 - ☐ BUN or UREA
 - ☐ Glucose
 - ☐ Albumin
 - ☐ Sodium
 - ☐ Potassium
 - ☐ Chloride
 - ☐ Calcium
 - ☐ Phosphate
 - ☐ Magnesium
 - ☐ Creatinine Clearance*
- *Screening only*

Serology Panel

- ☐ Hepatitis C
- ☐ Hepatitis B
- ☐ HIV *Optional*

Hematology Panel

- ☐ Hemoglobin
- ☐ Hematocrit
- ☐ Platelet Count
- ☐ WBC
- ☐ Differential:
Bands
Neutrophils
Lymphocytes
Eosinophils
Monocytes
Basophils
**plus additional differential cells
if reported*

Misc. Tests

- ☐ PSA
 - ☐ Testosterone*
- *Screening only*

Thyroid Panel

- ☐ TSH
 - ☐ FT3/T3 *required at
Screening, reflex on treatment*
 - ☐ FT4/T4 *required at
Screening, reflex on treatment*
- * FT3/T3 and FT4/T4 will be
performed if TSH is Abnormal*

Bristol-Myers Squibb - ICON Laboratory Services
Data Requisition – Version # 4 Date: 04-FEB-2022
Protocol v #2

123 Smith Street, Farmingdale New York 11735 Email Icon-Iris@iconplc.com

Lab Name _____
Lab Address _____

PROTOCOL NUMBER	CA209-7DXLS	SITE NUMBER	_____
SUBJECT NUMBER	_____	DATE OF BIRTH	01 - JUL - D D M M Y Y Y Y
<i>For Additional Instructions please see Site Manual.</i>		GENDER AT BIRTH	<input checked="" type="checkbox"/> Male
1. Write the performing Lab Name and Address (in English) if NOT present on the lab report. 2. Write the Site Number and Subject Number on the TOP of the FIRST page of the final lab report if NOT present. 3. Upload this requisition form with COMPLETE lab report to https://isite.iconplc.com for processing. 4. Limit ONE Requisition with report(s) per upload. 5. You MUST ALWAYS check the box for any of the following tests if they were not done: AST, ALT, Total Bilirubin			

Visit <i>Write in visit name in space provided</i>	Collection Date <i>(Example: 01 - Jan - 2017)</i>	Collection Time <i>(00:00 – 23:59)</i>	Fasting Status	Laboratory Testing Confirmation <i>(to avoid a query)</i>	Test Comment <i>You must Check the box if any of the following tests were not done. For all visits</i>
Screen	_ _ - _ _ - _ _ Y Y Y Y D D M M M Y Y Y Y Y	_ _ : _ _ _ _ : _ _	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	Check if Not Done <input type="checkbox"/> Chemistry (Including Creatinine Clearance) <input type="checkbox"/> Hematology <input type="checkbox"/> Thyroid <input type="checkbox"/> Serology <input type="checkbox"/> PSA <input type="checkbox"/> Testosterone	<input type="checkbox"/> AST <input type="checkbox"/> ALT <input type="checkbox"/> T. Bilirubin <input type="checkbox"/> Other
	_ _ - _ _ - _ _ Y Y Y Y D D M M M Y Y Y Y Y	_ _ : _ _ _ _ : _ _	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	Check if Not Done <input type="checkbox"/> Chemistry (Including Creatinine Clearance) <input type="checkbox"/> Hematology <input type="checkbox"/> Thyroid <input type="checkbox"/> Serology <input type="checkbox"/> PSA <input type="checkbox"/> Testosterone	<input type="checkbox"/> AST <input type="checkbox"/> ALT <input type="checkbox"/> T. Bilirubin <input type="checkbox"/> Other
Additional Comments: (indicate collection date if visit specific)					

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Data Requisition – Version # 4 Date: 04-FEB-2022
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123 Smith Street, Farmingdale New York 11735 Email icon-lris@iconplc.com

Lab Name _____
Lab Address _____

Arm A and B

PROTOCOL NUMBER	CA209-7DXLS	SITE NUMBER	_____
SUBJECT NUMBER	_____	DATE OF BIRTH	01 - JUL - D D M M Y Y Y Y
<i>For Additional Instructions please see Site Manual.</i>		GENDER AT BIRTH	<input checked="" type="checkbox"/> Male
1. Write the performing Lab Name and Address (in English) if NOT present on the lab report. 2. Write the Site Number and Subject Number on the TOP of the FIRST page of the final lab report if NOT present. 3. Upload this requisition form with COMPLETE lab report to https://isite.iconplc.com for processing. 4. Limit ONE Requisition with report(s) per upload. 5. You MUST ALWAYS check the box for any of the following tests if they were not done: AST, ALT, Total Bilirubin			

Visit <i>Write in visit name in space provided</i>	Collection Date <i>(Example: 01 - Jan - 2006)</i>	Collection Time <i>(00:00 – 23:59)</i>	Fasting Status	Laboratory Testing Confirmation <i>(to avoid a query)</i>	Test Comment <i>You must Check the box if any of the following tests were not done. For all visits</i>
C 1 D 1	_____ D D M M M Y Y Y Y <input type="checkbox"/> Visit was not collected	____ : ____	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	Check if Not Done <input type="checkbox"/> Chemistry <input type="checkbox"/> Hematology <input type="checkbox"/> Thyroid <input type="checkbox"/> PSA	<input type="checkbox"/> AST <input type="checkbox"/> ALT <input type="checkbox"/> T. Bilirubin <input type="checkbox"/> Other
C ____ D ____	_____ D D M M M Y Y Y Y <input type="checkbox"/> Visit was not collected	____ : ____	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	By sending this visit, you confirm that all available required tests are present. A query will not be sent for missing tests.	<input type="checkbox"/> AST <input type="checkbox"/> ALT <input type="checkbox"/> T. Bilirubin <input type="checkbox"/> Other
C ____ D ____	_____ D D M M M Y Y Y Y <input type="checkbox"/> Visit was not collected	____ : ____	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	By sending this visit, you confirm that all available required tests are present. A query will not be sent for missing tests.	<input type="checkbox"/> AST <input type="checkbox"/> ALT <input type="checkbox"/> T. Bilirubin <input type="checkbox"/> Other
C ____ D ____	_____ D D M M M Y Y Y Y <input type="checkbox"/> Visit was not collected	____ : ____	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	By sending this visit, you confirm that all available required tests are present. A query will not be sent for missing tests.	<input type="checkbox"/> AST <input type="checkbox"/> ALT <input type="checkbox"/> T. Bilirubin <input type="checkbox"/> Other
C ____ D ____	_____ D D M M M Y Y Y Y <input type="checkbox"/> Visit was not collected	____ : ____	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	By sending this visit, you confirm that all available required tests are present. A query will not be sent for missing tests.	<input type="checkbox"/> AST <input type="checkbox"/> ALT <input type="checkbox"/> T. Bilirubin <input type="checkbox"/> Other
C ____ D ____	_____ D D M M M Y Y Y Y <input type="checkbox"/> Visit was not collected	____ : ____	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	By sending this visit, you confirm that all available required tests are present. A query will not be sent for missing tests.	<input type="checkbox"/> AST <input type="checkbox"/> ALT <input type="checkbox"/> T. Bilirubin <input type="checkbox"/> Other
C ____ D ____	_____ D D M M M Y Y Y Y <input type="checkbox"/> Visit was not collected	____ : ____	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	By sending this visit, you confirm that all available required tests are present. A query will not be sent for missing tests.	<input type="checkbox"/> AST <input type="checkbox"/> ALT <input type="checkbox"/> T. Bilirubin <input type="checkbox"/> Other
Additional Comments: (indicate collection date if visit specific)					

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123 Smith Street, Farmingdale New York 11735 Email Icon-Iris@iconplc.com

Lab Name

Lab Address

Arm A and B

PROTOCOL NUMBER	CA209-7DXLS	SITE NUMBER	_____
SUBJECT NUMBER	_____	DATE OF BIRTH	01 - JUL - D D M M Y Y Y Y
<i>For Additional Instructions please see Site Manual.</i>		GENDER AT BIRTH	<input checked="" type="checkbox"/> Male
1. Write the performing Lab Name and Address (in English) if NOT present on the lab report. 2. Write the Site Number and Subject Number on the TOP of the FIRST page of the final lab report if NOT present. 3. Upload this requisition form with COMPLETE lab report to https://isite.iconplc.com for processing. 4. Limit ONE Requisition with report(s) per upload. 5. You MUST ALWAYS check the box for any of the following tests if they were not done: AST, ALT, Total Bilirubin			

Visit <i>Write in visit name in space provided</i>	Collection Date <i>(Example: 01 - Jan - 2006)</i>	Collection Time <i>(00:00 – 23:59)</i>	Fasting Status	Laboratory Testing Confirmation <i>(to avoid a query)</i>	Test Comment <i>You must Check the box if any of the following tests were not done. For all visits</i>
F/U V1	_____ D D M M Y Y Y Y <input type="checkbox"/> Visit was not collected	_____ : _____	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	Check if Not Done <input type="checkbox"/> Chemistry <input type="checkbox"/> Hematology <input type="checkbox"/> Thyroid <input type="checkbox"/> PSA	<input type="checkbox"/> AST <input type="checkbox"/> ALT <input type="checkbox"/> T. Bilirubin <input type="checkbox"/> Other
F/U V2 *Optional	_____ D D M M Y Y Y Y <input type="checkbox"/> Visit was not collected	_____ : _____	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	Check if Not Done <input type="checkbox"/> LDH <input type="checkbox"/> Glucose <input type="checkbox"/> Phosphorus <input type="checkbox"/> Magnesium <input type="checkbox"/> Thyroid <input type="checkbox"/> PSA	<input type="checkbox"/> AST <input type="checkbox"/> ALT <input type="checkbox"/> T. Bilirubin <input type="checkbox"/> Other
Additional Comments: (indicate collection date if visit specific)					

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Lab Name _____
Lab Address _____

Arm A and B

PROTOCOL NUMBER	CA209-7DXLS	SITE NUMBER	_____
SUBJECT NUMBER	_____	DATE OF BIRTH	01 - JUL - D D M M Y Y Y Y
<i>For Additional Instructions please see Site Manual.</i>		GENDER AT BIRTH	<input checked="" type="checkbox"/> Male
1. Write the performing Lab Name and Address (in English) if NOT present on the lab report. 2. Write the Site Number and Subject Number on the TOP of the FIRST page of the final lab report if NOT present. 3. Upload this requisition form with COMPLETE lab report to https://isite.iconplc.com for processing. 4. Limit ONE Requisition with report(s) per upload. 5. You MUST ALWAYS check the box for any of the following tests if they were not done: AST, ALT, Total Bilirubin			

Visit	Collection Date	Collection Time	Fasting Status	Laboratory Testing Confirmation	Test Comment
<i>Write in visit name in space provided</i>	<i>(Example: 01 - Jan - 2006)</i>	<i>(00:00 – 23:59)</i>		<i>(to avoid a query)</i>	<i>You must Check the box if any of the following tests were not done. For all visits</i>
Unscheduled <input type="checkbox"/> Unscheduled <input type="checkbox"/> Retest of _____ <input type="checkbox"/> EOT/Subject Discontinued	_____ D D M M M Y Y Y Y <input type="checkbox"/> Visit was not collected	_____ : _____	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	See attached report <i>*Only protocol required tests will be processed*</i>	
Unscheduled <input type="checkbox"/> Unscheduled <input type="checkbox"/> Retest of _____ <input type="checkbox"/> EOT/Subject Discontinued	_____ D D M M M Y Y Y Y <input type="checkbox"/> Visit was not collected	_____ : _____	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	See attached report <i>*Only protocol required tests will be processed*</i>	
Unscheduled <input type="checkbox"/> Unscheduled <input type="checkbox"/> Retest of _____ <input type="checkbox"/> EOT/Subject Discontinued	_____ D D M M M Y Y Y Y <input type="checkbox"/> Visit was not collected	_____ : _____	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	See attached report <i>*Only protocol required tests will be processed*</i>	
Unscheduled <input type="checkbox"/> Unscheduled <input type="checkbox"/> Retest of _____ <input type="checkbox"/> EOT/Subject Discontinued	_____ D D M M M Y Y Y Y <input type="checkbox"/> Visit was not collected	_____ : _____	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	See attached report <i>*Only protocol required tests will be processed*</i>	
Unscheduled <input type="checkbox"/> Unscheduled <input type="checkbox"/> Retest of _____ <input type="checkbox"/> EOT/Subject Discontinued	_____ D D M M M Y Y Y Y <input type="checkbox"/> Visit was not collected	_____ : _____	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	See attached report <i>*Only protocol required tests will be processed*</i>	
Unscheduled <input type="checkbox"/> Unscheduled <input type="checkbox"/> Retest of _____ <input type="checkbox"/> EOT/Subject Discontinued	_____ D D M M M Y Y Y Y <input type="checkbox"/> Visit was not collected	_____ : _____	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	See attached report <i>*Only protocol required tests will be processed*</i>	

Additional Comments: (indicate collection date if visit specific)

**** Tests Performed at Site Data Requisition ****

Bristol-Myers Squibb - ICON Laboratory Services

123 Smith Street, Farmingdale New York 11735 Email Icon-Iris@iconplc.com Tel: 631-306-9650

Version # 4 Date: 04-FEB-2022, Protocol v #2

Note: Only prepare and submit this page for results performed at site when a laboratory report is not available.

PROTOCOL NUMBER	CA209-7DXLS	SITE NUMBER	____
SUBJECT NUMBER	____	DATE OF BIRTH	01 - JUL - D D M M Y Y Y Y
GENDER AT BIRTH		<input checked="" type="checkbox"/> Male	
<p>1. Enter RESULT, UNIT and RANGE. 2. Site Representative must sign and date 3. Upload this requisition form with COMPLETE lab report to https://isite.iconplc.com for processing. 4. Limit ONE Requisition with report(s) per upload. For Additional Instructions please see Site Manual.</p>			

Results (Performed at Site)

Visit Name: _____

Collection Date: ____ - ____ - ____ - ____ - ____ - ____ - ____ - ____
D D M M Y Y Y Y

Collection Time: ____ : ____

Test	Result	Unit (write N/A if none)	Range (write N/A if none)
Creatinine Clearance			

Site Representative

Date

SAE Data Requisition

Version # 4 Date: 04-FEB-2022, Protocol v #2

123 Smith Street, Farmingdale New York 11735 Email Icon-Iris@iconplc.com

Tel: 631-306-9650

Lab Name _____
Lab Address _____

Only prepare and submit this page for an SAE related event. Check off ALL TESTS related to an SAE. Only tests that are checked off will be processed.

If test is not listed, write in additional tests section.

PROTOCOL NUMBER	CA209-7DXLS	SITE NUMBER	_____
SUBJECT NUMBER	_____	DATE OF BIRTH	01 - JUL - D D M M Y Y Y Y
<i>For Additional Instructions please see Site Manual.</i>		GENDER AT BIRTH	<input checked="" type="checkbox"/> Male
1. Write the performing Lab Name and Address (in English) if NOT present on the lab report. 2. Write the Site Number and Subject Number on the TOP of the FIRST page of the final lab report if NOT present. 3. Upload this requisition form with COMPLETE lab report to https://isite.iconplc.com for processing. 4. Limit ONE Requisition with report(s) per upload. 5. Protocol tests that are NOT checked or written in the additional tests section will NOT be processed. 6. Tests checked or written below MUST match the tests entered into the SAE form in RAVE or your site will be queried for differences.			

Visit	Collection Date (Example: 01 - Jan - 2006)	Collection Time (00:00 – 23:59)	Fasting Status
SAE	_____ D D M M M Y Y Y Y Y	_____ : _____ :	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown

Chemistry Panel <input type="checkbox"/> AST (SGOT) <input type="checkbox"/> ALT (SGPT) <input type="checkbox"/> Total Bilirubin <input type="checkbox"/> Alkaline Phosphatase <input type="checkbox"/> LDH <input type="checkbox"/> Creatinine <input type="checkbox"/> BUN or UREA <input type="checkbox"/> Glucose <input type="checkbox"/> Albumin <input type="checkbox"/> Sodium <input type="checkbox"/> Potassium <input type="checkbox"/> Chloride <input type="checkbox"/> Calcium <input type="checkbox"/> Phosphate <input type="checkbox"/> Magnesium <input type="checkbox"/> Creatinine Clearance Serology Panel <input type="checkbox"/> Hepatitis C <input type="checkbox"/> Hepatitis B <input type="checkbox"/> HIV	Hematology Panel <input type="checkbox"/> Hemoglobin <input type="checkbox"/> Hematocrit <input type="checkbox"/> Platelet Count <input type="checkbox"/> WBC Differential: <input type="checkbox"/> Bands <input type="checkbox"/> Neutrophils <input type="checkbox"/> Lymphocytes <input type="checkbox"/> Eosinophils <input type="checkbox"/> Monocytes <input type="checkbox"/> Basophils Additional Differential Cells _____ _____ _____ _____ _____ Misc. Tests <input type="checkbox"/> PSA <input type="checkbox"/> Testosterone	Thyroid Panel <input type="checkbox"/> TSH <input type="checkbox"/> FT3/T3 <input type="checkbox"/> FT4/T4 Additional Tests _____ _____ _____ _____ _____ _____ _____ _____ _____ _____
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Clinical Safety Program Requisition

Ver. # 4 Date: 04-FEB-2022 Protocol v #2

123 Smith Street, Farmingdale New York 11735 Email Icon-lris@iconplc.com

Tel: 631-306-9650

Lab Name
Lab Address

**Only prepare and submit this page for any Clinical Safety Program (CSP)-
Cardiovascular identified Event (e.g. Myocarditis, Myocardial Edema, Pericarditis)**

**Send any tests listed below (including all dates and times) if performed to evaluate and
monitor the cardiovascular event.**

Please upload as soon as possible to iSite

PROTOCOL NUMBER	CA209-7DXLS	SITE NUMBER	_____
SUBJECT NUMBER	_____	DATE OF BIRTH	01 - JUL - D D M M Y Y Y Y
GENDER AT BIRTH <input checked="" type="checkbox"/> Male			
1. Write the performing Lab Name and Address (in English) if NOT present on the lab report. 2. Write the Site Number and Subject Number on the TOP of the FIRST page of the final lab report if NOT present. 3. Upload this requisition form with COMPLETE lab report to https://isite.iconplc.com for processing. 4. Limit ONE Requisition with report(s) per upload. 5. Tests that are submitted without this Requisition Form will NOT be processed.			

<i>Visit</i>	Collection Date (Example: 01 - Jan - 2017)	Collection Time (00:00 – 23:59)	Cardiovascular Tests <i>Note: For each unique collection date and time, include any tests performed to evaluate the event from the list below.</i>
CSP-CV	<div> <div>D</div> <div>D</div> <div>M</div> <div>M</div> <div>M</div> <div>Y</div> <div>Y</div> <div>Y</div> <div>Y</div> </div>	<div> <div></div> <div>:</div> <div></div> </div>	C Reactive Protein ESR Troponin I Troponin T.....NT-proBNP Creatinine CK MB Isoenzyme ST2, Soluble BNP
CSP-CV	<div> <div>D</div> <div>D</div> <div>M</div> <div>M</div> <div>M</div> <div>Y</div> <div>Y</div> <div>Y</div> <div>Y</div> </div>	<div> <div></div> <div>:</div> <div></div> </div>	C Reactive Protein ESR Troponin I Troponin T.....NT-proBNP Creatinine CK MB Isoenzyme ST2, Soluble BNP
CSP-CV	<div> <div>D</div> <div>D</div> <div>M</div> <div>M</div> <div>M</div> <div>Y</div> <div>Y</div> <div>Y</div> <div>Y</div> </div>	<div> <div></div> <div>:</div> <div></div> </div>	C Reactive Protein ESR Troponin I Troponin T.....NT-proBNP Creatinine CK MB Isoenzyme ST2, Soluble BNP
CSP-CV	<div> <div>D</div> <div>D</div> <div>M</div> <div>M</div> <div>M</div> <div>Y</div> <div>Y</div> <div>Y</div> <div>Y</div> </div>	<div> <div></div> <div>:</div> <div></div> </div>	C Reactive Protein ESR Troponin I Troponin T.....NT-proBNP Creatinine CK MB Isoenzyme ST2, Soluble BNP
CSP-CV	<div> <div>D</div> <div>D</div> <div>M</div> <div>M</div> <div>M</div> <div>Y</div> <div>Y</div> <div>Y</div> <div>Y</div> </div>	<div> <div></div> <div>:</div> <div></div> </div>	C Reactive Protein ESR Troponin I Troponin T.....NT-proBNP Creatinine CK MB Isoenzyme ST2, Soluble BNP