

# LB=Laboratory Test Results

LBCAT=COAGULATION FUNCTION

QVAL when  
SUPPLB.QNAM=LBCLSIG

LBORRES

No.	Laboratory test item	Measured value	Unit	Determination of clinical significance	Note
LBSPID			LBORRESU		QVAL when SUPPLB.QNAM=LBTXT
5	International normalized ratio (INR)			<div><div>○ Normal</div><div>○ Abnormal without clinical significance</div><div>○ Abnormal with clinical significance</div><div>○ Not tested</div></div>	
	LBTESTCD=INR				
	LBTEST=Phothrombin Intl. Normalized Ratio				

Name of PI:\_\_\_\_\_

Account:\_\_\_\_\_

Date of Signature:\_\_\_\_\_

# EG=ECG Test Results

## 2.12 12-Lead ECG

Subject ID: _____	CRF status: <input type="radio"/> Not submitted <input type="radio"/> In review <input type="radio"/> Locked <input type="radio"/> Frozen <input type="radio"/> Signed by PI
Study site name: _____	Study site No.: _____
Investigator name: _____	Investigator ID: _____
Visit: screening period (D-7 to D-1)	Visit No.: 2
12-lead ECG	EGSTAT=NOT DONE when EGTESTCD=EGALL and EGTEST=All ECG Tests
12-lead ECG: <input type="radio"/> Not performed	
Examination date: _____ (DD-MM-YYYY)	EGDTC

No.	Examination item	Result	Unit
EGTESTCD=EGHRMN	Heart rate	EGTEST=ECG Mean Heart Rate	bpm
EGTESTCD=PRAG	PR	EGTEST=PR Interval, Aggregate	ms
EGTESTCD=QTAG	QT	EGTEST=QT Interval, Aggregate	ms
EGTESTCD=QTCFAG	QTc	EGTEST=QTcF Interval, Aggregate	ms

12-lead ECG result: <input type="radio"/> Normal <input type="radio"/> Abnormal without clinical significance <input type="radio"/> Abnormal with clinical significance	EGORRES when EGTESTCD=INTP	EGTEST=Interpretation
If abnormal, please describe: _____	QVAL when SUPPEG.QNAM=EGDESP	

Name of PI: \_\_\_\_\_

Account: \_\_\_\_\_

Date of Signature: \_\_\_\_\_

## CV=Cardiovascular System Findings

### 2.13 Echocardiography

Subject ID: _____	CRF status: <input type="radio"/> Not submitted <input type="radio"/> In review <input type="radio"/> Locked <input type="radio"/> Frozen <input type="radio"/> Signed by PI
Study site name: _____	Study site No.: _____
Investigator name: _____	Investigator ID: _____
Visit: screening period (D-7 to D-1)	Visit No.: 2
Echocardiography	CVSTAT=NOT DONE when CVTESTCD=CVALL and CVTEST=All CV Tests
Echocardiography: <input type="radio"/> Not performed	
Examination date: _____ (DD-MM-YYYY)	CVDTC
LVEF (%): _____	CVORRES when CVTESTCD=LVEF CVTEST=Left Ventricular Ejection Fraction
Result: <input type="radio"/> Normal <input type="radio"/> Abnormal without clinical significance <input type="radio"/> Abnormal with clinical significance	CVORRES when CVTESTCD=INTP CVTEST=Interpretation
If abnormal, please describe: _____	QVAL when SUPPCV.QNAM=CVDESP

CVORRESU=% when CVTESTCD=LVEF

Name of PI: \_\_\_\_\_

Account: \_\_\_\_\_

Date of Signature: \_\_\_\_\_

## LB=Laboratory Test Results

### 2.14 Blood Pregnancy Test

### LBCAT=BLOOD PREGNANCY TEST

Subject ID: _____	CRF status: <input type="radio"/> Not submitted <input type="radio"/> In review <input type="radio"/> Locked <input type="radio"/> Frozen <input type="radio"/> Signed by PI
Study site name: _____	Study site No.: _____
Investigator name: _____	Investigator ID: _____
Visit: screening period (D-7 to D-1)	<b>LBTEST=Choriogonadotropin Beta</b>
Blood pregnancy test <b>LBTESTCD=HCG</b>	<b>LBSTAT=NOT DONE when LBTESTCD=HCG and LBTEST=Choriogonadotropin Beta</b>
Blood pregnancy test: <input type="radio"/> Not performed	
Reason for not performing: <input type="radio"/> Menopause <input type="radio"/> Male <input type="radio"/> Others	<b>LBREASND</b>
Other reasons: <b>QVAL when SUPPLB.QNAM=LBREASOT</b>	
Test date: <b>LB DTC</b> (DD-MM-YYYY)	
Result: <input type="radio"/> Negative <input type="radio"/> Positive	<b>LBORRES when LBTESTCD=HCG and LBTEST=Choriogonadotropin Beta</b>

Name of PI: \_\_\_\_\_

Account: \_\_\_\_\_

Date of Signature: \_\_\_\_\_

## IE=Inclusion/Exclusion Criteria Not Met

### 2.15 Inclusion/Exclusion Criteria

Subject ID: _____	CRF status: <input type="radio"/> Not submitted <input type="radio"/> In review <input type="radio"/> Locked <input type="radio"/> Frozen <input type="radio"/> Signed by PI
Study site name: _____	Study site No.: _____
Investigator name: _____	Investigator ID: _____
Visit: screening period (D-7 to D-1)	Visit No.: 2
Inclusion/Exclusion criteria	
Did the subject meet all inclusion criteria and not meet any of the exclusion criteria? <input type="radio"/> No <input type="radio"/> Yes	

**[NOT SUBMITTED]**

**IECAT=Inclusion**

**IETEST**

No.	Inclusion criteria	Met or not?
<b>IESPID</b>	<b>IETESTCD</b>	<b>IEORRES</b>
1	With pathologically or cytologically confirmed gastric cancer (GC) or gastroesophageal junction carcinoma (GEJ) with evidence of being unresectable, locally advanced, or metastatic, and was histologically confirmed adenocarcinoma	<input type="radio"/> No <input type="radio"/> Yes
2	Aged 18 or above, male or female	<input type="radio"/> No <input type="radio"/> Yes
3	Patients who have not received systemic treatment (including HER-2 inhibitors) for advanced or metastatic GC / GEJ. Subjects who once received adjuvant or neoadjuvant therapy (including chemotherapy, radiotherapy, or radiochemotherapy) for GC/GEJ must have completed the last treatment at least 6 months prior to the first study treatment. Palliative radiotherapy is permitted, but it must be completed 2 weeks prior to the start of study treatment	<input type="radio"/> No <input type="radio"/> Yes
4	With an Eastern Cooperative Oncology Group (ECOG) PS score of 0-1	<input type="radio"/> No <input type="radio"/> Yes
5	With measurable lesion as per RECIST v1.1	<input type="radio"/> No <input type="radio"/> Yes
6	With a life expectancy of > 12 weeks	<input type="radio"/> No <input type="radio"/> Yes
7	All acute toxicities due to previous anti-cancer treatments or surgeries have resolved to Grade 0-1 (as per NCI CTCAE v4.03) or to the level specified in the inclusion/exclusion criteria, except for other toxicities such as alopecia that do not pose a safety risk on the patient as assessed by the investigator	<input type="radio"/> No <input type="radio"/> Yes

# IE=Inclusion/Exclusion Criteria Not Met

**IECAT=Inclusion**

**IETEST**

No.	Inclusion criteria	Met or not?
<b>IESPID</b>	<b>IETESTCD</b>	<b>IEORRES</b>
8a	With adequate organ and bone marrow functions, as defined below: a) Absolute neutrophil count (ANC) $\geq 1,500/\text{mm}^3$ ( $1.5 \times 10^9/\text{L}$ )	<input type="radio"/> No <input type="radio"/> Yes
8b	With adequate organ and bone marrow functions, as defined below: b) Platelet count (PLT) $\geq 100,000/\text{mm}^3$ ( $100 \times 10^9/\text{L}$ )	<input type="radio"/> No <input type="radio"/> Yes
8c	With adequate organ and bone marrow functions, as defined below: c) Hemoglobin (Hb) $\geq 9$ g/dL (90 g/L)	<input type="radio"/> No <input type="radio"/> Yes
8d	With adequate organ and bone marrow functions, as defined below: d) Serum creatinine $\leq 1.5 \times$ the upper limit of normal (ULN) or creatinine clearance $\geq 60$ mL/min	<input type="radio"/> No <input type="radio"/> Yes
8e	With adequate organ and bone marrow functions, as defined below: e) Total bilirubin (BIL) $\leq 1.5 \times$ ULN	<input type="radio"/> No <input type="radio"/> Yes
8f	With adequate organ and bone marrow functions, as defined below: f) Aspartate aminotransferase (AST/SGOT) or alanine aminotransferase (ALT/SGPT) $\leq 2.5 \times$ ULN; ALT and AST $\leq 5 \times$ ULN in case of liver metastasis	<input type="radio"/> No <input type="radio"/> Yes
8g	With adequate organ and bone marrow functions, as defined below: g) International normalized ratio (INR) $\leq 1.5$ , and prothrombin time (PT) and activated partial thromboplastin time (APTT) $\leq 1.5 \times$ ULN	<input type="radio"/> No <input type="radio"/> Yes
8 h	Adequate organ and bone marrow functions, as defined below: h) Urine protein $< 2+$ ; If urine protein is $\geq 2+$ , then the 24-hour urine protein must be $\leq 1$ g	<input type="radio"/> No <input type="radio"/> Yes
8i	With adequate organ and bone marrow functions, as defined below: i) Thyroid stimulating hormone (TSH) $\leq$ ULN; in case of abnormalities, T3 and T4 levels should be normal	<input type="radio"/> No <input type="radio"/> Yes

# IE=Inclusion/Exclusion Criteria Not Met

IECAT=Inclusion

No.	IESPID	Inclusion criteria	ETESTCD	ETEST	Met or not?	IEORRES
9		Woman of childbearing potential must have a negative serum pregnancy test within 3 days prior to the first dose, and be willing to use a recognized effective contraceptive measure (such as: intra-uterine contraceptive devices, contraceptive pills, or condoms) during the study and within 3 months after the last dose of study drug; male subjects with partners of childbearing potential must either be surgically sterilized or agree to take effective contraceptive measures during the study and within 3 months after the last dose of study drug			<input type="radio"/> No <input type="radio"/> Yes	
10		Subjects must agree and have signed the informed consent form, be willing and able to follow the scheduled visits, study treatment, laboratory test, and other study procedures			<input type="radio"/> No <input type="radio"/> Yes	

Only subjects who met all inclusion criteria (all "Yes" for inclusion criteria) can be enrolled

IECAT=Exclusion

No.	IESPID	Exclusion criteria	ETESTCD	ETEST	Met or not?	IEORRES
1		Known HER2-positive			<input type="radio"/> No <input type="radio"/> Yes	
2		Previously received PD-1/PD-L1 antibodies, CTLA-4 antibodies, or other treatments targeting PD-1/PD-L1 and/or VEGFR inhibitors			<input type="radio"/> No <input type="radio"/> Yes	
3		With known history of allergies to the study drugs or their excipients; with serious allergic reactions to other monoclonal antibodies			<input type="radio"/> No <input type="radio"/> Yes	
4		Having been treated by immunosuppressive drugs within 14 days prior to the first dose of SHR-1210, excluding intranasal and inhaled corticosteroids or systemic steroids of physiological doses (i.e., no more than 10 mg/d of prednisolone or equivalent physiological doses of other corticosteroids)			<input type="radio"/> No <input type="radio"/> Yes	
5		Having received live, attenuated vaccines within 4 weeks before the first dose or having such vaccination plan during the study.			<input type="radio"/> No <input type="radio"/> Yes	

# IE=Inclusion/Exclusion Criteria Not Met

IECAT=Exclusion

No.	IESPID	Exclusion criteria	IE TEST CD	IE TEST	Met or not?	IE OR RES
6		Presence of known uncontrolled or symptomatic active central nervous system (CNS) metastases, manifested as clinical symptoms, cerebral edema, spinal cord compression, carcinomatous meningitis, leptomeningeal disease, and/or progressive growth. With a history of central nervous system metastases or spinal cord compression, unless they were clearly treated and clinically stable 4 weeks after discontinuation of anticonvulsants and steroids before the first dose of study treatment			<input type="radio"/> No <input type="radio"/> Yes	
7		Presence of > grade 1 peripheral neuropathy			<input type="radio"/> No <input type="radio"/> Yes	
8		With advanced diseases that were symptomatic, disseminated to viscera, and at risk of life-threatening complications in the short term (including uncontrollable massive [pleural, pericardial, and abdominal] exudate, pulmonary lymphangitis, and more than 30% hepatic involvement)			<input type="radio"/> No <input type="radio"/> Yes	
9		Presence of any active autoimmune diseases or a history of autoimmune diseases (including but not limited to: autoimmune hepatitis, interstitial pneumonia, uveitis, enteritis, hepatitis, hypophysitis, vasculitis, nephritis, hyperthyroidism, hypothyroidism; adult patient with vitiligo or completely relieved childhood asthma may be enrolled if they did not require any intervention; patient with asthma requiring medical intervention with bronchodilators must not be enrolled)			<input type="radio"/> No <input type="radio"/> Yes	
10		Have been diagnosed with any other malignancies within 3 years before the enrollment, excluding adequately treated basal cell carcinoma or squamous cell skin cancer, or cervical carcinoma <i>in situ</i>			<input type="radio"/> No <input type="radio"/> Yes	
11		Infected with human immunodeficiency virus (HIV) or with known acquired immunodeficiency syndrome (AIDS), active hepatitis B (HBV DNA $\geq$ 500 IU/mL), hepatitis C (hepatitis C antibody being positive and HCV-RNA being above the lower limit of detection of the assay), or co-infection of hepatitis B and C			<input type="radio"/> No <input type="radio"/> Yes	



# IE=Inclusion/Exclusion Criteria Not Met

IECAT=Exclusion

No.	IESPID	Exclusion criteria	IE TEST CD	IE TEST	Met or not?	IE OR RES
12		With any of the following conditions observed within 6 months prior to enrollment: myocardial infarction, severe/unstable angina, NYHA Class > II cardiac insufficiency, poorly controlled arrhythmia (including males with QTcF > 450 ms and females with QTcF > 470 ms, QTcF interval calculated with the Fridericia's formula), symptomatic congestive cardiac failure, or cerebrovascular accident (including transient ischemic attack or symptomatic pulmonary embolism)			<input type="radio"/> No <input type="radio"/> Yes	
13		Had hypertension uncontrolled by antihypertensives (systolic blood pressure > 140 mmHg or diastolic blood pressure > 90 mmHg)			<input type="radio"/> No <input type="radio"/> Yes	
14		Had abnormal coagulation function (INR > 1.5 or APTT > 1.5 × ULN), bleeding tendency, or was receiving thrombolytics or anticoagulant therapy			<input type="radio"/> No <input type="radio"/> Yes	
15		With known hereditary or acquired hemorrhage and thrombophilia (such as hemophilia, coagulopathy, thrombocytopenia, and hypersplenism)			<input type="radio"/> No <input type="radio"/> Yes	
16		With obvious hemoptysis or a daily amount of hemoptysis of half a teaspoon (2.5 mL) or more within 2 months before the enrollment			<input type="radio"/> No <input type="radio"/> Yes	
17		With clinically significant hemorrhage symptoms or clear bleeding tendency within 3 months prior to participation in this study, such as GI bleeding, hemorrhagic gastric ulcer, baseline fecal occult blood++ and above, or vasculitis			<input type="radio"/> No <input type="radio"/> Yes	
18		Had events of arterial/venous thrombosis within 6 months prior to participation in this study, such as cerebrovascular accidents (including transient ischemic attacks, cerebral hemorrhage, cerebral infarction), deep vein thrombosis, and pulmonary embolism			<input type="radio"/> No <input type="radio"/> Yes	
19		With known hereditary or acquired hemorrhage and thrombophilia (such as hemophilia, coagulopathy, thrombocytopenia, and hypersplenism)			<input type="radio"/> No <input type="radio"/> Yes	
20		Required long-term anticoagulant therapy with warfarin or heparin; or requiring long-term antiplatelet therapy (aspirin ≥ 300 mg/day or clopidogrel ≥ 75 mg/day)			<input type="radio"/> No <input type="radio"/> Yes	

# IE=Inclusion/Exclusion Criteria Not Met

IECAT=Exclusion

No.	IESPID	Exclusion criteria	IETESTCD	IETEST	Met or not?	IEORRES
21		Had concurrent severe infection (such as one requiring intravenous infusion of antibiotics, antifungals, or antivirals) within 4 weeks prior to the first dose, or any unexplained fever of > 38.5 °C observed during screening period/prior to the first dose			<input type="radio"/> No <input type="radio"/> Yes	
22		With known history of allogeneic organ transplantation or allogeneic hematopoietic stem cell transplantation			<input type="radio"/> No <input type="radio"/> Yes	
23		Have participated in clinical trials concerning any other drugs within 4 weeks prior to the first dose, or less than 5 half-lives from the last dose of study drug			<input type="radio"/> No <input type="radio"/> Yes	
24		With a known history of psychotropic substance abuse or drug abuse			<input type="radio"/> No <input type="radio"/> Yes	
25		Had other severe physical or psychiatric disorders or laboratory abnormalities that may increase the risk of participation in the study or interfere with the study results, or was deemed unsuitable by the investigator			<input type="radio"/> No <input type="radio"/> Yes	

Only subjects who did not meet any of the exclusion criteria (all "No" for exclusion criteria) could be enrolled

Name of PI: \_\_\_\_\_

Account: \_\_\_\_\_

Date of Signature: \_\_\_\_\_

DS=Disposition

## 2.16 Enrollment Information

DSCAT=PROTOCOL MILESTONE  
when DSDECOD=ENROLLED or DSDECOD=RANDOMIZED

Subject ID: _____	CRF status: <input type="radio"/> Not submitted <input type="radio"/> In review <input type="radio"/> Locked <input type="radio"/> Frozen <input type="radio"/> Signed by PI
Study site name: _____	Study site No.: _____
Investigator name: _____	Investigator ID: _____
Visit: screening period (D-7 to D-1)	Visit No.: _____
Enrollment information	
Passed the screening or not? <input type="radio"/> Passed <input type="radio"/> Failed	DSDECOD=SCREEN FAILURE
DSCAT=DISPOSITION EVENT	
Main reason for exclusion: <input type="radio"/> Adverse event <input type="radio"/> Failed to meet inclusion criteria/met exclusion criteria <input type="radio"/> Lost to follow-up <input type="radio"/> Withdrawn by subject <input type="radio"/> Others	
Description of other reasons: DSTERM when DSDECOD=OTHER	
Date of randomization/enrollment: _____ (DD-MM-YYYY) DSSTDTC when DSDECOD=RANDOMIZED	
Randomization No.: QVAL when SUPPDM.QNAM=RANNUM	
Group: <input type="radio"/> Sequential therapy of SHR-1210 + capecitabine + oxaliplatin <input type="radio"/> SHR-1210 + apatinib ARM	

DSTERM

DSSCAT=End of Study when Adverse event or Loss to follow-up or Withdrawn by subject or Others

Name of PI: \_\_\_\_\_

Account: \_\_\_\_\_

Date of Signature: \_\_\_\_\_

SV=Subject Visits

Same as Page 3

### 3 C1\_D1

#### 3.1 Date of Visit

Subject ID: _____	CRF status: <input type="radio"/> Not submitted <input type="radio"/> In review <input type="radio"/> Locked <input type="radio"/> Frozen <input type="radio"/> Signed by PI
Study site name: _____	Study site No.: _____
Investigator name: _____	Investigator ID: _____
Visit: C1_D1	Visit No.: 3
Date of visit	
Date of visit: _____(DD-MM-YYYY)	

Name of PI: \_\_\_\_\_

Account: \_\_\_\_\_

Date of Signature: \_\_\_\_\_

### 3.2 ECOG PS Score

Subject ID: _____	CRF status: <input type="radio"/> Not submitted <input type="radio"/> In review <input type="radio"/> Locked <input type="radio"/> Frozen <input type="radio"/> Signed by PI
Study site name: _____	Study site No.: _____
Investigator name: _____	Investigator ID: _____
Visit: C1_D1	Visit No.: 3
ECOG PS score	
ECOG PS scoring: <input type="radio"/> Not performed	
Scoring date: _____ (DD-MM-YYYY)	
<p>ECOG PS score: <input type="radio"/> 0 point: Fully active, able to carry on all pre-disease performance without restriction <input type="radio"/> 1 point: Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work <input type="radio"/> 2 points: Ambulatory and capable of all selfcare but unable to carry out any work activities; up and about more than 50% of waking hours <input type="radio"/> 3 points: Capable of only limited selfcare, confined to bed or chair for more than 50% of waking hours <input type="radio"/> 4 points: Completely disabled, cannot carry on any selfcare, totally confined to bed or chair</p>	

Name of PI: \_\_\_\_\_

Account: \_\_\_\_\_

Date of Signature: \_\_\_\_\_

**3.3 Vital Signs**

Subject ID: _____	CRF status: <input type="radio"/> Not submitted <input type="radio"/> In review <input type="radio"/> Locked <input type="radio"/> Frozen <input type="radio"/> Signed by PI
Study site name: _____	Study site No.: _____
Investigator name: _____	Investigator ID: _____
Visit: C1_D1	Visit No.: 3
<b>Vital signs</b>	
Vital signs measurement: <input type="radio"/> Not performed	
Measurement date: _____(DD-MM-YYYY)	

No.	Measurement item	Result	Note
1	Temperature (°C)		
2	Pulse rate (beats/min)		
3	Respiratory rate (resp/min)		
4	Diastolic blood pressure (mmHg)		
5	Systolic blood pressure (mmHg)		

Name of PI: \_\_\_\_\_

Account: \_\_\_\_\_

Date of Signature: \_\_\_\_\_

**3.4 Physical Examination**

Subject ID: _____	CRF status: <input type="radio"/> Not submitted <input type="radio"/> In review <input type="radio"/> Locked <input type="radio"/> Frozen <input type="radio"/> Signed by PI
Study site name: _____	Study site No.: _____
Investigator name: _____	Investigator ID: _____
Visit: C1_D1	Visit No.: 3
Physical examination	
Physical examination: <input type="radio"/> Not performed	
Examination date: _____(DD-MM-YYYY)	

No.	Physical examination item	Result	If abnormal, please describe
1	General status	<input type="radio"/> Normal <input type="radio"/> Abnormal <input type="radio"/> Not examined	
2	Head and face	<input type="radio"/> Normal <input type="radio"/> Abnormal <input type="radio"/> Not examined	
3	Skin	<input type="radio"/> Normal <input type="radio"/> Abnormal <input type="radio"/> Not examined	
4	Lymph nodes	<input type="radio"/> Normal <input type="radio"/> Abnormal <input type="radio"/> Not examined	
5	Eyes	<input type="radio"/> Normal <input type="radio"/> Abnormal <input type="radio"/> Not examined	
6	Ears, nose, and throat	<input type="radio"/> Normal <input type="radio"/> Abnormal <input type="radio"/> Not examined	
7	Oral cavity	<input type="radio"/> Normal <input type="radio"/> Abnormal <input type="radio"/> Not examined	
8	Respiratory system	<input type="radio"/> Normal <input type="radio"/> Abnormal <input type="radio"/> Not examined	
9	Cardiovascular system	<input type="radio"/> Normal <input type="radio"/> Abnormal <input type="radio"/> Not examined	
10	Abdomen	<input type="radio"/> Normal <input type="radio"/> Abnormal <input type="radio"/> Not examined	
11	Reproductive-urinary system	<input type="radio"/> Normal <input type="radio"/> Abnormal <input type="radio"/> Not examined	
12	Musculoskeletal system	<input type="radio"/> Normal <input type="radio"/> Abnormal <input type="radio"/> Not examined	

PE=Physical Examination

Same as Page 19

No.	Physical examination item	Result	If abnormal, please describe
13	Nervous system	<input type="radio"/> Normal <input type="radio"/> Abnormal <input type="radio"/> Not examined	
14	Mental state	<input type="radio"/> Normal <input type="radio"/> Abnormal <input type="radio"/> Not examined	
15	Others	<input type="radio"/> Normal <input type="radio"/> Abnormal <input type="radio"/> Not examined	

Name of PI: \_\_\_\_\_

Account: \_\_\_\_\_

Date of Signature: \_\_\_\_\_



**3.5 Hematology**

Subject ID: _____	CRF status: <input type="radio"/> Not submitted <input type="radio"/> In review <input type="radio"/> Locked <input type="radio"/> Frozen <input type="radio"/> Signed by PI
Study site name: _____	Study site No.: _____
Investigator name: _____	Investigator ID: _____
Visit: C1_D1	Visit No.: 3
<b>Laboratory test</b>	
Laboratory test category: hematology	
This test: <input type="radio"/> Not performed	
Sampling date: _____ (DD-MM-YYYY)	
LAB name: <input type="radio"/> Central laboratory 1 <input type="radio"/> Central laboratory 2 <input type="radio"/> Central laboratory 3 <input type="radio"/> Central laboratory 4 <input type="radio"/> Central laboratory 5 <input type="radio"/> Others	
Others, please specify: _____	

No.	Laboratory test item	Measured value	Unit	Determination of clinical significance	Note
1	Red blood cell count (RBC)		$\circ 10^{12}/L$	<input type="radio"/> Normal <input type="radio"/> Abnormal without clinical significance <input type="radio"/> Abnormal with clinical significance <input type="radio"/> Not tested	
2	Hemoglobin (Hb)		$\circ g/L$	<input type="radio"/> Normal <input type="radio"/> Abnormal without clinical significance <input type="radio"/> Abnormal with clinical significance <input type="radio"/> Not tested	
3	Platelet count (PLT)		$\circ 10^9/L$	<input type="radio"/> Normal <input type="radio"/> Abnormal without clinical significance <input type="radio"/> Abnormal with clinical significance <input type="radio"/> Not tested	
4	White blood cell count (WBC)		$\circ 10^9/L$	<input type="radio"/> Normal <input type="radio"/> Abnormal without clinical significance <input type="radio"/> Abnormal with clinical significance <input type="radio"/> Not tested	
5	Absolute neutrophil count (ANC)		$\circ 10^9/L$	<input type="radio"/> Normal <input type="radio"/> Abnormal without clinical significance <input type="radio"/> Abnormal with clinical significance <input type="radio"/> Not tested	

No.	Laboratory test item	Measured value	Unit	Determination of clinical significance	Note
6	Lymphocyte count (LYM)		$\times 10^9/L$	<ul style="list-style-type: none"><li>○ Normal</li><li>○ Abnormal without clinical significance</li><li>○ Abnormal with clinical significance</li><li>○ Not tested</li></ul>	

Name of PI: \_\_\_\_\_

Account: \_\_\_\_\_

Date of Signature: \_\_\_\_\_

**3.6 Urinalysis**

Subject ID: _____	CRF status: <input type="radio"/> Not submitted <input type="radio"/> In review <input type="radio"/> Locked <input type="radio"/> Frozen <input type="radio"/> Signed by PI
Study site name: _____	Study site No.: _____
Investigator name: _____	Investigator ID: _____
Visit: C1_D1	Visit No.: 3
<b>Laboratory test</b>	
Laboratory test category: urinalysis	
This test: <input type="radio"/> Not performed	
Sampling date: _____ (DD-MM-YYYY)	
LAB name: <input type="radio"/> Central laboratory 1 <input type="radio"/> Central laboratory 2 <input type="radio"/> Central laboratory 3 <input type="radio"/> Central laboratory 4 <input type="radio"/> Central laboratory 5 <input type="radio"/> Others	
Others, please specify: _____	

No.	Laboratory test item	Measured value	Unit	Determination of clinical significance	Note
1	Urine white blood cells (WBC)		<input type="radio"/> cells/ $\mu$ L <input type="radio"/> /HP	<input type="radio"/> Normal <input type="radio"/> Abnormal without clinical significance <input type="radio"/> Abnormal with clinical significance <input type="radio"/> Not tested	
2	Urine red blood cells (RBC)		<input type="radio"/> cells/ $\mu$ L <input type="radio"/> /HP	<input type="radio"/> Normal <input type="radio"/> Abnormal without clinical significance <input type="radio"/> Abnormal with clinical significance <input type="radio"/> Not tested	
3	Urine protein (PRO)		<input type="radio"/> mg/L <input type="radio"/> Qualitative <input type="radio"/> g/L	<input type="radio"/> Normal <input type="radio"/> Abnormal without clinical significance <input type="radio"/> Abnormal with clinical significance <input type="radio"/> Not tested	

Name of PI: \_\_\_\_\_

Account: \_\_\_\_\_

Date of Signature: \_\_\_\_\_

**3.7 24-h Urine Protein Quantitation**

Subject ID: _____	CRF status: <input type="radio"/> Not submitted <input type="radio"/> In review <input type="radio"/> Locked <input type="radio"/> Frozen <input type="radio"/> Signed by PI
Study site name: _____	Study site No.: _____
Investigator name: _____	Investigator ID: _____
Visit: C1_D1	Visit No.: 3
<b>Laboratory test</b>	
Laboratory test category: 24-h urine protein quantitation	
This test: <input type="radio"/> Not performed	
Sampling date: _____ (DD-MM-YYYY)	
LAB name: <input type="radio"/> Central laboratory 1 <input type="radio"/> Central laboratory 2 <input type="radio"/> Central laboratory 3 <input type="radio"/> Central laboratory 4 <input type="radio"/> Central laboratory 5 <input type="radio"/> Others	
Others, please specify: _____	

No.	Laboratory test item	Measured value	Unit	Determination of clinical significance	Note
1	24-h urine protein measurement		<input type="radio"/> mg/24 h <input type="radio"/> g/24 h	<input type="radio"/> Normal <input type="radio"/> Abnormal without clinical significance <input type="radio"/> Abnormal with clinical significance <input type="radio"/> Not tested	

Name of PI: \_\_\_\_\_

Account: \_\_\_\_\_

Date of Signature: \_\_\_\_\_

## 3.8 Clinical Chemistry

Subject ID: _____	CRF status: <input type="radio"/> Not submitted <input type="radio"/> In review <input type="radio"/> Locked <input type="radio"/> Frozen <input type="radio"/> Signed by PI
Study site name: _____	Study site No.: _____
Investigator name: _____	Investigator ID: _____
Visit: C1_D1	Visit No.: 3
Laboratory test	
Laboratory test category: clinical chemistry	
This test: <input type="radio"/> Not performed	
Sampling date: _____ (DD-MM-YYYY)	
LAB name: <input type="radio"/> Central laboratory 1 <input type="radio"/> Central laboratory 2 <input type="radio"/> Central laboratory 3 <input type="radio"/> Central laboratory 4 <input type="radio"/> Central laboratory 5 <input type="radio"/> Others	
Others, please specify: _____	

No.	Laboratory test item	Measured value	Unit	Determination of clinical significance	Note
1	Alanine aminotransferase (ALT)		<input type="radio"/> U/L <input type="radio"/> IU/L	<input type="radio"/> Normal <input type="radio"/> Abnormal without clinical significance <input type="radio"/> Abnormal with clinical significance <input type="radio"/> Not tested	
2	Aspartate aminotransferase (AST)		<input type="radio"/> U/L <input type="radio"/> IU/L	<input type="radio"/> Normal <input type="radio"/> Abnormal without clinical significance <input type="radio"/> Abnormal with clinical significance <input type="radio"/> Not tested	
3	Gamma glutamyl transpeptidase (GGT)		<input type="radio"/> U/L <input type="radio"/> IU/L	<input type="radio"/> Normal <input type="radio"/> Abnormal without clinical significance <input type="radio"/> Abnormal with clinical significance <input type="radio"/> Not tested	
4	Total bilirubin (TBIL)		<input type="radio"/> $\mu\text{mol/L}$	<input type="radio"/> Normal <input type="radio"/> Abnormal without clinical significance <input type="radio"/> Abnormal with clinical significance <input type="radio"/> Not tested	
5	Direct bilirubin (DBIL)		<input type="radio"/> $\mu\text{mol/L}$	<input type="radio"/> Normal <input type="radio"/> Abnormal without clinical significance <input type="radio"/> Abnormal with clinical significance <input type="radio"/> Not tested	

No.	Laboratory test item	Measured value	Unit	Determination of clinical significance	Note
6	Alkaline phosphatase (AKP)		○ U/L ○ IU/L	○ Normal ○ Abnormal without clinical significance ○ Abnormal with clinical significance ○ Not tested	
7	Blood urea nitrogen (BUN)		○ mmol/L	○ Normal ○ Abnormal without clinical significance ○ Abnormal with clinical significance ○ Not tested	
8	Urea		○ mmol/L	○ Normal ○ Abnormal without clinical significance ○ Abnormal with clinical significance ○ Not tested	
9	Total protein (TP)		○ g/L	○ Normal ○ Abnormal without clinical significance ○ Abnormal with clinical significance ○ Not tested	
10	Albumin (ALB)		○ g/L	○ Normal ○ Abnormal without clinical significance ○ Abnormal with clinical significance ○ Not tested	
11	Creatinine (Cr)		○ μmol/L	○ Normal ○ Abnormal without clinical significance ○ Abnormal with clinical significance ○ Not tested	
12	Blood glucose (GLU)		○ mmol/L	○ Normal ○ Abnormal without clinical significance ○ Abnormal with clinical significance ○ Not tested	
13	Potassium (K)		○ mmol/L	○ Normal ○ Abnormal without clinical significance ○ Abnormal with clinical significance ○ Not tested	

# LB=Laboratory Test Results

Same as Page 27

No.	Laboratory test item	Measured value	Unit	Determination of clinical significance	Note
14	Sodium (Na)		○ mmol/L	<input type="radio"/> Normal <input type="radio"/> Abnormal without clinical significance <input type="radio"/> Abnormal with clinical significance <input type="radio"/> Not tested	
15	Calcium (Ca)		○ mmol/L	<input type="radio"/> Normal <input type="radio"/> Abnormal without clinical significance <input type="radio"/> Abnormal with clinical significance <input type="radio"/> Not tested	
16	Magnesium (Mg)		○ mmol/L	<input type="radio"/> Normal <input type="radio"/> Abnormal without clinical significance <input type="radio"/> Abnormal with clinical significance <input type="radio"/> Not tested	
17	Chlorine (Cl)		○ mmol/L	<input type="radio"/> Normal <input type="radio"/> Abnormal without clinical significance <input type="radio"/> Abnormal with clinical significance <input type="radio"/> Not tested	

Name of PI: \_\_\_\_\_

Account: \_\_\_\_\_

Date of Signature: \_\_\_\_\_

**3.9 Thyroid function**

Subject ID: _____	CRF status: <input type="radio"/> Not submitted <input type="radio"/> In review <input type="radio"/> Locked <input type="radio"/> Frozen <input type="radio"/> Signed by PI
Study site name: _____	Study site No.: _____
Investigator name: _____	Investigator ID: _____
Visit: C1_D1	Visit No.: 3
<b>Laboratory test</b>	
Laboratory test category: thyroid function	
This test: <input type="radio"/> Not performed	
Sampling date: _____ (DD-MM-YYYY)	
LAB name: <input type="radio"/> Central laboratory 1 <input type="radio"/> Central laboratory 2 <input type="radio"/> Central laboratory 3 <input type="radio"/> Central laboratory 4 <input type="radio"/> Central laboratory 5 <input type="radio"/> Others	
Others, please specify: _____	

No.	Laboratory test item	Measured value	Unit	Determination of clinical significance	Note
1	Thyroid stimulating hormone (TSH)		<input type="radio"/> mIU/L <input type="radio"/> µIU/mL	<input type="radio"/> Normal <input type="radio"/> Abnormal without clinical significance <input type="radio"/> Abnormal with clinical significance <input type="radio"/> Not tested	
2	Free triiodothyronine (FT3)		<input type="radio"/> pmol/L <input type="radio"/> ng/dL <input type="radio"/> pg/mL	<input type="radio"/> Normal <input type="radio"/> Abnormal without clinical significance <input type="radio"/> Abnormal with clinical significance <input type="radio"/> Not tested	
3	Free thyroxine (FT4)		<input type="radio"/> pmol/L <input type="radio"/> ng/dL <input type="radio"/> pg/mL	<input type="radio"/> Normal <input type="radio"/> Abnormal without clinical significance <input type="radio"/> Abnormal with clinical significance <input type="radio"/> Not tested	
4	Triiodothyronine (T3)		<input type="radio"/> nmol/L <input type="radio"/> ng/mL <input type="radio"/> pg/mL	<input type="radio"/> Normal <input type="radio"/> Abnormal without clinical significance <input type="radio"/> Abnormal with clinical significance <input type="radio"/> Not tested	



LB=Laboratory Test Results

Same as Page 29

No.	Laboratory test item	Measured value	Unit	Determination of clinical significance	Note
5	Thyroxine (T4)		<ul style="list-style-type: none"><li>○ nmol/L</li><li>○ ug/dL</li><li>○ pg/mL</li></ul>	<ul style="list-style-type: none"><li>○ Normal</li><li>○ Abnormal without clinical significance</li><li>○ Abnormal with clinical significance</li><li>○ Not tested</li></ul>	

Name of PI: \_\_\_\_\_

Account: \_\_\_\_\_

Date of Signature: \_\_\_\_\_

**3.10 Coagulation function**

Subject ID: _____	CRF status: <input type="radio"/> Not submitted <input type="radio"/> In review <input type="radio"/> Locked <input type="radio"/> Frozen <input type="radio"/> Signed by PI
Study site name: _____	Study site No.: _____
Investigator name: _____	Investigator ID: _____
Visit: C1_D1	Visit No.: 3
<b>Laboratory test</b>	
Laboratory test category: coagulation function	
This test: <input type="radio"/> Not performed	
Sampling date: _____ (DD-MM-YYYY)	
LAB name: <input type="radio"/> Central laboratory 1 <input type="radio"/> Central laboratory 2 <input type="radio"/> Central laboratory 3 <input type="radio"/> Central laboratory 4 <input type="radio"/> Central laboratory 5 <input type="radio"/> Others	
Others, please specify: _____	

No.	Laboratory test item	Measured value	Unit	Determination of clinical significance	Note
1	Activated partial thromboplastin time (APTT)		<input type="radio"/> sec	<input type="radio"/> Normal <input type="radio"/> Abnormal without clinical significance <input type="radio"/> Abnormal with clinical significance <input type="radio"/> Not tested	
2	Prothrombin time (PT)		<input type="radio"/> sec	<input type="radio"/> Normal <input type="radio"/> Abnormal without clinical significance <input type="radio"/> Abnormal with clinical significance <input type="radio"/> Not tested	
3	Thrombin time (TT)		<input type="radio"/> sec	<input type="radio"/> Normal <input type="radio"/> Abnormal without clinical significance <input type="radio"/> Abnormal with clinical significance <input type="radio"/> Not tested	
4	Fibrinogen (FIB)		<input type="radio"/> g/L <input type="radio"/> mg/dL	<input type="radio"/> Normal <input type="radio"/> Abnormal without clinical significance <input type="radio"/> Abnormal with clinical significance <input type="radio"/> Not tested	

No.	Laboratory test item	Measured value	Unit	Determination of clinical significance	Note
5	International normalized ratio (INR)			<ul style="list-style-type: none"><li>○ Normal</li><li>○ Abnormal without clinical significance</li><li>○ Abnormal with clinical significance</li><li>○ Not tested</li></ul>	

Name of PI: \_\_\_\_\_

Account: \_\_\_\_\_

Date of Signature: \_\_\_\_\_

**3.11 12-Lead ECG**

Subject ID: _____	CRF status: <input type="radio"/> Not submitted <input type="radio"/> In review <input type="radio"/> Locked <input type="radio"/> Frozen <input type="radio"/> Signed by PI
Study site name: _____	Study site No.: _____
Investigator name: _____	Investigator ID: _____
Visit: C1_D1	Visit No.: 3
<b>12-lead ECG</b>	
12-lead ECG: <input type="radio"/> Not performed	
Examination date: _____ (DD-MM-YYYY)	

No.	Examination item	Result	Unit
1	Heart rate		<input type="radio"/> bpm
2	PR		<input type="radio"/> ms
3	QT		<input type="radio"/> ms
4	QTc		<input type="radio"/> ms

12-lead ECG result: <input type="radio"/> Normal <input type="radio"/> Abnormal without clinical significance <input type="radio"/> Abnormal with clinical significance
If abnormal, please describe: _____

Name of PI: \_\_\_\_\_

Account: \_\_\_\_\_

Date of Signature: \_\_\_\_\_

EX=Exposure

EXTRT=SHR-1210

### 3.12 SHR1210 Administration Record

ECTRT=SHR-1210

Subject ID: _____	CRF status: <input type="radio"/> Not submitted <input type="radio"/> In review <input type="radio"/> Locked <input type="radio"/> Frozen <input type="radio"/> Signed by PI
Study site name: _____	Study site No.: _____
Investigator name: _____	Investigator ID: _____
Visit: C1_D1 <b>VISIT</b>	Visit No.: 3
SHR1210 administration record	
SHR-1210 intravenous drip infusion: <input type="radio"/> Not administered	<b>ECSTAT</b>
Initiation date of administration: _____(DD-MM-YYYY)	date of EXSTDTC date of ECSTDTC
Start time: _____(hh: mm)	time of EXSTDTC time of ECSTDTC
Completion date of administration: _____(DD-MM-YYYY)	date of EXENDTC date of ECENDTC
End time: _____(hh: mm)	time of EXENDTC time of ECENDTC
Did administration duration exceed 60 min? <input type="radio"/> No <input type="radio"/> Yes	QVAL when SUPPEC.QNAM=ECEXCE
Reason for exceeding: <input type="radio"/> AE <input type="radio"/> Management factors <input type="radio"/> Others	QVAL when SUPPEC.QNAM=ECEXCRES
Please specify for other reasons: _____	QVAL when SUPPEC.QNAM=ECEXCREO
Was the 200 mg administration completed? <input type="radio"/> No <input type="radio"/> Yes	QVAL when SUPPEC.QNAM=ECCOMP
Reason for incompleteness: <input type="radio"/> AE <input type="radio"/> Others	QVAL when SUPPEC.QNAM=ECICOMRE
Please specify for other reasons: _____	QVAL when SUPPEC.QNAM=ECICOMRO
Percentage of actual dose (%): _____	QVAL when SUPPEC.QNAM=ECPACT
Note: _____	QVAL when SUPPEC.QNAM=ECNOTE

SVSTDTC

Name of PI: \_\_\_\_\_

Account: \_\_\_\_\_

Date of Signature: \_\_\_\_\_

DA=Drug Accountability

EXTRT=Capecitabine

DACAT=Capecitabine

ECTRT=Capecitabine

### 3.13 Capecitabine Dispensation/Return

Subject ID: _____	CRF status: <input type="radio"/> Not submitted <input type="radio"/> In review <input type="radio"/> Locked <input type="radio"/> Frozen <input type="radio"/> Signed by PI	
Study site name: _____	Study site No.: _____	
Investigator name: _____	Investigator ID: _____	
Visit: C1_D1	Visit No.: 3	
Capecitabine dispensation/return		
Drug dispensation: <input type="radio"/> None	[NOT SUBMITTED]	
Date of dispensation: _____ (DD-MM-YYYY)	DADTC when DATESTCD=DISPAMT	
Amount dispensed (0.5 g/tablet): _____	DAORRES when DATESTCD=DISPAMT	DASCAT when DATESTCD=DISPAMT
Amount dispensed (0.15 g/tablet): _____		
Date of first dose: _____ (DD-MM-YYYY)	EXSTDTC	ECSTDTC
Note: _____	OVAL when SUPPDA.QNAM=DANOTE	

Name of PI: \_\_\_\_\_

Account: \_\_\_\_\_

Date of Signature: \_\_\_\_\_