

RELEASE_PII_v1

RELEASE_v1

Subject Label Expression: SCREENINING_V:COVER_F:USUBJID

Date of Birth Expression: SCREENINING_V:DM_F:BRTHDTC

Gender Expression:

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Visit Schedule

VisitCode: SCREENINING_V VisitName: Screening, Repeats: 1

Form: COVER_F, Registration , Single
Form: SVSTDTC_DAY_F, Visit Date , Single, VisitDate eForm
Form: IETEST_F, Inclusion and Exclusion Criteria , Single
Form: RFIC_F, Informed Consent Signature , Single
Form: COVIDTEST_F, SARS-CoV-2 Testing , Single
Form: DM_F, Demographic Data , Single
Form: SYMPTOMS_F, Symptoms , Single
Form: ALLERGY_F, Allergies , Single
Form: PREV_MED_F, Previous and Concomitant Medication , Single
Form: MH_F, Past Medical/Surgical History , Single
Form: PEXAM_F, Physical Examination , Single
Form: VS_F, Vital Signs , Single
Form: RESPIR_F, Respiratory Status , Single
Form: RADIOGRAP_F, Radiographic Findings , Single
Form: LB_F, Laboratory , Single
Form: IMMUNO_F, Markers of Immunological Function , Single
Form: BLOOD_SAMP_F, Additional Blood Sample , Single
Form: PREGNANCY_F, Pregnancy Test , Single
Form: NEWS_SCALE_F, NEWS Scale , Single
Form: SCALE7POINT_F, 7-Point Ordinal Scale , Single
Form: RANDOM_F, Randomization , Single

VisitCode: D3_V VisitName: D3, Repeats: 1

Form: SVSTDTC_DAY_F, Visit Date , Single, VisitDate eForm
Form: PEXAM_F, Physical Examination , Single
Form: VS_F, Vital Signs , Single
Form: RESPIR_F, Respiratory Status , Single
Form: LB_F, Laboratory , Single
Form: BLOOD_SAMP_F, Additional Blood Sample , Single
Form: DONOR_F, Donor Chimerism , Single
Form: NEWS_SCALE_F, NEWS Scale , Single
Form: SCALE7POINT_F, 7-Point Ordinal Scale , Single
Form: CM_YN_F, Concomitant Medication , Single
Form: AE_YN_F, Adverse Events , Single

VisitCode: D7_V VisitName: D7, Repeats: 1

Form: SVSTDTC_DAY_F, Visit Date , Single, VisitDate eForm
Form: COVIDTEST_F, SARS-CoV-2 Testing , Single
Form: PEXAM_F, Physical Examination , Single
Form: VS_F, Vital Signs , Single
Form: RESPIR_F, Respiratory Status , Single
Form: LB_F, Laboratory , Single
Form: IMMUNO_F, Markers of Immunological Function , Single
Form: BLOOD_SAMP_F, Additional Blood Sample , Single
Form: DONOR_F, Donor Chimerism , Single
Form: NEWS_SCALE_F, NEWS Scale , Single
Form: SCALE7POINT_F, 7-Point Ordinal Scale , Single
Form: ADMIN2_F, Second Dose , Single
Form: CM_YN_F, Concomitant Medication , Single
Form: AE_YN_F, Adverse Events , Single

VisitCode: D14_V VisitName: D14, Repeats: 1

Form: SVSTDTC_DAY_F, Visit Date , Single, VisitDate eForm
Form: COVIDTEST_F, SARS-CoV-2 Testing , Single
Form: PEXAM_F, Physical Examination , Single
Form: VS_F, Vital Signs , Single
Form: RESPIR_F, Respiratory Status , Single
Form: LB_F, Laboratory , Single
Form: IMMUNO_F, Markers of Immunological Function , Single
Form: BLOOD_SAMP_F, Additional Blood Sample , Single
Form: DONOR_F, Donor Chimerism , Single
Form: NEWS_SCALE_F, NEWS Scale , Single
Form: SCALE7POINT_F, 7-Point Ordinal Scale , Single
Form: CM_YN_F, Concomitant Medication , Single
Form: AE_YN_F, Adverse Events , Single

VisitCode: D21_V VisitName: D21, Repeats: 1

Form: SVSTDTC_DAY_F, Visit Date , Single, VisitDate eForm
Form: COVIDTEST_F, SARS-CoV-2 Testing , Single
Form: PEXAM_F, Physical Examination , Single
Form: VS_F, Vital Signs , Single
Form: RESPIR_F, Respiratory Status , Single
Form: LB_F, Laboratory , Single
Form: IMMUNO_F, Markers of Immunological Function , Single
Form: BLOOD_SAMP_F, Additional Blood Sample , Single
Form: DONOR_F, Donor Chimerism , Single
Form: NEWS_SCALE_F, NEWS Scale , Single
Form: SCALE7POINT_F, 7-Point Ordinal Scale , Single
Form: CM_YN_F, Concomitant Medication , Single

CASE REPORT FORM PHASE I

A phase I/II dose-escalation multi center study to evaluate the safety of infusion of NatuRal KillEr cells or MEMory T cells as Adoptive therapy in coronavirus pnEunomia and/or lymphopenia

RELEASE

Center No

SITEID

Patient No

SUBJID

Patient ID

USUBJID

ID	CODE	NAME	EXP.CODE	TYPE	FMT/LEN	DERIVATION	CAT. VALUES
1	SITEID	SITEID	SITEID	Text	3	See Appendix	
2	SUBJID	SUBJID	SUBJID	Integer	#9	person:personid	
3	USUBJID	USUBJID	USUBJID	Text	6	SITEID & '1' & SUBJID	

Date

SVSTDTC

ID	CODE	NAME	EXP.CODE	TYPE	FMT/LEN	DERIVATION	CAT. VALUES
1	SVSTDTC	SVSTDTC	SVSTDTC	Date/Time	dd/mm/yyyy, Optional		

INCLUSION AND EXCLUSION CRITERIA

The following **INCLUSION CRITERIA SHOULD** be answered as **YES** to include the patient in the trial

1. Male and female patientes =< 80 years of age Yes **ICTEST_1**
 No
2. Patients with diagnosis of COVID-19 infection with laboratory confirmation by reverse-transcription PCR (RT-PCR) of SARS-CoV-2 prior to study entry Yes **ICTEST_2**
 No
3. Onset of symptoms < 12 days prior to administration of study treatment Yes **ICTEST_3**
 No
4. No more than 72 hours (3 days) of hospitalization before study treatment administration Yes **ICTEST_4**
 No
5. Patients requiring hospitalization with pneumonia diagnosed with chest radiograph or computed tomography imaging or lymphopenia (absolute lymphocyte counts below 1.2×10^9 cells/L) AND O2Sat =< 94 % on room air at screening, requiring or no oxygen supplementation (nasal cannula, oxygen mask with reservoir, non-invasive ventilation, etc), but excluding mechanical ventilation Yes **ICTEST_5**
 No
6. Have a negative pregnancy test documented prior to enrollment (for females of childbearing potential) Yes **ICTEST_6**
 No
 Not Applicable
7. Be willing and able to comply with study procedures Yes **ICTEST_7**
 No
8. Patients with the ability to comprehend and sign the informed consent Yes **ICTEST_8**
 No
9. Written informed consent obtained prior to any screening procedures Yes **ICTEST_9**
 No

The following **EXCLUSION CRITERIA SHOULD** be answered as **NO** to include the patient in the trial

1. Enrolled in another Clinical Trial for COVID19 Yes **IETEST_1**
 No
2. Rapidly progressive disease with anticipated life-expectancy < 72 hours Yes **IETEST_2**
 No
3. Patients requiring mechanical ventilation Yes **IETEST_3**
 No
4. Patients with multiorgan failure Yes **IETEST_4**
 No
5. Mild-moderate (grade ≥ 3) organ impairment (liver, kidney, respiratory) according to criteria from the National Cancer Institute (NCI CTCAE version 5.0) Yes **IETEST_5**
 No
6. Severe and/or uncontrolled concurrent medical disease that in opinion of the investigator could cause unacceptable safety risks or compromise compliance with the protocol Yes **IETEST_6**
 No
7. Have a known history of human immunodeficiency virus infection, Hepatitis B or Hepatitis C; testing is not required in the absence of prior documentation or known history Yes **IETEST_7**
 No
8. Pregnant or nursing (lactating) women, where pregnancy is defined as the state of a female after conception and until the termination of gestation, confirmed by a positive hCG laboratory test Yes **IETEST_8**
 No
 Not Applicable
9. Any other condition that, in the opinion if the investigator, may interfere with the efficacy and/or safety evaluation of the trial Yes **IETEST_9**
 No

ID	CODE	NAME	EXP.CODE	TYPE	FMT/LEN	DERIVATION	CAT. VALUES
1	ICTEST_1	ICTEST_1	ICTEST_1	Category	3		1=Yes 0=No
2	ICTEST_2	ICTEST_2	ICTEST_2	Category	3		1=Yes 0=No
3	ICTEST_3	ICTEST_3	ICTEST_3	Category	3		1=Yes 0=No
4	ICTEST_4	ICTEST_4	ICTEST_4	Category	3		1=Yes 0=No
5	ICTEST_5	ICTEST_5	ICTEST_5	Category	3		1=Yes 0=No
6	ICTEST_6	ICTEST_6	ICTEST_6	Category	14		1=Yes 0=No 99=Not Applicable
7	ICTEST_7	ICTEST_7	ICTEST_7	Category	3		1=Yes 0=No
8	ICTEST_8	ICTEST_8	ICTEST_8	Category	3		1=Yes 0=No
9	ICTEST_9	ICTEST_9	ICTEST_9	Category	3		1=Yes 0=No
10	IETEST_1	IETEST_1	IETEST_1	Category	3		1=Yes 0=No
11	IETEST_2	IETEST_2	IETEST_2	Category	3		1=Yes 0=No
12	IETEST_3	IETEST_3	IETEST_3	Category	3		1=Yes 0=No
13	IETEST_4	IETEST_4	IETEST_4	Category	3		1=Yes 0=No
14	IETEST_5	IETEST_5	IETEST_5	Category	3		1=Yes 0=No
15	IETEST_6	IETEST_6	IETEST_6	Category	3		1=Yes 0=No
16	IETEST_7	IETEST_7	IETEST_7	Category	3		1=Yes 0=No
17	IETEST_8	IETEST_8	IETEST_8	Category	14		1=Yes 0=No 99=Not Applicable
18	IETEST_9	IETEST_9	IETEST_9	Category	3		1=Yes 0=No

INFORMED CONSENT SIGNATURE

Informed Consent Signature

- No RFIC
 Yes

ID	CODE	NAME	EXP.CODE	TYPE	FMT/LEN	DERIVATION	CAT. VALUES
1	RFIC	RFIC	RFIC	Category	3		0=No 1=Yes

SARS-CoV-2 TESTING

Date COVIDTESTDTC

Result Positive COVIDTESTRESUL
 Negative
 Indeterminate

ID	CODE	NAME	EXP.CODE	TYPE	FMT/LEN	DERIVATION	CAT. VALUES
1	COVIDTESTDTC	COVIDTESTDTC	COVIDTESTDTC	Date/Time	dd/mm/yyyy		
2	COVIDTESTRESUL	COVIDTESTRESUL	COVIDTESTRESUL	Category	13		1=Positive 0=Negative 99=Indeterminate

DEMOGRAPHIC DATA

Date of Birth **BRTHDTC**

Gender Male **SEX**
 Female

ID	CODE	NAME	EXP.CODE	TYPE	FMT/LEN	DERIVATION	CAT. VALUES
1	BRTHDTC	BRTHDTC	BRTHDTC	Date/Time	dd/mm/yyyy		
2	SEX	SEX	SEX	Category	6		M=Male F=Female

SYMPTOMS

Symptoms start date SYMP_DTC

Fever > 38 °C Yes SYMP_FEVER
 No
 Unknown

Dysnea Yes SYMP_DYSNEA
 No
 Unknown

Chills Yes SYMP_CHILLS
 No
 Unknown

Nauseas Yes SYMP_NAUSEA
 No
 Unknown

Muscle pain (Mialgia) Yes SYMP_MUSCLEP
 No
 Unknown

Vomiting Yes SYMP_VOMIT
 No
 Unknown

Nasal mucus (Rhinorhea) Yes SYMP_NASALM
 No
 Unknown

Headache Yes SYMP_HEADP
 No
 Unknown

Throat pain Yes SYMP_THROATP
 No
 Unknown

Abdominal pain Yes SYMP_ABDOMP
 No
 Unknown

Cough Yes SYMP_COUGH
 No
 Unknown

Diarrhea Yes SYMP_DIARRH
 No
 Unknown

Other Yes SYMP_OTHER Specify SYMP_OTHER_SPE
 No
 Unknown

ID	CODE	NAME	EXP.CODE	TYPE	FMT/LEN	DERIVATION	CAT. VALUES
1	SYMP_DTC	SYMP_DTC	SYMP_DTC	Date/Time	dd/mm/yyyy		
2	SYMP_FEVER	SYMP_FEVER	SYMP_FEVER	Category	7		1=Yes 0=No 99=Unknown
3	SYMP_DYSNEA	SYMP_DYSNEA	SYMP_DYSNEA	Category	7		1=Yes 0=No 99=Unknown
4	SYMP_CHILLS	SYMP_CHILLS	SYMP_CHILLS	Category	7		1=Yes 0=No 99=Unknown
5	SYMP_NAUSEA	SYMP_NAUSEA	SYMP_NAUSEA	Category	7		1=Yes 0=No 99=Unknown
6	SYMP_MUSCLEP	SYMP_MUSCLEP	SYMP_MUSCLEP	Category	7		1=Yes 0=No 99=Unknown
7	SYMP_VOMIT	SYMP_VOMIT	SYMP_VOMIT	Category	7		1=Yes 0=No 99=Unknown
8	SYMP_NASALM	SYMP_NASALM	SYMP_NASALM	Category	7		1=Yes 0=No 99=Unknown
9	SYMP_HEADP	SYMP_HEADP	SYMP_HEADP	Category	7		1=Yes 0=No 99=Unknown
10	SYMP_THROATP	SYMP_THROATP	SYMP_THROATP	Category	7		1=Yes 0=No 99=Unknown
11	SYMP_ABDOMP	SYMP_ABDOMP	SYMP_ABDOMP	Category	7		1=Yes 0=No 99=Unknown
12	SYMP_COUGH	SYMP_COUGH	SYMP_COUGH	Category	7		1=Yes 0=No 99=Unknown
13	SYMP_DIARRH	SYMP_DIARRH	SYMP_DIARRH	Category	7		1=Yes 0=No 99=Unknown
14	SYMP_OTHER	SYMP_OTHER	SYMP_OTHER	Category	7		1=Yes 0=No 99=Unknown
15	SYMP_OTHER_SPE	SYMP_OTHER_SPE	SYMP_OTHER_SPE	Text	30		

ALLERGIES

Are any patient allergies known, including drugs, pollen, mites, ...?

- No ALLERGY_YN
 Yes

Allergy

ALLERGY_TERM

ID	CODE	NAME	EXP.CODE	TYPE	FMT/LEN	DERIVATION	CAT. VALUES
1	ALLERGY_YN	ALLERGY_YN	ALLERGY_YN	Category	3		0=No 1=Yes
Repeating Question Group: , Borders: Yes, RowStatus: No, RowNumbers: Yes, DisplayRows: 1, InitialRows: 1, Min Repeats: 0, Max Repeats: 99, Main Row Type: Single-Line, Sub Row Type: Multi-Line							
2	ALLERGY_TERM	ALLERGY_TERM	ALLERGY_TERM	Text	30		

PREVIOUS AND CONCOMITANT MEDICATION

Is the patient taking any medication?

- No PREV_MED_YN
 Yes

Please complete the information in the Previous and Concomitant Medication form

ID	CODE	NAME	EXP.CODE	TYPE	FMT/LEN	DERIVATION	CAT. VALUES
1	PREV_MED_YN	PREV_MED_YN	PREV_MED_YN	Category	3		0=No 1=Yes
2	Hotlink			Hotlink		CM_V:CM_F	

PAST MEDICAL/SURGICAL HISTORY

Does the patient have any relevant medical or surgical history?

- No MH_YN
- Yes

Medical and surgical history <input type="text" value="MH_TERM"/>	<input type="radio"/> Diagnoses date <input type="text" value="MH_DXDTG"/>	Ongoing <input type="radio"/> No
	<input type="radio"/> Not available MH_DX	<input type="radio"/> Yes MH_ONG

ID	CODE	NAME	EXP.CODE	TYPE	FMT/LEN	DERIVATION	CAT. VALUES
1	MH_YN	MH_YN	MH_YN	Category	3		0=No 1=Yes
Repeating Question Group: , Borders: Yes, RowStatus: No, RowNumbers: Yes, DisplayRows: 1, InitialRows: 1, Min Repeats: 0, Max Repeats: 99, Main Row Type: Single-Line, Sub Row Type: Multi-Line							
2	MH_TERM	MH_TERM	MH_TERM	Text	30		
3	MH_DX	MH_DX	MH_DX	Category	14		1=Diagnoses date 0=Not available
4	MH_DXDT	MH_DXDT	MH_DXDT	Date/Time	dd/mm/yyyy		
5	MH_ONG	MH_ONG	MH_ONG	Category	3		0=No 1=Yes

PHYSICAL EXAMINATION

Body System

If abnormal, please specify the abnormality

Dermatologic

- Not Done PE_DERMA
- Normal
- Abnormal

 PE_DERMA_ABN

Head and Neck

- Not Done PE_HEAD
- Normal
- Abnormal

 PE_HEAD_ABN

Eyes, Ears, Nose & Throat

- Not Done PE_EYES
- Normal
- Abnormal

 PE_EYES_ABN

Cardiovascular

- Not Done PE_CARDIO
- Normal
- Abnormal

 PE_CARDIO_ABN

Respiratory

- Not Done PE_RESPIR
- Normal
- Abnormal

 PE_RESPIR_ABN

Gastrointestinal

- Not Done PE_GASTRO
- Normal
- Abnormal

 PE_GASTRO_ABN

Musculoskeletal

- Not Done PE_MUSCULO
- Normal
- Abnormal

 PE_MUSCULO_ABN

Psychologic

- Not Done PE_PSICHO
- Normal
- Abnormal

 PE_PSICHO_ABN

Other

- Not Done PE_OTHER
- Normal
- Abnormal

Specify the physical exam

 PE_OTHER_SPE
 PE_OTHER_ABN

ID	CODE	NAME	EXP.CODE	TYPE	FMT/LEN	DERIVATION	CAT. VALUES
1	PE_DERMA	PE_DERMA	PE_DERMA	Category	8		0=Not Done 1=Normal 2=Abnormal
2	PE_DERMA_ABN	PE_DERMA_ABN	PE_DERMA_ABN	Text	30		
3	PE_HEAD	PE_HEAD	PE_HEAD	Category	8		0=Not Done 1=Normal 2=Abnormal
4	PE_HEAD_ABN	PE_HEAD_ABN	PE_HEAD_ABN	Text	30		
5	PE_EYES	PE_EYES	PE_EYES	Category	8		0=Not Done 1=Normal 2=Abnormal
6	PE_EYES_ABN	PE_EYES_ABN	PE_EYES_ABN	Text	30		
7	PE_CARDIO	PE_CARDIO	PE_CARDIO	Category	8		0=Not Done 1=Normal 2=Abnormal
8	PE_CARDIO_ABN	PE_CARDIO_ABN	PE_CARDIO_ABN	Text	30		
9	PE_RESPIR	PE_RESPIR	PE_RESPIR	Category	8		0=Not Done 1=Normal 2=Abnormal
10	PE_RESPIR_ABN	PE_RESPIR_ABN	PE_RESPIR_ABN	Text	30		
11	PE_GASTRO	PE_GASTRO	PE_GASTRO	Category	8		0=Not Done 1=Normal 2=Abnormal
12	PE_GASTRO_ABN	PE_GASTRO_ABN	PE_GASTRO_ABN	Text	30		
13	PE_MUSCULO	PE_MUSCULO	PE_MUSCULO	Category	8		0=Not Done 1=Normal 2=Abnormal
14	PE_MUSCULO_ABN	PE_MUSCULO_ABN	PE_MUSCULO_ABN	Text	30		
15	PE_PSICHO	PE_PSICHO	PE_PSICHO	Category	8		0=Not Done 1=Normal 2=Abnormal
16	PE_PSICHO_ABN	PE_PSICHO_ABN	PE_PSICHO_ABN	Text	30		
17	PE_OTHER_SPE	PE_OTHER_SPE	PE_OTHER_SPE	Text	30		
18	PE_OTHER	PE_OTHER	PE_OTHER	Category	8		0=Not Done 1=Normal 2=Abnormal
19	PE_OTHER_ABN	PE_OTHER_ABN	PE_OTHER_ABN	Text	30		

VITAL SIGNS

Blood Pressure (mmHg) SYSTOLIC / DIASTOLIC

Heart Rate (bpm) HEART_RATE

Temperature (°C) TEMPERATURE

Weight (kg) WEIGHT

ID	CODE	NAME	EXP.CODE	TYPE	FMT/LEN	DERIVATION	CAT. VALUES
1	SYSTOLIC	SYSTOLIC	SYSTOLIC	Integer	##9		
2	DIASTOLIC	DIASTOLIC	DIASTOLIC	Integer	##9		
3	HEART_RATE	HEART_RATE	HEART_RATE	Integer	##9		
4	TEMPERATURE	TEMPERATURE	TEMPERATURE	Real	99.9		
5	WEIGHT	WEIGHT	WEIGHT	Real	#99.9		

RESPIRATORY STATUS

Respiratory Rate Not Done RESPIR_RATE_NR
 Done (bpm) RESPIR_RATE

SpO2 (%) SPO2

PaO2 Not Done PAO2_NR
 Done (%) PAO2

Fraction of inspired oxygen Not Done FIO2_NR
 Done (%) FIO2

Oxygen supplementation Not used OXYGEN_SUPP
 Nasal cannula
 High flow oxygen therapy
 Mask with a reservoir bag
 Non-invasive ventilation
 Mechanical ventilation or ECMO

Ongoing OXYGEN_SUPP_ONG
 End date OXYGEN_SUPP_DTC

ID	CODE	NAME	EXP.CODE	TYPE	FMT/LEN	DERIVATION	CAT. VALUES
1	RESPIR_RATE_NR	RESPIR_RATE_NR	RESPIR_RATE_NR	Category	8		0=Not Done 1=Done
2	RESPIR_RATE	RESPIR_RATE	RESPIR_RATE	Integer	#9		
3	SPO2	SPO2	SPO2	Integer	##9		
4	PAO2	PAO2	PAO2	Integer	##9		
5	PAO2_NR	PAO2_NR	PAO2_NR	Category	8		0=Not Done 1=Done
6	FIO2_NR	FIO2_NR	FIO2_NR	Category	8		0=Not Done 1=Done
7	FIO2	FIO2	FIO2	Integer	##9		
8	OXYGEN_SUPP	OXYGEN_SUPP	OXYGEN_SUPP	Category	30		See Appendix
9	OXYGEN_SUPP_ONG	OXYGEN_SUPP_ONG	OXYGEN_SUPP_ONG	Category	8		0=Ongoing 1=End date
10	OXYGEN_SUPP_DTC	OXYGEN_SUPP_DTC	OXYGEN_SUPP_DTC	Date/Time	dd/mm/yyyy		

RADIOGRAPHIC FINDINGS

- Not Done RADIOGRAP_NR
- Done

Date RADIOGRAPDTC

- Chest XRay RADIOGRAP_TYPE
- Chest CT

Result Normal RADIOGRAP_RES
 Abnormal

Specify the abnormality RADIOGRAP_ABN

ID	CODE	NAME	EXP.CODE	TYPE	FMT/LEN	DERIVATION	CAT. VALUES
1	RADIOGRAP_NR	RADIOGRAP_NR	RADIOGRAP_NR	Category	8		0=Not Done 1=Done
2	RADIOGRAPDTC	RADIOGRAPDTC	RADIOGRAPDTC	Date/Time	dd/mm/yyyy		
3	RADIOGRAP_TYPE	RADIOGRAP_TYPE	RADIOGRAP_TYPE	Category	10		1=Chest XRay 2=Chest CT
4	RADIOGRAP_RES	RADIOGRAP_RES	RADIOGRAP_RES	Category	8		1=Normal 2=Abnormal
5	RADIOGRAP_ABN	RADIOGRAP_ABN	RADIOGRAP_ABN	Text	30		

LABORATORY

Laboratory Date LBDTC

Hematocrit Not Done HCT_NR HCT % HCT_UNITS NCS HCT_CS
 Done Other units HCT_UNITSO CS

Hemoglobin Not Done HGB_NR HGB g/dL HGB_UNITS NCS HGB_CS
 Done g/L CS
 Other units HGB_UNITSO

MCHC Not Done MCHC_NR MCHC g/dL MCHC_UNITS NCS MCHC_CS
 Done g/L CS
 Other units MCHC_UNITSO

MCV Not Done MCV_NR MCV mm³ MCV_UNITS NCS MCV_CS
 Done fL CS
 Other units MCV_UNITSO

Platelets Not Done PLAT_NR PLAT x10³/microL PLAT_UNITS NCS PLAT_CS
 Done Other units PLAT_UNITSO CS

Red blood cells Not Done RBC_NR RBC 10⁶/mCL RBC_UNITS NCS RBC_CS
 Done Other units RBC_UNITSO CS

White blood cells Not Done WBC_NR WBC x 10³/UL WBC_UNITS NCS WBC_CS
 Done x 10⁹/UL CS
 Other units WBC_UNITSO

ID	CODE	NAME	EXP.CODE	TYPE	FMT/LEN	DERIVATION	CAT. VALUES
1	LBDC	LBDC	LBDC	Date/Time	dd/mm/yyyy		
2	HCT_NR	HCT_NR	HCT_NR	Category	8		0=Not Done 1=Done
3	HCT_UNITS	HCT_UNITS	HCT_UNITS	Category	11		1=% 9=Other units
4	HCT_CS	HCT_CS	HCT_CS	Category	3		0=NCS 1=CS
5	HCT	HCT	HCT	Real	#####9.9		
6	HCT_UNITSO	HCT_UNITSO	HCT_UNITSO	Text	8		
7	HGB_UNITS	HGB_UNITS	HGB_UNITS	Category	11		1=g/dL 2=g/L 9=Other units
8	HGB_NR	HGB_NR	HGB_NR	Category	8		0=Not Done 1=Done
9	HGB_CS	HGB_CS	HGB_CS	Category	3		0=NCS 1=CS
10	HGB	HGB	HGB	Real	#####9.9		
11	HGB_UNITSO	HGB_UNITSO	HGB_UNITSO	Text	8		
12	MCHC_UNITS	MCHC_UNITS	MCHC_UNITS	Category	11		1=g/dL 2=g/L 9=Other units
13	MCHC_NR	MCHC_NR	MCHC_NR	Category	8		0=Not Done 1=Done
14	MCHC_CS	MCHC_CS	MCHC_CS	Category	3		0=NCS 1=CS
15	MCHC	MCHC	MCHC	Real	#####9.9		
16	MCHC_UNITSO	MCHC_UNITSO	MCHC_UNITSO	Text	8		
17	MCV_UNITS	MCV_UNITS	MCV_UNITS	Category	11		1=mm3 2=fL 9=Other units
18	MCV_NR	MCV_NR	MCV_NR	Category	8		0=Not Done 1=Done
19	MCV_CS	MCV_CS	MCV_CS	Category	3		0=NCS 1=CS
20	MCV	MCV	MCV	Real	#####9.9		
21	MCV_UNITSO	MCV_UNITSO	MCV_UNITSO	Text	8		
22	PLAT_NR	PLAT_NR	PLAT_NR	Category	8		0=Not Done 1=Done
23	PLAT_UNITS	PLAT_UNITS	PLAT_UNITS	Category	12		1=x10e3/microl 9=Other units
24	PLAT_CS	PLAT_CS	PLAT_CS	Category	3		0=NCS 1=CS
25	PLAT	PLAT	PLAT	Real	#####9.9		
26	PLAT_UNITSO	PLAT_UNITSO	PLAT_UNITSO	Text	8		
27	RBC_NR	RBC_NR	RBC_NR	Category	8		0=Not Done 1=Done
28	RBC_UNITS	RBC_UNITS	RBC_UNITS	Category	11		1=10e6/mCL 9=Other units
29	RBC_CS	RBC_CS	RBC_CS	Category	3		0=NCS 1=CS
30	RBC	RBC	RBC	Real	#####9.9		
31	RBC_UNITSO	RBC_UNITSO	RBC_UNITSO	Text	8		
32	WBC_UNITS	WBC_UNITS	WBC_UNITS	Category	11		1=x 10^3/UL 2=x 10^9/UL 9=Other units
33	WBC_NR	WBC_NR	WBC_NR	Category	8		0=Not Done 1=Done
34	WBC_CS	WBC_CS	WBC_CS	Category	3		0=NCS 1=CS
35	WBC	WBC	WBC	Real	#####9.9		
36	WBC_UNITSO	WBC_UNITSO	WBC_UNITSO	Text	8		

Basophils Not Done BASO_NR Done BASO

% BASO_UNITS
 x 10³/UL
 x 10⁹/UL
 Other units BASO_UNITSO

NCS BASO_CS
 CS

Eosinophils Not Done EOS_NR Done EOS

% EOS_UNITS
 x 10³/UL
 x 10⁹/UL
 Other units EOS_UNITSO

NCS EOS_CS
 CS

Lymphocytes Not Done LYM_NR Done LYM

% LYM_UNITS
 x 10³/UL
 x 10⁹/UL
 Other units LYM_UNITSO

NCS LYM_CS
 CS

Monocytes Not Done MONO_NR Done MONO

% MONO_UNITS
 x 10³/UL
 x 10⁹/UL
 Other units MONO_UNITSO

NCS MONO_CS
 CS

Neutrophils Not Done NEUT_NR Done NEUT

% NEUT_UNITS
 x 10³/UL
 x 10⁹/UL
 Other units NEUT_UNITSO

NCS NEUT_CS
 CS

Glucosa Not Done GLU_NR Done GLU

mg/dL GLU_UNITS
 Other units GLU_UNITSO

NCS GLU_CS
 CS

Urea Not Done UREA_NR Done UREA

mg/dL UREA_UNITS
 Other units UREA_UNITSO

NCS UREA_CS
 CS

ID	CODE	NAME	EXP.CODE	TYPE	FMT/LEN	DERIVATION	CAT. VALUES
37	BASO_UNITS	BASO_UNITS	BASO_UNITS	Category	11		1=% 2=x 10^3/UL 3=x 10^9/UL 9=Other units
38	BASO_NR	BASO_NR	BASO_NR	Category	8		0=Not Done 1=Done
39	BASO_CS	BASO_CS	BASO_CS	Category	3		0=NCS 1=CS
40	BASO	BASO	BASO	Real	#####9.9		
41	BASO_UNITSO	BASO_UNITSO	BASO_UNITSO	Text	8		
42	EOS_UNITS	EOS_UNITS	EOS_UNITS	Category	11		1=% 2=x 10^3/UL 3=x 10^9/UL 9=Other units
43	EOS_NR	EOS_NR	EOS_NR	Category	8		0=Not Done 1=Done
44	EOS_CS	EOS_CS	EOS_CS	Category	3		0=NCS 1=CS
45	EOS	EOS	EOS	Real	#####9.9		
46	EOS_UNITSO	EOS_UNITSO	EOS_UNITSO	Text	8		
47	LYM_UNITS	LYM_UNITS	LYM_UNITS	Category	11		1=% 2=x 10^3/UL 3=x 10^9/UL 9=Other units
48	LYM_NR	LYM_NR	LYM_NR	Category	8		0=Not Done 1=Done
49	LYM_CS	LYM_CS	LYM_CS	Category	3		0=NCS 1=CS
50	LYM	LYM	LYM	Real	#####9.9		
51	LYM_UNITSO	LYM_UNITSO	LYM_UNITSO	Text	8		
52	MONO_UNITS	MONO_UNITS	MONO_UNITS	Category	11		1=% 2=x 10^3/UL 3=x 10^9/UL 9=Other units
53	MONO_NR	MONO_NR	MONO_NR	Category	8		0=Not Done 1=Done
54	MONO_CS	MONO_CS	MONO_CS	Category	3		0=NCS 1=CS
55	MONO	MONO	MONO	Real	#####9.9		
56	MONO_UNITSO	MONO_UNITSO	MONO_UNITSO	Text	8		
57	NEUT_UNITS	NEUT_UNITS	NEUT_UNITS	Category	11		1=% 2=x 10^3/UL 3=x 10^9/UL 9=Other units
58	NEUT_NR	NEUT_NR	NEUT_NR	Category	8		0=Not Done 1=Done
59	NEUT_CS	NEUT_CS	NEUT_CS	Category	3		0=NCS 1=CS
60	NEUT	NEUT	NEUT	Real	#####9.9		
61	NEUT_UNITSO	NEUT_UNITSO	NEUT_UNITSO	Text	8		
62	GLU_NR	GLU_NR	GLU_NR	Category	8		0=Not Done 1=Done
63	GLU_UNITS	GLU_UNITS	GLU_UNITS	Category	11		1=mg/dL 9=Other units
64	GLU_CS	GLU_CS	GLU_CS	Category	3		0=NCS 1=CS
65	GLU	GLU	GLU	Real	#####9.9		
66	GLU_UNITSO	GLU_UNITSO	GLU_UNITSO	Text	8		
67	UREA_NR	UREA_NR	UREA_NR	Category	8		0=Not Done 1=Done
68	UREA_UNITS	UREA_UNITS	UREA_UNITS	Category	11		1=mg/dL 9=Other units
69	UREA_CS	UREA_CS	UREA_CS	Category	3		0=NCS 1=CS
70	UREA	UREA	UREA	Real	#####9.9		
71	UREA_UNITSO	UREA_UNITSO	UREA_UNITSO	Text	8		

Creatinine Not Done CREAT_NR CREAT mg/dL CREAT_UNITS NCS CREAT_CS
 Done umol/L CS
 Other units CREAT_UNITSO

Sodium Not Done NA_NR NA mEq/L NA_UNITS NCS NA_CS
 Done mmol/L CS
 Other units NA_UNITSO

Potassium Not Done K_NR K mEq/L K_UNITS NCS K_CS
 Done mmol/L CS
 Other units K_UNITSO

Calcium Not Done CA_NR CA mg/dL CA_UNITS NCS CA_CS
 Done Other units CA_UNITSO

Chloride Not Done CL_NR CL mEq/L CL_UNITS NCS CL_CS
 Done mmol/L CS
 Other units CL_UNITSO

Total Protein Not Done PROT_NR PROT g/dL PROT_UNITS NCS PROT_CS
 Done Other units PROT_UNITSO

Albumin Not Done ALB_NR ALB g/dL ALB_UNITS NCS ALB_CS
 Done g/L CS
 Other units ALB_UNITSO

Total Bilirubin Not Done BILI_NR BILI mg/dL BILI_UNITS NCS BILI_CS
 Done umol/L CS
 Other units BILI_UNITSO

Direct Bilirubin Not Done BILDIR_NR BILDIR mg/dL BILDIR_UNITS NCS BILDIR_CS
 Done umol/L CS
 Other units BILDIR_UNITSO

ID	CODE	NAME	EXP.CODE	TYPE	FMT/LEN	DERIVATION	CAT. VALUES
72	CREAT_UNITS	CREAT_UNITS	CREAT_UNITS	Category	11		1=mg/dL 2=umol/L 9=Other units
73	CREAT_NR	CREAT_NR	CREAT_NR	Category	8		0=Not Done 1=Done
74	CREAT_CS	CREAT_CS	CREAT_CS	Category	3		0=NCS 1=CS
75	CREAT	CREAT	CREAT	Real	#####9.9		
76	CREAT_UNITSO	CREAT_UNITSO	CREAT_UNITSO	Text	8		
77	NA_UNITS	NA_UNITS	NA_UNITS	Category	11		1=mEq/L 2=mmol/L 9=Other units
78	NA_NR	NA_NR	NA_NR	Category	8		0=Not Done 1=Done
79	NA_CS	NA_CS	NA_CS	Category	3		0=NCS 1=CS
80	NA	NA	NA	Real	#####9.9		
81	NA_UNITSO	NA_UNITSO	NA_UNITSO	Text	8		
82	K_UNITS	K_UNITS	K_UNITS	Category	11		1=mEq/L 2=mmol/L 9=Other units
83	K_NR	K_NR	K_NR	Category	8		0=Not Done 1=Done
84	K_CS	K_CS	K_CS	Category	3		0=NCS 1=CS
85	K	K	K	Real	#####9.9		
86	K_UNITSO	K_UNITSO	K_UNITSO	Text	8		
87	CA_NR	CA_NR	CA_NR	Category	8		0=Not Done 1=Done
88	CA_UNITS	CA_UNITS	CA_UNITS	Category	11		1=mg/dL 9=Other units
89	CA_CS	CA_CS	CA_CS	Category	3		0=NCS 1=CS
90	CA	CA	CA	Real	#####9.9		
91	CA_UNITSO	CA_UNITSO	CA_UNITSO	Text	8		
92	CL_UNITS	CL_UNITS	CL_UNITS	Category	11		1=mEq/L 2=mmol/L 9=Other units
93	CL_NR	CL_NR	CL_NR	Category	8		0=Not Done 1=Done
94	CL_CS	CL_CS	CL_CS	Category	3		0=NCS 1=CS
95	CL	CL	CL	Real	#####9.9		
96	CL_UNITSO	CL_UNITSO	CL_UNITSO	Text	8		
97	PROT_NR	PROT_NR	PROT_NR	Category	8		0=Not Done 1=Done
98	PROT_UNITS	PROT_UNITS	PROT_UNITS	Category	11		1=g/dL 9=Other units
99	PROT_CS	PROT_CS	PROT_CS	Category	3		0=NCS 1=CS
100	PROT	PROT	PROT	Real	#####9.9		
101	PROT_UNITSO	PROT_UNITSO	PROT_UNITSO	Text	8		
102	ALB_UNITS	ALB_UNITS	ALB_UNITS	Category	11		1=g/dL 2=g/L 9=Other units
103	ALB_NR	ALB_NR	ALB_NR	Category	8		0=Not Done 1=Done
104	ALB_CS	ALB_CS	ALB_CS	Category	3		0=NCS 1=CS
105	ALB	ALB	ALB	Real	#####9.9		
106	ALB_UNITSO	ALB_UNITSO	ALB_UNITSO	Text	8		
107	BILI_UNITS	BILI_UNITS	BILI_UNITS	Category	11		1=mg/dL 2=umol/L 9=Other units
108	BILI_NR	BILI_NR	BILI_NR	Category	8		0=Not Done 1=Done
109	BILI_CS	BILI_CS	BILI_CS	Category	3		0=NCS 1=CS
110	BILI	BILI	BILI	Real	#####9.9		
111	BILI_UNITSO	BILI_UNITSO	BILI_UNITSO	Text	8		
112	BILDIR_UNITS	BILDIR_UNITS	BILDIR_UNITS	Category	11		1=mg/dL 2=umol/L 9=Other units
113	BILDIR_NR	BILDIR_NR	BILDIR_NR	Category	8		0=Not Done 1=Done
114	BILDIR_CS	BILDIR_CS	BILDIR_CS	Category	3		0=NCS 1=CS
115	BILDIR	BILDIR	BILDIR	Real	#####9.9		
116	BILDIR_UNITSO	BILDIR_UNITSO	BILDIR_UNITSO	Text	8		

AST Not Done AST_NR AST U/L AST_UNITS AST_UNITSO NCS AST_CS
 Done Other units

ALT Not Done ALT_NR ALT U/L ALT_UNITS ALT_UNITSO NCS ALT_CS
 Done Other units

LDH Not Done LDH_NR LDH U/L LDH_UNITS LDH_UNITSO NCS LDH_CS
 Done Other units

Ferritin Not Done FERRITIN_NR FERRITIN ug/L FERRITIN_UNITS FERRITIN_UNITSO NCS FERRITIN_CS
 Done ng/mL Other units

CRP Not Done CRP_NR CRP mg/L CRP_UNITS CRP_UNITSO NCS CRP_CS
 Done Other units

Troponine Not Done TROPONIN_NR TROPONIN ng/L TROPONIN_UNITS TROPONIN_UNITSO NCS TROPONIN_CS
 Done Other units

D-Dimer Not Done DDIMER_NR DDIMER ng/mL DDIMER_UNITS DDIMER_UNITSO NCS DDIMER_CS
 Done Other units

Triglycerides Not Done TRIG_NR TRIG mg/dL TRIG_UNITS TRIG_UNITSO NCS TRIG_CS
 Done mmol/L Other units

Fibrinogen Not Done FIBRINO_NR FIBRINO mg/dL FIBRINO_UNITS FIBRINO_UNITSO NCS FIBRINO_CS
 Done Other units

ID	CODE	NAME	EXP.CODE	TYPE	FMT/LEN	DERIVATION	CAT. VALUES
117	AST_NR	AST_NR	AST_NR	Category	8		0=Not Done 1=Done
118	AST_UNITS	AST_UNITS	AST_UNITS	Category	11		1=U/L 9=Other units
119	AST_CS	AST_CS	AST_CS	Category	3		0=NCS 1=CS
120	AST	AST	AST	Real	#####9.9		
121	AST_UNITSO	AST_UNITSO	AST_UNITSO	Text	8		
122	ALT_NR	ALT_NR	ALT_NR	Category	8		0=Not Done 1=Done
123	ALT_UNITS	ALT_UNITS	ALT_UNITS	Category	11		1=U/L 9=Other units
124	ALT_CS	ALT_CS	ALT_CS	Category	3		0=NCS 1=CS
125	ALT	ALT	ALT	Real	#####9.9		
126	ALT_UNITSO	ALT_UNITSO	ALT_UNITSO	Text	8		
127	LDH_NR	LDH_NR	LDH_NR	Category	8		0=Not Done 1=Done
128	LDH_UNITS	LDH_UNITS	LDH_UNITS	Category	11		1=U/L 9=Other units
129	LDH_CS	LDH_CS	LDH_CS	Category	3		0=NCS 1=CS
130	LDH	LDH	LDH	Real	#####9.9		
131	LDH_UNITSO	LDH_UNITSO	LDH_UNITSO	Text	8		
132	FERRITIN_UNITS	FERRITIN_UNITS	FERRITIN_UNITS	Category	11		1=ug/L 2=ng/mL 9=Other units
133	FERRITIN_NR	FERRITIN_NR	FERRITIN_NR	Category	8		0=Not Done 1=Done
134	FERRITIN_CS	FERRITIN_CS	FERRITIN_CS	Category	3		0=NCS 1=CS
135	FERRITIN	FERRITIN	FERRITIN	Real	#####9.9		
136	FERRITIN_UNITSO	FERRITIN_UNITSO	FERRITIN_UNITSO	Text	8		
137	CRP_NR	CRP_NR	CRP_NR	Category	8		0=Not Done 1=Done
138	CRP_UNITS	CRP_UNITS	CRP_UNITS	Category	11		1=mg/L 9=Other units
139	CRP_CS	CRP_CS	CRP_CS	Category	3		0=NCS 1=CS
140	CRP	CRP	CRP	Real	#####9.9		
141	CRP_UNITSO	CRP_UNITSO	CRP_UNITSO	Text	8		
142	TROPONIN_UNITS	TROPONIN_UNITS	TROPONIN_UNITS	Category	11		1=ng/L 9=Other units
143	TROPONIN_NR	TROPONIN_NR	TROPONIN_NR	Category	8		0=Not Done 1=Done
144	TROPONIN_CS	TROPONIN_CS	TROPONIN_CS	Category	3		0=NCS 1=CS
145	TROPONIN	TROPONIN	TROPONIN	Real	#####9.9		
146	TROPONIN_UNITSO	TROPONIN_UNITSO	TROPONIN_UNITSO	Text	8		
147	DDIMER_NR	DDIMER_NR	DDIMER_NR	Category	8		0=Not Done 1=Done
148	DDIMER_UNITS	DDIMER_UNITS	DDIMER_UNITS	Category	11		1=ng/mL 9=Other units
149	DDIMER_CS	DDIMER_CS	DDIMER_CS	Category	3		0=NCS 1=CS
150	DDIMER	DDIMER	DDIMER	Real	#####9.9		
151	DDIMER_UNITSO	DDIMER_UNITSO	DDIMER_UNITSO	Text	8		
152	TRIG_UNITS	TRIG_UNITS	TRIG_UNITS	Category	11		1=mg/dL 2=mmol/L 9=Other units
153	TRIG_NR	TRIG_NR	TRIG_NR	Category	8		0=Not Done 1=Done
154	TRIG_CS	TRIG_CS	TRIG_CS	Category	3		0=NCS 1=CS
155	TRIG	TRIG	TRIG	Real	#####9.9		
156	TRIG_UNITSO	TRIG_UNITSO	TRIG_UNITSO	Text	8		
157	FIBRINO_UNITS	FIBRINO_UNITS	FIBRINO_UNITS	Category	11		1=mg/dL 9=Other units
158	FIBRINO_NR	FIBRINO_NR	FIBRINO_NR	Category	8		0=Not Done 1=Done
159	FIBRINO_CS	FIBRINO_CS	FIBRINO_CS	Category	3		0=NCS 1=CS
160	FIBRINO	FIBRINO	FIBRINO	Real	#####9.9		
161	FIBRINO_UNITSO	FIBRINO_UNITSO	FIBRINO_UNITSO	Text	8		

IL-6

Not Done INTLK6_NR
 Done

INTLK6

pg/mL INTLK6_UNITS
 Other units

INTLK6_UNITSO

NCS INTLK6_CS
 CS

ID	CODE	NAME	EXP.CODE	TYPE	FMT/LEN	DERIVATION	CAT. VALUES
162	INTLK6_UNITS	INTLK6_UNITS	INTLK6_UNITS	Category	11		1=pg/mL 9=Other units
163	INTLK6_NR	INTLK6_NR	INTLK6_NR	Category	8		0=Not Done 1=Done
164	INTLK6_CS	INTLK6_CS	INTLK6_CS	Category	3		0=NCS 1=CS
165	INTLK6_UNITSO	INTLK6_UNITSO	INTLK6_UNITSO	Text	8		
166	INTLK6	INTLK6	INTLK6	Real	#####9.9		

MARKERS OF IMMUNOLOGICAL FUNCTION

IgG Not Done IGG_NR IGG mg/dL IGG_UNITS Other units IGG_UNITSO
 Done

IgA Not Done IGA_NR IGA mg/dL IGA_UNITS Other units IGA_UNITSO
 Done

IgM Not Done IGM_NR IGM mg/dL IGM_UNITS Other units IGM_UNITSO
 Done

CD3 Not Done CD3_NR CD3 10e3/mCL CD3_UNITS Other units CD3_UNITSO
 Done

CD4 Not Done CD4_NR CD4 10e3/mCL CD4_UNITS Other units CD4_UNITSO
 Done

ratio CD4/CD8 Not Done CD8_CD4_NR CD8_CD4
 Done

T cells Not Done TCELLS_NR TCELLS 10e3/mCL TCELLS_UNITS Other units TCELLS_UNITSO
 Done

CD4+ cells Not Done CD4CELLS_NR CD4CELLS 10e3/mCL CD4CELLS_UNITS Other units CD4CELLS_UNITSO
 Done

CD8+ cells Not Done CD8_NR CD8 10e3/mCL CD8_UNITS Other units CD8_UNITSO
 Done

B cells Not Done BCELLS_NR
 Done

ID	CODE	NAME	EXP.CODE	TYPE	FMT/LEN	DERIVATION	CAT. VALUES
1	IGG_NR	IGG_NR	IGG_NR	Category	8		0=Not Done 1=Done
2	IGG_UNITS	IGG_UNITS	IGG_UNITS	Category	11		1=mg/dL 9=Other units
3	IGG	IGG	IGG	Real	#####9.9		
4	IGG_UNITSO	IGG_UNITSO	IGG_UNITSO	Text	8		
5	IGA_NR	IGA_NR	IGA_NR	Category	8		0=Not Done 1=Done
6	IGA_UNITS	IGA_UNITS	IGA_UNITS	Category	11		1=mg/dL 9=Other units
7	IGA	IGA	IGA	Real	#####9.9		
8	IGA_UNITSO	IGA_UNITSO	IGA_UNITSO	Text	8		
9	IGM_NR	IGM_NR	IGM_NR	Category	8		0=Not Done 1=Done
10	IGM_UNITS	IGM_UNITS	IGM_UNITS	Category	11		1=mg/dL 9=Other units
11	IGM	IGM	IGM	Real	#####9.9		
12	IGM_UNITSO	IGM_UNITSO	IGM_UNITSO	Text	8		
13	CD3_NR	CD3_NR	CD3_NR	Category	8		0=Not Done 1=Done
14	CD3_UNITS	CD3_UNITS	CD3_UNITS	Category	11		1=10e3/mCL 9=Other units
15	CD3	CD3	CD3	Real	#####9.9		
16	CD3_UNITSO	CD3_UNITSO	CD3_UNITSO	Text	8		
17	CD4_NR	CD4_NR	CD4_NR	Category	8		0=Not Done 1=Done
18	CD4_UNITS	CD4_UNITS	CD4_UNITS	Category	11		1=10e3/mCL 9=Other units
19	CD4	CD4	CD4	Real	#####9.9		
20	CD4_UNITSO	CD4_UNITSO	CD4_UNITSO	Text	8		
21	CD8_CD4_NR	CD8_CD4_NR	CD8_CD4_NR	Category	8		0=Not Done 1=Done
22	CD8_CD4	CD8_CD4	CD8_CD4	Real	#####9.9		
23	TCELLS_NR	TCELLS_NR	TCELLS_NR	Category	8		0=Not Done 1=Done
24	TCELLS_UNITS	TCELLS_UNITS	TCELLS_UNITS	Category	11		1=10e3/mCL 9=Other units
25	TCELLS	TCELLS	TCELLS	Real	#####9.9		
26	TCELLS_UNITSO	TCELLS_UNITSO	TCELLS_UNITSO	Text	8		
27	CD4CELLS_NR	CD4CELLS_NR	CD4CELLS_NR	Category	8		0=Not Done 1=Done
28	CD4CELLS_UNITS	CD4CELLS_UNITS	CD4CELLS_UNITS	Category	11		1=10e3/mCL 9=Other units
29	CD4CELLS	CD4CELLS	CD4CELLS	Real	#####9.9		
30	CD4CELLS_UNITSO	CD4CELLS_UNITSO	CD4CELLS_UNITSO	Text	8		
31	CD8_NR	CD8_NR	CD8_NR	Category	8		0=Not Done 1=Done
32	CD8_UNITS	CD8_UNITS	CD8_UNITS	Category	11		1=10e3/mCL 9=Other units
33	CD8	CD8	CD8	Real	#####9.9		
34	CD8_UNITSO	CD8_UNITSO	CD8_UNITSO	Text	8		
35	BCELLS_NR	BCELLS_NR	BCELLS_NR	Category	8		0=Not Done 1=Done

- 10e3/mCL BCELLS_UNITS
- Other units

ID	CODE	NAME	EXP.CODE	TYPE	FMT/LEN	DERIVATION	CAT. VALUES
36	BCELLS_UNITS	BCELLS_UNITS	BCELLS_UNITS	Category	11		1=10e3/mCL 9=Other units

BCELLS

BCELLS_UNITSO

NK cells

- Not Done
 Done

NKCREPER_NR

NKCREPER

- 10e3/mCL
 Other units

NKCREPER_UNITS

NKCREPER_UNITSO

CD4+RA+

- Not Done
 Done

CD4POS_RAPOS_NR

CD4POS_RAPOS

- %
 Other units

CD4P_RAP_UNITS

CD4P_RAP_UNITSO

CD4+RA-

- Not Done
 Done

CD4POS_RANEG_NR

CD4POS_RANEG

- %
 Other units

CD4P_RAN_UNITS

CD4P_RAN_UNITSO

CD8+RA+

- Not Done
 Done

CD8POS_RAPOS_NR

CD8POS_RAPOS

- %
 Other units

CD8P_RAP_UNITS

CD8P_RAP_UNITSO

CD8+RA-

- Not Done
 Done

CD8POS_RANEG_NR

CD8POS_RANEG

- %
 Other units

CD8P_RAN_UNITS

CD8P_RAN_UNITSO

NKT cells

- Not Done
 Done

NKTC_NR

NKTC

- %
 Other units

NKTC_UNITS

NKTC_UNITSO

Memory B cells

- Not Done
 Done

MEMOBC_NR

- %
 Other units

MEMOBC_UNITS

ID	CODE	NAME	EXP.CODE	TYPE	FMT/LEN	DERIVATION	CAT. VALUES
37	BCELLS	BCELLS	BCELLS	Real	#####9.9		
38	BCELLS_UNITSO	BCELLS_UNITSO	BCELLS_UNITSO	Text	8		
39	NKCREPER_NR	NKCREPER_NR	NKCREPER_NR	Category	8		0=Not Done 1=Done
40	NKCREPER_UNITS	NKCREPER_UNITS	NKCREPER_UNITS	Category	11		1=10e3/mCL 9=Other units
41	NKCREPER	NKCREPER	NKCREPER	Real	#####9.9		
42	NKCREPER_UNITSO	NKCREPER_UNITSO	NKCREPER_UNITSO	Text	8		
43	CD4POS_RAPOS_NR	CD4POS_RAPOS_NR	CD4POS_RAPOS_NR	Category	8		0=Not Done 1=Done
44	CD4P_RAP_UNITS	CD4P_RAP_UNITS	CD4P_RAP_UNITS	Category	11		1=% 9=Other units
45	CD4POS_RAPOS	CD4POS_RAPOS	CD4POS_RAPOS	Real	#####9.9		
46	CD4P_RAP_UNITSO	CD4P_RAP_UNITSO	CD4P_RAP_UNITSO	Text	8		
47	CD4POS_RANEG_NR	CD4POS_RANEG_NR	CD4POS_RANEG_NR	Category	8		0=Not Done 1=Done
48	CD4P_RAN_UNITS	CD4P_RAN_UNITS	CD4P_RAN_UNITS	Category	11		1=% 9=Other units
49	CD4POS_RANEG	CD4POS_RANEG	CD4POS_RANEG	Real	#####9.9		
50	CD4P_RAN_UNITSO	CD4P_RAN_UNITSO	CD4P_RAN_UNITSO	Text	8		
51	CD8POS_RAPOS_NR	CD8POS_RAPOS_NR	CD8POS_RAPOS_NR	Category	8		0=Not Done 1=Done
52	CD8P_RAP_UNITS	CD8P_RAP_UNITS	CD8P_RAP_UNITS	Category	11		1=% 9=Other units
53	CD8POS_RAPOS	CD8POS_RAPOS	CD8POS_RAPOS	Real	#####9.9		
54	CD8P_RAP_UNITSO	CD8P_RAP_UNITSO	CD8P_RAP_UNITSO	Text	8		
55	CD8POS_RANEG_NR	CD8POS_RANEG_NR	CD8POS_RANEG_NR	Category	8		0=Not Done 1=Done
56	CD8P_RAN_UNITS	CD8P_RAN_UNITS	CD8P_RAN_UNITS	Category	11		1=% 9=Other units
57	CD8POS_RANEG	CD8POS_RANEG	CD8POS_RANEG	Real	#####9.9		
58	CD8P_RAN_UNITSO	CD8P_RAN_UNITSO	CD8P_RAN_UNITSO	Text	8		
59	NKTC_NR	NKTC_NR	NKTC_NR	Category	8		0=Not Done 1=Done
60	NKTC_UNITS	NKTC_UNITS	NKTC_UNITS	Category	11		1=% 9=Other units
61	NKTC	NKTC	NKTC	Real	#####9.9		
62	NKTC_UNITSO	NKTC_UNITSO	NKTC_UNITSO	Text	8		
63	MEMOBC_NR	MEMOBC_NR	MEMOBC_NR	Category	8		0=Not Done 1=Done
64	MEMOBC_UNITS	MEMOBC_UNITS	MEMOBC_UNITS	Category	11		1=% 9=Other units



MEMOBC

ID	CODE	NAME	EXP.CODE	TYPE	FMT/LEN	DERIVATION	CAT. VALUES
65	MEMOBC	MEMOBC	MEMOBC	Real	#####9.9		

MEMOBC_UNITSO

T cells GD

Not Done ACTTC_NR
 Done

ACTTC

% ACTTC_UNITS
 Other units

ACTTC_UNITSO

T regs

Not Done TREGS_NR
 Done

TREGS

% TREGS_UNITS
 Other units

TREGS_UNITSO

CD3+HLADR+

Not Done CD3_HLADR_NR
 Done

CD3_HLADR

% CD3_HLADR_UNITS
 Other units

CD3HLADR_UNITSO

ratio Treg/Tcon

Not Done TGEN_TCON_NR
 Done

TGEN_TCON

ID	CODE	NAME	EXP.CODE	TYPE	FMT/LEN	DERIVATION	CAT. VALUES
66	MEMOBC_UNITSO	MEMOBC_UNITSO	MEMOBC_UNITSO	Text	8		
67	ACTTC_NR	ACTTC_NR	ACTTC_NR	Category	8		0=Not Done 1=Done
68	ACTTC_UNITS	ACTTC_UNITS	ACTTC_UNITS	Category	11		1=% 9=Other units
69	ACTTC	ACTTC	ACTTC	Real	#####9.9		
70	ACTTC_UNITSO	ACTTC_UNITSO	ACTTC_UNITSO	Text	8		
71	TREGS_NR	TREGS_NR	TREGS_NR	Category	8		0=Not Done 1=Done
72	TREGS_UNITS	TREGS_UNITS	TREGS_UNITS	Category	11		1=% 9=Other units
73	TREGS	TREGS	TREGS	Real	#####9.9		
74	TREGS_UNITSO	TREGS_UNITSO	TREGS_UNITSO	Text	8		
75	CD3_HLADR_NR	CD3_HLADR_NR	CD3_HLADR_NR	Category	8		0=Not Done 1=Done
76	CD3_HLADR_UNITS	CD3_HLADR_UNITS	CD3_HLADR_UNITS	Category	11		1=% 9=Other units
77	CD3_HLADR	CD3_HLADR	CD3_HLADR	Real	#####9.9		
78	CD3HLADR_UNITSO	CD3_HLADR_UNITSO	CD3HLADR_UNITSO	Text	8		
79	TGEN_TCON_NR	TGEN_TCON_NR	TGEN_TCON_NR	Category	8		0=Not Done 1=Done
80	TGEN_TCON	TGEN_TCON	TGEN_TCON	Real	#####9.9		

BLOOD SAMPLE FOR ADDITIONAL INVESTIGATIONAL STUDIES

Blood sample for additional investigational studies has been extracted?

- Yes BLOOD_SAMP_YN
 No

ID	CODE	NAME	EXP.CODE	TYPE	FMT/LEN	DERIVATION	CAT. VALUES
1	BLOOD_SAMP_YN	BLOOD_SAMP_YN	BLOOD_SAMP_YN	Category	3		1=Yes 0=No

DONOR CHIMERISM

- No Realizado DCHIMERISM_NR
- Realizado

Donor Chimerism (%)

 DONOR_CHIMERISM

ID	CODE	NAME	EXP.CODE	TYPE	FMT/LEN	DERIVATION	CAT. VALUES
1	DCHIMERISM_NR	DCHIMERISM_NR	DCHIMERISM_NR	Category	12		0=No Realizado 1=Realizado
2	DONOR_CHIMERISM	DONOR_CHIMERISM	DONOR_CHIMERISM	Real	###9.9###		

PREGNANCY TEST

Not Done PREGNANCY_NR
 Done

Urine PREGNANCY_TYPE
 Blood

Negative PREGNANCY_RES
 Positive

ID	CODE	NAME	EXP.CODE	TYPE	FMT/LEN	DERIVATION	CAT. VALUES
1	PREGNANCY_NR	PREGNANCY_NR	PREGNANCY_NR	Category	8		0=Not Done 1=Done
2	PREGNANCY_TYPE	PREGNANCY_TYPE	PREGNANCY_TYPE	Category	5		1=Urine 2=Blood
3	PREGNANCY_RES	PREGNANCY_RES	PREGNANCY_RES	Category	8		0=Negative 1=Positive

NEWS SCALE

- Not Done NEWS_SCALE_NR
- Done

Points

NEWS_SCALE

ID	CODE	NAME	EXP.CODE	TYPE	FMT/LEN	DERIVATION	CAT. VALUES
1	NEWS_SCALE_NR	NEWS_SCALE_NR	NEWS_SCALE_NR	Category	8		0=Not Done 1=Done
2	NEWS_SCALE	NEWS_SCALE	NEWS_SCALE	Integer	#9		

7-POINT ORDINAL SCALE

- Not Done SCALE7POINT_NR
- Done

- Discharged (or ready for discharge as evidenced by normal body temperature and respiratory rate, and stable oxygen saturation on ambient air)
- Non-ICU hospital ward (or ready for hospital ward) not requiring supplemental oxygen
- Non-ICU hospital ward (or ready for hospital ward) requiring supplemental oxygen
- ICU or non-ICU hospital ward, requiring non-invasive ventilation or high-flow oxygen
- ICU, requiring intubation and mechanical ventilation
- ICU, requiring ECMO or mechanical ventilation and additional organ support (e.g., vasopressors, renal replacement therapy)
- Death

ID	CODE	NAME	EXP.CODE	TYPE	FMT/LEN	DERIVATION	CAT. VALUES
1	SCALE7POINT_NR	SCALE7POINT_NR	SCALE7POINT_NR	Category	8		0=Not Done 1=Done
2	SCALE7POINT	SCALE7POINT	SCALE7POINT	Category	171		See Appendix

RANDOMIZATION

Randomization Date

RANDOM_DTC

- Standard of Care (SoC) ARM
- Standard of Care (SoC) + Recommended Phase II Dose (RP2D)

ID	CODE	NAME	EXP.CODE	TYPE	FMT/LEN	DERIVATION	CAT. VALUES
1	RANDOM_DTC	RANDOM_DTC	RANDOM_DTC	Date/Time	dd/mm/yyyy		
2	ARM	ARM	ARM	Category	56		See Appendix

SECOND DOSE

A second dose has been administrated?

- Yes ADMIN2_YN
- No

ID	CODE	NAME	EXP.CODE	TYPE	FMT/LEN	DERIVATION	CAT. VALUES
1	ADMIN2_YN	ADMIN2_YN	ADMIN2_YN	Category	3		1=Yes 0=No

PATIENT EVOLUTION

Has the patient suffer any symptoms? No SYMP_YN
 Yes

Specify

 SYMP_SPEC

Has the patient suffer any complications after discharge? No COMPLI_YN
 Yes

Specify

 COMPLI_SPEC

ID	CODE	NAME	EXP.CODE	TYPE	FMT/LEN	DERIVATION	CAT. VALUES
1	SYMP_YN	SYMP_YN	SYMP_YN	Category	3		0=No 1=Yes
2	SYMP_SPEC	SYMP_SPEC	SYMP_SPEC	Text	50		
3	COMPLI_YN	COMPLI_YN	COMPLI_YN	Category	3		0=No 1=Yes
4	COMPLI_SPEC	COMPLI_SPEC	COMPLI_SPEC	Text	50		

CONCOMITANT MEDICATION

Has the patient taken any new Concomitant Medication?

- No CM_YN
 Yes

Please complete the information in the Previous and Concomitant Medication

ID	CODE	NAME	EXP.CODE	TYPE	FMT/LEN	DERIVATION	CAT. VALUES
1	CM_YN	CM_YN	CM_YN	Category	3		0=No 1=Yes
2	Hotlink			Hotlink		CM_V:CM_F	

ADVERSE EVENTS

Has the patient suffered any Adverse Event?

- No AE_YN
 Yes

Please complete the information in the Adverse Events form

ID	CODE	NAME	EXP.CODE	TYPE	FMT/LEN	DERIVATION	CAT. VALUES
1	AE_YN	AE_YN	AE_YN	Category	3		0=No 1=Yes
2	Hotlink			Hotlink		AE_V:AE_F	

END OF STUDY REASON

- Ineligibility
- Withdrawal of consent
- Discharge from the hospital/institution
- Concomitant illness
- Toxicity
- Subject request to discontinue
- Subject's non-compliance
- Pregnancy
- Death
- Day 90
- Other

EOS_REASON

Discharge date

DISCHARGE_DTC

EOS_REASON_SPE

ID	CODE	NAME	EXP.CODE	TYPE	FMT/LEN	DERIVATION	CAT. VALUES
1	EOS_REASON	EOS_REASON	EOS_REASON	Category	39		See Appendix
2	DISCHARGE_DTC	DISCHARGE_DTC	DISCHARGE_DTC	Date/Time	dd/mm/yyyy		
3	EOS_REASON_SPE	EOS_REASON_SPE	EOS_REASON_SPE	Text	30		

PATIENT RECOVERY

No fever patient date

ASYMPTOM_DTC

SatO2 normalization date (> 94% for 24 hours)

NORMAL_SPO2_DTC

ID	CODE	NAME	EXP.CODE	TYPE	FMT/LEN	DERIVATION	CAT. VALUES
1	ASYMPTOM_DTC	ASYMPTOM_DTC	ASYMPTOM_DTC	Date/Time	dd/mm/yyyy		
2	NORMAL_SPO2_DTC	NORMAL_SPO2_DTC	NORMAL_SPO2_DTC	Date/Time	dd/mm/yyyy		

PRINCIPAL INVESTIGATOR SIGNATURE

I reviewed this eCRF and confirm that the information completed in this eCRF is complete and accurate data and accurately reflect the information of this patient. I confirm that the study was carried out according to the protocol of the same and the informed consent was obtained in writing before the beginning of the study.

Reviewed RVWD

Principal Investigator Name

RVWD_BY

Date

RVWDDTC

ID	CODE	NAME	EXP.CODE	TYPE	FMT/LEN	DERIVATION	CAT. VALUES
1	RVWD	RVWD	RVWD	Category	8		1=Reviewed
2	RVWD_BY	RVWD_BY	RVWD_BY	Text	50	user:username	
3	RVWDDTC	RVWDDTC	RVWDDTC	Date/Time	dd/mm/yyyy	dateof(RVWD)	

PREVIOUS AND CONCOMITANT MEDICATION

Medication	Indication	Dose	Units	Frequency	Route	
CM_TRT	CM_IND	CM_DOS	CM_DOSU	CM_DOSFRQ	CM_ROUTE	
<input type="radio"/> End Date	CM_ENDDTC					<input type="radio"/> Start Date CM_STDTC
<input type="radio"/> Ongoing	CM_END					<input type="radio"/> Not available CM_ST

ID	CODE	NAME	EXP.CODE	TYPE	FMT/LEN	DERIVATION	CAT. VALUES
Repeating Question Group: , Borders: Yes, RowStatus: No, RowNumbers: Yes, DisplayRows: 1, InitialRows: 1, Min Repeats: 0, Max Repeats: 99, Main Row Type: Single-Line, Sub Row Type: Multi-Line							
1	CM_TRT	CM_TRT	CM_TRT	Text	30		
2	CM_IND	CM_IND	CM_IND	Text	30		
3	CM_DOSE	CM_DOSE	CM_DOSE	Text	8		
4	CM_DOSU	CM_DOSU	CM_DOSU	Text	8		
5	CM_DOSFRQ	CM_DOSFRQ	CM_DOSFRQ	Category	14		See Appendix
6	CM_ROUTE	CM_ROUTE	CM_ROUTE	Category	20		See Appendix
7	CM_ST	CM_ST	CM_ST	Category	13		1=Start Date 0=Not available
8	CM_STDTC	CM_STDTC	CM_STDTC	Date/Time	dd/mm/yyyy		
9	CM_END	CM_END	CM_END	Category	8		1=End Date 0=Ongoing
10	CM_ENDDTC	CM_ENDDTC	CM_ENDDTC	Date/Time	dd/mm/yyyy		

ADVERSE EVENTS

Adverse Event Description <input type="text" value="AE_TERM"/>	Onset Date <input type="text" value="AE_STDTC"/>	<input type="radio"/> End Date <input type="text" value="AE_ENDDTC"/> <input type="radio"/> Ongoing AE_END	Severity (CTCAE v5 Grade) <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Life-threatening <input type="radio"/> Death AE_SEV	Relationship to Study Intervention <input type="radio"/> Related <input type="radio"/> Not Related AE_REL	Expectedness <input type="radio"/> Expected <input type="radio"/> Unexpected AE_EXP	Outcome <input type="radio"/> Recovering <input type="radio"/> Recovered <input type="radio"/> Recovered with sequelae AE_OUT
Serious <input type="radio"/> No <input type="radio"/> Yes AE_SER	Treatment for the Event <input type="radio"/> No <input type="radio"/> Yes AE_CONTRT					

ID	CODE	NAME	EXP.CODE	TYPE	FMT/LEN	DERIVATION	CAT. VALUES
Repeating Question Group: , Borders: Yes, RowStatus: No, RowNumbers: Yes, DisplayRows: 1, InitialRows: 1, Min Repeats: 0, Max Repeats: 99, Main Row Type: Single-Line, Sub Row Type: Multi-Line							
1	AE_TERM	AE_TERM	AE_TERM	Text	30		
2	AE_STDTC	AE_STDTC	AE_STDTC	Date/Time	dd/mm/yyyy		
3	AE_END	AE_END	AE_END	Category	8		1=End Date 0=Ongoing
4	AE_ENDDTC	AE_ENDDTC	AE_ENDDTC	Date/Time	dd/mm/yyyy		
5	AE_SEV	AE_SEV	AE_SEV	Category	16		1=Mild 2=Moderate 3=Severe 4=Life-threatening 5=Death
6	AE_REL	AE_REL	AE_REL	Category	11		1=Related 0=Not Related
7	AE_EXP	AE_EXP	AE_EXP	Category	10		1=Expected 0=Unexpected
8	AE_OUT	AE_OUT	AE_OUT	Category	23		1=Recovering 2=Recovered 3=Recovered with sequelae
9	AE_SER	AE_SER	AE_SER	Category	3		0=No 1=Yes
10	AE_CONTRT	AE_CONTRT	AE_CONTRT	Category	3		0=No 1=Yes

CODE	NAME	TYPE	EXPRESSION
ARM	ARM	Category Values	0=Standard of Care (SoC) 1=Standard of Care (SoC) + Recommended Phase II Dose (RP2D)
CM_DOSFRQ	CM_DOSFRQ	Category Values	Q24H=Every 24 hours Q12H=Every 12 hours Q8H=Every 8 hours Q6H=Every 6 hours Q4H=Every 4 hours PRN=As needed QM=Every Month
CM_ROUTE	CM_ROUTE	Category Values	IM=Intramuscular Route IV=Intravenous Route VB=Buccal Route VIC=Intracavernous Route VINH=Inhalation Route VO=Oral Route VOF=Ophthalmic Route VP=Parenteral Route VR=Rectal Route VSC=Subcutaneous Route VSI=Sublingual Route VT=Topical Route VTD=Transdermal Route VV=Vaginal Route
EOS_REASON	EOS_REASON	Category Values	1=Ineligibility 2=Withdrawal of consent 3=Discharge from the hospital/institution 4=Concomitant illness 5=Toxicity 6=Subject request to discontinue 7=Subject's non-compliance 8=Pregnancy 9=Death 10=Day 90 11=Other
OXYGEN_SUPP	OXYGEN_SUPP	Category Values	0=Not used 1=Nasal cannula 2=High flow oxygen therapy 3=Mask with a reservoir bag 4=Non-invasive ventilation 5=Mechanical ventilation or ECMO
SCALE7POINT	SCALE7POINT	Category Values	1=Discharged (or ready for discharge as evidenced by normal body temperature and respiratory rate, and stable oxygen saturation on ambient air or < 2L supplemental oxygen) 2=Non-ICU hospital ward (or ready for hospital ward) not requiring supplemental oxygen 3=Non-ICU hospital ward (or ready for hospital ward) requiring supplemental oxygen 4=ICU or non-ICU hospital ward, requiring non-invasive ventilation or high-flow oxygen 5=ICU, requiring intubation and mechanical ventilation 6=ICU, requiring ECMO or mechanical ventilation and additional organ support (e.g., vasopressors, renal replacement therapy) 7=Death
SITEID	SITEID	Derivation	<pre> case((person:trialsite = 'demo', '000'), (person:trialsite = 'hlapaz', '001'), (person:trialsite = 'hryc', '002'), (person:trialsite = 'hcruces', '003'), (person:trialsite = 'hgaldak', '004'), (person:trialsite = 'hcvai', '005'), (person:trialsite = 'halicant', '006')) </pre>