RELEASE_PII_v1

RELEASE_v1

Subject Label Expression: SCREENINING_V:COVER_F:USUBJID

Date of Birth Expression: SCREENINING_V:DM_F:BRTHDTC

Gender Expression:

Created: 22/04/2021 01:31
| Visit Code | Visit Name | Repeats |
|------------|------------|---------|
| SCREENINING_V | Screening | 1 |
| D3_V | D3 | 1 |
| D14_V | D14 | 1 |
| D21_V | D21 | 1 |

Visit Schedule

Created: 22/04/2021 01:31
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 pneumonia 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 & '-' & SUBJID |                           |
| 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 patients =< 80 years of age
   - Yes
   - 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
   - No

3. Onset of symptoms < 12 days prior to administration of study treatment
   - Yes
   - No

4. No more than 72 hours (3 days) of hospitalization before study treatment administration
   - Yes
   - No

5. Patients requiring hospitalization with pneumonia diagnosed with chest radiograph or computed tomography imaging or lymphopenia (absolute lymphocyte counts below 1.2 x 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
   - No

6. Have a negative pregnancy test documented prior to enrollment (for females of childbearing potential)
   - Yes
   - No
   - Not Applicable

7. Be willing and able to comply with study procedures
   - Yes
   - No

8. Patients with the ability to comprehend and sign the informed consent
   - Yes
   - No

9. Written informed consent obtained prior to any screening procedures
   - Yes
   - 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
   - No

2. Rapidly progressive disease with anticipated life-expectancy < 72 hours
   - Yes
   - No

3. Patients requiring mechanical ventilation
   - Yes
   - No

4. Patients with multiorgan failure
   - Yes
   - 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
   - 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
   - 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
   - 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
   - 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
   - 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 | 3 | 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 99=Not Applicable |
| 17 | IETEST_8 | IETEST_8 | IETEST_8 | Category | 3 | 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
- 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 | COVIDTESTRESULT |
|       | 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

Gender
- Male
- 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

| Symptom                        | Yes | No | Unknown |
|--------------------------------|-----|----|---------|
| **Symptoms start date**        |     |    |         |
| **Fever > 38 °C**              |     |    |         |
| Yes                            |     |    |         |
| No                             |     |    |         |
| Unknown                        |     |    |         |
| **Dysnea**                     |     |    |         |
| Yes                            |     |    |         |
| No                             |     |    |         |
| Unknown                        |     |    |         |
| **Chills**                     |     |    |         |
| Yes                            |     |    |         |
| No                             |     |    |         |
| Unknown                        |     |    |         |
| **Nauseas**                    |     |    |         |
| Yes                            |     |    |         |
| No                             |     |    |         |
| Unknown                        |     |    |         |
| **Muscle pain (Mialgia)**      |     |    |         |
| Yes                            |     |    |         |
| No                             |     |    |         |
| Unknown                        |     |    |         |
| **Vomiting**                   |     |    |         |
| Yes                            |     |    |         |
| No                             |     |    |         |
| Unknown                        |     |    |         |
| **Nasal mucus (Rhinorhea)**    |     |    |         |
| Yes                            |     |    |         |
| No                             |     |    |         |
| Unknown                        |     |    |         |
| **Headache**                   |     |    |         |
| Yes                            |     |    |         |
| No                             |     |    |         |
| Unknown                        |     |    |         |
| **Abdominal pain**             |     |    |         |
| Yes                            |     |    |         |
| No                             |     |    |         |
| Unknown                        |     |    |         |
| **Diarrhea**                   |     |    |         |
| Yes                            |     |    |         |
| No                             |     |    |         |
| Unknown                        |     |    |         |
| **Other**                      |     |    |         |
| Yes                            |     |    |         |
| No                             |     |    |         |
| Unknown                        |     |    |         |

**Other Specify**
| ID | CODE         | NAME          | EXP_CODE | TYPE      | FMT/LEN | DERIVATION | CAT. VALUES |
|----|--------------|---------------|----------|-----------|---------|------------|-------------|
| 1  | SYMP_DTC     | SYMP_DTC      | SYMP_DTC | Date/Time | dd/mm/yyyy | 1=Yes 0=No 99=Unknown |
| 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
- [x] 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  ☑ 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
- Yes

Medical and surgical history

- Diagnoses date
- Not available

Ongoing

- No
- Yes
| ID | CODE  | NAME  | EXP_CODE | TYPE | FMT/LEN | DERIVATION | CAT. VALUES |
|----|-------|-------|----------|------|---------|------------|-------------|
| 1  | MH_YN | MH_YN | MH_YN    | Category | 3      | 0=No 1=Yes |
| 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 |

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
PHYSICAL EXAMINATION

| Body System                | If abnormal, please specify the abnormality |
|----------------------------|---------------------------------------------|
| Dermatologic               |                                             |
| Not Done                   |                                             |
| Normal                     |                                             |
| Abnormal                   |                                             |
| Head and Neck              |                                             |
| Not Done                   |                                             |
| Normal                     |                                             |
| Abnormal                   |                                             |
| Eyes, Ears, Nose & Throat  |                                             |
| Not Done                   |                                             |
| Normal                     |                                             |
| Abnormal                   |                                             |
| Cardiovascular             |                                             |
| Not Done                   |                                             |
| Normal                     |                                             |
| Abnormal                   |                                             |
| Respiratory                |                                             |
| Not Done                   |                                             |
| Normal                     |                                             |
| Abnormal                   |                                             |
| Gastrointestinal           |                                             |
| Not Done                   |                                             |
| Normal                     |                                             |
| Abnormal                   |                                             |
| Musculoskeletal            |                                             |
| Not Done                   |                                             |
| Normal                     |                                             |
| Abnormal                   |                                             |
| Psychologic                |                                             |
| Not Done                   |                                             |
| Normal                     |                                             |
| Abnormal                   |                                             |
| Other                      |                                             |
| Not Done                   |                                             |
| Normal                     | Specify the physical exam                   |
| Abnormal                   |                                             |

Specify the physical exam
| 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        | 0=Not Done 1=Normal 2=Abnormal |
| 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        | 0=Not Done 1=Normal 2=Abnormal |
| 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        | 0=Not Done 1=Normal 2=Abnormal |
| 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        | 0=Not Done 1=Normal 2=Abnormal |
| 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        | 0=Not Done 1=Normal 2=Abnormal |
| 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        | 0=Not Done 1=Normal 2=Abnormal |
| 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        | 0=Not Done 1=Normal 2=Abnormal |
| 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        | 0=Not Done 1=Normal 2=Abnormal |
| 17 | PE_OTHER_SPE | PE_OTHER_SPE | PE_OTHER_SPE | Text | 30        | 0=Not Done 1=Normal 2=Abnormal |
| 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        | 0=Not Done 1=Normal 2=Abnormal |
| Metric                        | Value       |
|------------------------------|-------------|
| Blood Pressure (mmHg)        |             |
| Heart Rate (bpm)             |             |
| Temperature (ºC)             |             |
| Weight (kg)                  |             |
| ID | CODE | NAME       | EXP.CODE | TYPE   | FMT/LEN | DERIVATION | CAT. VALUES |
|----|------|------------|----------|--------|---------|------------|-------------|
| 1  | SYSTOLIC | SYSTOLIC | SYSTOLIC | Integer | #9      | #9         |             |
| 2  | DIASTOLIC | DIASTOLIC | DIASTOLIC | Integer | #9      | #9         |             |
| 3  | HEART_RATE | HEART_RATE | HEART_RATE | Integer | #9      | #9         |             |
| 4  | TEMPERATURE | TEMPERATURE | TEMPERATURE | Real | #9.9    | #9.9       |             |
| 5  | WEIGHT | WEIGHT  | WEIGHT | Real | #99.9   | #99.9      |             |
RESPIRATORY STATUS

Respiratory Rate
- Not Done
- Done

SpO2 (%)

PaO2
- Not Done
- Done

Fraction of inspired oxygen
- Not Done
- Done

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

Ongoing
- End date
| 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   ☑ Done

Date

☐ Chest XRay   ☑ Chest CT

Result  ☐ Normal   ☑ Abnormal

Specify the abnormality
| 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      |            |             |
| Blood Component               | Not Done | Done | HCT_UNITS | HGB_UNITS | MCHC_UNITS | MCV_UNITS | PLAT_UNITS | RBC_UNITS | WBC_UNITS |
|------------------------------|----------|------|-----------|-----------|------------|-----------|------------|-----------|-----------|
| Laboratory Date              |          |      | LBDTC     |           |            |           |            |           |           |
| Hematocrit                   | ○        |      |           |           |            |           |            |           |           |
| Hemoglobin                   | ○        |      |           |           |            |           |            |           |           |
| MCHC                         | ○        |      |           |           |            |           |            |           |           |
| MCV                          | ○        |      |           |           |            |           |            |           |           |
| Platelets                    | ○        |      |           |           |            |           |            |           |           |
| Red blood cells              | ○        |      |           |           |            |           |            |           |           |
| White blood cells            | ○        |      |           |           |            |           |            |           |           |
| ID | CODE  | NAME       | EXP_CODE | TYPE     | FMT/LEN | DERIVATION | CAT. VALUES |
|----|-------|------------|----------|----------|---------|------------|-------------|
| 1  | LBDTC | LBDTC     | LBDTC   | 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=Percent 9=Other units |
| 4  | HCT_CS | HCT_CS    | HCT_CS  | Category | 3       | 0=NCS 1=CS |
| 5  | HCT | HCT | Real | #####9.9 |
| 6  | HCT_UNITS | HCT_UNITS | HCT_UNITS | Category | 11     | 1=pl/dL 2=pl/L 9=Other units |
| 7  | HGB_UNITS | HGB_UNITS | HGB_UNITS | Category | 3       | 0=Not Done 1=Done |
| 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 | Real | #####9.9 |
| 11 | HGB_UNITS | HGB_UNITS | HGB_UNITS | Text | 8 |
| 12 | MCHC_UNITS | MCHC_UNITS | MCHC_UNITS | Category | 11 | 1=pl/dL 2=pl/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 | Real | #####9.9 |
| 16 | MCHC_UNITS | MCHC_UNITS | MCHC_UNITS | Text | 8 |
| 17 | MOV_UNITS | MOV_UNITS | MOV_UNITS | Category | 11 | 1=mm3 2=pl 9=Other units |
| 18 | MOV_NR | MOV_NR    | MOV_NR  | Category | 8       | 0=Not Done 1=Done |
| 19 | MOV_CS | MOV_CS    | MOV_CS  | Category | 3       | 0=NCS 1=CS |
| 20 | MOV | MOV | Real | #####9.9 |
| 21 | MOV_UNITS | MOV_UNITS | MOV_UNITS | 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=x10^6/mcl 9=Other units |
| 24 | PLAT_CS | PLAT_CS   | PLAT_CS | Category | 3       | 0=NCS 1=CS |
| 25 | PLAT | PLAT | Real | #####9.9 |
| 26 | PLAT_UNITS | PLAT_UNITS | PLAT_UNITS | 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=x10^6/mcl 9=Other units |
| 29 | RBC_CS | RBC_CS    | RBC_CS  | Category | 3       | 0=NCS 1=CS |
| 30 | RBC | RBC | Real | #####9.9 |
| 31 | RBC_UNITS | RBC_UNITS | RBC_UNITS | Text | 8 |
| 32 | WBC_UNITS | WBC_UNITS | WBC_UNITS | Category | 11 | 1=x10^3/ul 2=x10^9/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 | Real | #####9.9 |
| 36 | WBC_UNITS | WBC_UNITS | WBC_UNITS | Text | 8 |
| Cell Type | Status | Unit Options | Notes |
|-----------|--------|--------------|-------|
| Basophils | Not Done | %, x 10^3/UL, x 10^9/UL, Other units | BASO_UNITS, BASO_CS, CS |
| Eosinophils | Not Done | %, x 10^3/UL, x 10^9/UL, Other units | EOS_UNITS, EOS_CS, CS |
| Lymphocytes | Not Done | %, x 10^3/UL, x 10^9/UL, Other units | LYM_UNITS, LYM_CS, CS |
| Monocytes | Not Done | %, x 10^3/UL, x 10^9/UL, Other units | MONO_UNITS, MONO_CS, CS |
| Neutrophils | Not Done | %, x 10^3/UL, x 10^9/UL, Other units | NEUT_UNITS, NEUT_CS, CS |
| Glucosa | Not Done | mg/dL, Other units | GLU_UNITS, GLU_CS, CS |
| Urea | Not Done | mg/dL, Other units | UREA_UNITS, 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         | 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          | 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          | 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         | 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         | 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          | 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         | Real     | #9.9        |              |                                                             |
| 71 | UREA_UNITSO | UREA_UNITSO  | UREA_UNITSO | Text 8 |        |              |                                                             |
| Parameter       | Status   | Units       | NCS | CS  |
|-----------------|----------|-------------|-----|-----|
| Creatinine      | Not Done | mg/dL       | CREAT | NCS | CS  |
| Sodium          | Not Done | mEq/L       | NA  | NCS | CS  |
| Potassium       | Not Done | mEq/L       | K   | NCS | CS  |
| Calcium         | Not Done | mg/dL       | CA  | NCS | CS  |
| Chloride        | Not Done | mEq/L       | CL  | NCS | CS  |
| Total Protein   | Not Done | g/dL        | PROT | NCS | CS  |
| Albumin         | Not Done | g/dL        | ALB | NCS | CS  |
| Total Bilirubin | Not Done | mg/dL       | BIL | NCS | CS  |
| Direct Bilirubin| Not Done | mg/dL       | BILD | NCS | CS  |
| ID  | CODE      | NAME       | EXP CODE   | TYPE | FMT/LEN | DERIVATION | CAT. VALUES |
|-----|-----------|------------|------------|------|---------|------------|-------------|
| 72  | CREATE_UNITS | CREATE_UNITS | CREATE_UNITS | Category | 11 | 1=mg/dL, 2=mmol/L, 9=Other units |
| 73  | CREATE_NR | CREATE_NR | CREATE_NR | Category | 8 | 0=Not Done, 1=Done |
| 74  | CREATE_CS | CREATE_CS | CREATE_CS | Category | 3 | 0=NCS, 1=CS |
| 75  | CREATE | CREATE | CREATE | Real | 9.9 |
| 76  | CREATE_UNITSISO | CREATE_UNITSISO | CREATE_UNITSISO | Text | 8 |
| 77  | NA_UNITS | NA_UNITS | NA_UNITS | Category | 11 | 1=mg/dL, 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 | Real | 9.9 |
| 81  | NA_UNITSISO | NA_UNITSISO | NA_UNITSISO | Text | 8 |
| 82  | K_UNITS | K_UNITS | K_UNITS | Category | 11 | 1=mg/dL, 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 | Real | 9.9 |
| 86  | K_UNITSISO | K_UNITSISO | K_UNITSISO | 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 | Real | 9.9 |
| 91  | CA_UNITSISO | CA_UNITSISO | CA_UNITSISO | Text | 8 |
| 92  | CL_UNITS | CL_UNITS | CL_UNITS | Category | 11 | 1=mg/dL, 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 | Real | 9.9 |
| 96  | CL_UNITSISO | CL_UNITSISO | CL_UNITSISO | 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=mg/dL, 9=Other units |
| 99  | PROT_CS | PROT_CS | PROT_CS | Category | 3 | 0=NCS, 1=CS |
| 100 | PROT | PROT | Real | 9.9 |
| 101 | PROT_UNITSISO | PROT_UNITSISO | PROT_UNITSISO | Text | 8 |
| 102 | ALB_UNITS | ALB_UNITS | ALB_UNITS | Category | 11 | 1=mg/dL, 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 | Real | 9.9 |
| 106 | ALB_UNITSISO | ALB_UNITSISO | ALB_UNITSISO | Text | 8 |
| 107 | BILI_UNITS | BILI_UNITS | BILI_UNITS | Category | 11 | 1=mg/dL, 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 | Real | 9.9 |
| 111 | BILI_UNITSISO | BILI_UNITSISO | BILI_UNITSISO | Text | 8 |
| 112 | BILDIR_UNITS | BILDIR_UNITS | BILDIR_UNITS | Category | 11 | 1=mg/dL, 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 | Real | 9.9 |
| 116 | BILDIR_UNITSISO | BILDIR_UNITSISO | BILDIR_UNITSISO | Text | 8 |
| Test  | Status | Test Code | Not Done | Done | Test Units | NCS | CS |
|-------|--------|-----------|----------|------|------------|-----|----|
| AST   |        | AST_NR    | Not Done | Done | U/L        | NCS | CS |
| ALT   |        | ALT_NR    | Not Done | Done | U/L        | NCS | CS |
| LDH   |        | LDH_NR    | Not Done | Done | U/L        | NCS | CS |
| Ferritin | | FERRITIN_NR | Not Done | Done | ug/L, ng/mL | NCS | CS |
| CRP   |        | CRP_NR    | Not Done | Done | mg/L       | NCS | CS |
| Troponine | | TROPONIN_NR | Not Done | Done | ng/L       | NCS | CS |
| D-Dimer | | DDIMER_NR | Not Done | Done | ng/mL      | NCS | CS |
| Triglycerides | | TRIG_NR | Not Done | Done | mg/dL, mmol/L | NCS | CS |
| Fibrinogen | | FIBRINO_NR | Not Done | Done | mg/dL      | NCS | CS |
| 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        | Real     | #        | #        | #          | #           |
| 121| ALT_UNITS | ALT_UNITS  | ALT_UNITS| Category | 11       | 1=U/L, 9=Other units |
| 122| ALT_CS    | ALT_CS     | ALT_CS   | Category | 3        | 0=NCS 1=CS |
| 123| ALT       | ALT        | Real     | #        | #        | #          | #           |
| 124| LDH_NR    | LDH_NR     | LDH_NR   | Category | 8        | 0=Not Done 1=Done |
| 125| LDH_UNITS | LDH_UNITS  | LDH_UNITS| Category | 11       | 1=U/L, 9=Other units |
| 126| FERRITIN_UNITS | FERRITIN_UNITS | Category | 11       | 1=ug/L, 2=ng/mL, 9=Other units |
| 127| FERRITIN_CS | FERRITIN_CS | Category | 3        | 0=NCS 1=CS |
| 128| FERRITIN  | FERRITIN   | Real     | #        | #        | #          | #           |
| 129| TRIG_UNITS | TRIG_UNITS | TRIG_UNITS| Category | 11       | 1=mg/dL, 2=mmol/L, 9=Other units |
| 130| TRIG_CS    | TRIG_CS    | TRIG_CS  | Category | 3        | 0=NCS 1=CS |
| 131| TRIG       | TRIG       | Real     | #        | #        | #          | #           |
| 132| DDIMER_UNITS | DDIMER_UNITS | Category | 11       | 1=ng/mL, 9=Other units |
| 133| DDIMER_CS  | DDIMER_CS  | DDIMER_CS| Category | 3        | 0=NCS 1=CS |
| 134| DDIMER    | DDIMER     | Real     | #        | #        | #          | #           |
| 135| FIBRINO_UNITS | FIBRINO_UNITS | Category | 11       | 1=mg/dL, 9=Other units |
| 136| FIBRINO_CS | FIBRINO_CS | FIBRINO_CS| Category | 3        | 0=NCS 1=CS |
| 137| FIBRINO    | FIBRINO    | Real     | #        | #        | #          | #           |
IL-6
- Not Done
- Done

pg/mL
- Other units

NCS
- 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  |     | ****5.9               |
### MARKERS OF IMMUNOLOGICAL FUNCTION

| Marker     | Status   | Value  | Units   | Other Units |
|------------|----------|--------|---------|-------------|
| IgG        |          |        | mg/dL   | Other units |
| IgA        |          |        | mg/dL   | Other units |
| IgM        |          |        | mg/dL   | Other units |
| CD3        |          |        | 10^3/mCL| Other units |
| CD4        |          |        | 10^3/mCL| Other units |
| T cells    |          |        | 10^3/mCL| Other units |
| CD4 cells  |          |        | 10^3/mCL| Other units |
| CD8 cells  |          |        | 10^3/mCL| Other units |
| B cells    |          |        |         |             |

**Values:**
- IGG_NR
- IGA_NR
- IGM_NR
- CD3_NR
- CD4_NR
- TCELLS_NR
- CMCELLS_NR
- CD8_NR
- SCCELLS_NR

**Units:**
- IGG_UNITS
- IGA_UNITS
- IGM_UNITS
- CD3_UNITS
- CD4_UNITS
- TCELLS_UNITS
- CMCELLS_UNITS
- CD8_UNITS
- SCCELLS_UNITS
| ID | CODE       | NAME       | EXP CODE | TYPE | FMT/LEN | DERIVATION | CAT. VALUES |
|----|------------|------------|----------|------|---------|------------|-------------|
| 1  | IGG_NR     | IGG_NR     | IGG_NR   |      |         |            | 0=Not Done 1=Done          |
| 2  | IGG_UNITS  | IGG_UNITS  | IGG_UNITS|      |         |            | 1=mg/dL 9=Other units         |
| 3  | IGG        | IGG        | IGG      |      |         |            |                          |
| 4  | IGG_UNITS  | IGG_UNITS  | IGG_UNITS|      |         |            |                          |
| 5  | IGA_NR     | IGA_NR     | IGA_NR   |      |         |            | 0=Not Done 1=Done          |
| 6  | IGA_UNITS  | IGA_UNITS  | IGA_UNITS|      |         |            | 1=mg/dL 9=Other units         |
| 7  | IGA        | IGA        | IGA      |      |         |            |                          |
| 8  | IGA_UNITS  | IGA_UNITS  | IGA_UNITS|      |         |            |                          |
| 9  | IGM_NR     | IGM_NR     | IGM_NR   |      |         |            | 0=Not Done 1=Done          |
| 10 | IGM_UNITS  | IGM_UNITS  | IGM_UNITS|      |         |            | 1=mg/dL 9=Other units         |
| 11 | IGM        | IGM        | IGM      |      |         |            |                          |
| 12 | IGM_UNITS  | IGM_UNITS  | IGM_UNITS|      |         |            |                          |
| 13 | CD3_NR     | CD3_NR     | CD3_NR   |      |         |            | 0=Not Done 1=Done          |
| 14 | CD3_UNITS  | CD3_UNITS  | CD3_UNITS|      |         |            | 1=10^6/mL 9=Other units      |
| 15 | CD3        | CD3        | CD3      |      |         |            |                          |
| 16 | CD3_UNITS  | CD3_UNITS  | CD3_UNITS|      |         |            |                          |
| 17 | CD4_NR     | CD4_NR     | CD4_NR   |      |         |            | 0=Not Done 1=Done          |
| 18 | CD4_UNITS  | CD4_UNITS  | CD4_UNITS|      |         |            | 1=10^6/mL 9=Other units      |
| 19 | CD4        | CD4        | CD4      |      |         |            |                          |
| 20 | CD4_UNITS  | CD4_UNITS  | CD4_UNITS|      |         |            |                          |
| 21 | CD8_CD4_NR | CD8_CD4_NR | CD8_CD4_NR|      |         |            | 0=Not Done 1=Done          |
| 22 | CD8_CD4    | CD8_CD4    | CD8_CD4  |      |         |            |                          |
| 23 | TCELLS_NR  | TCELLS_NR  | TCELLS_NR|      |         |            | 0=Not Done 1=Done          |
| 24 | TCELLS_UNITS | TCELLS_UNITS | TCELLS_UNITS|      |         |            | 1=10^6/mL 9=Other units      |
| 25 | TCELLS     | TCELLS     | TCELLS   |      |         |            |                          |
| 26 | TCELLS_UNITS | TCELLS_UNITS | TCELLS_UNITS|      |         |            |                          |
| 27 | CD4CELLS_NR | CD4CELLS_NR | CD4CELLS_NR|      |         |            | 0=Not Done 1=Done          |
| 28 | CD4CELLS_UNITS | CD4CELLS_UNITS | CD4CELLS_UNITS|      |         |            | 1=10^6/mL 9=Other units      |
| 29 | CD4CELLS   | CD4CELLS   | CD4CELLS |      |         |            |                          |
| 30 | CD4CELLS_UNITS | CD4CELLS_UNITS | CD4CELLS_UNITS|      |         |            |                          |
| 31 | CD8_NR     | CD8_NR     | CD8_NR   |      |         |            | 0=Not Done 1=Done          |
| 32 | CD8_UNITS  | CD8_UNITS  | CD8_UNITS|      |         |            | 1=10^6/mL 9=Other units      |
| 33 | CD8        | CD8        | CD8      |      |         |            |                          |
| 34 | CD8_UNITS  | CD8_UNITS  | CD8_UNITS|      |         |            |                          |
| 35 | BCELLS_NR  | BCELLS_NR  | BCELLS_NR|      |         |            | 0=Not Done 1=Done          |
○ 10e3/mCL
○ Other units
| ID | CODE     | NAME     | EXP.CODE | TYPE | FMT/LEN | DERIVATION | CAT. VALUES |
|----|----------|----------|----------|------|---------|------------|-------------|
| 36 | BCELLS_UNITS | BCELLS_UNITS | BCELLS_UNITS | Category | 11 | 1=10^6/mCL 9=Other units |
| Cell Type | Unit | Value | Other Units |
|-----------|------|-------|-------------|
| NK cells  |      |       |             |
| CD4+RA+   |      |       |             |
| CD4+RA-   |      |       |             |
| CD8+RA+   |      |       |             |
| CD8+RA-   |      |       |             |
| NKT cells |      |       |             |
| Memory B cells |      |       |             |
| 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 | 1=10^6/mL 9=Other units |             |
| 40  | NKCREPER_UNITS| NKCREPER_UNITS  | NKCREPER_UNITS | Category 11 | 0=Not Done 1=Done | 1=10^6/mL 9=Other units |             |
| 41  | 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 | 1=10^3/mL 9=Other units |             |
| 44  | CD4P_RAP_UNITS | CD4P_RAP_UNITS  | CD4P_RAP_UNITS | Category 11 | 0=Not Done 1=Done | 1=10^3/mL 9=Other units |             |
| 45  | CD4POS_RAPOS  | CD4POS_RAPOS    | Real      | #####9.9 |          |                          |             |
| 46  | CD4P_RAP_UNITS | CD4P_RAP_UNITS  | CD4P_RAP_UNITS | Text | 8       |                          |             |
| 47  | CD4POS_RANEG_NR | CD4POS_RANEG_NR | CD4POS_RANEG_NR | Category 8 | 0=Not Done 1=Done | 1=10^3/mL 9=Other units |             |
| 48  | CD4P_RAN_UNITS | CD4P_RAN_UNITS  | CD4P_RAN_UNITS | Category 11 | 0=Not Done 1=Done | 1=10^3/mL 9=Other units |             |
| 49  | CD4POS_RANEG  | CD4POS_RANEG    | Real      | #####9.9 |          |                          |             |
| 50  | CD4P_RAN_UNITS | CD4P_RAN_UNITS  | CD4P_RAN_UNITS | Text | 8       |                          |             |
| 51  | CD4POS_RAPOS_NR | CD4POS_RAPOS_NR | CD4POS_RAPOS_NR | Category 8 | 0=Not Done 1=Done | 1=10^3/mL 9=Other units |             |
| 52  | CD4P_RAP_UNITS | CD4P_RAP_UNITS  | CD4P_RAP_UNITS | Category 11 | 0=Not Done 1=Done | 1=10^3/mL 9=Other units |             |
| 53  | CD4POS_RAPOS  | CD4POS_RAPOS    | Real      | #####9.9 |          |                          |             |
| 54  | CD4P_RAP_UNITS | CD4P_RAP_UNITS  | CD4P_RAP_UNITS | Text | 8       |                          |             |
| 55  | CD4POS_RANEG_NR | CD4POS_RANEG_NR | CD4POS_RANEG_NR | Category 8 | 0=Not Done 1=Done | 1=10^3/mL 9=Other units |             |
| 56  | CD4P_RAN_UNITS | CD4P_RAN_UNITS  | CD4P_RAN_UNITS | Category 11 | 0=Not Done 1=Done | 1=10^3/mL 9=Other units |             |
| 57  | CD4POS_RANEG  | CD4POS_RANEG    | Real      | #####9.9 |          |                          |             |
| 58  | CD4P_RAN_UNITS | CD4P_RAN_UNITS  | CD4P_RAN_UNITS | Text | 8       |                          |             |
| 59  | NKTC_NR       | NKTC_NR         | NKTC_NR   | Category 8 | 0=Not Done 1=Done | 1=10^3/mL 9=Other units |             |
| 60  | NKTC_UNITS    | NKTC_UNITS      | NKTC_UNITS | Category 11 | 0=Not Done 1=Done | 1=10^3/mL 9=Other units |             |
| 61  | 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 | 1=10^3/mL 9=Other units |             |
| 64  | MEMOBC_UNITS  | MEMOBC_UNITS    | MEMOBC_UNITS | Category 11 | 0=Not Done 1=Done | 1=10^3/mL 9=Other units |             |
| ID | CODE  | NAME  | EXP.CODE | TYPE | FMT/LEN | DERIVATION | CAT. VALUES |
|----|-------|-------|----------|------|---------|------------|-------------|
| 65 | MEMOB | MEMOB | MEMOB    | Real | ######9.9 |            |             |
| Parameter | Not Done | Done | % | Other units |
|-----------|----------|------|---|-------------|
| T cells GD | ACTTC_NR | ACTTC | ACTTC_UNITS | ACTTC_UNITS |
| T regs | TREGS_NR | TREGS | TREGS_UNITS | TREGS_UNITS |
| CD3+HLADR+ | CD3_HLADR_NR | CD3_HLADR | CD3_HLADR_UNITS | CD3_HLADR_UNITS |
| Ratio Treg/Tcon | TGEN_TCON_NR | TGEN_TCON | TGEN_TCON | TGEN_TCON |
| ID | CODE            | NAME            | EXP_CODE | TYPE   | FMT/LEN | DERIVATION                  | CAT. VALUES          |
|----|-----------------|-----------------|----------|--------|---------|-----------------------------|----------------------|
| 66 | MEMOB_UNITSO    | MEMOB_UNITSO    | Text     | 8      |         |                             |                      |
| 67 | ACTTC_NR        | ACTTC_NR        | Category  | 8      |         |                             | 0=Not Done 1=Done    |
| 68 | ACTTC_UNITS     | ACTTC_UNITS     | Category  | 11     |         |                             | 1=#% 9=Other units   |
| 69 | ACTTC           | ACTTC           | Real     | #9999  |         |                             |                      |
| 70 | ACTTC_UNITSO    | ACTTC_UNITSO    | Text     | 8      |         |                             |                      |
| 71 | TREGS_NR        | TREGS_NR        | Category  | 8      |         |                             | 0=Not Done 1=Done    |
| 72 | TREGS_UNITS     | TREGS_UNITS     | Category  | 11     |         |                             | 1=#% 9=Other units   |
| 73 | TREGS           | TREGS           | Real     | #9999  |         |                             |                      |
| 74 | TREGS_UNITSO    | TREGS_UNITSO    | Text     | 8      |         |                             |                      |
| 75 | CD3_HLADR_NR    | CD3_HLADR_NR    | Category  | 8      |         |                             | 0=Not Done 1=Done    |
| 76 | CD3_HLADR_UNITS | CD3_HLADR_UNITS | Category  | 11     |         |                             | 1=#% 9=Other units   |
| 77 | CD3_HLADR       | CD3_HLADR       | Real     | #9999  |         |                             |                      |
| 78 | CD3_HLADR_UNITSO| CD3_HLADR_UNITSO| Text     | 8      |         |                             |                      |
| 79 | TGEN_TCON_NR    | TGEN_TCON_NR    | Category  | 8      |         |                             | 0=Not Done 1=Done    |
| 80 | TGEN_TCON       | TGEN_TCON       | Real     | #9999  |         |                             |                      |
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 | 2       |            | 1=Yes 0=No  |
DONOR CHIMERISM

- No Realizado
- Realizado

Donor Chimerism (%)

DONOR_CHIMERISM_NR
| 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   | #9.999999 |            |             |
PREGNANCY TEST

- Not Done
- Done

- Urine
- Blood

- Negative
- 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 |
| 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
- 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 | 371     |            | See Appendix              |
RANDOMIZATION

Randomization Date

- Standard of Care (SoC)
- 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  | ddmmyy   |            |             |
| 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
- Yes

Specify

Has the patient suffer any complications after discharge?

- No
- Yes

Specify
| ID | CODE   | NAME   | EXP_CODE | TYPE      | FMT/LEN | DERIVATION | CAT. VALUES |
|----|--------|--------|----------|-----------|---------|------------|-------------|
| 1  | SYMP_YN| SYMP_YN| SYMP_YN  | Category  | 3       |            |             |
| 2  | SYMP_SPEC| SYMP_SPEC| SYMP_SPEC| Text     | 50      |            |             |
| 3  | COMPL_YN| COMPL_YN| COMPL_YN  | Category  | 3       |            |             |
| 4  | COMPL_SPEC| COMPL_SPEC| COMPL_SPEC| Text     | 50      |            |             |

- 0=No 1=Yes
CONCOMITANT MEDICATION

Has the patient taken any new Concomitant Medication?

☐ No  ☐ 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       | CM_V:CM_F  | 0=No 1=Yes |
ADVERSE EVENTS

Has the patient suffered any Adverse Event?

- No
- 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

Discharge date

Other
| 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

SatO2 normalization date (> 94% for 24 hours)
| ID | CODE            | NAME            | EXP_CODE       | TYPE         | FMT/LEN  | DERIVATION | CAT. VALUES |
|----|-----------------|-----------------|----------------|--------------|----------|------------|-------------|
| 1  | ASYMPOTM_DTC    | ASYMPOTM_DTC    | ASYMPOTM_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

Principal Investigator Name

Date

Reviewed

Principal Investigator Name

Date
| 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  | RVWDTC | RVWDTC | RVWDTC   | Date/Time | dd/mm/yyyy | dateof(RVWD) |             |
### PREVIOUS AND CONCOMITANT MEDICATION

| Medication | Indication | Dose | Units | Frequency | Route | Start Date | Not available |
|------------|------------|------|-------|-----------|-------|------------|--------------|
| CM_TRT     | CM_IND     | CM_DOSE | CM_DOSE | CM_DOSFRQ | CM_ROUTE | CM_STDTTC | CM_ST        |

- **End Date**: CM_ENDDTC
- **Ongoing**: CM_END
| ID | CODE     | NAME     | EXP_CODE | TYPE    | FMT/LEN | DERIVATION | CAT. VALUES |
|----|----------|----------|----------|---------|---------|------------|-------------|
| 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 | Onset Date | Severity (CTCAE v5 Grade) | Relationship to Study Intervention | Expectedness | Outcome |
|---------------------------|------------|---------------------------|-----------------------------------|--------------|---------|
| AE_TERM                   | AE_STDTC   | AE_END                    | AE_END                           | AE_EXP       | AE_OUT  |

- **Serious**: No, Yes
- **Treatment for the Event**: No, Yes
- **Severity**: Mild, Moderate, Severe, Life-threatening, Death
- **Relationship to Study Intervention**: Related, Not Related
- **Expectedness**: Expected, Unexpected
- **Outcome**: Recovering, Recovered, Recovered with sequelae

**AE_CONTRT**

No Yes
| ID | CODE | NAME   | EXP CODE | TYPE | FMT/LEN | DERIVATION          | CAT. VALUES                                                                 |
|----|------|--------|----------|------|----------|---------------------|-----------------------------------------------------------------------------|
| 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_ENDDT | AE_ENDDT | AE_ENDDT | 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_CONTRT | AE_CONTRT | AE_CONTRT | 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 Q6H=Every 8 hours Q4H=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 VOI=Oral Intake VR=Rectal Route VSC=Subcutaneous Route VSI=Sublingual Route VT=Topical Route VTD=Transdermal Route VW=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 <= 2 L 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 L 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             | case( (person:trialsite = 'demo', '000') , (person:trialsite = 'hlapaz', '001') , (person:trialsite = 'hryc', '002') , (person:trialsite = 'hcruces', '003') , (person:trialsite = 'hgaldak', '004') , (person:trialsite = 'hcval', '005') , (person:trialsite = 'halicant', '006') ) |