**SUBJECT ID NUMBER: SITE CODE: SAMPLING DAY: DATE SAMPLES RECEIVED & PROCESSED:**

This form is for a sample set from a once-weekly sampling day (week 3 onwards, up to maximum week 14). One form should be used for each sampling week. The sampling week is indicated on the labels on the clinical samples e.g. Week 3 Tempus tube = W3\_TEMP. Aliquot vial labels corresponding to the same week should be used.

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Sample type Refer to table 2 & 3 below\*** | **Sample received?** (enter a cross in the box) | **Time received** (HH:MM  use 24h clock) | **Original sample labelled?** | **Time original sample entered freezer**  (HH:MM use 24h clock) | **Number of aliquot vials made** (as appropriate) | **Aliquot vials labelled?** (enter initials to confirm) | **Time aliquot vials entered freezer** (HH:MM use 24h clock) | **If sample NOT received on date indicated above, enter date below** | **Comments** |
| **\*EDTA tube x 1** | 🞏YES 🞏No |  | 🞏YES 🞏No 🞏NA | EDTA  pellet: | Plasma  vials: |  |  |  |  |
| **\*clotted tube x 1** | 🞏YES 🞏No |  | 🞏YES 🞏No 🞏NA | Clotted  pellet: | Serum  vials: |  |  |  |  |
| **Tempus tube x 1** | 🞏YES 🞏No |  | 🞏YES 🞏No 🞏NA |  | NA | NA | NA |  |  |
| **Urine** | 🞏YES 🞏No |  | 🞏YES 🞏No 🞏NA | NA | Urine  vials: |  |  |  |  |
| **Stool** | 🞏YES 🞏No |  | 🞏YES 🞏No 🞏NA |  | NA | NA | NA |  |  |
| **NP aspirate** | 🞏YES 🞏No |  | 🞏YES 🞏No 🞏NA | NA | NPA  vials: |  |  |  |  |
| **ET aspirate** | 🞏YES 🞏No |  | 🞏YES 🞏No 🞏NA | NA |  |  |  |  |  |
| **Flocked Swab + UTM** | 🞏YES 🞏No |  | 🞏YES 🞏No 🞏NA |  | NA | NA | NA |  |  |
| **Sputum** | 🞏YES 🞏No |  | 🞏YES 🞏No 🞏NA | NA | Sputum  vials: |  |  |  |  |
| **Infected Site swab** | 🞏YES 🞏No |  | 🞏YES 🞏No 🞏NA |  | NA | NA | NA |  |  |

**BMS NAME: DATE (DD/MM/YYYY):**  **BMS SIGNATURE:**

Table 2. Sampling pattern - In Patient Recruitment

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | Serial samples. | | | | | | | | | | | | | | |  |
|  | Recruitment | Week 1 | | | | | | Week 2 | | | | | | |  | Further samples | Convalescent samples |
| Day | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | Weekly until max 100 days | 3 months and 6 months after recruitment |
| 20 to 40kg | R |  | S |  | S |  | S |  | S |  | S |  |  |  |  | S | C |
| 10 to 20kg | R |  | S |  | S |  | S |  | S |  | S |  |  |  |  | S | C |
| 4 to 10kg | R |  | S |  | S |  | P |  | S |  | P |  |  |  |  | S | C |
| >4kg | R |  | S |  | S |  | P |  | S |  | P |  |  |  |  | S | C |
| Sample priority | 1 |  | 2 |  | 5 |  | 7 |  | 3 |  | 8 |  |  |  |  | 6 | 4 |

R = recruitment samples. S = serial samples including pathogen samples; P = research pathogen samples only; C = convalescent samples (see Table 3). In the event that local resource limitations require sampling frequency to decrease, samples will be prioritised as shown (1=highest priority). Serial sampling will stop when acute illness resolves or a patient is discharged from hospital: next samples taken will be the blood sample at 3 months and 6 months post recruitment.

Table 3. Samples

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Weight | Samples at recruitment (R) | Serial samples (S) | Convalescent samples | Total Volumes of blood taken |
| 20 to 40kg | 6ml (3x2ml) EDTA blood  3ml blood in serum(clotted) tube  3ml blood in blood RNA tube  Research pathogen samples | 1ml EDTA blood  2ml blood in blood RNA tube  Up to 3 additional 0.5ml samples in EDTA or fluoride oxalate tubes spread throughout dosing schedule for pharmacokinetic/pharmacodynamic studies.  Research pathogen samples | 1ml EDTA blood  3ml blood in serum(clotted) tube  2ml blood in blood RNA tube  Research pathogen samples | Maximum any day: 12ml (0.6ml/kg)  Maximum any 4 weeks: 42ml (maximum 2.1ml/kg) |
| 10 to 20kg | 2ml EDTA blood  2ml blood in serum(clotted) tube  2ml blood in blood RNA tube  Research pathogen samples | 1ml EDTA blood  1ml blood in blood RNA tube  Up to 3 additional 0.2ml samples in EDTA or fluoride oxalate tubes spread throughout dosing schedule for pharmacokinetic/pharmacodynamic studies.  Research pathogen samples | 1ml EDTA blood  1ml blood in serum(clotted) tube  1ml blood in blood RNA tube  Research pathogen samples | Maximum any day: 6ml (0.6ml/kg)  Maximum any 4 weeks: 23.6ml (maximum 2.36ml/kg) |
| 4 to 10kg | 1ml EDTA blood  1ml blood in serum(clotted) tube  ml blood in blood RNA tube  Research pathogen samples | 1ml EDTA blood  Up to 3 additional 0.2ml samples in EDTA or fluoride oxalate tubes spread throughout dosing schedule for pharmacokinetic/pharmacodynamic studies.  Research pathogen samples | 1ml EDTA blood  1ml blood in serum(clotted) tube  Research pathogen samples | Maximum any day: 2ml (0.5ml/kg)  Maximum any 4 weeks: 9.4ml (maximum 2.35ml/kg) |
| < 4kg | 0.5ml EDTA blood  0.1ml blood in serum(clotted) tube  ml blood in blood RNA tube  Research pathogen samples | 0.2ml EDTA blood  Up to 3 additional 0.1ml samples in EDTA or fluoride oxalate tubes spread throughout dosing schedule for pharmacokinetic/pharmacodynamic studies.  Research pathogen samples | 0.2ml EDTA blood  0.2ml blood in serum(clotted) tube  Research pathogen samples | Maximum any day: 0.8ml (~0.27ml/kg)  Maximum any 4 weeks: 2.4ml (maximum 2.4ml/kg) |
| Research pathogen samples (all patients) | Pathogen samples taken solely for research purposes:   1. In all patients: combined nose and throat swab 2. In all intubated patients: endotracheal aspirate   also where resources permit:   * 1. Nasopharyngeal aspirate (NPA) OR (if NPA impossible) flocked nose and throat swab   2. Urine (up to 10ml in sterile universal container, if available)   3. Rectal swab or stool (up to 10ml in sterile universal container or stool specimen container, if available)   4. Samples/swabs from infected sites or sores. | | | No patient will give more than 0.6ml/kg (>1% blood volume) on any one day, or more than 2.4ml/kg (approx 3% blood volume) in any four week period (MCRN recommendations). |
| Clinician-requested pathogen samples (all patients) | Where possible, we will obtain an aliquot of any residual and unwanted sample volume from specimens that have been sent by clinicians for pathogen detection, including those obtained before recruitment to the study: urine; stool; respiratory tract samples (NPA, ETA, BAL, sputum, ENT swabs); cerebrospinal fluid. | | |  |