**SUBJECT ID NUMBER: SITE CODE: SAMPLING DAY: D1 (RECRUITMENT) DATE OF SAMPLING:**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Sample typeRefer to table 2 & 3 below\*** | **Sample obtained?** (enter a cross in the box | **Time taken** (HH:MM use 24h clock) | **Study label applied and date & time of sampling written on the tube** (enter initials to confirm) | **If sample NOT taken on the date indicated above, enter the date below** | **Any comments** (include any deviations from sampling protocol) |
| **\*EDTA Tube 1** | 🞏YES 🞏No 🞏NA |  |  |  |  |
| **\*EDTA Tube 2(if >20kg)** | 🞏YES 🞏No 🞏NA |  |  |  |  |
| **\*EDTA Tube 3(if >20kg)** | 🞏YES 🞏No 🞏NA |  |  |  |  |
| **3ml clotted blood tube x 1** | 🞏YES 🞏No 🞏NA |  |  |  |  |
| **Tempus tube x 1** | 🞏YES 🞏No 🞏NA |  |  |  |  |
| **Urine** | 🞏YES 🞏No 🞏NA |  |  |  |  |
| **Stool** | 🞏YES 🞏No 🞏NA |  |  |  |  |
| **NP aspirate (NPA)** | 🞏YES 🞏No 🞏NA |  |  |  |  |
| **ET aspirate** **(ETA)** | 🞏YES 🞏No 🞏NA |  |  |  |  |
| **Flocked Swab in UTM1** | 🞏YES 🞏No 🞏NA*If YES, state type:*🞏 Nasopharyngeal🞏 Nose and throat |  |  |  |  |
| **Sputum2** | 🞏YES 🞏No 🞏NA |  |  |  |  |
| **Infected Site Swab3** | 🞏YES 🞏No 🞏NASite:  |  |  |  |  |

**SAMPLER’S NAME: SAMPLER’S SIGNATURE: DATE (DD/MM/YYYY):**

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 blood3ml blood in serum(clotted) tube3ml blood in blood RNA tubeResearch pathogen samples | 1ml EDTA blood2ml blood in blood RNA tubeUp 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 blood3ml blood in serum(clotted) tube2ml blood in blood RNA tubeResearch pathogen samples | Maximum any day: 12ml (0.6ml/kg)Maximum any 4 weeks: 42ml (maximum 2.1ml/kg) |
| 10 to 20kg | 2ml EDTA blood2ml blood in serum(clotted) tube2ml blood in blood RNA tubeResearch pathogen samples | 1ml EDTA blood1ml blood in blood RNA tubeUp 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 blood1ml blood in serum(clotted) tube1ml blood in blood RNA tubeResearch pathogen samples | Maximum any day: 6ml (0.6ml/kg)Maximum any 4 weeks: 23.6ml (maximum 2.36ml/kg) |
| 4 to 10kg | 1ml EDTA blood1ml blood in serum(clotted) tubeml blood in blood RNA tubeResearch pathogen samples | 1ml EDTA bloodUp 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 blood1ml blood in serum(clotted) tubeResearch pathogen samples | Maximum any day: 2ml (0.5ml/kg)Maximum any 4 weeks: 9.4ml (maximum 2.35ml/kg) |
| < 4kg | 0.5ml EDTA blood0.1ml blood in serum(clotted) tubeml blood in blood RNA tubeResearch pathogen samples | 0.2ml EDTA bloodUp 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 blood0.2ml blood in serum(clotted) tubeResearch 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. |  |