REMAP-CAP Laboratory SOP (STANDARD SAMPLING)

COVID-19 IMMUNOGLOBULIN THERAPY DOMAIN
Summary
In this domain of the REMAP-CAP trial, participants meeting the platform-entry criteria for REMAP-CAP will be randomised to receive interventions using immunoglobulins as the basis for treatment:

- No immunoglobulin against COVID-19 (no placebo)
- Convalescent Plasma

This laboratory manual includes information on sample processing, storage, recording, and transport of samples in the UK. There are two sampling structures for this clinical trial. **Standard sampling** will include serum and virology samples taken at baseline only (Baseline (Day 1) is defined as day patient is consented to be randomised into the trial). **Intensive sampling** includes up to 9 timepoints of repeated research blood sampling. Samples should be taken from all patients randomised into the Immunoglobulin Therapy Domain.

<table>
<thead>
<tr>
<th>Sample</th>
<th>Standard Sampling</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serum (red top or equivalent) 6 ml</td>
<td>Yes</td>
</tr>
<tr>
<td>Nasopharyngeal or Oropharyngeal swab</td>
<td>Yes</td>
</tr>
</tbody>
</table>

Your site has opted for the **Standard** sampling schedule (Table 1)

Contacts

Central Laboratory email
remap-plasma@kcl.ac.uk

Central Lab PI
Dr Manu Shankar-Hari

Trial Managers
Emma Laing (emma.laing@nhsbt.nhs.uk)
Amy Evans (amy.evans@nhsbt.nhs.uk)

Central Laboratory Team
Matthew Fish (Matthew.fish@kcl.ac.uk)
Aislinn Jennings (Aislinn.jennings@kcl.ac.uk)
Dr Silvia Trevelin Cellone (silvia.cellone_trevelin@kcl.ac.uk)
Dr Emma Timms (emma.timms@kcl.ac.uk)
1.1. Equipment  
Locally provided yellow top or red top or equivalent tube for serum (6mL)  
Locally provided respiratory sample (swab) collection tube  
Locally provided PPE as per local guideline

1.2. Types of samples  
1.2.1. Serum sample  
Collect one 6mL yellow top or equivalent tube.  
Label with randomisation ID.  
Store at room temperature and post with the virology sample.

1.2.2. Virology samples  
Collect one oropharyngeal or nasopharyngeal swab.  
Double bag the sample after collection.

1.3. Labelling samples  
Label each sample with  
- REMAP-CAP Randomisation Number  
- Date/time of sample collection  
- Sample type

1.4. Transfer of samples to central KCL site  
Complete the Sample Tracking Form (away from clinical area).  
Post the same day as collection* using pre-paid Royal Mail SafeBoxes  
(supplied by NHSBT CTU). Keep the SafeBoxes away from the clinical area.  
Notify the laboratory by email after posting with: remap-plasma@kcl.ac.uk

Core laboratory Address:  
MSH Group (REMAP Trial)  
Department of Immunobiology,  
2nd Floor Borough Wing, Admin Office,  
Guy's Hospital  
SE1 9RT.

*if not possible, store samples in a designated fridge and post as soon as possible.
Local Sample Tracking Log

*Please keep this on site.*

<table>
<thead>
<tr>
<th>Hospital Site: ________________________________</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>REMAP_CAP Randomisation Number</strong></td>
</tr>
<tr>
<td>-----------------------------------------------</td>
</tr>
<tr>
<td>☐ Blood ☐ Respiratory</td>
</tr>
<tr>
<td>☐ Blood ☐ Respiratory</td>
</tr>
<tr>
<td>☐ Blood ☐ Respiratory</td>
</tr>
<tr>
<td>☐ Blood ☐ Respiratory</td>
</tr>
<tr>
<td>☐ Blood ☐ Respiratory</td>
</tr>
<tr>
<td>☐ Blood ☐ Respiratory</td>
</tr>
<tr>
<td>☐ Blood ☐ Respiratory</td>
</tr>
<tr>
<td>☐ Blood ☐ Respiratory</td>
</tr>
<tr>
<td>☐ Blood ☐ Respiratory</td>
</tr>
<tr>
<td>☐ Blood ☐ Respiratory</td>
</tr>
<tr>
<td>☐ Blood ☐ Respiratory</td>
</tr>
</tbody>
</table>