



# SOP Harmonization

July 26, 2022

# Overview

| SOP                         | China  | South Africa | India  | Canada |
|-----------------------------|--------|--------------|--------|--------|
| Blood                       | ✓      | ✓            | ✓      | ✓      |
| OGTT                        | ✓      | ✓            | ✓      | ✓      |
| Urine                       | ✓      | ✓            | ✓      | --     |
| Saliva and Buccal Swab      | ✓      | ✓            | ✓      | --     |
| Placenta                    | ✓      | ✓            | ✓      | --     |
| Cord Blood                  | ✓      | --           | ✓      | --     |
| Cord                        | ✓      | --           | ✓      | --     |
| Breast Milk                 | ✓      | --           | --     | --     |
| Vaginal Swab                | ✓      | --           | --     | --     |
| Heel Prick/Dried Blood Spot | Shared | Shared       | Shared | --     |

 Harmonized  
 Under review <sup>2</sup>

# Blood Collection

| China   | South Africa  | India   | Canada  |
|---|---|---|---|
| Purple Top EDTA (2 x 5 mL) <ul style="list-style-type: none"> <li>• Plasma</li> <li>• Buffy Coat</li> </ul> | Purple Top EDTA (2 x 6 mL) <ul style="list-style-type: none"> <li>• Plasma</li> <li>• Buffy Coat</li> <li>• Whole Blood (4.5 mL)</li> </ul> | Purple Top EDTA (2 x 8 mL) <ul style="list-style-type: none"> <li>• Plasma</li> <li>• Buffy Coat</li> <li>• Whole Blood (1 mL)</li> </ul> | Purple Top EDTA (2 x 4 mL) <ul style="list-style-type: none"> <li>• Plasma</li> </ul> |
| Yellow Top SST-Serum<br>(1 x 5 mL)  | Yellow Top Serum<br>(1 x 5 mL)  | Red Top Clot-Serum<br>(1 x 3 mL)  | Gold Top SST-Serum<br>(1 x 5 mL)<br><br>Red Top SST-Serum<br>(1 x 5 mL)               |
| --  | Green Top Heparin<br>(1 x 4.5 mL)   | Green Top Heparin<br>(1 x 2 mL)   | --  |
| --  | --  | Clear Top PAXGene<br>(1 x 2.5 mL)   | --  |

# Blood Processing

| China                         | South Africa   | India   | Canada   |
|-------------------------------|--|---|--|
| Within 30 minutes             | Within 30 minutes  | Within 30 minutes   | --   |
| Plasma (16)<br>Buffy Coat (2) | Plasma (3)<br>Buffy Coat (2)<br>Whole Blood + DMSO (2)<br>Whole Blood + non-DMSO (2) | Plasma (10)<br>Buffy Coat (2)<br>Whole Blood + non-DMSO (1) | Plasma<br>Pellet<br>• (Erythrocytes and other cells) |
| Serum (8)                     | Serum (3)  | Serum (4)   | Serum  |
| --                            | Heparin (3)  | Heparin (3)   | --   |
| 300 uL aliquots               | 300 uL aliquots  | 300 uL aliquots   | 300 uL aliquots                                      |

# Blood Storage



| China                  | South Africa           | India                  | Canada  |
|------------------------|------------------------|------------------------|---|
| Store at -80°C freezer | Store at -80°C freezer | Store at -80°C freezer | <p>Temporary Storage at -20°C for delivery</p> <p>Every 2 weeks shipped to LTRI and stored at -80°C</p> <p>For immediate analysis:</p> <ul style="list-style-type: none"> <li>• EDTA = CBC and HbA1C</li> <li>• Gold top = CRP, glucose and lipids</li> </ul> |

# Blood Analysis

| China                 | South Africa     | India          | Canada   |
|-----------------------|------------------|----------------|--|
| No immediate analysis | Glucose<br>HbA1C | Glucose<br>CBC | Glucose<br>HbA1c<br>CBC<br>Serum CRP<br>Lipids |

# Urine Collection

| China                          | South Africa                   | India                          | Canada |
|--------------------------------|--------------------------------|--------------------------------|--------|
| Sterile Screw cap (45 mL)      | Sterile Screw cap (45 mL)      | Sterile Screw cap (40 mL)      | N/A    |
| Collect 15 mL minimum          | Collect 10 mL minimum          | Collect 10 mL minimum          | N/A    |
| Midstream urine flow           | Midstream urine flow           | Midstream urine flow           | N/A    |
| Temporary storage on ice (4°C) | Temporary storage on ice (4°C) | Temporary storage on ice (4°C) | N/A    |

 = differences  
 = pending

# Urine Processing and Storage

| China                    | South Africa  | India  | Canada |
|--------------------------|---|--|--------|
| Within 2 hours           | Within 2 hours<br>10 Urine Dipstick   | Within 2 hours   | N/A    |
| Orange cap cryovials (3) | Yellow/white cap cryovials (3)<br>Orange/blue cap cryovials (mineral oil) (3) | 4 mL cryovials (2)<br>4 mL cryovials (mineral oil) (2) | N/A    |
| 5 mL/aliquot             | 1 mL/aliquot  | 4 mL/aliquot   | N/A    |
| Store at -80°C           | Short term: -20°C (max. 30 days)<br>Long term: Store at -80°C                 | Store at -80°C   | N/A    |





# Saliva and Buccal Swab Collection

| China   | South Africa                                  | India                                       | Canada |
|---|---|---|--------|
| Screw Cap 20 mL Saliva collection cup (minimum 2 mL)  | --  | --  | N/A    |
| Buccal Swab bag (2 swabs)   | Buccal Swab bag (2 swabs)                     | Buccal swab bag (2 swabs)                   | N/A    |
| No consumption 1 hour prior to buccal swab<br>2 hours after eating for saliva                     | No consumption 1 hour prior to buccal swab    | Rinse mouth with water prior to buccal swab | N/A    |
| Swab L/R cheek for 10 seconds each (per swab)<br>Accumulate Saliva for 1 minute and spit into cup | Swab L/R cheek for 10 seconds each (per swab) | Swab L/R for 30 seconds each (per swab)     | N/A    |

= differences  
 = pending

# Saliva and Buccal Swab Processing and Storage

| China  | South Africa   | India   | Canada |
|--|--|---|--------|
| Blue cap cryovial<br>(2 buccal swabs)<br>• Storage Solution (iodized salt) | Blue cap cryovial<br>(2 buccal swabs)<br>• Storage Solution (iodized salt) | Store in original tube<br>(2 buccal swabs)<br>• <b>Storage Solution</b> | N/A    |
| Temporarily store saliva and buccal swab at 4°C                            | Temporarily store saliva and buccal swab at 4°C                            | --  | N/A    |
| Orange cap cryovial (2 saliva)<br>• 1.6 mL/aliquot                         | --   | --  | N/A    |
| Store at -80°C   | Store at -80°C   | Store at -80°C  | N/A    |

 = differences  
 = pending

# Discussion

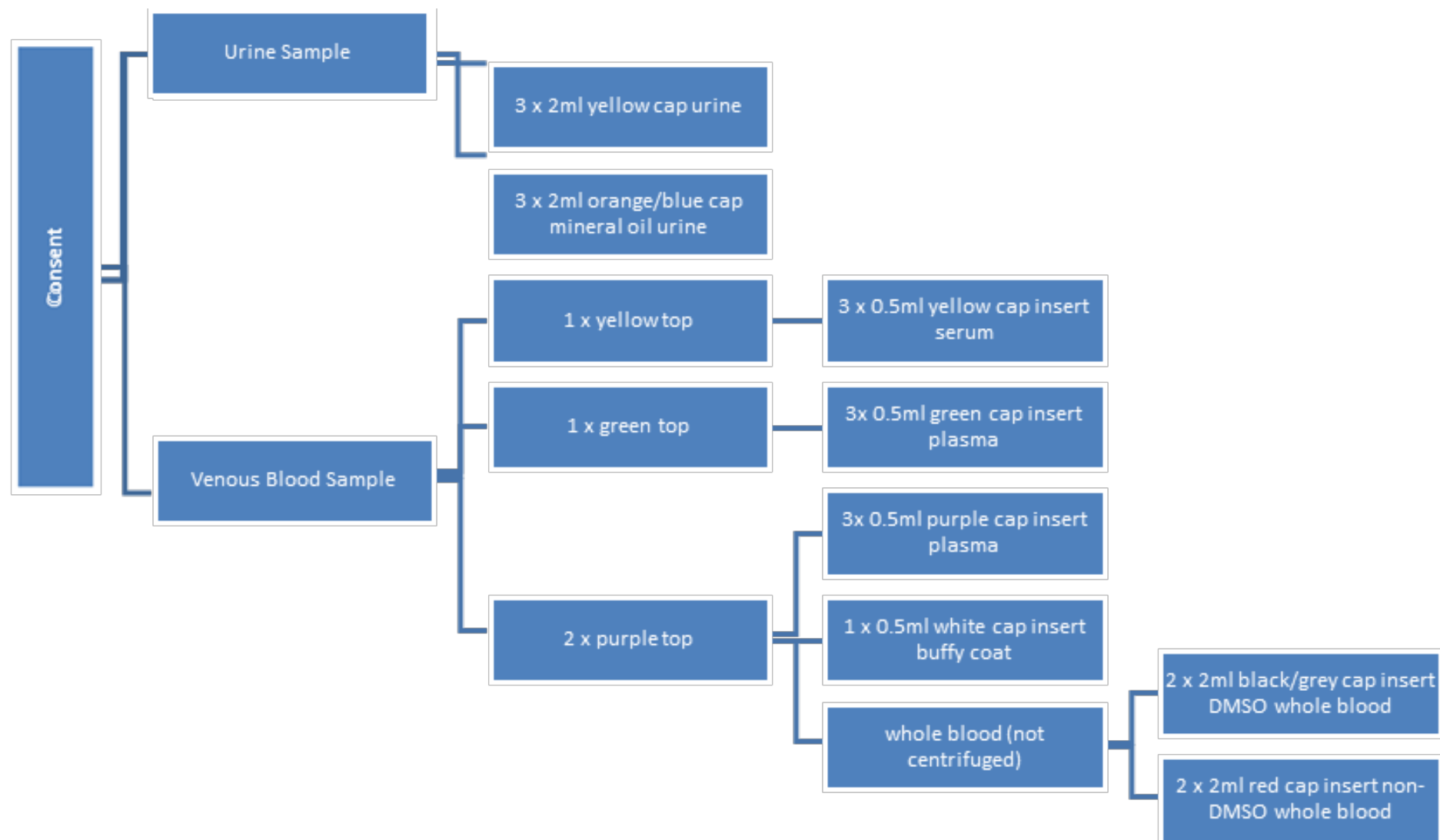
- Blood SOP
  - Heparin, DMSO, PAXGene
  - Number of Aliquots (Canada pending)
- Urine SOP
  - Mineral Oil (stabilizes  $\text{PCO}_2$ , pH level and  $\text{HCO}_3$ )
- Saliva and Buccal Swab
  - Saliva in China only
  - Buccal Swab preparation, collection, and storage solution TBC

# Future Directions

- Harmonize saliva and buccal swab, placenta, cord blood and cord
  - Placenta photograph
- Finalize India Master SOP
- Biospecimen Analysis Update

# Questions

# SA Blood and Urine



# India Blood

