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## KALADRUG-R: Clinical SOP#F

### Labelling clinical samples BHU/KAMRC

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#### A. Symptomatic VL cases

cohort of active VL cases admitted at KAMRC in WP3, collect spleen for parasite isolation (cSOP#G), spleen/BM for PCR (cSOP#B), and blood samples (cSOP#C).

##### *Labelling:*

- use the institutional abbreviation (**KAM-**) followed by patient number as basis = **identical code as in KAMRC database**
- **distinguish different times of sampling** of the same patient by indicating
  - (i) samples taken before (/0) or after treatment (/1)
  - (ii) at any 2<sup>nd</sup> and subsequent round of treatment, an abbreviation should be added after the patient number that indicates the nature of the treatment administered, **/AMPH** = amphotericin B, **/AMB**= ambisone, **/PMM** = paromomycine...

##### *Example of samples for hypothetical patient KAM-999:*

1. Label KAM-999/**0** is used for samples of patient KAM-999 taken before treatment at the time that he is first enrolled in Kaladrug-R. Patient KAM-999 (i) has no history of kala-azar, and thus receives his first treatment ever, or (ii) has been treated for kala-azar before, but received previous treatment outside the Kaladrug-R project.
2. Label KAM-999/**1** is used for samples of patient KAM-999 at the end of his 1<sup>st</sup> treatment within Kaladrug-R.
3. Label KAM-999/**AMPH/0** is used for samples of patient KAM-999 taken before a 2<sup>nd</sup> round of treatment, here amphotericin B as indicated by the abbreviation AMPH. If patient KAM-999 were to relapse again after the amphotericine B treatment, and receive a 3<sup>rd</sup> treatment then the samples taken before that 3<sup>rd</sup> treatment would be labelled KAM-999/**PMM/0**. **The treatment abbreviations are crucial to distinguish the samples taken at each round of treatment.**
4. Label BPK999/**AMPH/1** is used for samples of patient BPK999 taken at the end of the 2<sup>nd</sup> treatment amphotericin B.

- distinguish different types of samples by the following additional 2-letter coding: BM = bone marrow, BL = blood; SP = spleen; PI = parasite isolate

*Sample labels for samples of hypothetical patients KAM-999:*

1. KAM-999/0 PI, KAM-999/0 BL, KAM-999/0 FP, KAM-999/0 BM are labels of parasite isolate, blood sample, filter paper and bone marrow sample respectively, collected from patient KAM-999 at time of first enrolment in the Kaladug-R study before treatment.
2. KAM-999/1 BL, KAM-999/1 FP and KAM-999/1 BM are labels of blood sample, filter paper and bone marrow sample respectively, collected from patient KAM-999 at the end of the 1<sup>st</sup> treatment since enrolled in the Kaladug-R study. IF this patient showed any signs of non-response to this treatment, then an attempt for parasite isolation would have been done as well and that parasite isolate would be labelled KAM-999/1 PI.

- pre-print the label with the complete code

## 2. Asymptomatic cases

household contacts of active or past (<1 yr) treated KA cases, collect blood samples for PCR + two separate drops of plain blood on filter paper (Whatman no.3) (cSOP#C)

Labelling household contacts of past MIL treated patients:

- use code of patient to which the contact is linked and add identification of the household contact = HHC1, HHC2, etc.
- indicate the sample time-point as /0
- add 'BL' to indicate nature of the sample is blood (only blood samples are taken from asymptomatic cases)
- pre-print the label with the complete code e.g. KAM-123 HHC1/0 BL, KAM-123 HHC2/0 BL, KAM-123 HHC3/0 BL... (Note: HHC numbers would start from 1 in each household)

## 3. PKDL:

Past VL cases for which pre-treatment material (clinical sample, microscopic smear....) is already available from VL stage of disease will be re-sampled for skin biopsies.

Labelling past VL case with acute PKDL:

- use code of patient (if a code is already existing; the format will depend of previous study, could be a KAM patient number, or a patient number from another drug trial...etc)
- if patient has no KAMRC patient number yet, then give the patient a new KAMRC code.

- indicate this sample concerns a past case with active PKDL by including '/PKDL'
- add 'SK' to indicate nature of the sample is skin
- pre-print the label with the complete code e.g. KAM-123/PKDL SK