# KALADRUG-R: Clinical SOP#E

**Labelling clinical samples BPKIHS**

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**A. Symptomatic VL cases**

**category I:** cohort of active VL cases admitted at BPKIHS in WP4, collect BM for parasite isolation (cSOP#1), BM/spleen for PCR (cSOP#2), and blood samples (SOP#3).

*Labelling:*

- use the institutional abbreviation (BPK) followed by patient number as basis
- distinguish different times of sampling by indicating the **number of months since first enrolment** in Kaladrug-R

*Example for samples of hypothetical patient BPK999:*

1. Label BPK999/0 is used for samples of patient BPK999 at the time that he is first enrolled in Kaladrug-R and about to receive his kala-azar treatment. Patient BPK999 (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 BPK999/1 is used for samples of patient BPK999 at the end of his 1st treatment within Kaladrug-R.
3. Label BPK999/1 can also be used for samples of patient BPK999 at the beginning of his 2nd round of treatment ≤ 1 month after enrolment in Kaladrug-R. By example, if patient BPK999 is enrolled in Kaladrug-R, starts Miltefosine treatment but defaults after a couple of days, and comes back within a month to receive a full Miltefosine treatment. The samples taken before this 2nd full course Miltefosine should be labelled BPK999/1.
4. Label BPK999/3 is used for samples of patient BPK999 who starts a 2nd round of treatment upon re-admission 3 months after his enrolment date in Kaladrug-R. His samples taken at the end of treatment should be labelled BPK999/4.

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

*Sample labels for samples of hypothetical patient BPK999:*

1. BPK999/0 PI, BPK999/0 BL, BPK999/0 FP, BPK999/0 BM are labels of parasite isolate, blood sample, filter paper and bone marrow sample respectively, collected from patient BPK999 at time of first enrolment in the Kaladrug-R study before treatment.
2. BPK999/1 BL, BPK999/1 FP and BPK999/1 BM are labels of blood sample, filter paper and bone marrow sample respectively, collected from patient BPK999 at the end of the 1st treatment since enrolled in the Kaladrug-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 BPK999/1 PI.

- pre-print the label with the complete code

**category II (this category of samples is currently on hold):** rk39+ & clinical symptomatic cohort from sentinel sites WP2, collect TAPVAL blood for PCR + two separate drops of plain blood on filter paper (Whatman no.3) (cSOP#C)

Labelling:

- use the appropriate 3 letter abbreviation to indicate sentinel site where the sample was collected e.g. ITA for Itahari, followed by patient number (start counting from 001) as basis. The list of sentinel sites and their abbreviation for the labelling will be provided soon.
- distinguish different times of sampling by indicating the number of months since enrolment in Kaladrug-R (/0, /3, /6…)
- add 'BL' to indicate nature of the sample is blood (only blood samples are taken at sentinel sites)
- pre-print the label with the complete code e.g. ITA001/0 BL

**2. Asymptomatic cases**

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

Labelling <u>household contacts</u> 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.NEP123 HHC1/0 BL, NEP123 HHC2/0 BL, NEP123 HHC3/0 BL… (Note: HHC numbers would start from 1 in each household)

**2. 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 <u>acute PKDL</u>:

- use code of patient (if a code is already existing; the format will depend of previous study, could be a BPK patient number, a NEP patient number…etc)
- if PKDL case was never admitted before in BPKIHS, then give him a new 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. NEP123/PKDL SK