Background:

Visceral Leishmaniasis (VL) also known as Kala-Azar, is a protozoan infection caused by the *L. donovani* complex and transmitted by sandflies. Early detection of leishmaniasis is critical in management of patients, and for successful control and elimination of the disease. Definitive diagnosis of visceral Leishmaniasis is by parasitological demonstration of parasites in splenic, lymph node or bone marrow aspirates, which are collected using invasive methods that are unsuitable in the field. This study aimed to evaluate new less invasive urine based ELISA and rapid diagnostic test (RDT) test for diagnosis of VL.

Methods:

The newly developed urine ELISA test was evaluated using archived and fresh urine samples collected from parasitologically confirmed VL patients and non-VL cases. Lateral flow assay (LFA) using the ELISA reagents were conducted for day0 samples. Serological tests (DAT, rk28 ICT) were conducted for every patient in the study.

Results:

In 198 patients with suspected VL, urine rapid test had a sensitivity of 72.2% and exhibited a specificity of 93.42 %. Leishmania antigen ELISA had a sensitivity of 83.33 % and a specificity of 95.05 %. All VL- confirmed cases were followed up during the treatment period, the leishmania antigen ELISA became negative 2 months after completion of treatment in most patients.

Conclusion:

Urine lateral flow assay is a simple addition to the diagnostics of VL particularly at field level and as a complementary test for the diagnosis of VL in smear-negative cases. Further enhancement of the test will define its performance in monitoring treatment. Further studies are recommended to
evaluate the performance of both tests in the diagnosis of HIV co-infected cases.