

Piloting shipping of sample from MDP study sites to the central laboratory

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Background: As part of the MDP Pilot study, sites were requested to send 5% of enrolment serum samples to Contract Laboratory Services (CLS). This exercise was an important pre-study procedure as laboratories in Africa have limited experience in shipping samples according to defined criteria and may be far-removed from courier networks.

Objectives: To pilot the sample retrieval and shipping procedures and for CLS to perform a quality control check for HIV and HSV 2 IgG antibodies on the samples involved. **Methods:** The sample numbers were selected randomly from the MDP database and sent to the sites. The sites had retrieve the correct samples and ship them to CLS according to a Standard Operating Shipping Procedure using a reputable courier agency selected by the Central laboratory. CLS re-tested the samples for HIV and HSV 2 antibodies.

Results: 5/6 sites were able to get samples to CLS within 8 weeks after the instruction was issued. All sites were able to correctly identify and retrieve samples. The transit time ranged from "overnight" (SA sites) to 7 days. All samples were received in a satisfactory condition. 100% agreement was achieved between results at site and at CLS. The following problems were experienced: one site had a long delay in obtaining Local Health Authority authorization, experienced a break in the Cold chain in transit from MDP site to local lab and hold-up at JHB international airport at customs due to waybill made out incorrectly. This increased the delay in shipping samples to CLS by 4 months. One sample had insufficient volume. Another site shipped samples with samples for another study. The courier did not supply packaging material for one of the sites. **Lessons learnt** included: sites must familiarize themselves with their Local Health Authority regarding the local requirements for shipping samples out of the country and to follow the Shipping and Courier SOP meticulously to ensure adequate volumes are shipped at correct temperature.

Conclusion: This exercise demonstrated the importance of piloting sample shipping procedures, as it identifies problems, which could interfere with sample viability and achieving acceptable transit times. Addressing these obstacles, should allow relatively problem-free shipping during the phase 3 study.

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