Dear Manufacturer,

Re: Round 7 of WHO Malaria RDT Product Testing Programme

1. **Confirmation of final list of products**

   We wish to confirm the acceptance of the following products for inclusion in WHO Malaria RDT Product Testing Programme - Round 7.

2. **Verification of ISO 13485 authenticity**

   ISO 13485 certificate authenticity is being investigated over the coming weeks. You may be contacted by a WHO consultant, Dr. Sophie Jones to resolve any issues. Kindly cooperate with her request(s).

3. **Payment of Fees**

   In October, 2015, an invoice for the costs of participation will be issued. A fee of 8’000 USD will be charged per product indicated on the final product list. The payment is due on the deadline for RDT delivery to US CDC (23 October 2015). If a decision is made to withdraw products from Round 7 prior to the fee payment deadline, then the invoice will be modified appropriately; however, if a decision to withdraw a product is made AFTER payment of fees, there will be no reimbursement.

4. **Shipment of RDTs to CDC, Atlanta**

   Detailed instructions for shipment of RDTs are included in Annex 1. Products **must arrive at the CDC, Atlanta by 23 October 2015** Confirmation of receipt will be sent via email.
5. **Temperature monitors for RDT Shipments (OPTIONAL)**

To request a temperature monitor, on a first come, first serve basis, send an email to: bruniquelv@who.int with a copy to Malaria_rdt@who.int.

Temperature monitors will be shipped in specially formatted envelopes the week of 28 September 2015, to requesting parties.

Instructions on how to fill in the required information on the envelopes is included in Annex 2 (enclosed).

6. **Reminder - obtaining panels of cultured parasites (P. falciparum) for preliminary testing of products by manufacturers (OPTIONAL)**

The manufacturer's panels are still available. To request a panel, the company must complete and follow instructions outlined in Annex 3 (enclosed).

Panels are provided free of charge, but the manufacturer is responsible for organizing and paying the costs of courier, and organizing all passage through ports and customs once the sample has left the production site at the United States Centre for Disease Control and Prevention (US CDC) in Atlanta, USA. **Samples should be shipped on Dry Ice (-78°C).** The courier company needs to liaise with Jeffrey Glenn of Centre for Disease Control and Prevention (CDC), Atlanta, USA (khl2@cdc.gov) for arranging the schedules of pick-up of the parasite dilution samples. Loss or spoilage of shipments is the responsibility of consignee, and the shipper engaged by the consignee. Due to the limited number of available samples, WHO cannot guarantee that spoilt or lost shipments will be replaced.

7. **Manufacturing site thermal stability testing (OPTIONAL)**

As per recommendations in 2010, performance of on-site thermostability evaluation of the submitted lots by the manufacturer using a reference sample and SOP provided by the programme is **OPTIONAL. Participation and submission of these results to WHO is not required.**

However, should a manufacturer wish to follow these procedures using the reference sample from US CDC, and stocks are sufficient, these will be made available. Further information is enclosed in Annex 4 including a cover note, stability testing protocol and results template.

Please don't hesitate to contact me should you have any questions or concerns.

Sincerely,

Dr Jane Cunningham
Technical Officer
WHO Global Malaria Programme
World Health Organization