GUIDELINES FOR THE USE OF RAPID DIAGNOSTIC TESTS

1. Preamble

The early diagnosis and prompt treatment of cases of malaria is an important strategy of the National Vector Borne Disease Control Programme. The full recommended treatment must be started as early as possible for providing medical relief to the patient and to prevent severe complications and death. Early diagnosis and prompt treatment (EDPT) is also an important strategy for interrupting the transmission of the disease. Malaria is an acute infection with presenting symptoms of fever, chills and headache. These symptoms are common for other acute infections also. The diagnosis of malaria is confirmed by examination of peripheral blood smears. Nearly 100 million blood smears from fever cases are examined annually to confirm the diagnosis of malaria. Of these less than 2 million test positive for malaria. About 48% of the positive malaria cases are due to *P.faliciparum* and the rest due to *P.vivax*. The incidence rate and the proportion of *Pf* cases vary widely in the country. About 80% of the malaria cases are confined to the north eastern states and tribal areas of 100 districts in 8 states under EMCP and a few other districts. Malaria is seasonal in most parts of the country.

The areas of high transmission of malaria are largely hilly, forested and remote with inadequate health and communication facilities, lacking in public transportation and often with high vacancy of personnel. The time lag between collection of the blood slide and onset of radical treatment is often delayed due to operational problems related to difficult terrain, poor public transportation and other communication facilities and high vacancy of laboratory technicians.

Village volunteers provide presumptive treatment with chloroquine (4 tablets of 150 mg each – total 600 mg for adult patients and lower doses for children in different age groups) pending laboratory results. Radical treatment is given to patients testing positive for malaria. Health personnel and medical officers provide presumptive radical treatment on clinical suspicion of malaria in the high risk areas during the high transmission period.

2. Supply of rapid diagnostic kits under NVBDCP

Limited quantities of rapid diagnostic kits (25 tests per kit) are being supplied for remote inaccessible high-risk pockets to be used by the MLVs/ FTDs. Radical treatment will be provided immediately at first contact to those febrile cases that are positive for *Pf* malaria. The statewise quantities of RDT to be provided in 2003-04 are shown in the attached statement. Based on the average annual blood examination rate of 20, it is expected that one MLV/ FTD will see 200 cases of fever in a population of 2000 (two villages) during the 5 Months (i.e. August to December) of the high transmission season or an average of 40 cases per month. He will thus require 8 kits for the 5 month period. Initially half the number of kits may be provided, <u>after training</u>; rest being supplied as per need after the previous stocks have been exhausted.

The piloting of the use of RDT in remote villages by non-health personnel will provide feedback, which will be useful for extending the use of RDT to other areas and to document the cost effectiveness of this measure for the control of *P. falciparum* malaria.

3. Criteria for the selection of villages/ subcentre areas

The criteria suggested below are for selection of villages for RDT use. Criteria a. and b. are important and other factors should be considered additionally.

- a. Consistently high API, high proportion of *Pf* cases, and/or reported deaths
- b. Inaccessible (cut off during the high transmission season), remote location
- c. Limited road and public transportation facilities and poor access to facilities for the treatment of severe and complicated cases requiring immediate medical attention
- d. Areas operationally difficult for indoor residual spray (IRS) because of difficult terrain, exophilic vectors (indoor biters but outdoor resters) and practice of frequent mud plastering of walls
- e. Socio-economically disadvantaged
- f. Children of tribal school / ashram school hostels

4. Use of rapid diagnostic tests

Efforts should be made to ensure the community is aware and that they approach the MLV/FTD concerned early after the onset of fever to confirm diagnosis. It must be ensured that pregnant women and young children are examined as quickly as possible after the onset of fever so that the recommended radical treatment is started early.

The RDTs will be used during the high transmission season to increase its cost effectiveness and optimal utilization for the radical treatment of *P. falciparum* malaria

5. Radical treatment of patients

The recommended radical treatment with chloroquine (CQ) is 600 mg on day 1 and 2 and 300 mg on day 3 (total 1500 mg) for adult patients. In addition, 45 mg of primaquine (PQ) is given on day 1 to patients with *Pf* malaria. Patient with Pv are given 15 mg primaquine daily for 5 days. Blister packs for the radical treatment of all patients above 15 years of age (except pregnant women) should be available in all the villages where RDTs are used. Use of blister packs are expected to improve acceptability of anti malaria drugs and compliance of the full course by the patients. Pregnant women (no primaquine) and children should continue to be provided treatment with loose tablets, as is currently the practice. The recommended age-wise doses are given below.

<u>Radical Treatment to P. falciparum cases</u> (patients found positive with RD test)

	Day 1		Day 2	Day -3
<u>Age in years</u>	Tab.	Primaquine	Tab.	Tab.
	Chloroquine	(7.5 mg)	Chloroquine	Chloroquine
<1	1/2	0	1/2	1/4
1-4	1	1	1	1/2
5-8	2	2	2	1
8-14	3	4	3	1 1/2
>14*	Blister Packs			

Dosage as per age groups

* Except in pregnant women who should be given 4 tablets of Chloroquine on day 1, 4 tablets on day 2 and 2 tablets on day 3.

6. Preparatory activities

It is important that preparatory work is done to ensure optimal use of RDTs and prompt radical treatment of patients with *P. falciparum* malaria. The following activities must be completed prior to the distribution of the RDTs.

- a. Selection of area(s)
- b. Rapid survey of the area number of households, number of persons in each household, number of pregnant women and children under 5 years of age
 - Fever rate during the previous two years
 - Utilization of DDCs/ FTDs for treatment
- c. Identification and involvement of community representatives, self help groups, women's organizations and NGOs to encourage early diagnosis and prompt treatment of malaria in the community
- d. Preparation of the list of MLVs/ FTDs to be trained
- e. Advocacy among the community for the early confirmation of the diagnosis of malaria; for ensuring that pregnant women and young children get their blood examined as early as possible after the onset of fever.
- f. Training of personnel and supply of RDTs and blister packs.
- g. Arrangements for field supervision and monitoring

7. Training

A half-day training should be given to all MLVs/FTDs and MPWs of the area in the proper use of RDT and interpretation of results. The batch size should not be more than 20. Training should be hands-on, preferably on cases of fever, if the training can be organized in a health facility such as a PHC. These will ensure that a few positive results are seen by the trainees. Training should be completed prior to the distribution of the RDTs. The MLVs and FTDs should continue to prepare blood smears from all fever cases, negative by RDT for the diagnosis of *Pv* cases.

8. Follow up action

- a. Regular visits by the health personnel of the area to check RDT use and radical treatment
- b. Monthly reports from the MLVs/ FTDs as per format given
- c. Monitoring of fever cases and confirmed cases of malaria
- d. Monitoring of compliance of radical treatment