

Malaria Rapid Diagnostic Tests

Background

- According to the latest iteration of the World Malaria Report released by WHO in December 2021, there were an estimated 241 million malaria cases in 2020. This is an increase of 6 % over figures from 2019 and an indication of a continuing upward trend in malaria cases that started in 2015. Children under 5 years are the most vulnerable group affected by malaria globally: in 2020 77 % of malaria deaths (627,000) worldwide were in this age group.
- Malaria is preventable and curable when diagnosed timely and treated promptly.
- Rapid and accurate diagnosis of malaria is critical, and especially in young children and pregnant women, as left untreated it can rapidly progress towards severe disease and death. The use of quality assured diagnostics with high specificity reduces unnecessary administration of antimalarial drugs and improves management of other causes of febrile illnesses. It is therefore recommended that all cases of suspected malaria are confirmed using parasite-based diagnostic testing, either microscopy or a malaria rapid diagnostic test. Malaria rapid diagnostic tests are the recommended form of confirmatory malaria diagnosis where microscopy is not feasible, for example, and especially, hard to reach areas.
- Guided by the Strategic Plan for 2022-2025 that aims to ensure that every child survives and thrives (Goal Area 1), UNICEF works with global, regional, and country partners to deliver material resources, including rapid diagnostic tests, for malaria response, centering it on infants, children, adolescents, pregnant women, and mothers.

Purpose

- This bulletin seeks to provide key information on malaria rapid diagnostic tests (mRDTs) available for procurement through UNICEF Supply Division.

Quality Assurance

- UNICEF follows WHO prequalification recommendation for selection of all malaria rapid diagnostic tests. List of WHO prequalified IVDs can be found here: [WHO PQ IVDs](#)

Product Selection

- In-country product selection will be based on national policies and guidelines.

Lot Testing

- Following the introduction of WHO pre-qualification program for malaria RDTs, UNICEF has discontinued mandatory pre-delivery lot testing. It is however can be organized on request. It is also recommended that end users perform post-delivery lot testing to ensure that the received products meet the specified performance requirements.

UNICEF Long Term Arrangement (LTAs) for mRDTs

- UNICEF established long-term arrangements with manufacturers for a range of WHO prequalified mRDTs.
- A list of all mRDTs that are available for procurement through UNICEF Supply Division is presented in Table 1.

mRDTs with safety lancets

- UNICEF recommends the use of safety lancets to minimize risk of transmission of infectious diseases/bloodborne pathogens. mRDTs available for procurement through UNICEF that include safety lancets are listed in Table 2.

UNICEF Supply Catalogue

- Please refer to UNICEF Supply Catalogue for updated prices and detailed technical information for mRDTs tests available for procurement through UNICEF. UNICEF Supply Catalogue is available online
<https://supply.unicef.org/all-materials/in-vitro-diagnostics-tests/malaria-test-kits.html>

Table 1. mRDTs available for procurement through UNICEF Supply Division

Material No	Short description	Kit contents	Panel detection score at 200 parasites/ μ l		Indicative price* per kit (US\$)
			Pf	Pv	
S0003342	ParaHit Malaria Pf, kit/50	50 x Test devices (individually packed in a foil pouch with a desiccant) 1 x Buffer bottle (12ml) 50 x Specimen transfer devices (single-use, disposable plastic pipettes) 50 x Alcohol swabs 50 x Sterile non-safety lancets 1 x Instructions for use	84.9 %	N/A	10.00
S0003775	First Response Malaria Pf HRP2, kit/25	25 x Test devices (individually packed in a foil pouch with a desiccant) 1 x Buffer bottle 25 x Blood transfer devices 25 x Alcohol swabs 25 x Sterile non-safety lancets 1 x Instruction for use	91.0 %	N/A	7.12
S0003816	ParaHIT Malaria Pf cassette, kit/25	25 x Test devices (individually packed in a foil pouch with a desiccant) 1 x Buffer bottle (6ml) 25 x Specimen transfer devices (single-use, disposable plastic pipettes) 25 x Alcohol swabs 25 x Sterile non-safety lancets 1 x Instructions for use	84.9 %	N/A	5.00
S0003856	AdvDx Malaria Pf, kit/25	25 x Test devices (individually packed in a foil pouch with a desiccant) 1 x Buffer bottle 25 x Sample applicator 25 x Alcohol swabs 25 x Sterile non-safety lancets 1 x Instructions for use	80.0 %	N/A	6.25
S0003863	FirstResponse MalAgPf/Pv CardTest,kit/25	25 x Test devices (individually packed in a foil pouch with a desiccant) 1 x Assay buffer bottle 25 x Specimen transfer devices 25 x Alcohol swabs	94.0 %	100.0 %	9.87

		25 x Sterile non-safety lancets 1 x Instructions for use			
S0003867	FirstResponse MalAgpLDH/HRP2Com bo,kit/25	25 x Test devices (individually packed in a foil pouch with a desiccant) 1 x Assay buffer bottle 25 x Specimen transfer devices 25 x Alcohol swabs 25 x Sterile non-safety lancets 1 x Instructions for use	82.0 %	91.4 %	9.87
S0003871	One Step MERISCREEN Mal Pf/Pv Ag, kit/30	30 x Test cassettes (individually packed in a foil pouch with a desiccant) 2 x Assay buffer bottle (3ml) 30 x Specimen transfer devices (5µl) 30 x Alcohol swabs 30 x Sterile non-safety lancets 1 x Instructions for use	78.0 %	85.7 %	8.70
S0003975	STANDARD Q Malaria Pf Ag Test,kit/25	25 x Test devices (individually packed in a foil pouch with a desiccant) 1 x Buffer bottle (4ml) 25 x Inverted cup (5µl) 25 x Alcohol swabs 25 x Sterile non-safety lancets 1 x Instructions for use	87.0 %	N/A	8.25
S0003976	STANDARD Q Malaria Pf/Pan Ag Test,kit/25	25 x Test devices (individually packed in a foil pouch with a desiccant) 1 x Buffer bottle (4ml) 25 x Inverted cup (5µl) 25 x Alcohol swabs 25 x Sterile non-safety lancets 1 x Instructions for use	88.0 %	100.0 %	12.50
S0003977	STANDARD Q Malaria Pf/Pv Ag Test,kit/25	25 x Test devices (individually packed in a foil pouch with a desiccant) 1 x Buffer bottle (4ml) 25 x Inverted cup (5µl) 25 x Alcohol swabs 25 x Sterile non-safety lancets 1 x Instructions for use	85.0 %	100.0 %	12.50
S0003981	NxTekEliminateMalPfN onSafetyLanc,kit/25	25 x Test devices (individually packed in a foil pouch with a desiccant) 1 x Assay diluent vial (5ml) 25 x Disposable inverted cup (5µl) 25 x Alcohol swabs 25 x Sterile non-safety lancets 1 x Instructions for use	98.0 %	N/A	7.50
S0003987	NxTekEliminatMalPfNo nSafetLanc,1T/kitx25	25 x Each kit contains a test device, an assay diluent, a disposable	98.0 %	N/A	12.40

		inverted cup (5µl), an alcohol swab, a sterile non-safety lancet and summarized instructions for use for a single test 1 x Instructions for use			
S0003988	NxTekEliminateMalPfsafetyLanc,1T/kitx25	25 x Each kit contains a test device, an assay diluent, a disposable inverted cup (5µl), an alcohol swab, a safety lancet and summarized instructions for use for a single test 1 x Instructions for use	98.0 %	N/A	12.90
S0003989	NxTekEliminateMalPfsafetyLanc,kit/25	25 x Test devices (individually packed in a foil pouch with a desiccant) 1 x Assay diluent vial (5ml) 25 x Disposable inverted cup (5µl) 25 x Alcohol swabs 25 x Safety lancets 1 x Instructions for use	98.0 %	N/A	11.30
S0004031	BiolineMalAgPf/PanNonSafeLnct,1T/kitx25	25 x Test cassettes (individually packed in a foil pouch with a desiccant) 25 x Assay diluent vials (180µl/vial) 25 pouches x Each containing 1 specimen transfer device (5µl), 1 sterile non-safety lancet, 1 alcohol swab 25 x Summarized instructions for use 1 x Instructions for use	94.0 %	91.4 %	17.50
S0004032	BiolineMalAgPf/PanNonSafetyLancet,kit/25	25 x Test cassettes, individually packed in a foil pouch with a desiccant 1 x Assay diluent vial (5ml) 25 x Specimen transfer devices (5µl) 25 x Alcohol swabs 25 x Sterile non-safety lancets 1 x Instructions for use	94.0 %	91.4 %	15.00
S0004033	BiolineMalAgPf/PanNonSafetyLancet,kit/30	30 x Test cassettes, individually packed in a foil pouch with a desiccant 30 x Assay diluent vials (180µl/vial) 30 x Specimen transfer devices (5µl) 30 x Alcohol swabs 30 x Sterile non-safety lancets 30 x Dried swabs 30 x 2 packs of latex gloves 1 x Instructions for use	94.0 %	91.4 %	18.00

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S0004034	BiolineMalAgPf/PanSafetyLancet,1T/kitx25	25 x Test cassettes (individually packed in a foil pouch with a desiccant) 25 x Assay diluent vials (180µl/vial) 25 pouches x Each containing 1 specimen transfer device (5µl), 1 safety lancet, 1 alcohol swab 25 x Summarized instructions for use 1 x Instructions for use	94.0 %	91.4 %	18.75
S0004035	BiolineMalAg Pf/Pan SafetyLancet,kit/25	25 x Test cassettes, individually packed in a foil pouch with a desiccant 1 x Assay diluent vial (5ml) 25 x Specimen transfer devices (5µl) 25 x Alcohol swabs 25 x Safety lancets 1 x Instructions for use	94.0 %	91.4 %	16.25
S0004036	BiolineMalAgPf/PvNon SafeLancet,1T/kitx25	25 x Test cassettes (individually packed in a foil pouch with a desiccant) 25 x Assay diluent vials (180µl/vial) 25 pouches x Each containing 1 specimen transfer device (5µl), 1 sterile non-safety lancet, 1 alcohol swab 25 x Summarized instructions for use 1 x Instructions for use	92.0 %	94.3 %	17.50
S0004037	BiolineMalAgPf/PvNon SafetyLancet,kit/10	10 x Test cassettes (individually packed in a foil pouch with a desiccant) 1 x Assay diluent vials (3ml) 10 x Specimen transfer devices (5µl) 10 x Alcohol swabs 10 x Sterile non-safety lancets 1 x Instructions for use	92.0 %	94.3 %	6.50
S0004038	BiolineMalAgPf/PvNon SafetyLancet,kit/25	25 x Test cassettes, individually packed in a foil pouch with a desiccant 1 x Assay diluent vial (5ml) 25 x Specimen transfer devices (5µl) 25 x Alcohol swabs 25 x Sterile non-safety lancets 1 x Instructions for use	92.0 %	94.3 %	15.00
S0004039	BiolineMalAgPf/PvSafetyLancet,1T/kitx25	25 x Test cassettes (individually packed in a foil pouch with a desiccant)	92.0 %	94.3 %	18.75

		25 x Assay diluent vials (180µl/vial) 25 pouches x Each containing 1 specimen transfer device (5µl), 1 safety lancet, 1 alcohol swab 25 x Summarized instructions for use 1 x Instructions for use			
S0004040	BiolineMalAg Pf/Pv SafetyLancet,kit/25	25 x Test cassettes, individually packed in a foil pouch with a desiccant 1 x Assay diluent vial (5ml) 25 x Specimen transfer devices (5µl) 25 x Alcohol swabs 25 x Safety lancets 1 x Instructions for use	92.0 %	94.3 %	16.25
S0004041	BiolineMalAgPf NonSafetyLancet,1T/kitx25	25 x Test cassettes (individually packed in a foil pouch with a desiccant) 25 x Assay diluent vials (180µl/vial) 25 pouches x Each containing 1 specimen transfer device (5µl), 1 sterile non-safety lancet, 1 alcohol swab 25 x Summarized instructions for use 1 x Instructions for use	95.0 %	N/A	14.25
S0004042	Bioline Mal Ag Pf NonSafetyLancet,kit/25	25 x Test cassettes, individually packed in a foil pouch with a desiccant 1 x Assay diluent vial (5ml) 25 x Specimen transfer devices (5µl) 25 x Alcohol swabs 25 x Sterile non-safety lancets 1 x Instructions for use	95.0 %	N/A	7.50
S0004043	Bioline Mal Ag Pf SafetyLancet,1T/kitx25	25 x Test cassettes (individually packed in a foil pouch with a desiccant) 25 x Assay diluent vials (180µl/vial) 25 pouches x Each containing 1 specimen transfer device (5µl), 1 safety lancet, 1 alcohol swab 25 x Summarized instructions for use 1 x Instructions for use	95.0 %	N/A	15.50
S0004044	Bioline Mal Ag Pf SafetyLancet,kit/25	25 x Test cassettes, individually packed in a foil pouch with a desiccant 1 x Assay diluent vial (5ml) 25 x Specimen transfer devices (5µl) 25 x Alcohol swabs	95.0 %	N/A	13.00

		25 x Safety lancets 1 x Instructions for use			
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* All prices are FCA-based (INCOTERMS 2020).

Table 2. mRDTs with safety lancets available for procurement through UNICEF Supply Division

Material No	Short Description	Indicative price* per kit (US\$)
S0003988	NxTekEliminateMalPfSafetyLanc,1T/kitx25	12.90
S0003989	NxTekEliminateMalPfSafetyLanc,kit/25	11.30
S0004034	BiolineMalAgPf/PanSafetyLancet,1T/kitx25	18.75
S0004035	BiolineMalAg Pf/Pan SafetyLancet,kit/25	16.25
S0004039	BiolineMalAgPf/PvSafetyLancet,1T/kitx25	18.75
S0004040	BiolineMalAg Pf/Pv SafetyLancet,kit/25	16.25
S0004043	Bioline Mal Ag Pf SafetyLancet,1T/kitx25	15.50
S0004044	Bioline Mal Ag Pf SafetyLancet,kit/25	13.00

* All prices are FCA-based (INCOTERMS 2020).