

# Malaria Rapid Diagnostic Tests: Market and Supply Update

UNICEF Supply Division

February 2023

## Malaria Rapid Diagnostic Tests Market and Supply Update February 2023

This update provides information on UNICEF's historical and projected malaria rapid diagnostic tests supply, demand, and market developments. It highlights the importance for countries to improve demand forecast accuracy, accept product diversification, and to diversify funding availability to improve market health.

### 1. Summary

- UNICEF procures malaria rapid diagnostic tests (mRDTs) in support of country programmes to increase malaria testing coverage and improve access to lifesaving antimalaria treatment. The early and accurate detection of malaria is essential for effective malaria management and surveillance.
- UNICEF has been procuring mRDTs since 2008, averaging approximately 10-11 million tests a year since 2011, ranging between 5 and 18 million tests a year. The fluctuation in UNICEF's mRDT procurement over the years reflects the dependency on country programme financing and challenges of accurate forecasting. National governments do not typically forecast well their demand for mRDTs or integrate them into their national annual budget plans, as compared to other prioritized health products, and its procurement is heavily dependent on funding availability.
- Efforts by UNICEF and partners to scale up access to mRDTs have contributed to global market growth reaching an estimated 413 million tests in 2021,<sup>1</sup> in which UNICEF represents approximately a 4 per cent share of global procurement volume.
- UNICEF's weighted average price (WAP) for mRDTs, despite some fluctuation reflecting product preferences, has decreased substantially over the years, from a high of USD 0.65 in 2013 to reach a stable USD 0.36 in 2021, representing an overall reduction of 55 per cent over eight years. UNICEF anticipates the current WAP of USD 0.36 to remain stable for the immediate future.
- The global supply for mRDTs, and RDTs in general, is increasingly being dominated by fewer manufacturers. In order to secure and ensure a healthier market and expand UNICEF's sources of supply for these products, UNICEF is seeking to diversify country level demand. UNICEF is leveraging internal resources to improve country demand procurement forecasts for mRDTs. Currently UNICEF has long-term arrangements (LTAs) with six suppliers, with a combined mRDT listing of 13 products. UNICEF launched a global forecasting exercise in September 2022 to support countries for a range of products for 2023, including mRDTs and concluded a need for 18.8 million tests.

### 2. Background

Malaria is a preventable and treatable parasitic disease. It is transmitted to humans by the female anopheles mosquito infected with *plasmodium* parasites. More than 200 *plasmodium* parasite species exist, although only five cause malaria in humans with variable prevalence and severity based on geographical area (Table 1).

Table 1 Malaria Causing *Plasmodium* Parasites in Humans

| <i>Plasmodium</i> species         | Observation   |
|-----------------------------------|---|
| <i>Plasmodium falciparum</i> (Pf) | The deadliest species, responsible for most case fatalities, prevalent in tropical and subtropical areas worldwide, predominantly in Africa. It can cause severe malaria, anaemia, as well as fatal cerebral malaria. |
| <i>Plasmodium vivax</i> (Pv)      | The most widely distributed species, prevalent mostly in Asia, Latin America, and some parts of Africa. It can cause relapses several months or years after initial infection.  |
| <i>Plasmodium malariae</i> (Pm)   | Also prevalent worldwide. It can cause life-long, re-occurring chronic infection. The current diagnostic methodology is not able to document reliably the disease burden.   |
| <i>Plasmodium ovale</i> (Po)      | Mostly prevalent in Africa. The current diagnostic methodology is not able to document reliably the disease burden.   |
| <i>Plasmodium knowlesi</i> (Pk)   | Prevalent only in Southeast Asia. A zoonotic malaria prevalent primarily in monkeys but gaining attention over recent years as human cases now occurring in Southeast Asia.   |

Source: United States Centres for Disease Control and Prevention.

<sup>1</sup> World Health Organization, [World Malaria Report 2022](#), WHO, Geneva, December 2022, p xxvi

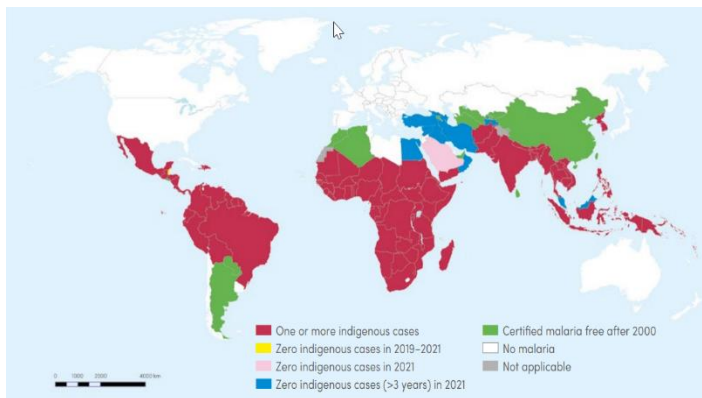


Climate change is also affecting the pattern of diseases. The *Anopheles stephensi* is a mosquito species native to south Asia and parts of the Arabian Peninsula. It can transmit both *P. falciparum* and *P. vivax* malaria parasites. Over the past decades, it has been spreading across Africa, having been detected in Djibouti (2012), Ethiopia and Sudan (2016), Somalia (2019) and Nigeria (2020).<sup>2</sup> It thrives in urban settings and has been found to be resistant to many insecticides used in public health posing an added challenge to its control. The spread of this mosquito across a region where the burden of malaria is highest is particularly worrying and is thought to have contributed to a resurgence of malaria in Djibouti and at least one outbreak in Ethiopia.

Malaria epidemics to date still have a disproportionate impact on children and adolescents and nearly half of the world's population is at risk of the disease, as it is one of the leading causes of child mortality. In 2021, the parasites cause an estimated 247 million cases of malaria and an estimated 619 thousand deaths.<sup>3</sup> More than 95 per cent of cases occur in Africa, and children account for approximately 80 per cent of all deaths, of which four African countries accounted for just over half of all malaria deaths worldwide: Nigeria (31.3 per cent), the Democratic Republic of the Congo (12.6 per cent), United Republic of Tanzania (4.1 per cent), and Niger (3.9 per cent).

Malaria diagnosis can be confirmed by good-quality microscopy or with a safe, good quality, and optimal performing malaria antigen-detecting RDT for both *P. falciparum* and non-*falciparum* infections. The World Health Organization recommends parasitological confirmation of malaria in all settings prior to treatment using quality assured diagnostics. It recommends countries to use mRDTs or microscopy for clinical malaria diagnosis in all transmission settings.

Figure 1 Countries with Cases of Malaria in 2022<sup>4</sup>



Source: WHO

The United Nations General Assembly launched the Sustainable Development Goals (SDGs) in 2015 identifying 21 health-related targets to ensure people live healthy lives. The SDG target 3.3 specifically identifies malaria and calls for the end of all epidemics that remain among the biggest public health challenges globally. The World Health Organization and partners seek to eliminate malaria and have set ambitious global targets for 2030. The SDG seeks to reduce malaria mortality rates, case incidence, and malaria transmission from other countries, as well as to prevent the re-establishment of malaria in malaria-free countries.

The World Health Organization and partners target a reduction of at least 40 per cent by 2020; 75 per cent by 2025, and at least 90 per cent by 2030, as compared to levels registered in 2015 (Figure 1).<sup>5</sup> To achieve this, UNICEF works with global, regional, and country partners to deliver programmes and services in support of malaria response, focusing on pregnant women, mothers, infants, children and adolescents.

Globally, significant progress has been achieved since 2000 in malaria control, having reduced the number of global cases by 12 per cent and deaths from malaria by 45 per cent. This has been achieved largely on account of the scale-up of core vector control interventions, and notably the use of long-lasting insecticidal nets (LLINs).<sup>6</sup> UNICEF procures WHO prequalified LLINs on behalf of countries and partners in support of malaria control and elimination programmes. UNICEF provides updated information on LLINs, highlighting product supply, demand and market developments, as well as its supply arrangements with multiple suppliers for new and innovative LLIN technologies that can help stem the rise in insecticide resistance. It also applies supply chain cost and sustainability considerations to address some of the challenges undermining environmental sustainability risks associated with LLIN shipments and price volatility.<sup>7</sup>

<sup>2</sup> Ibid., p 6.

<sup>3</sup> World Health Organization, [Malaria Key Facts](#), WHO, Geneva, December 2022.

<sup>4</sup> WHO, [World Malaria Report 2022](#), p 15.

<sup>5</sup> World Health Organization, [World Malaria Report 2021](#), WHO, Geneva, 2021, p. 23.

<sup>6</sup> S. Bhatt, Weiss, D., Cameron, E. et al., [The Effect of Malaria Control on Plasmodium falciparum in Africa between 2000 and 2015](#), Nature, Berlin, September 2015, p. 207-211.

<sup>7</sup> UNICEF, [Long-lasting Insecticidal Nets Market and Supply Update](#), UNICEF, Copenhagen, October 2022.

Over the past few years, even before the COVID-19 pandemic, progress in malaria control had levelled off,<sup>8</sup> requiring a need for urgent renewed engagement and accelerated action. In addition, new and innovative products are also needed to control malaria, such as new LLIN technology to address insecticide resistance, as well as malaria vaccines. In August 2021, WHO recommended the widespread use of the new malaria vaccine, RTS,S/AS01 (RTS,S), amongst children in sub-Saharan Africa as well as other regions with *P. falciparum* malaria transmission.<sup>9</sup> UNICEF anticipates the vaccine to be made available for supply from late 2023. However, the supply of malaria vaccine will be constrained for the next two to five years and the supplier will only have sufficient malaria vaccine supply to meet expected demand sometime between 2026 and 2028.<sup>10</sup>

### 3. Malaria Diagnosis

The early detection, diagnosis, and treatment of malaria reduces disease incidence, prevalence, and mortality, and also contributes to reducing malaria transmission, as well as the overuse of artemisinin-based combination therapies (ACTs). The World Health Organization recommends all cases of suspected malaria to be confirmed using parasite-based diagnostic testing prior to being administered any treatment.<sup>11</sup> Diagnostic testing will enable health workers to accurately identify and differentiate between the many non-malarial febrile illnesses, which are often misdiagnosed as malaria based symptomatic fever.<sup>12</sup> Expanding access to timely diagnostic testing will strengthen accurate malaria diagnosis, treatment, and surveillance data in all settings and contribute to improved malaria management and control. The World Health Organization recommends countries to use mRDTs or microscopy for the clinical diagnosis of malaria in all transmission settings prior to administering any antimalarial treatment.<sup>13</sup>

Whereas microscopy for malaria diagnostic testing requires laboratory conditions, equipment, and technically trained staff, there is often a delay in getting the immediate results and being able to expand its use as it is limited and dependent on the existence of health facilities and infrastructure. The safe and effective use of mRDTs does not require laboratory infrastructure and can be performed at any point of care. They are easy to use and can return a result in 20 minutes or less. Malaria RDTs offer an effective alternative in all situations, especially where reliable microscopic diagnosis is not available.

Malaria RDTs are immunochromatographic in vitro diagnostics and often come in a dipstick or cassette format, providing results in approximately 20 minutes. Current WHO recommended mRDTs for use in malaria-endemic countries can detect four types of malaria parasite antigens: *P. falciparum* (*Pf*); *P. vivax* (*Pv*); both *Pf* and *Pv*, and *Pf* and pan,<sup>14</sup> to mean all non-*Pf* parasites: *Pv*, *P. ovale* (*Po*), and *P. malariae* (*Pm*).

Even though mRDTs offer a useful alternative to microscopy in situations where reliable microscopic diagnosis is not readily available, the use of mRDTs does not entirely eliminate altogether the need for malaria microscopy, as they may not detect some lower parasite titer infections, and some lesser common species of malaria may be misdiagnosed (i.e. *Po* and *Pm*).<sup>15</sup>

Malaria RDTs are temperature-controlled products that must be kept at room temperature (between 1-45°C) depending on the product throughout the entire supply chain.<sup>16</sup> The World Health Organization issued guidance for the transport, storage, and handling of temperature sensitive products, which can be accessed [here](#).<sup>17</sup> Malaria RDTs typically have a shelf-life of between 24-30 months.

#### 3.1 Quality Standards

Malaria RDTs have been developed to detect the presence of malarial antigens in the blood. They detect antigens including the histidine-rich protein II (HRP-II), aldolase, and the parasite lactate dehydrogenase (pLDH). Histidine-rich protein II is a

---

<sup>8</sup> WHO, [World Malaria Report 2021](#), p. vi.

<sup>9</sup> World Health Organization, [WHO Recommends Groundbreaking Malaria Vaccine for Children at Risk](#), WHO, Geneva, October 2021.

<sup>10</sup> UNICEF, [Malaria Vaccine Questions and Answers](#), UNICEF, Copenhagen, August 2022.

<sup>11</sup> WHO, [Malaria Key Facts](#).

<sup>12</sup> World Health Organization, [Global Technical Strategy for Malaria 2016-2030](#), WHO, Geneva, July 2021, p. 12.

<sup>13</sup> Ibid.

<sup>14</sup> Pan = Ancient Greek to mean 'all, every'.

<sup>15</sup> Kho, S., Anstey, N.M., Barber, B.E. et al, [Diagnostic Performance of a 5-plex Malaria Immunoassay in Regions Co-endemic for Plasmodium falciparum, P. vivax, P. knowlesi, P. malariae and P. ovale](#), Scientific Reports, Volume 12, 7286, May 2022.

<sup>16</sup> World Health Organization, [WHO publishes interesting new Guidance for the Storage and Transport of Pharmaceutical Products](#), ECA Foundation, Manheim, June 2015.

<sup>17</sup> Ibid.

naturally occurring protein in *Pf*,<sup>18</sup> and can therefore only detect and diagnose *Pf* malaria. Parasite lactate dehydrogenase (pLDH) is produced by the asexual and sexual stages of malaria parasites, and the test kits can detect the pLDH from all four species of *Plasmodium*. They can distinguish between *Pf* and non-*Pf* species, but they cannot distinguish between *Pm*, *Po*, and *Pv*. Tests that detect pLDH also do not generate persistent positive results following chemotherapy, like the HRP-II test.<sup>19</sup> Aldolase is a major enzyme involved in the reproductive cycle of *Plasmodium*, released into the blood during infection or localized in the cytoplasm inside the cell.

**Table 2 World Health Organization In Vitro Diagnostics Prequalification Risk Classes**

| Classification | Individual Risk |        | Public Health Risk |
|----------------|-----------------|--------|--------------------|
| Class A IVD    | Low             | and    | Low                |
| Class B IVD    | Moderate        | and    | Low                |
| Class C IVD    | High            | and/or | Moderate           |
| Class D IVD    | High            | and    | High               |

In order to standardize and minimize any risks in the procurement of diagnostics, WHO's prequalification programme for in vitro diagnostics (WHO PQ for IVDs) teams assess and prequalify IVDs for diagnosis and treatment monitoring, focusing on high burden, priority diseases.<sup>20</sup> The World Health Organization classifies mRDTs under different risk classes that relate to critical aspects specific to resource limited settings compared to those that apply to many high-income countries (HICs).

Source: WHO

These relate to issues such as differences in disease endemicity and prevalence, the availability of follow-up or reference testing, differences in the level of training of health care professionals. The risk classification in countries with limited resources is higher than in HICs. As such, mRDTs are classified under risk categories C and D (Table 2).<sup>21</sup> Because of the high risks associated with the procurement of mRDTs, UNICEF only procures mRDTs that have been prequalified by WHO (Table 3).

In 2019, WHO recommended the procurement of WHO prequalified mRDTs. They also advised that country product selections consider mRDTs that can detect HRP-II and pLDH antigens and can distinguish between *Pf* and non-*Pf* malaria, and/or *Pf* and *Pv*.<sup>22</sup> UNICEF procures products that have been WHO prequalified and that can detect HRP-II, and pLDH antigens. Over the last few years, WHO has prequalified 15 new mRDTs. It currently lists 25 prequalified mRDTs from nine manufacturers (Table 3).<sup>23</sup> Seven other manufacturers anticipate WHO prequalifying a further eleven mRDT products.

**Table 3 World Health Organization Prequalified Malaria Rapid Diagnostic Tests - Continued overleaf**

| Manufacturer             | Product                                    | WHO Prequal. | Packaging                                    | Link to access public report  |
|--------------------------|--|--------------|--|---|
| Abbott Diagnostics Korea | Bioline Malaria Ag <i>Pf</i>               | 2010         | 1T / kit × 25 each<br>25T / kit              | <a href="https://extranet.who.int/pqweb/content/public-report-sd-bioline-malaria-ag-pf-and-sd-bioline-malaria-ag-pf-poct-pqdx-0031-012-01">https://extranet.who.int/pqweb/content/public-report-sd-bioline-malaria-ag-pf-and-sd-bioline-malaria-ag-pf-poct-pqdx-0031-012-01</a> |
|                          | Bioline Malaria Ag <i>Pf</i> (HRP2 / pLDH) | 2015         | 1T / kit × 25 each<br>25T / kit              | <a href="https://extranet.who.int/pqweb/content/public-report-pqdx-0209-012-00">https://extranet.who.int/pqweb/content/public-report-pqdx-0209-012-00</a>   |
|                          | Bioline Malaria Ag <i>Pf</i> / <i>Pv</i>   | 2018         | 1T / kit<br>25T / kit                        | <a href="https://extranet.who.int/pqweb/content/public-report-pdx-0297-012-00">https://extranet.who.int/pqweb/content/public-report-pdx-0297-012-00</a>   |
|                          | Bioline Malaria Ag <i>Pf</i> / <i>Pv</i>   | 2015         | 1T / kit × 25 each<br>10T / kit<br>25T / kit | <a href="https://extranet.who.int/pqweb/content/public-report-pqdx-0125-012-00">https://extranet.who.int/pqweb/content/public-report-pqdx-0125-012-00</a>   |
|                          | Bioline Malaria Ag <i>Pf</i> / pan         | 2013         | 1T / kit<br>25T / kit<br>30T / kit           | <a href="https://extranet.who.int/pqweb/content/public-report-sd-bioline-malaria-ag-pfpan-0030-012">https://extranet.who.int/pqweb/content/public-report-sd-bioline-malaria-ag-pfpan-0030-012</a>   |
|                          | NxTek Eliminate Malaria <i>Pf</i>          | 2019         | 1T / kit × 25 each<br>25T / kit              | <a href="https://extranet.who.int/pqweb/content/public-report-pqdx-0349-012-00">https://extranet.who.int/pqweb/content/public-report-pqdx-0349-012-00</a>   |

<sup>18</sup> Noedl Harald, Walther H. Wernsdorfer, Rober S. Miller, et al., *Histidine-rich Protein II: a Novel Approach to Malaria Drug Sensitivity Testing*, American Society for Microbiology Journals, Vol. 46, No. 6, Washington, June 2002.

<sup>19</sup> Centres for Disease, Control, and Prevention, *Blood Specimens - Detection of Parasite Antigens*, CDC, Atlanta, May 2016.

<sup>20</sup> World Health Organization, *Welcome to Prequalification of In Vitro Diagnostics*, WHO, Geneva, August 2022.

<sup>21</sup> World Health Organization, *IVD Risk-based Classification*, WHO, Geneva, August 2022.

<sup>22</sup> World Health Organization, *Selecting and Procuring Malaria RDTs*, WHO, Geneva, 2021.

<sup>23</sup> World Health Organization, *Prequalified In Vitro Diagnostics*, WHO, Geneva, August 2022.

| Manufacturer                | Product  | WHO Prequal. | Packaging  | Link to access public report  |
|-----------------------------|--|--------------|--|---|
| Access Bio                  | CareStart Malaria HRP2 ( <i>Pf</i> ) *   | 2015         | 25T / kit<br>40T / kit<br>50T / kit  | <a href="https://extranet.who.int/pqweb/content/public-report-carestart%E2%84%A2-malaria-hrp2-pf-pqdx-0137-049-00">https://extranet.who.int/pqweb/content/public-report-carestart%E2%84%A2-malaria-hrp2-pf-pqdx-0137-049-00</a>   |
|                             | CareStart Malaria HRP2 / pLDH ( <i>Pf</i> ) *  | 2015         | 25T / kit<br>40T / kit<br>50T / kit  | <a href="https://extranet.who.int/pqweb/content/public-report-carestart%E2%84%A2-malaria-hrp2pldh-pf-pqdx-0188-049-00">https://extranet.who.int/pqweb/content/public-report-carestart%E2%84%A2-malaria-hrp2pldh-pf-pqdx-0188-049-00</a>   |
|                             | CareStart Malaria HRP2 / pLDH ( <i>Pf</i> / pan) combo *                                       | 2015         | 25T / kit<br>40T / kit<br>50T / kit  | <a href="https://extranet.who.int/pqweb/content/public-report-carestart%E2%84%A2-malaria-hrp2pldh-pfpan-combo-pqdx-0136-049-00">https://extranet.who.int/pqweb/content/public-report-carestart%E2%84%A2-malaria-hrp2pldh-pfpan-combo-pqdx-0136-049-00</a>                                   |
|                             | CareStart Malaria HRP2 / pLDH ( <i>Pf</i> / <i>Pv</i> ) combo *                                | 2015         | 25T / kit<br>40T / kit<br>50T / kit  | <a href="https://extranet.who.int/pqweb/content/public-report-carestart%E2%84%A2-malaria-hrp2pldh-pfpv-combo-pqdx-0138-049-00">https://extranet.who.int/pqweb/content/public-report-carestart%E2%84%A2-malaria-hrp2pldh-pfpv-combo-pqdx-0138-049-00</a>                                     |
|                             | *CareStart Malaria pLDH (pan)  | 2015         | 25T / kit<br>40T / kit<br>50T / kit  | <a href="https://extranet.who.int/pqweb/content/public-report-carestart%E2%84%A2-malaria-pldh-pan-pqdx-0234-049-00">https://extranet.who.int/pqweb/content/public-report-carestart%E2%84%A2-malaria-pldh-pan-pqdx-0234-049-00</a>   |
| Advy Chemical               | AdvDx Malaria <i>Pf</i> Rapid Malaria Ag Detection Test  | 2019         | 25 T / kit   | <a href="https://extranet.who.int/pqweb/content/public-report-advdx-malaria-pf-rapid-malaria-ag-detection-test-pqdx-0345-101-00">https://extranet.who.int/pqweb/content/public-report-advdx-malaria-pf-rapid-malaria-ag-detection-test-pqdx-0345-101-00</a>                                 |
| ARKRAY Healthcare           | ParaHIT f Ver. 1.0 Rapid Test for <i>Pf</i> Malaria Device                                     | 2014         | 10T / kit<br>25T / kit<br>50T / kit  | <a href="https://extranet.who.int/pqweb/content/public-report-parahit-f-ver-10-rapid-test-p-falciparum-malaria-device-pqdx-0062-023-00">https://extranet.who.int/pqweb/content/public-report-parahit-f-ver-10-rapid-test-p-falciparum-malaria-device-pqdx-0062-023-00</a>                   |
| Meril Diagnostics           | One Step test for Malaria <i>Pf</i> /pan Ag MERISCREEN Malaria <i>Pf</i> / pan Ag              | 2020         | 10T / kit<br>25T / kit<br>30T / kit<br>50T / kit                           | <a href="https://extranet.who.int/pqweb/WHOPR/public-report-one-step-test-malaria-pfpan-ag-meriscreen-malaria-pfpan-ag-pqdx-0330-074-00">https://extranet.who.int/pqweb/WHOPR/public-report-one-step-test-malaria-pfpan-ag-meriscreen-malaria-pfpan-ag-pqdx-0330-074-00</a>                 |
|                             | One Step test for Malaria <i>Pf</i> / <i>Pv</i> Ag MERISCREEN Malaria <i>Pf</i> / <i>Pv</i> Ag | 2018         | 10T / kit<br>25T / kit<br>30T / kit<br>50T / kit                           | <a href="https://extranet.who.int/pqweb/content/public-report-one-step-test-malaria-pf-pv-ag-meriscreen-malaria-pfpv-ag-pqdx-0294-074-00">https://extranet.who.int/pqweb/content/public-report-one-step-test-malaria-pf-pv-ag-meriscreen-malaria-pfpv-ag-pqdx-0294-074-00</a>               |
|                             | One Step test for Malaria <i>Pf</i> HRP-II Ag MERISCREEN Malaria <i>Pf</i> HRP-II Ag           | 2022         | 10T / kit<br>25T / kit<br>50T / kit  | <a href="https://extranet.who.int/pqweb/WHOPR/public-report-one-step-test-malaria-pf-hrp-ii-ag-meriscreen-pqdx-0470-074-00">https://extranet.who.int/pqweb/WHOPR/public-report-one-step-test-malaria-pf-hrp-ii-ag-meriscreen-pqdx-0470-074-00</a>   |
| Orchid Biomedical Systems   | Paracheck <i>Pf</i> - Rapid Test for <i>Pf</i> Malaria Device (Ver. 3)                         | 2020         | 5T / kit<br>10T / kit<br>25T / kit<br>100T / kit                           | <a href="https://extranet.who.int/pqweb/WHOPR/public-report-paracheck-pf-rapid-test-pfalciparum-malaria-device-ver-3-pqdx-0321-024-00">https://extranet.who.int/pqweb/WHOPR/public-report-paracheck-pf-rapid-test-pfalciparum-malaria-device-ver-3-pqdx-0321-024-00</a>                     |
| Premier Medical Corporation | First Response Malaria Ag. <i>Pf</i> / <i>Pv</i> Card Test                                     | 2018         | 10 × single test<br>25 × single test<br>30 × multi test<br>25 × multi test | <a href="https://extranet.who.int/pqweb/content/public-report-first-response%C2%AE-malaria-ag-pf-pv-card-test-pqdx-0329-010-00">https://extranet.who.int/pqweb/content/public-report-first-response%C2%AE-malaria-ag-pf-pv-card-test-pqdx-0329-010-00</a>                                   |
|                             | First Response Malaria Ag. pLDH / HRP2 combo Card Test   | 2018         | 10 × single kit<br>25 × single kit<br>25 × multi kit<br>30 × multi kit     | <a href="https://extranet.who.int/pqweb/content/public-report-first-response%C2%AE-malaria-ag-pldhhrp2-combo-card-test-pqdx-0285-010-00">https://extranet.who.int/pqweb/content/public-report-first-response%C2%AE-malaria-ag-pldhhrp2-combo-card-test-pqdx-0285-010-00</a>                 |
|                             | First Response Malaria Antigen <i>Pf</i> (HRP2) Card Test                                      | 2018         | 25 × single kit<br>10 × single kit<br>25 × multi kit<br>30 × multi kit     | <a href="https://extranet.who.int/pqweb/content/public-report-first-response%C2%AE-malaria-antigen-p-falciparum-hrp2-card-test-pqdx-0283-010-00">https://extranet.who.int/pqweb/content/public-report-first-response%C2%AE-malaria-antigen-p-falciparum-hrp2-card-test-pqdx-0283-010-00</a> |
| SD Biosensor                | STANDARD Q Malaria <i>Pf</i> Ag Test   | 2020         | 25T / kit  | <a href="https://extranet.who.int/pqweb/content/public-report-standard-q-malaria-pf-ag-test-pqdx-0346-117-00">https://extranet.who.int/pqweb/content/public-report-standard-q-malaria-pf-ag-test-pqdx-0346-117-00</a>   |
|                             | STANDARD Q Malaria <i>Pf</i> / pan Ag Test   | 2020         | 25T / kit  | <a href="https://extranet.who.int/pqweb/content/public-report-standard-q-malaria-pfpan-ag-test-pqdx-0347-117-00">https://extranet.who.int/pqweb/content/public-report-standard-q-malaria-pfpan-ag-test-pqdx-0347-117-00</a>   |
|                             | STANDARD Q Malaria <i>Pf</i> / <i>Pv</i> Ag Test   | 2020         | 25T / kit  | <a href="https://extranet.who.int/pqweb/content/public-report-standard-q-malaria-pfpv-ag-test-pqdx-0348-117-00">https://extranet.who.int/pqweb/content/public-report-standard-q-malaria-pfpv-ag-test-pqdx-0348-117-00</a>   |

| Manufacturer       | Product                                      | WHO Prequal. | Packaging   | Link to access public report  |
|--------------------|--|--------------|---|---|
| Zephyr Biomedicals | FalciVax - Rapid test for Malaria Pf / Pv    | 2020         | 10T / kit<br>25T / kit<br>50T / kit<br>100T / kit | <a href="https://extranet.who.int/pqweb/WHOPR/public-report-falcivax-rapid-test-malaria-pv-pf-pqdx-0290-025-00">https://extranet.who.int/pqweb/WHOPR/public-report-falcivax-rapid-test-malaria-pv-pf-pqdx-0290-025-00</a>       |
|                    | Parascreen - Rapid test for Malaria Pf / pan | 2020         | 10T / kit<br>25T / kit<br>50T / kit<br>100T / kit | <a href="https://extranet.who.int/pqweb/WHOPR/public-report-parascreen-rapid-test-malaria-pan-pf-pqdx-0291-025-00">https://extranet.who.int/pqweb/WHOPR/public-report-parascreen-rapid-test-malaria-pan-pf-pqdx-0291-025-00</a> |

Source: WHO

**Note** \*: Products subject to a WHO Notice of Concern.

### 3.2 Selection Criteria

The use of particular mRDTs is decided by countries in accordance with their national policies, their testing guidelines, strategies, and nationally validated testing protocols. There are two complementary WHO mRDT quality assurance initiatives on the different mRDTs available that are submitted for assessment (Table 4).

**Table 4 World Health Organization Malaria Rapid Diagnostic Tests Product Testing and Quality Assurance Programmes**

| Quality Assurance Initiative                           | Description  |
|--|--|
| WHO Global Malaria Programme (GMP)                     | <ul style="list-style-type: none"> <li>- Issues mRDT selection guidance and recommendations.</li> <li>- Forms the basis for WHO mRDT procurement and shared through an information note for use by countries and organizations, published on WHO's GMP website.</li> </ul>   |
| WHO Prequalification of In Vitro Diagnostics Programme | <ul style="list-style-type: none"> <li>- WHO's prequalification programme assesses and evaluates mRDTs for performance, quality, and safety through the review of the dossier, laboratory performance evaluation, and manufacturer site inspections. Products that successfully meet the acceptance criteria are included in the list of prequalified products and are eligible for UN procurement.</li> <li>- Currently, WHO has 25 prequalified mRDT products from 9 suppliers: <ul style="list-style-type: none"> <li>• 10 Pf, 8 Pf-Pv, 6 Pf-pan</li> </ul> </li> </ul> |

Source: UNICEF Supply Division

In 2018, WHO issued its latest recommended selection criteria for the procurement of mRDTs as well as an overview of considerations (Table 3).<sup>24</sup>

**Table 5 World Health Organization Malaria Rapid Diagnostics Tests Selection Procurement Criteria**

| Selection Criteria         | Considerations  |
|----------------------------|---|
| <i>P. falciparum</i> PDS * | PDS against <i>P. falciparum</i> should be minimum 75% at 200 parasites / $\mu$ L.                                      |
| <i>P. vivax</i> PDS        | PDS against <i>P. vivax</i> should be minimum 75% at 200 parasites / $\mu$ L.   |
| False positive rate        | False positive rate should be <10%.   |
| Invalid rate               | Invalid test rate should be <5%.  |
| Temperature stability      | Malaria RDTs with high thermal stability are recommended in areas with very high temperatures.                          |
| Ease of use                | Product choice / decision making considerations should include:   |
| Price                      | Blood safety, quality, number of procedural steps, time to result, blood transfer device, format, and kit completeness. |
| Programmatic needs         | Price consideration should be after all other above factors.  |
|                            | Diagnostic performance is dependent on the above-mentioned parameters, including:                                       |
|                            | Training effectiveness, supervision, supply chain delivery, quantification, budgeting, monitoring and evaluation.       |

Source: WHO

**Note** \*: PDS = mRDT performance data is assessed against a panel detection score (PDS). A PDS is a combined positivity-rate parameter measure against different parasite panels.

## 4. Current Market Situation

The market for mRDTs has grown rapidly, driven by the introduction of WHO recommendations to test all suspected malaria cases prior to administering any treatment. This is in addition to the global drive by donor commitments to consolidate international and national efforts to ensure universal access to malaria diagnosis. According to mRDT product testing

<sup>24</sup> World Health Organization, [WHO Global Malaria Programme Information Note on Recommended Selection Criteria for Procurement of Malaria Rapid Diagnostic Tests \(RDTs\)](#), WHO, Geneva, December 2018, p. 3.



programme data, up to 3.1 billion mRDTs were sold globally between 2010-2020,<sup>25</sup>. The biggest share in demand was from sub-Saharan African countries, which accounted for 81 per cent the mRDT share, which stands to reason given that 95 per cent of all malaria cases occur in Africa. Considering the needs and the sharp growth in procurement volumes over recent years, as well as the continuous rise in malaria cases globally between 2020 and 2021, UNICEF anticipates the global public procurement volume of mRDTs will grow further.

By value, independent market research for malaria diagnostics over the course of 2022-2028 is estimated to grow from approximately USD 775,5 million in 2022 to reach up to USD 1.1 billion by 2028, representing a compound annual growth rate (CAGR) of six per cent a year. Efforts to eradicate malaria through diagnosis and treatment, covering the segments of microscopy, RDTs, molecular diagnostic tests, conventional PCR, and real-time PCR are all anticipated to drive this growth.<sup>26</sup>

The COVID-19 pandemic has had a significant impact on non-COVID-19 diagnostics, and in particular on mRDTs, where products are subject to WHO prequalification and the number of suppliers is limited. Through 2020, there were serious constraints in the mRDT market, in addition to price increases from the few mRDT suppliers by an average of just under eight per cent. Some mRDT suppliers shifted or re-purposed their production lines to pursue COVID-19 diagnostic production. This had an impact on overall production lead-times. In addition to a decrease in production capacity, the shipment of all non-COVID-19 diagnostic tests were also affected by much longer shipment timelines, which was compounded by there being fewer flights available, as a result of flights being reserved for the dispatch of COVID-19 product shipments. However, the collaboration within the global malaria community has since stabilized the market, noting that production lead times are longer than prior to the COVID19 pandemic.

Research suggests multiple factors have contributed to an increase in malaria in sub-Saharan Africa during the COVID-19 pandemic. Most notably, there has been a reduction in sufficient financial investments in a context where countries have a high native malaria burden, weakened surveillance systems, limited medical resources, and low socioeconomic development levels.<sup>27</sup> In addition, there was a shift in the allocation of medical resources from malaria control programmes in the early stages of the COVID-19 pandemic towards health workers and personal protective equipment (PPE), as well as the production of diagnostic reagents, and therapeutics. This disrupted, reduced, and delayed many malaria-control measures, leading to a significant negative impact on malaria control. In particular, a funding shortfall from both international and domestic resources, resulting in the reduced access to proven malaria control tools. Basic research appeared to experience the largest absolute decline in funding in 2021 (-12%) and vector control production saw a decrease of just under 20% since 2020. Diagnostics funding received 2.5% of total malaria funding in 2021, its lowest share since 2013.<sup>28</sup>

Seventy per cent of mRDTs are shipped by air, with larger volume orders shipped by sea, representing approximately 30 per cent. Logistical challenges have had a negative impact in delaying critical deliveries and also resulting in increased landed costs.<sup>29</sup> However, during the second half of 2022, globally, the transport and logistics sectors are improving. Over the past few months, UNICEF has been noticing improvements in several critical areas of transport and shipping, including booking lead-times. Overall, the logistics market is showing signs of improvement, albeit still not at the same levels as pre-pandemic.

Despite cautious optimism, UNICEF still faces some challenges in shipping imposed by external factors. Currently, ocean shipping rates have declined, but they are still higher than pre-COVID-19 levels. At the same time, the sea shipping industry is seeking different strategies to keep its rates high and have as such reduced their shipping capacity. In terms of airfreight rates, demand has declined, but the price of fuel remains high and contributes to keeping overall costs high. Lower consumer demand has allowed more access to belly hold freight space, although the industry is in a negative growth.

## 4.1 Demand

Malaria RDTs are nationally regulated products, and country mRDT procurement channelled through UNICEF is dependent on national product registration, several performance evaluations, and national testing protocols. The World Health Organization and FIND, a global health non-profit product development organization that helps develop diagnostic innovation

---

<sup>25</sup> World Health Programme, [Rapid Diagnostics Tests](#), WHO, Geneva, 2021.

<sup>26</sup> Biospace, [Malaria Diagnostics Market Analysis 2022-2030- Efforts To Eradicate Malaria To Drive Market Growth](#), Biospace, Urbandale, April 2022.

<sup>27</sup> Gao Liping, Qi Shi, Zhiguo Liu, et al., [Impact of the COVID-19 Pandemic on Malaria Control in Africa: A Preliminary Analysis](#), Tropical Medicine and Infectious Disease, Basel, January 2023, p. 67.

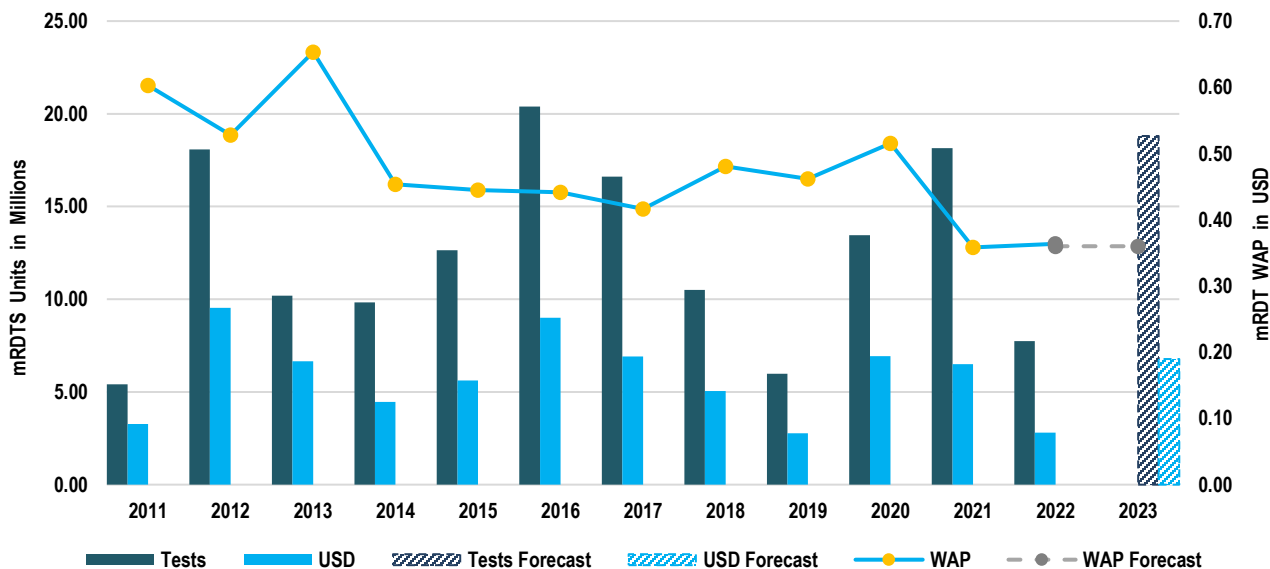
<sup>28</sup> WHO, [World Malaria Report 2022](#), p xxv.

<sup>29</sup> UNICEF, [COVID-19 Impact Assessment on Global Logistics and Supplies](#), UNICEF, Copenhagen, September 2021.



as an integral part of health systems, launched in 2003 at the World Health Assembly in Geneva, have been working together to improve the diagnosis of febrile illnesses to reduce deaths from fever and malaria.<sup>30</sup> While WHO and FIND's product testing programme in 2009 contributed to increasing the acceptance of mRDTs, with the support of malaria diagnostics advocacy by the Roll Back Malaria (RBM) partnership, WHO's guidelines for the treatment of malaria in 2010 drove mRDT adoption and scale-up by recommending universal diagnosis. A growing number of countries subsequently adopted a policy of providing diagnostic testing to all age groups, representing 88 per cent of endemic countries in 2011, up from 85 per cent in 2010, and 74 per cent in 2009. These policy adoptions have contributed to the rapid growth in the mRDT market.

Figure 2 UNICEF Procurement and Weighted Average Price Data 2011-2023



Source: UNICEF Supply Division

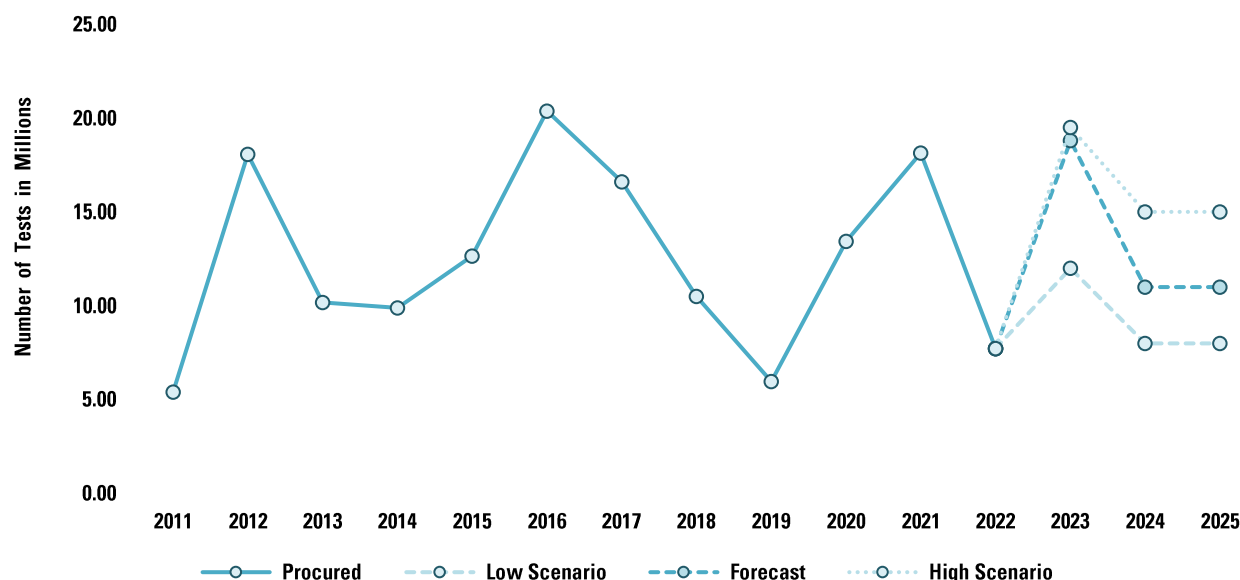
Between 2011 and 2021, UNICEF procured 141 million mRDTs, representing approximately 4.5 per cent of the global volume of 3.1 billion over the same period, accounting for USD 69.5 million (Figure 2), and includes the mRDTs it procures for its warehouse in Copenhagen. UNICEF's annual mRDTs procurement has averaged of approximately 12 million tests a year, fluctuating widely between 5.4 million and 20 million tests a year, and between USD 2.8 million and USD 9.5 million a year. This high level of fluctuation reflects the dependency on country programme financing and those countries that do not typically forecast well their demand for mRDTs. Nor do they integrate their financing into their national annual budget plans, especially when compared to other prioritized health products, such as vaccines. As such, mRDT procurement is heavily dependent on funding availability and the procurement of mRDTs between 2021 and 2022 reflects a decrease in funding of almost 50 per cent. This is despite the number of countries procuring mRDTs through UNICEF having doubled from 24 countries on average per year over the course of in 2015-2016, to on average 40 countries per year over the course of 2017-2022. National inventory systems are subject to complex supply chains and national distribution systems.

UNICEF initiated its first global mRDT forecasting exercise with countries in 2015. The response rate was too low for any of the results to be useful. In 2018, UNICEF included mRDTs into its annual forecast for health and immunization products covering the most critical products UNICEF procures, and which includes vaccines, all immunization and cold chain equipment, as well as bed nets. UNICEF registered a higher level of engagement through national offices and malaria programmes. UNICEF validates and amends this forecast data against its historical procurement volumes to ensure it is as realistic as possible and can be viewed in the context of the global trends in demand. UNICEF's forecast for mRDTs in 2023 (Figure 3, next page) still shows signs of fluctuation in the context of the global mRDTs public sector procurement. However, it does not anticipate any significant increase in demand over the next few years. UNICEF also does not anticipate demand through UNICEF to increase significantly due to countries procuring mRDTs through other procurement channels, also independently. As such, UNICEF expects the annual procurement of its mRDTs over the course of 2023-2024 to range

<sup>30</sup> FIND, [Fever and Malaria](#), FIND, Geneva, 2023.

between 11-18 million tests, representing an estimated annual value of between USD 3.9 million to USD 6.7 million based on the current trend in WAP.

Figure 3 UNICEF Malaria Rapid Diagnostics Tests Procurement and Demand Forecast 2011-2025



Source: UNICEF Supply Division

There are currently nine manufacturers with WHO prequalified mRDTs and are eligible to supply through UNICEF. UNICEF currently has six LTAs with six different companies located in India and South Korea (Table 6), having a total of 13 different products. However, certain manufacturers of mRDTs have been increasingly consolidating their hold in the market over recent years, resulting in 51 per cent of the tests, and 60 per cent of the value procured through UNICEF coming through just one supplier, dominating the market.

Table 6 UNICEF's List of Manufacturers with Long-term Arrangements

| Supplier                                   | LTA duration (years and months) | Start date | End date  |
|--|---------------------------------|------------|-----------|
| Abbott Rapid Dx International, South Korea | 2 years                         | 18-Feb-22  | 17-Feb-24 |
| Advy Chemical India                        | 4 years + 2 months              | 06-Nov-19  | 31-Dec-23 |
| Arkay Healthcare, India                    | 5 years                         | 01-Jan-19  | 31-Dec-23 |
| Meril Diagnostics, India                   | 4 years + 2 months              | 06-Nov-19  | 31-Dec-23 |
| Premier Medical, India                     | 5 years                         | 01-Feb-19  | 31-Jan-24 |
| SD Biosensor, South Korea                  | 2 years + 8 months              | 12-Apr-21  | 31-Dec-23 |

Source: UNICEF Supply Division

To date, 83 per cent of UNICEF's procurement of mRDTs has been concentrated through three of the six suppliers. Country programmes supported by UNICEF account for 74 per cent of mRDTs supply through UNICEF. The procurement by developing country governments and implementing partners account for an additional 11 per cent. UNICEF procures the remaining 15 per cent for use in its various medical kits,<sup>31</sup> which are held as stock items in UNICEF's warehouse in Copenhagen for emergency preparedness and response, and for use with other products in primary health care settings.

## 4.2 Supply

UNICEF seeks to improve product access, affordability, and to ensure it can sustain supply security. To do so, it promotes product diversification and flexibility, as it supports countries, partnerships, and initiatives to diversify and increase the number of products they accept from different manufacturers where possible. Product diversification contributes significantly to a

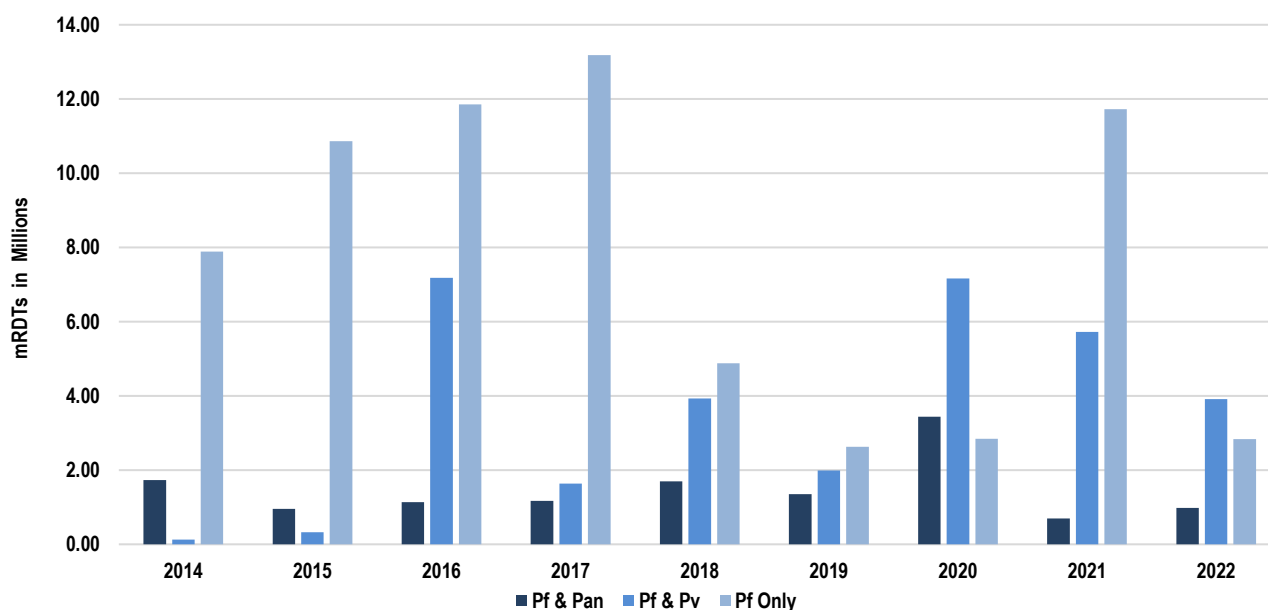
<sup>31</sup> UNICEF, [Interagency Emergency Health Kits: Information Note](#), UNICEF, Copenhagen, December 2019.

healthier market by improving product availability and eliminates supply dependency through single sourcing and many of its associated risks.

Over the past five years, from 2018-2022, UNICEF has supplied approximately six million tests (Figure 4, next page), of which most have been for *Pf* mRDTs only, representing 45 per cent of the volume, whereas 41 per cent has been for *Pf* & *Pv* mRDTs, and 14 per cent has been for *Pf* and pan. Malaria RDTs for *Pf* only diagnosis have historically prevailed as the preferred type of test supplied reflecting the global market trend for the majority (88 per cent) of tests being delivered to sub-Saharan African countries, where *P. falciparum* is the prevailing malaria parasite.

Manufacturers of mRDTs generally do not maintain significant inventories of finished products, as these products are made to order, not to stock, and usually require a four- to eight-week production time. However, this product segment's overall production capacity is not considered limited to the current level of demand, nor does UNICEF assess that this will likely be a barrier as a result of any unforeseen short- or medium-term substantial increase in demand.

**Figure 4 Malaria Rapid Diagnostics Tests Procurement through UNICEF by Malaria Test Type 2018-2022**



Source: UNICEF Supply Division

UNICEF published a technical bulletin on mRDTs to provide information on products available for procurement through UNICEF, available [here](#).<sup>32</sup> It covers a range of topics from product availability to quality assurance to inform programmes and countries.

### 4.3 Pricing

UNICEF's WAP for mRDTs, despite some fluctuation, has been decreasing substantially over the years, from a high of USD 0.65 in 2013 to reach USD 0.36 in 2021, representing an overall reduction of 55 per cent over eight years. The price variations reflect changes in demand patterns and different products that have increased compared to previous years, notably the procurement of more expensive mRDTs for *Pf*, *Pv*, and *Pf/pan* (Figure 4). The current WAP has remained stable and UNICEF does not anticipate any major changes in the immediate future.

UNICEF lists its indicative pricing for mRDTs through its catalogue, available [here](#).<sup>33</sup>

## 5. Sustainable Procurement

Sustainable procurement is an approach to procurement that incorporates the three sustainability pillars of social, economic, and environmental impact considerations. It goes beyond the more familiar “green” public procurement, to ensure that all


<sup>32</sup> UNICEF, [Malaria Rapid Diagnostics Technical Bulletin](#), UNICEF, Copenhagen, May 2019.

<sup>33</sup> UNICEF, [Supply Catalogue](#), UNICEF, Copenhagen, August 2021.



products and services procured support local economic and social development, with the least environmental impact, and the best value for money.

In February 2018, UNICEF released its Procedure on sustainable procurement ([SUPPLY/PROCEDURE/2018/001](#)). The procedure constitutes UNICEF's policy on sustainable procurement and is applicable across all UNICEF offices engaged in supply planning and procurement, wherever feasible and applicable, whether for goods or services, or for programmes or office assets, read more [here](#).<sup>34</sup>



**Sustainable Procurement Considerations**

In implementing sustainable procurement, UNICEF will seek to include green manufacturing quality management system and social considerations, sustainable procurement criteria in tender commercial evaluations, and specific supply targets to develop local industry capacity in programme countries.

In applying sustainable procurement, many UNICEF procurement decisions will face trade-offs between sustainable procurement's three (economic, social, and environmental) pillars, and present key operational challenges, especially between environmental and social considerations, with the latter often being more difficult to quantify.

The absence of any evidence to make informed trade-off decisions will be part of the challenge. The other challenge will be the difficulty to make value judgments to prioritize one pillar over the other. However, solutions will be situation specific, and priorities based on readiness, market influence, and targeted objectives.

Some sustainable procurement elements, notably under the social pillar, may put some pressure on short-term costs that generate longer-term savings, such as investments in fairer employment working conditions, or health and safety, which would be offset by increased motivation, productivity, and reductions in work-related injury and absenteeism. To achieve higher tangible economic benefits and value for money, UNICEF and industry will strive to manage procurement decisions based on longer-term perspectives, considering the advantages of environmentally, socially sound products and services, and better performing staff, bring in the long-term.

## 6. Issues and Challenges

- There are a limited number of WHO prequalified products available that are non-Pf mRDTs.
- Despite there being a wide range of WHO prequalified mRDT products available, country product demand is concentrated around a preferred subset of specific products and manufacturers. This limits the market's ability to ensure supply diversity, security, and production capacity. This increasing consolidation of the mRDTs market in fewer suppliers, risks restricting consumer choice and country demand.
- Related to this is the challenge manufacturers face by the low product demand from countries and their reluctance and lack of interest in adopting alternative products, whether by changing brands selected for the national algorithms, or due to the cost implications associated with making any product switch.
- A significant share of UNICEF's mRDT procurement is dependent on national and external country programme donor funding support. In addition, governments are not choosing to sufficiently budget enough resources to sustain the demand and develop their country's market for these products.
- The lack of accurate country mRDT forecast data from countries risks undermining the ability of UNICEF and suppliers to meet any increased needs from country demand efficiently and effectively. Malaria RDTs are made to order and are not kept in stock. As such, any significant unplanned country orders may be subject to long lead-times for delivery if not planned or forecast in advance. Long lead-times for delivery could be managed by staggering the deliveries over a given time for orders generally made on an annual basis. Planned deliveries would also mitigate any risks related to the need to store large quantities of mRDTs in accordance with manufacturer instructions. Large orders with short delivery times also generate higher production risk for manufacturers.
- Malaria RDTs are not well forecasted or integrated into national annual budgets compared to other prioritized health products, and their procurement is heavily subjected to funding availability. As such, countries continue to face funding gaps and access by patients to diagnostics remains low despite guidelines recommending wide use in endemic countries.
- A limited product range in some countries as result of restrictive national regulatory requirements can limited product availability and accessibility, especially as most countries have rigid preferences for a particular brand of mRDT product.

<sup>34</sup> UNICEF, [Sustainable Procurement](#), UNICEF, Copenhagen, September 2018.

## 7. Steps Forward

- UNICEF is planning an improved global forecast exercise to improve future procurement strategies and tenders. It will be based on country product selection decisions, product pipelines, and country readiness to adopt new products, product performance, and funding availability.
- In order to ensure that continued diverse products from different manufacturers remain accessible and available in the market, UNICEF is monitoring market developments, especially related to potential mergers and acquisitions. UNICEF seeks to avoid the dominance by any one manufacturer in the market at the risk of curtailing countries having a choice of products. UNICEF will look to design and apply market influencing and shaping strategies to influence product and demand diversification in countries.
- UNICEF will work with countries and partners to share information and raise awareness of any new and innovative mRDTs products that may fit the needs and contexts of different country malaria programmes, and that will be made already available for procurement through UNICEF.

For further questions or additional information, please contact:

Abdallah Makhlof  
Chief, Health and Technology Centre  
UNICEF Supply Division  
+45 45 33 55 18  
[amakhlof@unicef.org](mailto:amakhlof@unicef.org)

Tatsiana Ptashnik  
Contracts Manager  
UNICEF Supply Division  
+45 45 33 56 96  
[tpashnik@unicef.org](mailto:tpashnik@unicef.org)

Aadrian Sullivan  
Information Management  
UNICEF Supply Division  
+45 45 33 57 68  
[asullivan@unicef.org](mailto:asullivan@unicef.org)

Other UNICEF information notes can be found at: <https://www.unicef.org/supply/market-notes-and-updates>

UNICEF issues market and information notes on products and supplies that are essential for the needs of children, and by extension their families. While some products are easily available and affordable, the availability of others can be limited, or in some instances, non-existent in the quality and price required. UNICEF places a strategic focus on these supplies to shape healthy markets. UNICEF seeks to influence the market to achieve greater coverage, affordable prices, diversified supplier bases, competitive market landscapes, and product quality that is fit for purpose and in the right form for children.