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# Narrative Review of Diagnostic Innovations in Malaria

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## ABSTRACT

Malaria remains one of the most pressing global health challenges, with hundreds of millions of cases annually and a disproportionate impact on sub-Saharan Africa and South Asia. Accurate and timely diagnosis is essential for effective case management, disease surveillance, and elimination strategies. Traditional diagnostic methods such as microscopy and rapid diagnostic tests (RDTs) continue to play a central role, but their limitations in sensitivity, species differentiation, and field applicability highlight the need for innovation. Advances in molecular diagnostics, including polymerase chain reaction (PCR), loop-mediated isothermal amplification (LAMP), and serological methods, have enhanced detection capabilities, though high costs and infrastructure requirements restrict widespread deployment. More recent innovations, such as next-generation sequencing (NGS), CRISPR-based diagnostics, and portable point-of-care technologies, offer promising opportunities to overcome persistent diagnostic gaps. However, challenges remain in integrating these tools into health systems, addressing ethical issues around data privacy and informed consent, and ensuring accessibility in resource-limited settings. This review synthesizes existing knowledge on traditional and emerging malaria diagnostic technologies, examines their strengths and weaknesses, and explores pathways to their sustainable adoption for global malaria control and eventual elimination.

**Keywords:** Malaria diagnostics, Rapid diagnostic tests (RDTs), Molecular techniques (PCR, LAMP), Next-generation sequencing (NGS), and Point-of-care innovations.

## INTRODUCTION

Malaria remains a major health problem in some tropical regions, despite global malaria eradication initiatives resulting in more than a 10% decline in morbidity and mortality during the 21st century [1]. In 2015, Africa recorded an estimated 218 million cases and 395,000 deaths. Imported malaria is increasing in non-endemic regions such as Europe and the US [2, 3]. The lack of tools for early and accurate detection of asymptomatic carriers with low parasitemia has contributed to malaria's persistence [4-8]. In such populations, current methods fall short; microscopy and rapid tests lack sufficient sensitivity and are often too expensive and low-throughput to be routinely used. There is therefore a critical need for effective diagnostic strategies that can be used to rapidly evaluate infection even in the most resource-limited settings. The malaria diagnostic market is complex [9-13]. Access to accurate diagnosis remains out of reach for many. Misdiagnosis leads to a wholesale wastage of resources and poor disease management, which, when left unchecked, has a direct impact on the poverty level in these low-resourced communities. Despite significant advances in diagnostic technology, no new technologies have reached the field in over 30 years, except for lateral flow assays [14-19]. This indicates that development efforts are often misdirected and that there are fundamental barriers to new technology adoption. Understanding the available funding streams, programmatic goals, and end users is crucial to developing relevant tools that can be brought to market sustainably. Malaria diagnosis is a very difficult market [20-24]. Resources are primarily donor-dependent, health systems are often weak, and malaria epidemiology and programmatic priorities continue to evolve; thus, the market is not stocked with the fundamentals required for commercial investment. Success thus requires a clear understanding of programmatic gaps and market sustainability, as well as dedicated entry points. Six specific market segments exist: case management in low-resource countries, parasite screening for elimination, surveillance, clinical research laboratories, microscopy quality control, and markets for returned travelers. Each of these markets varies substantially in size and scale, limiting the possible return on investment and often requiring sole reliance on donor involvement or new business models to succeed financially. Development efforts that are able to obtain the commitment of well-defined stakeholders therefore stand the best chance of not only successfully developing the required technology, but also of seeing it scaled [25-30].



## Overview of Malaria

Malaria poses one of the world's oldest and deadliest public health problems, with over 2 billion cases recorded in the twentieth century, mainly in tropical countries [31-35]. Malaria transmission is fundamentally dependent on interactions between humans and mosquitoes; disease severity and pattern can vary with host factors such as age, immune status, haemoglobin genotype, and the presence of co-morbidities [36-39]. Geographically, the greatest burden is borne by countries in the African tropical region through which the equator passes. At the same time, malaria is an important disease in South-East Asia and the New World tropics. Malaria is transmitted to humans through the bite of female Anopheles mosquitoes and is caused by five Plasmodium species, of which Plasmodium falciparum is the most dangerous and is responsible for the majority of malaria deaths. Following transmission, a symptomless incubation period of 7 to 30 days is followed by clinical illness [40-43]. Symptoms include fever/chills, headache, vomiting, diarrhoea, musculoskeletal pain, and drowsiness; these make clinical diagnosis difficult, particularly without a history of recent travel to, or residence in, a malarious region. If untreated, severe malaria develops; this varies according to age, endemicity, biogeographical region, and level of access to care [44-48]. Prognosis depends on prompt diagnosis and appropriate treatment [2, 5].

## Epidemiology

Malaria, among the most life-threatening infectious diseases, is caused by Plasmodium parasites transmitted through infected female Anopheles mosquitoes [1]. Approximately 120 Plasmodium species infect both humans and animals worldwide, with five species, P. ovale, P. malariae, P. vivax, P. falciparum, and the emerging P. knowlesi affecting humans [49-53]. These mosquitoes become infected by ingesting blood from carriers and subsequently transmit the parasites during later blood meals. The parasites undergo a complex life cycle involving two stages of development in mammals (liver and blood) and mosquitoes (midgut and salivary glands) [2]. Malaria cases continue to rise globally, due in part to limited access to accurate and timely diagnosis [54-59]. Annually, approximately 216 million documented cases and 445,000 deaths occur, predominantly in sub-Saharan Africa and South Asia [1, 3]. Furthermore, the proliferation of non-immune travelers, soldiers, and refugee populations arriving in Europe and the United States from endemic areas has elevated concerns about increased transmission. In 2017, Africa experienced a disproportionate burden, with 92% of cases and 93% of fatalities [60-64]. Despite ongoing international control initiatives, the reduction in malaria morbidity observed between 2005 and 2015 has plateaued. In addition to health impacts, malaria imposes a substantial economic burden, leading to over US$12 billion in productivity losses [1, 5]. Delays in accessing accurate diagnostic services and appropriate treatment often result in complications and increased mortality; consequently, enhancing timely and accurate malaria diagnosis is essential for patient care and global eradication efforts [65-70].

## Transmission Dynamics

Malaria transmission involves a human host and a mosquito vector. Parasites require a period of development within the vector before a subsequent vertebrate host can be infected. Anopheline mosquitoes become infected when they ingest blood containing gametocytes of Plasmodium falciparum or P. vivax[71-74]. These gametocytes then develop over 8 to 10 days to sporozoites, which invade the mosquito salivary glands and are subsequently inoculated into the skin during the next blood meal. Other human malaria species require shorter sporogonic development of 6 to 7 days before sporozoite invasion of the salivary glands [4, 6]. After inoculation into the host, several forms of the parasite circulate. The sporozoite migrates rapidly into the circulation and then invades hepatocytes, where it develops as the pre-erythrocytic stage [75-79]. The mature hepatocyte schizont releases the exoerythrocytic merozoite into the blood, which subsequently infects red blood cells to initiate erythrocytic stage infection. The parasite initially multiplies asexually in the erythrocytes, with merozoites released every 48 to 72 h. In 48 to 72 h, some parasites differentiate to haploid sexual erythrocytic gametocytes capable of infecting mosquitoes; otherwise, the erythrocytic asexual replication cycle continues [2]. For P. vivax and P. ovale, the liver may also contain hypnozoites that may remain in the liver as quiescent latent forms and reinitiate erythrocytic infection at delayed intervals of weeks, months, or years after the initial infection [80-81].

## Clinical Manifestations

Malaria is transmitted to humans through the bite of an infected female Anopheles mosquito and causes an estimated 247 million cases and 619,000 deaths globally each year [7, 11]. The disease affects mainly children under five and pregnant women who are at increased risk of death and consequences such as anaemia, neurological sequelae, and low birthweight[13]. In most cases, symptoms appear 10–15 days after infection and include fever, chills, sweats, headaches, fatigue, nausea, vomiting, and body aches. Malaria parasites infect human liver cells where they mature and multiply. In the case of the Plasmodium vivax and Plasmodium ovale species, the parasite remains dormant in the liver, forming hypnozoites that can reactivate weeks or months after the initial infection and cause relapse [3, 4]. Parasites then infect erythrocytes (the asexual stage), leading to their multiplication and ultimately, lysis [6]. Parasite burden increases until symptomatic malaria develops [4]. Data indicate that Plasmodium falciparum malaria remains a major complication in pregnancy, especially in East and Southern Africa, whereas infection with Plasmodium vivax is the dominant species in Asia and Latin America [23]. Infected erythrocytes with the P. falciparum species undergo rosetting and sequestration, causing placental malaria. The WHO recommends intermittent preventive treatment during pregnancy for malaria routinely using sulphadoxine-pyrimethamine[4].



## Traditional Diagnostic Methods

Microscopy and rapid diagnostic tests (RDTs) are the two traditional malaria diagnostic approaches still employed in the endemic world [1]. Microscopy involves the examination of Giemsa-stained blood smears with an optical microscope to detect the parasite itself, which remains the “gold standard” for malaria diagnosis in many reference settings [1]. But it requires a high level of expertise, time, and expensive infrastructure; in addition, its sensitivity and accuracy are greatly dependent on the parasitaemia of the blood sample involved. In contrast, RDTs are immunoassays performed on a nitrocellulose strip and cassettes that detect specific Plasmodium antigens through the use of antibodies [1, 6]. They offer several advantages, including rapidity, ease of use, and the fact that they do not require complex training or specialized instruments, which makes them suitable for use in remote settings. They also enable the differential diagnosis of different Plasmodium species (P. falciparum, P. vivax, P. ovale, and P. malariae), an ability unavailable to microscopy. Nevertheless, RDTs have limited sensitivity, particularly when the parasite count is below 100 parasites/μL. Moreover, ongoing antigenic variability undermines the reliability of these methods and is a challenge for developers wishing to ensure wide-range effectiveness [7].

## Microscopy

Microscopy remains the gold standard for the detection, quantification, and specification of malaria parasites in blood films at the point of care [5]. The presence of intraerythrocytic parasites or circulating gametocytes confers a definitive diagnosis. Thick blood films used at high magnification allow for low-density parasitaemia detection (↓ parasite/μL; best-case limit of detection ~5 parasite/μL) due to examination of larger blood volumes. Thin blood films are used to identify Plasmodium species and quantify parasite density accurately [5]. Expert microscopists capable of differentiating artefacts and common blood pathogens from intraerythrocytic Plasmodium are scarce. This has prompted the development of automated microscopy systems that use computer vision to classify parasites in the field [4, 5]. These systems have progressed substantially towards fully integrated platforms combining sample preparation, slide scanning, and image analysis, with capabilities extending to species determination and parasite quantification. Field-ready solutions must balance portability, diagnostic accuracy, and detection limits; several technologies have achieved this stage and undergone clinical field evaluation [4, 5].

## Rapid Diagnostic Tests (RDTs)

In malaria-endemic regions, rapid diagnostic tests (RDTs) constitute a pivotal line of defence against disease [4, 5]. They enable prompt identification of suspected infections, particularly among vulnerable populations such as asylum-seekers, travelers, and children, and thereby facilitate appropriate treatment and help to conserve supplies of antimalarial medications [6]. Conventional RDTs, conceived over two decades ago, rely upon immunochromatographic detection of Plasmodium-specific protein markers, commonly the falciparum-specific histidine-rich protein 2 (PfHRP2) or one of several pan-Plasmodial lactate dehydrogenase isoforms (PfLDH or pLDH) or the glycolytic enzyme aldolase [5, 7]. To assess the performance of widely employed malaria RDTs in a non-endemic setting, a multicentre investigation enrolled 1,311 samples from 1,075 individuals presenting with suspected malaria. Sensitivities for P. falciparum exceeded 95% at parasite densities above 100/μl for all evaluated RDTs [6]. One phenomenon observed was the dissociation between clinical status and microscopic or RDT findings, with a considerable fraction of asymptomatic individuals harbouring microscopic or PCR-confirmed parasitaemia [6]. This circumstance particularly complicated the interpretation of samples yielding discordant results, for instance, microscopy-negative/PCR-positive specimens, and likewise rendered the classification of certain patients who had undergone prior successful treatment perplexing. Among the various products tested, the Carestart Malaria Pf/Pan displayed the overall highest sensitivities, reaching 97.3%, 91.2% and 96.4% for P. falciparum, P. ovale, and P. vivax, respectively [6]. Specificities surpassed 95% for all RDTs apart from the Advantage™ MalCard, which ranged between 91.6% and 94.4% [6].

## Molecular Diagnostic Techniques

Malaria presents with a wide spectrum of clinical manifestations, further dependent on the infecting species [1]. In response to the increasing demand for highly sensitive malaria diagnostic techniques, molecular-based methods are gaining recognition [8, 9]. Diagnostic indicators for malaria are relatively multifaceted, dictated by clinical presentation, the availability of techniques, and the facility's expertise. Conventional methods are continually improved, and new approaches are explored for clinical diagnosis and field applications [1].

## Polymerase Chain Reaction (PCR)

PCR is a molecular technique for detecting Plasmodium nucleic acids in blood and body fluids [7]. It is more accurate and sensitive than microscopy and rapid diagnostic tests (RDTs), particularly for low-grade parasitaemia and active infections [7]. PCR employs repetitive temperature cycles controlled by a thermocycler, during which DNA fragments are amplified to increase the target quantity. The technique permits species differentiation in malaria diagnosis through primers specific to parasite genes 8. Nested PCR is a two-step amplification that uses primers derived from within the original DNA fragment, enhancing sensitivity and specificity. It detects as few as 1 to 4 P. falciparum parasites per 50 L of blood, identifies mixed infections, and reveals contamination levels down to 1%. Although nested PCR increases amplification, sensitivity, and product quantity, it entails longer development time and higher contamination risk [7]. Development of single-tube nested PCRs seeks to reduce contamination and false positives while retaining the method9s benefits. Real-time PCR can incorporate nested approaches for complementary detection, but challenges include nonspecific primer binding and elevated costs [8]. Fluorescent labeling techniques enable direct visualization of amplified fragments, aiding rapid identification of Plasmodium. Emerging platforms combine RT-PCR with immunoassays using up-converting phosphors to capture Plasmodium transcripts, aiming to provide the sensitivity of nucleic acid-based tests in point-of-care devices [8].

## Loop-Mediated Isothermal Amplification (LAMP)

Precision diagnostics play an essential role in medicine. Every disease has its own disease-specific diagnostic tool: viral diseases have RT-PCR; bacterial diseases have CRISPR; diarrheal diseases have Liquid-Chromatography Mass-Spectrometry; and so on[3, 9]. Malaria diagnosis, likewise, relies on diagnostic tools developed to detect the presence of Plasmodium parasites in a host. Among the many molecular methods of detecting Plasmodium, loop-mediated isothermal amplification (LAMP) stands out [8,9]. LAMP is a highly sensitive, great-value, and accurate method for the detection of Plasmodium DNA 9. The principle of LAMP remains the same as standard nucleic acid amplification methods: a specific DNA region is amplified on a large scale [9]. The difference is that, while most nucleic-acid-amplification methods, such as conventional or quantitative polymerase chain reaction (PCR/qPCR), require temperature changes, LAMP amplifies the target DNA at a single temperature (about 64 °C) isothermally within 30–60 min. Loosely, then, LAMP is a simple, rapid, and highly time- and cost-effective technology for the detection of Plasmodium malaria[9].

## Serological Methods

Recent evolution of the serological methodologies constitutes an important advancement towards the development of tools improved in sensitivity and automated for providing large-scale serological profiles of populations [10]. This high-throughput technical arsenal represents a fundamental opportunity to advance our understanding of the acquisition, maintenance, and nature of malaria immune responses [10]. The main remaining challenge is to better define the protective immune response and to integrate more antibody competitors for which genetic variants are mutually exclusive in the parasite population and which surprisingly co-exist in the different human subpopulations to tackle the redundancy and shepherd a potentially finite set of a few antigens as targets in vaccine developments [10].

## Enzyme-Linked Immunosorbent Assay (ELISA)

Enzyme-linked immunosorbent assay (ELISA) and Western blotting constitute the principal serological methods used in malaria diagnostics [10]. These techniques detect parasite-specific immunoglobulins and confirm antibody presence by molecular weight, respectively. Several studies have provided insights into the practical application of ELISA tests for malaria detection [10]. For example, an analysis of the serological reactivity of individuals with a clinical history of malaria employed two distinct ELISA designs: a commercial assay and an in-house test across 365 serum samples. The commercial ELISA yielded 53% positive reactivity, while the in-house version detected 60% [10]. Concordance between the tests reached 67%, and both exhibited 100% agreement with negative controls. The enhanced antigenic reactivity observed in the in-house ELISA suggested the presence of additional Plasmodium falciparum antigens in the crude extract that contribute significantly to the serological response during infection. Another investigation developed an immunosensor using a sandwich ELISA on JD2 gold screen-printed electrodes, achieving detection limits of 2.14 ng/mL in buffer and 2.95 ng/mL in spiked serum samples for the biomarker PfHRP 2. Signal amplification with gold nanoparticle conjugates further reduced the detection limit to 36 pg/mL in buffer and 40 pg/mL in serum [10, 16]. This approach offers a highly sensitive, portable, and cost-effective method for detecting Plasmodium falciparum histidine-rich protein [2, 11]. Furthermore, fluorescence-linked immunosorbent assay (FLISA) based on coumarin-derived dendrimer fluorophores has demonstrated applicability for malaria antigen detection. While polymerase chain reaction (PCR) assays targeting RNA or DNA provide alternatives, their requirement for equipped laboratory facilities limits field deployment. Immunological assays employing antibodies, despite some sensitivity constraints, remain central to commercial diagnostic kits. Monoclonal antibodies directed against conserved Plasmodium lactate dehydrogenase regions have shown promise, and ELISA serves as an efficient tool for epidemiological surveys due to its high throughput. Incorporating LED-based biosensors with organic fluorophores like coumarin-derived dendrimers enhances the practicality of immunoassays for malaria diagnosis outside laboratory settings [8, 12].



## Western Blotting

Western blotting detects total antibodies against blood-stage malaria parasites[1, 7]. It serves as a confirmatory test when the results of an enzyme-linked immunosorbent assay (ELISA) or indirect fluorescent antibody test (IFAT) are indeterminate or inconsistent with a patient's medical history[1, 13]. The assay distinguishes, through gel electrophoresis and Western blotting, between Plasmodium falciparum and Plasmodium vivax infections by comparing the differences in their antibody patterns [1].

## Innovative Technologies

Next-generation sequencing (NGS) and CRISPR-based diagnostic techniques represent promising innovations in malaria detection [1]. NGS offers a cost-effective alternative to traditional sequencing platforms by enabling the simultaneous sequencing of millions of DNA molecules, thus facilitating large-scale metabarcoding analyses. CRISPR-based diagnostics have been developed using the collateral cleavage activity of certain CRISPR-associated nucleases, which can be harnessed for sequence-specific detection of nucleic acids[1, 2]. Their sensitivity is further enhanced when combined with isothermal amplification methods, allowing for the detection of minute quantities of parasite genomes [2].

## Next-Generation Sequencing (NGS)

The fight against malaria demands accurate, sensitive, and timely diagnosis to contain the spread of the disease and manage treatment [13]. Next-generation sequencing (NGS) has recently made important advances in malaria diagnostics [13, 16]. New applications in cultivation, diagnosis, drug resistance profiling, and vaccine development are opening fresh avenues for the identification and detection of Plasmodium species [13]. NGS tools can separate infections into distinct clades, and also detect deletions in genes associated with histidine-rich protein 2 (HRP2) and histidine-rich protein 3 (HRP3), relevant to rapid diagnostic tests (RDTs). Diagnostic procedures based on metagenomics generally involve whole-genome sequencing to establish parasite identity in clinical samples and parasite drug resistance when supplying treatment recommendations to the clinician, promising improvements for malaria control and elimination [24]. The ability of NGS to empower the fight against malaria emerges not only from its application in sequencing the malaria parasite itself, but also through its wider role in genetic research. Along with accompanying molecular techniques that facilitate targeted experiments in the laboratory, NGS has increased the pace of malaria research and has enabled epidemiologists to characterise the spatial and temporal evolution of parasite populations, conduct genome-wide association studies, and gain an in-depth understanding of drug resistance development [13, 14]. Whole-genome sequencing elucidates the genes involved in drug resistance and suggests new therapeutic candidates. Molecular assays based on NGS underpin the construction of laboratory and field surveillance systems that track the emergence and spread of drug and insecticide resistance, along with descriptions of population dynamics [14, 17]. Supervisory tools to detect the origin and spread of resistance constitute a key component of the strategy to contain drug resistance, limiting the expansion of resistant parasites. The capacity of NGS to detect unsuspected or emerging pathogens already finds application in malaria research, helping meet the World Health Organization's agenda for malaria elimination. Genomic epidemiology traces transmission chains in challenging regions, helping to detect outbreaks and strengthening surveillance [18]. Analysis of fragments and oligonucleotides contributes to drug discovery and the identification of vaccine candidates. Whilst not a substitute for microscopy and RDTs, NGS appears set to contribute substantially to the control of neglected infectious diseases, such as malaria[11, 13].

## CRISPR-Based Diagnostics

Clustered regularly interspaced short palindromic repeats (CRISPR) systems constitute a family of nucleic-acid binding proteins that can be programmed with a guide RNA to bind and cut DNA or RNA at sequences complementary to the guide[13, 15]. Derivatives of these proteins lacking nucleolytic activity exhibit target-specific binding, allowing coupling to other functions such as enhanced fluorescence for ultrasensitive, PCR-free

DNA and RNA detection at the point of care [15]. Renewed interest in CRISPR diagnostics has surged after the discovery of the Cas12 and Cas13 proteins that, upon target recognition, exhibit collateral cleavage activity on nearby single-stranded DNA and RNA[12, 15]. These latent ribonuclease activities enable a direct transduction mechanism for single-molecule detection with single-base specificity. The SHERLOCK system, based on Cas13, combines colorimetric, fluorescent, mobile phone, quantitative, multiplex, and cheap paper-readout options with a simple isothermal amplification step, making CRISPR-based assays programmable, inexpensive, sensitive, highly specific, rapid, and portable. This approach combines the programmability and specificity of nucleic acid tests with the simplicity and ease of use of immunoassays [15].



## Point-of-Care Testing

Malaria is a major global health concern. Detecting the parasite during the early stages of infection is crucial for treatment [1]. Point-of-care (POC) tests are receiving the attention of healthcare workers, health authorities, and the scientific community alike because they eliminate many of the issues related to delivery and use [1]. Mobile, compact, lightweight, and inexpensive, POC devices have been developed to perform real-time diagnostics in the field without the need for medical infrastructure and personnel [1]. These include a mobile health (mHealth) app for the quick quantification of erythrocytes, leukocytes, and malaria parasites in stained blood smears using a tablet or a smartphone [16]. A lab-on-chip device capable of extracting specimens and performing quantitative PCR and melting curve analysis to overcome the technical hurdles and complex interpretation of these molecular tests has also been developed[1, 3].

## Mobile Health Applications

Mobile health systems have transformed the architecture of malaria surveillance and control strategies, particularly in regions where the disease remains a threat [17]. In the context of the mobile phone revolution and within a framework of vector surveillance, mobile device-based systems represent future epidemiological platforms capable of ensuring fast and real-time information collection from the field 18. Low-cost, reliable, mobile device-based sensors enable primary diagnoses at the point-of-care, supporting medical attention in rural and underdeveloped areas [11]. The broad versatility of mobile communication allows additional epidemiological information to be collected systematically and combined with other strategies to explore the temporal and spatial dynamics of disease transmission. Mobile health monitoring systems can therefore improve the accuracy and effectiveness of disease control, while a potentially vast epidemiological dataset can improve modeling studies, support monitoring, and contribute to the effective management of funds. Consequently, mobile health applications play a major role as a complementary source of epidemiological information to reinforce and increase the quality of disease control [10].

## Portable Diagnostic Devices

Malaria is a severe parasitic disease caused primarily by four Plasmodium species [11]. It remains a leading cause of morbidity and mortality worldwide, with millions of cases and hundreds of thousands of deaths per year. Plasmodium transmission occurs through the bite of the female Anopheles mosquito vector [19]. Disease manifestation ranges from asymptomatic patent infections at low parasite density to severe complications that can lead to death when untreated. Both clinical awareness and prompt access to a reliable diagnostic assay are crucial for appropriate diagnosis and treatment [19]. The use of a portable device to detect malaria is of significant research interest due to the disease's substantial global health impact. Microfluidic technology enables the design of portable biosensors for the early detection of malaria. A portable sensor based on dielectric spectroscopy that can be used for pre-diagnosis and malaria parasite detection was demonstrated [19]. The sensor system comprises a separation zone to isolate white blood cells and a detection zone, connected to a portable impedance circuit, to measure the dielectric properties of red blood cells to identify infection [20]. Development of smart, automated diagnostic systems that operate on mobile devices offers new opportunities for infectious disease management. An automated mobile device–based diagnostic system for malaria was developed, known as The Malaria System MicroApp [18].

## Integration of Diagnostics into Health Systems

Malaria diagnostics serve as an essential entry point to health systems, yet the practical challenges of ensuring the uptake of novel tools, alongside unresolved issues such as data connectivity and reporting, remain apparent[5, 7]. These common implementation barriers, applicable across a range of health conditions, highlight that the challenge is not necessarily a lack of appropriate technologies, but rather the capacity, or rather incapacity, of health systems to effectively deliver and use them [21]. For example, in Malawi, establishing Malawi's Google as an ambitious national digital data hub has been repeatedly stymied by an insufficient workforce of skilled workers to enter, clean, and maintain an ever-growing volume of health data [23]. Faced with a crisis in software support, it has been suggested that the original cloud-based platforms at the heart of the ambitious plan be substituted with more manageable Edge computing models [24]. Health systems in even the most 'advanced' countries undergo a cyclical evolution as new technologies become embedded and fully exploited; caution is required when designing new implementations so as not to generate unnecessary 'pushback' from overly confident system operators, or end up rebuilding entirely new systems on shifting sands[21].

**Challenges in Implementation**

Traditional approaches perform well in many settings. For example, microscopy remains the WHO-recommended standard due to its ability to detect parasitaemia above 50 parasites/μL at low cost [21]. RDTs ease access by eliminating the need for electricity, consumables, and specialist training [22]. Nonetheless, where available, clinicians still sometimes treat patients without undergoing a test or even after a negative test result. Challenges include supply chain deficiencies, limited quality assurance activities, understaffing, insufficient guideline coverage, and entrenched case-management paradigms. Provider perceptions and preparedness for change further affect adherence; social dynamics such as provider–patient interaction norms and the affordability of RDTs also influence implementation success. Limited engagement of providers in policymaking contributes to fragmented health sector reform [20]. Overall, weaknesses in health system capacity, as well as socio-economic, political, and historical factors, act as major obstacles to successful integration [21, 22].



**Case Studies**

This chapter presents case studies on the integration of molecular malaria diagnostics into existing health systems and reflects on how longer pipelines affect downstream applications of new diagnostic technologies [3, 7]. They highlight lessons from remote, high-burden settings, child-care and specialist referral centres, and routine health services, emphasizing shared challenges, such as diagnostic impact, role within care pathways, sector dynamics, and integration into decentralized services [1, 15]. Continued technological innovation and flexible pipeline designs are recognized as pivotal to addressing existing shortcomings [21]. The landscape of malaria diagnostics is diverse [7]. Microscopy relies on manual examination of stained blood smears, identifying parasite presence with operator skill. Rapid diagnostic tests (RDTs) enable enzyme-detection of parasite antigens but lack the capacity to differentiate species or detect low-level infections [8]. Polymerase chain reaction (PCR) offers a sensitive means to amplify parasite nucleic acids, yet it depends on fixed laboratory infrastructure and skilled staff. Loop-mediated isothermal amplification (LAMP) provides a simpler nucleic-acid-amplification technique with fewer laboratory requirements. Serological methods, such as ELISA and Western blotting, detect anti-malaria antibodies and serve as auxiliary tools [21]. Emerging technologies, including next-generation sequencing, direct nucleic acid amplification tests, CRISPR-based diagnostics, and nanotechnology-enhanced biosensors, represent cutting-edge approaches [13]. Point-of-care testing extends diagnosis into the field through mobile-health applications and handheld devices [3]. Within low-income countries, most of these methods are too costly for widespread field deployment, resulting in a continued dependence on microscopy and RDTs alongside clinical assessment [2].

**Ethical Considerations**

Access to reliable malaria diagnostics is essential for informed disease management and effective public health programmes. Traditional methods, such as microscopy and rapid diagnostic tests (RDTs), remain out of reach for many communities in need [2]. Molecular diagnostic techniques, including polymerase chain reaction (PCR) and loop-mediated isothermal amplification (LAMP), offer improvements in sensitivity and specificity. Next-generation sequencing and CRISPR-based diagnostics are shaping the future. Point-of-care testing facilitates real-time results in resource-constrained settings. The translation of novel diagnostic technologies to health policies and programmes is a complex and seldom straightforward process [21]. Low access to malaria diagnostics worldwide increases the risk of misusing anti-malarials, yet insufficient evidence exists to guide the development and deployment of new diagnostics. Understanding the data needed to support the malaria diagnostic adoption process from early innovation to implementation is therefore a priority. Case studies reveal distinct challenges at different health-system levels [12]. These include forecasting end-user readiness, need, and cost; application of designs and specifications from early global-level decision-makers; generation of safety and quality impact data relevant to control programmes; translation of evident parasite clearance and test-to-treatment bundles into influence 'on-the-ground'; and the securing of regulatory and policy approval[13]. Ethical issues may arise depending on the policy and regulations governing health systems, and the nature of data collected via remote diagnostics. Careful consideration of patient confidentiality, informed consent, and data privacy is essential to uphold ethical standards [14].

**Data Privacy**

The application of mobile health (mHealth) apps and devices shows significant potential for remote, real-time, and resource-efficient malaria diagnostics [1]. However, challenges in health system integration are impediments to the widespread implementation of innovative testing services. Introduction of new datasets raises fundamental questions about privacy and consent with respect to sensitive health records that require explicit solutions for future mHealth adoption [16]. Recent advances in next-generation sequencing and CRISPR diagnostics illustrate the potential for extensive detection of low-density and asymptomatic infections, as well as broad genomic surveillance at multiple scales [22]. In addition to improved active population surveillance, the cost and overhead of these technologies are now minimal, opening the possibility of mobile and low-resource assays that do not require laboratory infrastructure [2].



## Informed Consent

Informed consent represents a cornerstone of research ethics: it manifests respect for autonomy, can protect privacy, promote societal trust in research, and is central to good research practice [1]. In research involving human subjects, the fundamental principle is the right to autonomous decision-making; participation should be voluntary and adequately informed [23]. Ethics committees typically require that a study have a sound and justifiable scientific basis, and that risks to participants are balanced by adequate benefits. Only participants who receive information about the nature and purpose of a study, what participation involves, and any potential risks and benefits, can make informed and rational choices about involvement [2]. They should be aware of their right to refuse participation or withdraw at any time without penalty [20]. Within regulated research, the process of imparting and receiving this information is known as informed consent. Where the research is not regulated by statute in social sciences or on anonymous genetic analyses, for example, researchers are still obliged to meet appropriate ethical standards [17]. Obtaining informed consent remains an important principle, particularly when data are collected directly from human subjects or from recorded material that is, or may become, identifiable to them [18]. However, implementation will necessarily vary according to the nature of the research. For instance, questionnaires for anonymous participants may not require formal consent. Researchers, referees, editors, and publishers commonly prioritize informed consent within the spectrum of research ethics; nevertheless, it is not an absolute necessity in all cases, and there are instances when it is appropriate to retain information withheld or with consent [14, 15].

## Future Directions in Malaria Diagnostics

Malaria diagnostics have witnessed significant advancements, with emerging technologies promising rapid, sensitive, and affordable detection [1]. The current landscape includes biosensing technologies, nucleic acid amplification methods, and microfluidics devices, among others [24]. Concurrent innovation in therapeutics has renewed impetus for developing complementary diagnostic tools [4]. Top priorities in malaria diagnostics encompass the detection of parasitaemia, identification of circulating parasite proteins, assessment of physiological changes in infected individuals, and evaluation of parasite drug resistance. Broader access to diagnosis, especially in remote and resource-limited settings, remains a critical goal, with various biosensing strategies under investigation to address this need [2]. Future trends involve the integration of next-generation sequencing, CRISPR-based diagnostics, and mobile health platforms, aligned with global health initiatives that seek to enhance the control of tropical and infectious diseases [1].

## Emerging Technologies

Diagnostic testing has been fundamental to malaria control and elimination programmes, with several serology-based assay formats demonstrating utility in clinical and research settings [12]. Continued innovation in existing and emerging molecular and immunological diagnostic technologies is creating new opportunities to address the remaining challenges posed by malaria infections [23]. The launch of initiatives to eradicate the deadly parasitic disease has resulted in a decline in morbidity and mortality worldwide. Nevertheless, malaria remains a foremost global health threat, especially in tropical regions; in the first quarter of 2017 alone, approximately 212 million cases resulting in 429,000 deaths were recorded [1, 24]. The geographical scope of countries reporting local transmission of malaria has also expanded over the years, and cases of imported malaria are steadily increasing in non-endemic regions, such as Europe and the US. One major factor that has ensured the persistence of malaria is the lack of analytical sensing tools for the early and accurate detection of the disease in asymptomatic individuals with low parasitaemia levels [1, 5]. The microscopy and rapid diagnostic test (RDT) approaches that are currently employed in malaria-endemic areas do not possess satisfactory sensitivity for malaria parasitaemia, are often cost-prohibitive, and offer low-throughput analysis. Thus, there is an urgent need to develop effective diagnostic strategies that are suitable for field applications and capable of operating in both highly- and lowly-resourced health care settings [23]. Recent technological advances are now focusing on the development of rapid, point-of-care (POC) test formats that offer an improvement in the test parameters and algorithms for the detection of parasite determinants; these new test formats, when validated clinically, can help to strengthen the current malaria diagnostic platforms in endemic regions[2, 5]. Efforts being driven by various research groups and institutions are underway to improve or develop new diagnostic techniques involving high-throughput immunochemical assays, highly sensitive nucleic acid detection techniques, identification of novel biomolecular signatures for malaria infection, and the use of biosensing approaches for the detection of malaria infections [19]. All these developments will ultimately enable the identification of disease-specific biomarkers that can be applied both in clinical and seroepidemiological settings [1, 18].

## Global Health Initiatives



Malaria diagnostics have a central role in malaria control and elimination programmes, particularly in sub-Saharan Africa. Despite WHO guidance on testing all suspected malaria infections, only half of febrile children reported to national household surveys are tested. Case management relies heavily on diagnoses made using rapid diagnostic tests (RDTs) and microscopy [24]. Existing diagnostic methods suffer from a range of limitations. RDTs suffer from false negatives caused by false-negatives caused by changing parasite genetics and low-density infections, and false positives due to persistent antigenaemia and the detection of gametocytes rather than asexual parasites; and commercial tests have variable performance [23]. Microscopy requires considerable investment in the training and sustainability of skilled technicians, alongside infrastructure and overhead costs [1]. The development of more sensitive and specific diagnostic tests is therefore actively pursued. Access to high-quality diagnostics constitutes a fundamental step towards universal health coverage [2]. This was particularly highlighted by the COVID-19 pandemic, but in comparison with therapeutics and vaccines, diagnostics receive comparatively less attention and limited investment, especially in resource-limited settings. In 2018, the WHO published the first Essential Diagnostics List (EDL) and the World Health Assembly passed a resolution to strengthen diagnostic capacity and ensure equitable access. Developing and adopting new technologies requires a long process involving multiple stakeholders, including industry, government agencies, normative bodies, global organisations, donors, regulators, researchers, healthcare providers, and end-users [21]. Paper review highlights an important observation: lessons from the past should be considered carefully before defining new development pathways. Greater emphasis should be placed on understanding the practical challenges associated with the successful integration of the technologies into existing healthcare systems, where innovative malaria diagnostics have the potential to make a significant contribution [21, 22, 24]. A realistic assessment of diagnostic gaps also requires a clear appraisal of the effectiveness and shortfalls of existing technologies, rather than the reiteration of the burden of malaria and fever cases. Because existing technologies are already very effective, original instrumentation with new characteristics is often unnecessary [2].

## CONCLUSION

Malaria diagnosis stands at the intersection of technological innovation and public health necessity. While microscopy and RDTs remain the backbone of diagnostic practice in endemic regions, their shortcomings underscore the urgency for more sensitive, affordable, and field-adaptable alternatives. Molecular tools such as PCR and LAMP, along with serological assays, offer improved detection but require substantial resources, limiting their scalability. Cutting-edge approaches NGS, CRISPR-based diagnostics, and mobile health platforms, demonstrate transformative potential for early detection, drug resistance monitoring, and large-scale surveillance. Yet, successful integration of these innovations depends on strengthening health systems, building local capacity, securing sustainable funding, and addressing ethical concerns such as data privacy and informed consent. Ultimately, bridging the gap between laboratory breakthroughs and field application is crucial. Achieving this balance will not only improve patient outcomes but also accelerate progress toward malaria elimination, ensuring that diagnostic innovations fulfill their promise in both high-burden and resource-limited settings.

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