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MINISTRY OF HEALTH

# Kenya Essential Diagnostics List (KEDL)

**Published by the Ministry of Health Kenya**

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# Contents

## List of Tables



## List of Figures

# Foreword

The World Health Organization (WHO) introduced the concept of a model list of essential diagnostics (WHO EDL) in 2018 and encouraged member states to adapt the WHO EDL to national contexts using a systematic approach. Without diagnostics, medicine is blind.[1] The Kenya Essential Diagnostic List (KEDL) is a guideline that will enable the prioritization, increased availability and rational use of essential diagnostic tests for priority diseases of national and global health concern. With increasing prevalence of antimicrobial resistance, increased access to testing will limit inappropriate use of medications.[2 3]

The Division of National Laboratory Services (NLS) and Directorate of Health Products and Technologies (DHPT) played a critical role in selecting key resource persons with immense experience and competences, varied skill sets, multidisciplinary expertise and specialization that was harnessed for the benefit of delivering this guideline. Engaging the country's technical experts at national and county level was key to achieving this milestone. The evidence-driven process to inform development of the KEDL was consultative, collaborative and centered on research evidence and expertise in its decision making for any inclusion or exclusion of In vitro Diagnostics (IVDs).

Diagnostics are an important pillar in healthcare service delivery.[2 3] By guiding treatment decisions and disease surveillance activities, they support the right to the highest attainable standard of health and protection of health. This is in line with article 43(1) a.-d., and article 46 of the Kenyan Constitution 2010.[4] However, they have not received much attention in Kenyan health financing systems that, have historically prioritized vaccines & drugs in its economic investment models for prioritizing various healthcare services. This guideline will inform policy and decision making for increased prioritization and financing to support access to quality assured laboratory and point-of-care diagnostics.

Healthcare service delivery is a devolved function as detailed in the fouth schedule of the constitution.[4] We recommend that national and county levels of government, private and non-governmental organizations work in mutual synergy and collaboration in rolling out this important guideline.

**Nakhumicha S. Wafula**
**CABINET SECRETARY**
**MINISTRY OF HEALTH**

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We also acknowledge the representation of the County government, the Kenya Medical Laboratory Technicians and Technologists Board (KMLTTB), the Kenya Association of Clinical Pathologists (KACP), the Kenya Tissue and Transplant Authority (KTTA), the Kenya Medical Supplies Authority (KEMSA), National referral hospitals (Kenyatta National Hospital, Moi Teaching and Referral Hospital) and private facilities (Aga Khan Hospital, Nairobi).

We also wish to thank the World Health Organization (WHO) for the guidance, and for the ongoing policy advice to optimize the KEDL as a priority-setting tool for Universal Health Coverage (UHC).

Finally, we would also like to appreciate the logistical and technical support from the Clinton Health Access Initiative (CHAI) and financial support provided by the Foundation for Innovative New Diagnostics (FIND).

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# Executive Summary

The Kenya Essential Diagnostic List (KEDL 2023) contains a list of 249 essential in-vitro diagnostics (IVDs) for clinical management, public health surveillance and forensic testing for Kenya's priority communicable and non-communicable diseases. The development of the KEDL 2023 drew on the previous Kenya Essential Medical Laboratory Commodities List developed in 2014 (KEMLCL 2014) and the third edition of the WHO model list for essential IVDs (WHO EDL 2021).

Development of the KEDL 2023 was evidence-driven, consultative and collaborative as it was centered on research evidence and technical expertise for any inclusion or exclusion of In vitro Diagnostics (IVDs). The development process was done by a Technical Working Group (TWG), appointed by the Director General for Health, comprising of experts from national and county level, private sector, relevant regulatory bodies and professional associations, and a consultant who worked with an evidence review team.

To ensure credibility of the KEDL 2023, a comprehensive systematic literature review was done using Population Intervention Comparator Outcome (PICO) format, an evidence-based method for structuring research questions. Alignment of the KEDL 2023 to the Kenya Essential Medicine List (KEML) 2023 was done by considering IVDs for clinical diagnosis of conditions for listed medicines. The KEDL 2023 was also aligned to the Kenya Essential List for Medical Supplies (KEMSL).

The IVD tests in KEDL 2023 are categorized as general tests *(used for routine care, detection of multiple conditions or detection of a set of symptoms that occur together)* and disease-specific tests *(used for detecting specific diseases or target infections)* across 12 test disciplines in line with the WHO EDL 2021 and KEMLC 2014, respectively. The 12 test disciplines include histopathology & cytopathology; bacteriology; virology; parasitology; mycology; hematology; clinical chemistry; Immunology; blood transfusion & transplant services; food and water analysis; clinical & forensic toxicology and forensic biology. Across the 12 disciplines, a total of 249 tests were included in the KEDL 2023 with 98 general tests and 151 disease specific tests.

The KEDL provides an evidence-based priority diagnostic list to facilitate decision-making for appropriate selection, quantification, procurement and resource allocation for priority diagnostics. The listing does not imply preference for one diagnostic test over another. Within each category, diagnostic tests are listed with the appropriate specimen type, test technique and healthcare level of use. An accompanying document (aligned to KEDL 2023) detailing specifications for reagents, equipment and consumables has been availed separately to guide procurement.

The KEDL 2023 should be used to guide:

1. Healthcare financing and essential diagnostics supply quantification and budgeting
2. Health insurance schemes
3. Procurement, warehousing & distribution
4. Management of donations
5. Healthcare workforce development
6. Diagnostics regulation and monitoring (including quality assurance)
7. Promoting rational use of diagnostics
8. Diagnostic test local manufacturing

For KEDL 2023 to have an impact on health service delivery, adequate resource allocations specifically funding for procurement of listed reagents, consumables and equipment is key, availability of technical laboratory staff in adequate numbers and supportive infrastructure are required by level of care. Counties need to adapt the list to their unique burden of disease profiles. All counties implementing the KEDL must assess the health system and societal factors such as acceptability and potential effects on equity.

**Dr. Patrick Amoth, EBS**
**DIRECTOR GENERAL FOR HEALTH**

# List of Abbreviations

| | |
|---|---|
| AAS | Atomic Absorption Spectrometry |
| AEFI | Adverse Events Following Immunization |
| AFB | Acid-fast Bacilli |
| AFP | Alpha-Fetoprotein |
| ALP | Alkaline Phosphatase |
| ALT | Alanine Aminotransferase |
| AIDS | Acquired Immunodeficiency Syndrome |
| AMSTAR | A Measurement tool for Assessment of Systematic Reviews |
| ANA | Antinuclear Antibodies |
| ANCA | Antineutrophil Cytoplasmic Antibodies |
| ANTI-CCP | Anti-cyclic Citrullinated Peptide |
| APTT | Activated Partial Thromboplastin Time |
| ASLM | African Society for Laboratory Medicine |
| ASOT | Antistreptolysin O Titers |
| AST | Aspartate Aminotransferase |
| BAL | Bronchoalveolar lavage |
| BMA | Bone Marrow Aspirate |
| BRCA1 | Breast Cancer Gene 1 |
| BRCA2 | Breast Cancer Gene 2 |
| BUN | Blood Urea Nitrogen |
| CA | Cancer |
| CEA | Carcinoembryonic Antigen |
| CHAI | Clinton Health Access Initiative |
| CHMT | County Health Management Teams |
| CGTRH | Coast General Teaching and Referral Hospital |
| CMLC | County Medical Laboratory Coordinator |
| COVID | Coronavirus Disease |
| CPGs | Clinical Practice Guidelines |
| CrAg | Cryptococcal Antigen |
| CRP | C-Reactive Protein |
| CSF | Cerebral Spinal Fluid |
| DAT | Direct Antiglobulin Test |
| DBS | Dried Blood Spot |
| DHIS-2 | District Health Information System -2 |
| DHPT | Directorate of Health Products and Technologies |
| DS DNA | Double-stranded deoxyribonucleic acid |
| DST | Drug Susceptibility Testing |
| E test | Epsilometer tests |
| EDL | Essential Diagnostics List |
| EDTA | Ethylenediamine Tetracetic acid |
| EGFR | Epidermal Growth Factor Receptors |
| ELISA | Enzyme-Linked Immunosorbent Assay |
| EML | Essential Medicines List |
| ENA | Extractable Nuclear Antigen |

| | |
|---|---|
| ESR | Erythrocyte Sedimentation Rate |
| EtD | Evidence to Decision |
| FDP | Fibrinogen Degradation Product |
| FIND | Foundation for Innovative New Diagnostics |
| FM | Fluorescence Microscopy |
| FNA | Fine-Needle Aspirate |
| FOBT | Fecal Occult Blood Test |
| FSH | Follicle Stimulating Hormone |
| FTA-ABS | Fluorescent Treponemal Antibody Absorption |
| G6PD | Glucose-6-Phosphate Dehydrogenase |
| GGT | Gamma-Glutamyl transferase |
| GRADE | Grading of Recommendations, Assessment, Development and Evaluations |
| H. pylori | Helicobacter Pylori |
| HAV | Hepatitis A Virus |
| Hb | Hemoglobin |
| HBcAB | Hepatitis B core Antibody |
| HBcAg | Hepatitis B core Antigen |
| HBsAB | Hepatitis B surface Antibody |
| HBsAg | Hepatitis B surface Antigen |
| HCG | Human Chorionic Gonadotropin |
| HCV AB | Hepatitis C Virus Antibody |
| HDL | High Density Lipoprotein |
| HIV | Human Immunodeficiency Virus |
| HLA | Human Leukocyte Antigen |
| HPV | Human Papilloma Virus |
| HSV | Herpes Simplex Virus |
| HVS | High Vaginal Swab |
| IAT | Indirect Antiglobulin Test |
| IDSR | Integrated Disease Surveillance and Response |
| IgG | Immunoglobulin G |
| IgM | Immunoglobulin M |
| IHC | Immunohistochemistry |
| ISE | Ion-Selective Electrode |
| IVD | In vitro Diagnostic |
| KEDL | Kenya Essential Diagnostics List |
| KEML | Kenya Essential Medicines List |
| KEMLCL | Kenya Essential Medical Laboratory Commodities List |
| KEMRI | Kenya Medical Research Institute |
| KEMSA | Kenya Medical Supplies Authority |
| KEMSL | Kenya Essential Medical Supplies List |
| KEPH | Kenya Essential Package for Health |
| KMLTTB | Kenya Medical Laboratory Technicians and Technologists Board |
| KNH | Kenyatta National Hospital |
| KOH | Potassium Hydroxide |
| LAM | Lipoarabinomannan |
| LDH | Lactate Dehydrogenase |
| LDL | Low-density lipoproteins |

| | |
|---|---|
| LPA | Line Probe Assay |
| MIC | Minimum Inhibitory Concentration |
| MDR TB | Multi-Drug-Resistant Tuberculosis |
| MoH | Ministry of Health |
| MTB/RIF | Mycobacterium Tuberculosis/ Rifampicin Resistance |
| NAAT | Nucleic Acid Amplification Test |
| NEDL | National Essential Diagnostics List |
| NFL | Non-facility Laboratory |
| NGS | Next Generation Sequencing |
| NPHL | National Public Health Laboratory |
| NTRL | National Tuberculosis Reference Laboratory |
| PCR | Polymerase Chain Reaction |
| pH | Power of Hydrogen |
| PICO | Population, Intervention, Comparator, Outcome |
| PSA | Prostate Specific Antigen |
| PT/INR | Prothrombin Time / International Normalized Ratio |
| PTT | Partial Thromboplastin Time |
| RBT | Rose Bengal Test |
| RDT | Rapid Diagnostic Tests |
| RF | Rheumatoid Factor |
| Rh | Rhesus Factor |
| RIGHT | Reporting Items for Practice Guidelines in Healthcare |
| rK39 | Recombinant K 39 |
| RT-PCR | Real-Time-Polymerase Chain Reaction |
| RT-qPCR | Reverse Transcription-quantitative real-time PCR |
| RVF | Rift Valley Fever |
| SARI | Severe Acute Respiratory Infection |
| SARS-CoV 2 | Severe Acute Respiratory Syndrome-Corona Virus 2 |
| SAT | Serum Agglutination Test |
| SFBG | Sex Hormone Binding Globulin |
| SOTS | Sample Other Than Sputum |
| STI | Sexually Transmitted Infection |
| TnI | Troponin Test |
| TB | Tuberculosis |
| TB LAMP | Tuberculosis Loop-mediated Isothermal Amplification |
| TPHA | Treponema pallidum Hemagglutination Assay |
| TSH | Thyroid Stimulating Hormone |
| TWG | Technical Working Group |
| UHC | Universal Health coverage |
| VDRL | Venereal Disease Research Laboratory |
| VHF | Viral Hemorrhagic Fevers |
| WGS | Whole Genome Sequencing |
| WHO | World Health Organization |
| XDR TB | Extensively Drug-Resistant Tuberculosis |
| ZN | Ziehl Nelsen |

# Definition of Terms

| | |
|---|---|
| Antimicrobials | Medicines including antibiotics, antivirals, antifungals and antiparasitic that are used to treat infections. |
| Antimicrobial Resistance | When infections caused by bacteria, viruses, fungi and parasites no longer respond to medicines. |
| BCR-ABL | A mutation that is formed by a combination of two genes, known as BCR and ABL |
| Drug resistance | Ability of a micro organism to multiply despite the administration and absorption of a medicine given in doses equal to or higher than those usually recommended but within the tolerance of the subject, provided drug exposure at the site of action is adequate |
| Essential Diagnostics | Tests that satisfy the priority health care needs of the population and are selected with due regard to disease prevalence, public health relevance, evidence of utility and accuracy and comparative cost-effectiveness. |
| Extensively Drug-Resistant Tuberculosis (XDR) | TB bacteria resistant to any fluoroquinolone and to at least one of the three second-line injectable drugs (capreomycin, kanamycin and amikacin), in addition to multidrug resistance. |
| In Vitro Diagnostics | Devices intended for the in vitro examination of specimens derived from the human body to provide information for diagnosis or monitoring for compatibility purposes e.g. reagents, calibrators, control material and test kits. |
| Multidrug Resistant TB | TB bacteria resistant to at least both isoniazid and rifampicin. |
| Multiplex testing | Tests that simultaneously analyse samples for multiple disease pathogens. |
| Stand-alone Laboratory | A laboratory not affiliated with a health facility. |

# 1.0 Introduction

## 1.1 Background

Essential lists of health products and technologies play a crucial role in meeting the priority healthcare needs of a country's population[11 12] and also facilitate Universal Health Coverage.[9] The concept of an essential medicines list was introduced by the World Health Organization (WHO) in 1977 and is revised every two years.[13] This serves as a guide for the development of the Kenya Essential Medicines List (KEML).[14] The Ministry of Health expanded this concept to include medical diagnostic tests and supplies through the creation of the Kenya Essential Medical Laboratory Commodities List (KEMLCL) in 2014[7] and the Kenya Essential Medical Supplies List (KEMSL) in 2016.[15]

In 2018, the WHO introduced the Model list for Essential In vitro Diagnostics (IVD) to complement its Essential Medicines List. Since then, three versions of the WHO Model List of Essential Diagnostics (WHO EDL) have been published (2018[5], 2019[16], and 2021[8]), and the fourth update is currently underway. Member states are expected to adapt the list to their national needs based on factors such as public health relevance, evidence of efficacy and safety, quality, comparative cost-effectiveness, and local suitability and appropriateness.[6] The implementation of the Essential Diagnostics List (EDL) is expected to bring several benefits, such as increased prioritization and access to laboratory tests, improved patient care, enhanced ability to diagnose diseases during outbreaks, standardized laboratory services, improved affordability of tests, strengthened regulation and quality of diagnostic tests, and improved capabilities of national laboratory services.

## 1.2 Diagnostic challenges in Kenya

The Kenya Laboratory Capacity report of 2023 revealed large gaps in the laboratory health system at the national and county levels in the areas of commodity, equipment and policy management, quality, safety, zoonotic testing and surveillance.[3] This report also revealed a poorly resourced sector; only 8% of sampled facilities met the minimum staffing criteria and a skewed funding support; tests for donor-supported public health programs such as HIV and TB had better accessibility, referral networks and regular equipment service contracts.

A cross-sectional study by Bahati and colleagues[17] on the availability of laboratory diagnostic services in Kenya found that the median testing capacity across Kenyan hospitals was 40% (IQR: 33.8 to 51.9), with a wider range of testing services observed in private hospitals compared to public hospitals. Despite being limited by the poor reporting of laboratory testing on the District Health Information System-2 platform (DHIS-2), the available data suggests that access to laboratory testing is unequal and inconsistent across general hospitals in Kenya.[17]

In Kenya, the current National Laboratory strategic plan is under review for 2023-2027 and in the final stages of finalization tentatively by October 2023.

## 1.3 Rationale

The lack of an EDL has been a hindrance in guiding policy makers, decision-making, and ensuring laboratory commodity security for priority diseases. The Kenya Essential Medical Laboratory Commodities List was introduced in 2014[7] to guide the prioritization of laboratory testing but it was neither disseminated nor operationalized.

To address these shortcomings in the diagnostic landscape, the Kenya Essential Diagnostics List (KEDL) will serve as a foundation for the development of diagnostic testing capacity, standardization of services, quality assurance and improve on evidence-based management of patients in the country.

This list will prioritize and provide access to high quality, safe, and cost-effective in vitro diagnostics (IVDs) in Kenya, and contribute to the realization of Kenya's Universal Health Coverage (UHC) policy goal for 2020-2030,[9] which states that "all Kenyans should have access to essential quality health services without incurring financial hardship".

Since the development of the KEMLCL in 2014[7], the healthcare landscape has undergone significant changes, with the introduction of new tests and the emergence of new outbreaks and pandemics. The burden of disease has shifted, with a growing prevalence of non-communicable diseases. However, the KEMLCL lacked an evidence-based methodology, and was not officially endorsed, disseminated, or implemented, hindering its impact on access to diagnostics and the quality of health services.

The development of a national EDL anchored on solid evidence base and contextually relevant to the setting, can guide in prioritizing diagnostics based on disease burden and health system requirements. Following the introduction of the concept of EDL by the World Health Organization, countries such as India and Nigeria have published their respective national EDLs.[19-21] The creation of a Kenyan EDL will allow for comparisons and harmonization with other member states' essential lists for in vitro diagnostics.

## 1.4 Goal

To enhance quality laboratory service delivery through increasing access to affordable laboratory diagnostics services across all health care levels to improve health outcomes.

## 1.5 Objectives

To establish an evidence-based priority diagnostic list that will facilitate:

1. Decision-making for appropriate selection, quantification, procurement and resource allocation for priority diagnostics.
2. Strengthening of KEDL implementation framework for diagnostic services offered at all facility levels.

## 1.6 Target population coverage of priority diseases and end users of KEDL

This list of diagnostic tests applies to all populations in Kenya at risk of disease or afflicted with disease irrespective of age, gender, place of residence, education, occupation, socioeconomic status, ethnicity or religion.

The intended primary users of the KEDL include policy makers, procurement managers, program managers, laboratory managers and personnel, supply chain institutions/experts, health care workers and public health practitioners in all national, county and non-governmental health settings.

## 1.7 Main uses of the KEDL

The main uses of the KEDL include:

1. **Healthcare financing and essential diagnostics supply budgeting:** The KEDL should be used as a basis for prioritization of investment of available healthcare finances and, together with accurate quantification of HPT needs, for the estimation of required annual diagnostics supply budgets at all levels of the healthcare system. It should be the starting point for determining diagnostics financing by development partners.

2. **Health insurance schemes:** Diagnostics are a major cost element in healthcare financing for Government, healthcare providers, insurance schemes and partners. KEDL 2023 will be the basis for selection of diagnostics for implementing the defined UHC benefits package. As the health sector elaborates a comprehensive healthcare financing system, the KEDL should be used as the basis for expanding coverage or reimbursement of diagnostics costs.

3. **Procurement, warehousing & distribution (including donations):** The KEDL should be used as a basis for determining diagnostics procurement requirements for all healthcare levels in public, faith-based, non- governmental organization (NGO), private sector and other actors. Use of the KEDL will help focus management efforts on a need-based and prioritized list of critical items and can greatly improve the functioning and efficiency of diagnostics supply systems. The level of use (LOU) designation should be used to guide the supply and use of diagnostics at the appropriate levels of care, as defined in the Health Act, 2017.[10]

4. **Management of donations:** Potential diagnostic donors and recipients should use the KEDL to determine the most appropriate types and presentations of diagnostics for donation to meet public health priorities, including health emergencies. This should be done in line with up-to-date national guidelines on donation of diagnostics and health products.

5. **Healthcare workforce development:** Up-to-date clinical and laboratory guidelines and KEDL should be key references in the training of healthcare human resources for health, to provide correct orientation on evidence-based use of diagnostics for the screening, diagnosis, appropriate treatment selection, susceptibility risk assessment, monitoring of therapy, and public health surveillance. This includes pre- and in-service training, as well as continuous professional education for human resources for health (HRH) in accordance with Kenya's HRH norms and standards.[22]

6. **Diagnostics regulation and monitoring (including quality assurance):** The KEDL should be used as a basis for ensuring an effective system of regulation of all activities involving diagnostics (including import, export, local production, registration, levels of distribution/use, quality monitoring and post-market surveillance). The KEDL should guide diagnostics regulation decision-making, aimed at enhancing access to essential diagnostics and standardization of diagnostic services. This may include fast-tracking registration and incentives to stimulate local production of listed diagnostics. Information that is comprehensive and unbiased should be made available to health workers and the public.

7. **Promoting rational use of diagnostics:** The KEDL should be used as a basis for designing strategies and initiatives to promote the rational use of diagnostics by health professionals, patients and the public. Such activities should focus on promoting and improving utilization of essential diagnostics as the most appropriate for attaining maximum health benefits. In particular, the KEDL should be used as the focus of surveys, studies, and operational research by the National Medicines & Therapeutics Committee (NMTC) and institutional MTCs. This will improve the availability, affordability, appropriateness and use of diagnostics for greater public health impact.

8. **Diagnostic test manufacturing:** The KEDL should be used as a basis for local manufacturing decisions focusing on priority public health products. Incentives for local production should primarily target products listed on the KEDL.

# 2.0 Methodology

This is a standard Essential Diagnostics List (EDL) containing a list of recommended IVDs for Kenya's priority diseases and additional information on specimen type and test technique for each included IVD (See tables 1 and 2).

A separate specifications document detailing required reagents, equipment and consumables for each listed IVD will accompany the KEDL. An EDL with no additional test information about its accompanying supplies may not be considered comprehensive enough to support procurement.[23]

## 2.1 Overview of the KEDL development process

An evidence-based approach utilizing the integration of expertise with varied skill sets and specialization, synthesis of best available research evidence and application of evidence to the Kenyan context was adopted.

In developing the KEDL, the team laid down document delivery strategies based on steps outlined by the WHO guidance for developing national EDLs [6].

i. Review of relevant national documentation and data on burden of disease and IVDs
ii. Comparison exercise: WHO EDL vs list of candidate IVD tests categories available in the country
iii. Public consultation on the outputs of step 2 to inform the next step, including a call for submissions to the NEDL
iv. A call for submissions to the NEDL by the NEDL Secretariat
v. Standardized review and evaluation of applications
vi. Selection of IVD tests
vii. Finalization of the lists by the NEDL TWG and submission to the National Medicines & Therapeutics Committee (NMTC) and the Ministry of Health for approval
viii. Recognition by the Ministry of Health of the NEDL as a policy and encouragement of implementation
ix. Periodic update of the NEDL by DHPT/NMTC (Three-yearly in accordance with MoH)

The review team adapted the WHO EDL 3 (2021)[8] while building on the KEMLCL (2014)[7] and drawing on examples from the Indian NEDL (2019)[19] and Nigerian NEDL (2022). [20] [21] The KEMLCL 2014 contained 105 IVDs listed across 12 test disciplines.

Alignment of the KEDL to the KEML was done by considering IVDs for clinical management that have an associated medicine category in Kenya's essential list for medicines (KEML).[14] The KEML includes medicines for communicable and non-communicable diseases. We also aligned the KEDL to the essential list for medical supplies (KEMSL) by considering relevant supplies listed in the essential medical supplies list. The KEMSL lists essential medical supplies, devices and technologies.[15]

Where applicable, we have reported this document in accordance with the Reporting Items for practice Guidelines in Healthcare (RIGHT statement).[24] This guideline will be updated in three-year intervals.

## 2.2 Establishing the KEDL Technical Working Group

The group that developed the KEDL comprised a Secretariat, Technical Working Group (TWG), Consultant and evidence review team.

**The Secretariat** consisted of Ministry of Health officers from NPHLS and DHPT. The secretariat coordinated this process with support from the technical partner, Clinton Health Access Initiative (CHAI).

**The TWG members** were selected in consideration of their diversity of expertise, gender and healthcare settings, consisting of regulatory authorities, heads of programs, laboratory managers, Medical Laboratory Officers and Technologists, Pathologists, Supply chain managers, Government chemists, Nurses and Clinicians from public and private facilities at national and county levels.

**The Consultant and Evidence review team** consisted of a group of research scientists from the Kenya Medical Research Institute (KEMRI) selected due to their expertise in evidence-based health care methodology. The list of individual participants is available in Annex 1.

## 2.3 The KEDL TWG meetings

The KEDL TWG meetings consisted of in-person workshops and online meetings. There were four in-person workshops to develop the Kenya EDL in line with existing clinical practices, priorities and new products in the market in view of the emerging local and global evidence and disease burden.

The aims of the workshops were to reach consensus on the scope, selection criteria and presentation for included IVDs (1st - 3rd November 2022); to select and categorize IVDs per facility levels based on the evidence review (29th November - 2nd December 2022); to review specifications of the IVDs included in the EDL (7th - 9th February 2023), and incorporate feedback received on the draft guideline from internal and external reviewers (16th - 18th May 2023) respectively. The Secretariat (NPHLS, DHPT) also had regular online meetings with the evidence review team (KEMRI) and logistics team (CHAI) to discuss input from the TWG and make decisions of the way forward. Where further clarifications were needed from the TWG, communication was done via electronic mail, phone or conference calls where appropriate.

## 2.4 Methodology for developing the KEDL

### 2.4.1 Scope and inclusion criteria

#### *2.4.1.1 Scope*

Adoption of the WHO definition of essential tests as tests that satisfy the priority health care needs of the population and are selected according to disease prevalence, public health relevance, evidence of utility and accuracy and cost- effectiveness. [5 8 16]

The agreed scope for the KEDL is IVDs that support evidence driven clinical management, public health surveillance and forensic testing of priority communicable and non-communicable diseases affecting the Kenyan human population (Annex 2).

#### *2.4.1.2 Inclusion criteria*

The agreed selection criteria for including tests in the KEDL were national burden of disease; regulatory status and commercial availability of IVDs and evidence on test performance, utility, resources, acceptability, feasibility and equity (Table 1). The TWG inferred from the criteria previously listed in KEMLCL[3] and WHO EDL edition 3 documents[8] to develop this selection criteria.

To determine the burden of disease, the TWG inferred from published (2018 version)[25] and

developing draft versions (ongoing)[26] of the Kenyan MoH Integrated Disease Surveillance and Response (IDSR) lists for priority diseases and updated it with reports from government publications[27-29] and their expert opinion. The Kenyan IDSR list is adapted from the WHO IDSR list of priority diseases for Africa.[30] Diseases listed in the Kenyan IDSR with no IVDs such as trachoma and guinea worm were excluded from the KEDL. Annex 2 details the list of included diseases.

### 2.4.2 Test categorization and presentation

#### *2.4.2.1 Test categorization*

To present the IVDs listed in the KEDL, the TWG inferred from categories of the WHO EDL version 3[8] (General versus Disease Specific tests) and test disciplines outlined in the previous KEMLCL 2014.[7] The 12 test disciplines were, histopathology & cytopathology, bacteriology, virology, parasitology, mycology, haematology, clinical chemistry, Immunology, blood transfusion & transplant services, food and water analysis, clinical & forensic toxicology and forensic biology. Genetic/genomics tests were also considered across these 12 disciplines where appropriate.

General tests were defined as all IVDs used for routine care, detection of multiple conditions or detection of a set of symptoms that suggest the presence or risk of a certain disease on the Kenyan priority disease list (Annex 2).

Disease-specific tests were defined as IVDs used for detecting specific diseases or target infections in the Kenyan priority disease list (Annex 2). Multiplex tests that analyze samples for multiple disease pathogens simultaneously were also included.

#### *2.4.2.2 Test presentation*

Each included IVD was presented with additional information on specimen type and test technique. Presenting the test purpose (e.g. screening, diagnosis, monitoring, surveillance etc.) is useful in guiding decisions on the utility of tests in practice as well as guiding their reimbursement.[31] However, unlike the WHO EDL 3,[8] the TWG did not list the test purpose of each included IVD test [8] They discussed the variation in the use of the tests in practice across different health facility levels and settings in Kenya based on their expertise and knowledge of current practices in Kenya. The TWG will consider the inclusion of test purpose in the next EDL once better and robust data is available on the use of tests across the different settings in Kenya (see suggestions for future research section in the KEDL).

**Table 1: Scope, inclusion criteria and presentation of KEDL**

| | |
|---|---|
| **Scope** | **Disease**<br>• Priority* communicable and non-communicable diseases in Kenya<br><br>**Test**<br>• IVDs for clinical management, public health surveillance and forensic testing for human populations at risk or affected by disease. |
| **Selection criteria** | • Public health impact of the test category, as determined for example by the local demographics and disease burden*<br>• Availability of commercial IVDs<br>• Approval by appropriate regulatory bodies based on quality and safety data<br>• Evidence on:<br>o Test performance: diagnostic accuracy<br>o Clinical utility and public health impact<br>o Costs and resources required<br>o Acceptability: aligns with local suitability /appropriateness to stakeholders<br>o Feasibility: infrastructural requirements including staffing, storage conditions, specimen handling, associated equipment and information technology capabilities<br>o Equity concerns: distribution of required tests to vulnerable populations |
| **Exclusion criteria** | • Priority diseases without associated IVDs<br>• Tests not recommended by WHO EDLs and Kenyan guidelines (e.g. phased out tests) |
| **Test categories** | **General tests**<br>• IVDs used for routine care and detection of multiple conditions or a set of symptoms suggestive of diseases on the Kenyan priority disease list.<br><br>**Disease specific tests**<br>• IVDs for detecting specific diseases or target infections on the Kenyan priority disease list. Multiplex tests for testing for multiple disease pathogens simultaneously also included.<br><br>General and disease specific tests are grouped across 12 test disciplines** in the KEDL. |
| *Disease burden based on Kenyan disease surveillance documents including the MOH IDSR list, DHIS-2 and current morbidity and mortality reports.<br><br>**Histopathology & cytopathology; bacteriology; virology; parasitology; mycology; haematology; clinical chemistry; Immunology; blood transfusion & transplant services; food and water analysis; clinical & forensic toxicology and forensic biology. | |

### 2.4.3 Evidence reviews

The evidence team used rapid guideline approaches[32 33] utilizing broad searches to conduct the evidence review. Figure 1 summarizes the process of including IVDs into the KEDL.

### 2.4.3.1 *Review of national documentation*

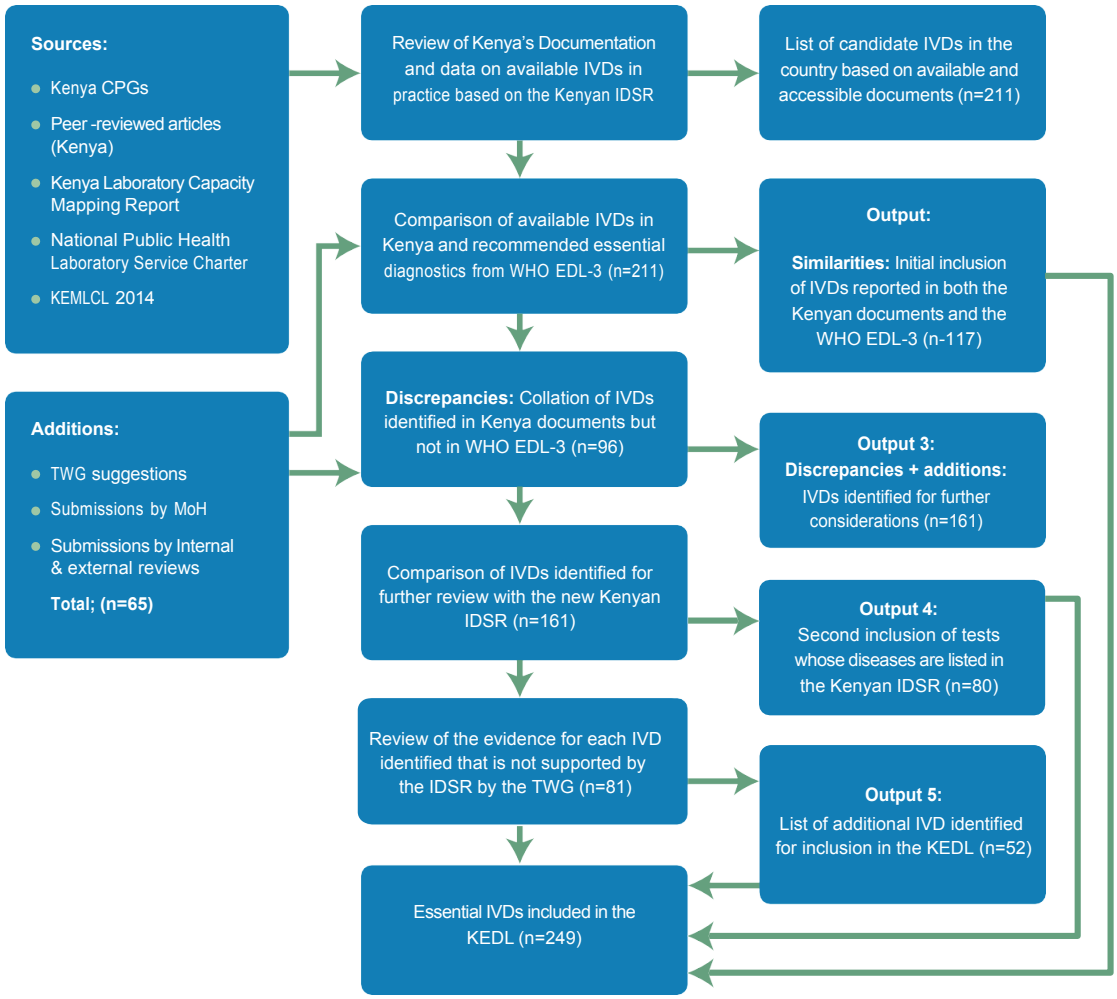
The evidence team first reviewed all relevant national guidelines/policy documents (n=79) and research publications on essential diagnostics to identify listed IVDs in the Kenyan setting. The team obtained Kenyan policy documents, health guidelines, journal articles from relevant websites (MoH, NPHLS), search engines (Google Scholar and PubMed) and MoH experts. Broad search terms "Essential" "Diagnostics" "Tests" "Kenya" was utilized with the search engines to identify relevant peer reviewed articles on essential diagnostics in Kenya.

### 2.4.3.2 *Comparison of WHO list with national guidelines*

A collated list of IVDs was extracted from the search output and then compared to the third edition of WHO EDL (WHO EDL3)[8] list. Similarities and discrepancies were noted. Tests that appeared in both the WHO EDL[3] and identified list of Kenyan guidelines, policy documents or KEMLCL 2014[7] were added to the KEDL without further evidence review. Discrepant IVDs that appeared in either the WHO or Kenyan policy documents (but not both) were flagged for further evidence review to guide their selection into the KEDL. Tests listed under the "Do Not Do recommendations" section in the WHO EDL3 were not included. A list of new test submissions to MoH was also added to the collated list for evidence review. A total of 81 IVDs were marked for evidence review to guide their selection.

## Inclusion of essential IVDs into the KEDL

**Figure 1: The process of inclusion of essential IVDs into the KEDL**



#### *2.4.3.3 Literature review*

##### *2.4.3.3.1 Population Intervention Comparator Outcome (PICO) Question*

The literature review was based on the Population Intervention Comparator Outcome (PICO) format, an evidence-based method for structuring research questions. (Table 2).

Table 2: PICO for EDL evidence review

| | |
|---|---|
| **Population** | Human populations are at risk or infected by a priority* communicable or non-communicable disease.<br>*Priority according to Kenya MOH IDSR list of diseases |
| **Intervention** | IVDs defined as "Devices intended for the in-vitro examination of specimens derived from the human body to provide information for diagnosis or monitoring for compatibility purposes."[6] |
| **Comparison** | Any comparator test |
| **Outcome** | Accuracy/ Efficacy/Effectiveness/Safety/Quality<br><br>Other decisional factors (quantitative/qualitative outputs) including Costs, Human resources, Feasibility, Acceptability, Equity |

##### *2.4.3.3.2 Study search and selection*

To enable selection of relevant guidance to enable selection of shortlisted tests (n=81), we followed guidance from resources supporting trustworthy, rapid and equitable evidence synthesis and guideline development. This guidance recommends that efforts must be made to avoid unnecessary duplication of effort.[32] Hence, priority was first given to identifying relevant evidence in recent test guidelines (WHO and Kenyan clinical practice guidelines), then recent systematic reviews and if necessary, recent primary studies published in the last five years.

Searches across the selection criteria for each IVD test (test performance, acceptability, feasibility, resources and costs, equity) were conducted with the PubMed or Google scholar search engine using broad searches e.g. PubMed search terms for acceptability were; (Meningitis OR Encephalitis) AND (Accept* [tiab] OR Prefer* [tiab] OR Value* [tiab] OR Perception [tiab]) AND (CSF [tiab]) AND Kenya until 30th November 2022.

The list of tests was split into three groups with one junior scientist assigned to conduct searches of each group (at least n=25). A senior scientist double-checked a sample of the searches in each group for accuracy. Another senior scientist conducted quality assessment on identified systematic reviews of test performance only using a measurement tool for assessment of systematic reviews (AMSTAR).[34]

##### *2.4.3.3.3 Evidence syntheses*

Evidence was synthesized narratively. Due to the large number of tests (n=81) amidst a short timeline between TWG meetings, the evidence team used rapid evidence syntheses approaches including an inventory approach (listing evidence available on the topic) and rapid response brief approach. Evidence profiles (summary of the best available evidence in a synthesized and contextualized manner) were presented in an Excel format during the TWG meetings to guide IVD selection. Evidence profiles can be obtained by emailing the NPHLS at *info@nphl.go.ke.*

### 2.4.4 Evidence to Decision (EtD) process

In line with WHO EDL guidance, 8 agreements were made though consensus defined as agreement confirmed by 75% or more of TWG members present. Where there was moderate

agreement (<75%), deliberations were made until consensus was achieved. Where there were major disagreements, the tests were excluded (Annex 3).

The evidence team utilized global evidence to make judgments on criteria about test performance and local (Kenyan) evidence to make judgements on the supporting criteria (acceptability, feasibility, resources and equity). Where no research evidence was available (most commonly local research for criteria on resources, acceptability, feasibility and equity), the TWG made judgements based on their expertise or through additional considerations presented in government reports[3] and research articles[17] about the capacity of laboratories or diagnostics in Kenya.

The team was not fully able to use advanced EtD frameworks such as GRADE [35 36] but inferred from the principles of GRADE criteria in making judgements through consideration of research evidence and expertise. National stakeholders at an earlier stakeholder forum on evidence-based diagnostics in Kenya found global EtD frameworks too complex to use. Further, a published qualitative study[37] among policymakers reported challenges in using the rigorous GRADE methodology in making policies about active case finding for TB by policy makers in low-to-middle-income countries.

For the modified EtD, each selection criterion, presented in an Excel sheet, was scored (no, unsure, partial, yes) based on the evidence and expertise insights. No overall score was given for each test. Instead, tests were included or excluded by consensus after discussions on the individual criterion scores in the context of the recommended facility levels (Levels I to VI, non-facility labs) of the test.

### 2.4.5 Health facility grouping of selected IVDs

Kenya's Health sector is devolved and managed by the national government and 47 county governments in accordance with the Fourth Schedule of the 2010 Constitution.[4] There are six different levels of health care facilities according to Kenya's essential package for health (KEPH). Level 1 to 5 are managed by the county level and Level 6 by the national government. [38 39]

**Community Health Unit: Level 1** - Provide community health services as per the KEPH with an average catchment population of 5,000 people. These include strip-based tests administered by qualified health professionals in the community.

**Primary Care facilities: Level 2 and 3** - Provide outpatient services, basic emergency services, basic oral health services, individual health education, maternity services, basic diagnostic and laboratory services with average catchment population of 10,000 to 30,000 people. These include Dispensaries and Health Centres.

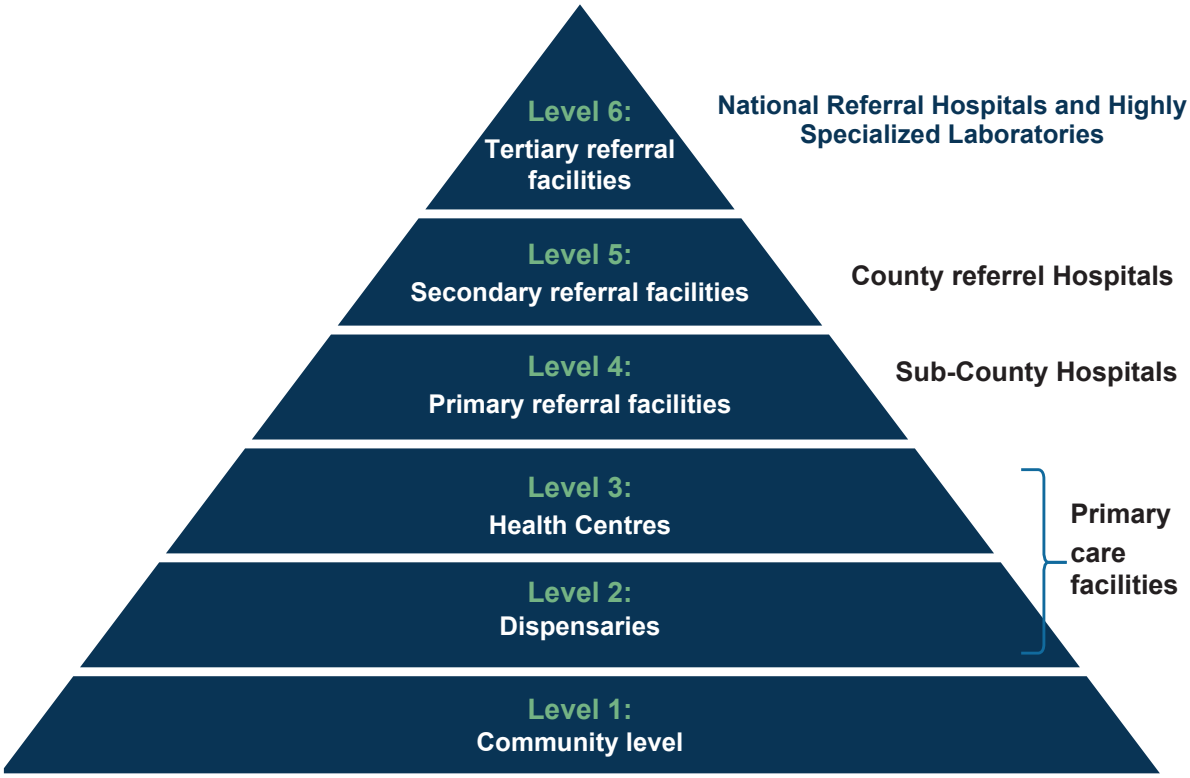
**Primary Referral Facilities (Sub-County hospitals): Level 4** - This provides immediate care to the catchment population of primary health facilities networks and patients referred to by the dispensaries and primary health centres, provides both inpatient and outpatient services, carrying out planning activities for the catchment dispensaries and primary health centres and supervises training centres. It serves an average catchment population of 100,000 to 150,000 people.

**Secondary Referral Facilities (County referral hospitals): Level 5** - Offers specialized care with an approximate catchment population of 250,000 to 500,000 people. They are also known as County Referral Hospitals and County Teaching and Referral Hospitals.

**Tertiary Referral Facilities (National referral hospitals): Level 6** - Offers more specialized care, mentorship, training and research services. It's at the National level with an average catchment population of approximately 1 million. They are also known as National Referral Hospitals. Highly

specialized laboratories including government chemist labs, NPHLS, research institution labs and the Kenya blood transfusion and transplant service (Kenya Tissue and Transplant Authority) were considered as Level 6 facilities according to Kenya's national laboratory policy[3 18] and categorization by the Kenya Medical Laboratory Technicians and Technologists Board (KMLTTB).

***Figure 2: Levels of health care facilities***




* Note: Stand-alone laboratories can be considered across different KEPH levels 2-6.

### 2.4.6 Review and validation

The draft guideline underwent independent review by MoH officers (internal validation) and other stakeholders (external validation). External reviewers included stakeholders from Academic and Research institutions, the Kenya Association of Clinical Pathologists, the African Society of Laboratory Medicine and FIND. (Annex 1 for list of external reviewers). Feedback was discussed and incorporated at the 4th TWG meeting where appropriate.

# 3.0 Tests included in the KEDL 2023

There were 81 tests assessed for inclusion based on an evidence review across the stated criteria. These comprised new test submissions and discordant tests between Kenyan guideline or policy documents and WHO EDL edition 3. Of these, 52 were included and 25 excluded (Annex 3). These 52 included studies which were added to the already included list of IVD tests that comprised concordant tests between Kenyan policy documents and WHO EDL edition 3.

In total, the TWG selected 249 tests into the KEDL and grouped them as per facility level (Levels I to VI). There were 98 tests included under the general test section (Table 3) and 151 tests included under the disease-specific test section (Table 3). The detailed categorization of IVDs per facility level is presented in Annex 4.

The previous KEMLCL 2014 contained 105 IVDs listed across 12 test disciplines.

## 3.1 List of General and disease specific IVDs

**Definition of general IVDs:** all IVDs used for routine care, detection of multiple conditions or detection of a set of symptoms that occur together suggest the presence or risk of a certain disease on the Kenyan disease priority list.[8] **Definition of disease-specific IVDs:** IVDs used for detecting specific diseases or target infections in the Kenyan disease priority list.[8] Multiplex tests that analyze samples for multiple disease pathogens simultaneously were also included.

Table 3: List of general and disease-specific in-vitro diagnostic tests based on the disciplines

* A separate KEDL **specifications document** contains additional details (reagents, equipment and consumables) for each listed IVD

** Level of use (LoU) indicates the lowest level that an IVD can be available e, g, LoU 4 means level 4 and above

***Disease-specific tests for some diseases fall across different test disciplines e.g. cancer.

| Test category | In vitro diagnostic test* | Specimen type | Test technique | LoU** |
|---|---|---|---|---|
| Bacteriology | | | | |
| General | Microscopy, culture and identification of microbes | Stool, tissues, pus, urine, bronchial and abscess aspirates, body fluids, swabs, isolated bacterial colonies, sputum, (samples other than sputum-SOTS), cerebrospinal fluid (CSF), central line catheter | Direct microscopy, Indian ink, gram stain, Ziehl Neelsen (ZN) /modified ZN stains, serotyping | 3 |
| | | | Culture (manual or automated methods), | 4 |
| | | | Polymerase chain reaction (PCR) | 5 |
| | Antimicrobial susceptibility tests (AST) | Microbial isolate | Fully automated/Kirby Bauer methods | 4 |
| | | | PCR for antimicrobial resistance (AMR) | 5 |
| | Blood culture | Whole Blood | Culture (manual/automated) | 4 |
| Disease-specific*** | | | | |

| Test category | In vitro diagnostic test* | Specimen type | Test technique | LoU** |
|---|---|---|---|---|
| **Tuberculosis** | Mycobacterium tuberculosis bacteria test | Sputum, SOTS, ascitic fluid, CSF, gastric lavage, autopsy | Acid-Fast Bacillus (AFB) microscopy: ZN/ fluorescence microscopy (FM) | 2 |
| | Mycobacterium tuberculosis deoxyribonucleic acid (DNA) test | Sputum | Loop-mediated isothermal amplification (LAMP) | 2 |
| | | | Nucleic acid amplification tests (NAATs) (chip-based) | 3 |
| | | Sputum, ascitic fluid, gastric lavage, autopsy, stool, biopsy, fine needle aspirates (FNA), bone marrow, pleural effusion | NAATs (cartridge-based) | 3 |
| | TB Lipoarabino-mannan (LAM) | Urine | Lateral flow assay (LFA) | 2 |
| | Mycobacterium tuberculosis DNA mutations associated with resistance test | Sputum, SOTS, culture isolates | 1st and 2nd Line probe Assay (LPA)<br>-PCR | 5 |
| | Histological test for TB | Cadaveric tissue | Microscopy | 5 |
| | TB Whole Genome Sequencing (WGS)/ Next Generation Sequencing (NGS) | Raw sputum, culture isolates, SOTS | Genome sequencing | 6 |
| | Drug susceptibility testing of Mycobacterium tuberculosis | Sputum and SOTS | Drug susceptibility testing | 6 |
| **Pneumonia** | Microscopy, culture/ identification and sensitivity for bacterial pneumonia | Blood, sputum bronchial wash, FNA, lower respiratory samples | Direct microscopy, Indian ink, gram stain, Ziehl Neelsen (ZN) /modified ZN stains, serotyping | 3 |
| | | | Culture and sensitivity | 4 |
| | NAATs for bacterial pneumonia | Bacterial isolates | PCR, sequencing | 5 |
| **Syphilis** | Venereal disease research laboratory (VDRL) for syphilis | Blood serum | Agglutination test | 2 |
| | Treponema pallidum haemagglutination (TPHA) test for syphilis | | Haemagglutination test | 5 |
| | Fluorescent treponemal antibody absorbed (FTA- ABS) test for syphilis | Blood, serous fluid from syphilis lesions, other body fluids e.g. CSF | Fluorescent microscopy | 3 |
| | NAATs for syphilis | Serum, whole blood | PCR | 5 |

| Test category | In vitro diagnostic test* | Specimen type | Test technique | LoU** |
|---|---|---|---|---|
| Gonorrhoea and Chlamydia | NAATs for Chlamydia trachomatis and Neisseria gonorrhoea infections | Urine, urethral swabs, endocervical swabs, vaginal swabs, rectal swabs, oropharyngeal swabs, liquid cytology | PCR | 5 |
| | Microscopy, culture and antibiotic susceptibility testing for Gonorrhoea and Chlamydia | Urethral swabs, vaginal swabs, eye swabs, throat swabs | Direct microscopy, Indian ink, gram stain, Ziehl Neelsen (ZN) /modified ZN stains, serotyping | 3 |
| | | | Culture and sensitivity | 4 |
| Clostridium infection | Clostridium difficile antigen test | Stool | Immunochromatographic assay (rapid test) | 3 |
| | NAATs for Clostridium difficile | | PCR | 5 |
| Peptic ulcers | Helicobacter pylori antigen test | Stool | Immunochromatographic assay (rapid test) | 2 |
| Cholera | Cholera antigen detection rapid test | Stool | Immunochromatographic assay (rapid test) | 2 |
| | Culture and antimicrobial susceptibility tests for cholera | Stool, rectal swab | Stool culture and antimicrobial testing | 4 |
| | Serotyping-cholera | Cholera isolates | Slide agglutination | 4 |
| | NAATs for cholera | | PCR, sequencing | 5 |
| Typhoid fever | Salmonella antigen testing | Stool, whole blood | Immunochromatographic assay (rapid test) | 2 |
| | Salmonella culture and antimicrobial susceptibility tests | Stool, blood, bacterial isolates | Stool/blood isolates culture | 4 |
| | NAATs for salmonella | Bacterial Isolates and whole blood | PCR | 5 |
| Dysentery | Culture and antimicrobial susceptibility tests for dysentery | Stool | Stool culture and antimicrobial testing | 4 |
| | Serotyping-Shigella | Shigella isolates | Slide agglutination | 4 |
| Meningococcal meningitis | NAATs for meningococcal meningitis | CSF | PCR | 5 |
| | Culture and antimicrobial susceptibility tests for meningococcal meningitis | | Culture and antimicrobial susceptibility testing | 4 |
| | Serotyping for meningococcal meningitis | | Meningococcal meningitis serotyping | 4 |
| Anthrax | Culture and antimicrobial susceptibility tests for anthrax | Blood, skin lesion swabs, spinal fluid, respiratory secretions | Anthrax culture and susceptibility testing | 6 |

| Test category | In vitro diagnostic test* | Specimen type | Test technique | LoU** |
|---|---|---|---|---|
| Anthrax | Enzyme-linked immunosorbent assay (ELISA) for anthrax | Blood | ELISA | 6 |
| | Gram stain microscopy for anthrax | Skin swabs | Microscopy | 6 |
| | NAATs for anthrax | Cutaneous lesion, lesion swab, blood, pleural fluid, ascitic fluid, sputum, and bacterial Isolates | PCR, sequencing | 6 |
| Brucellosis | Rose Bengal (RBT) for brucellosis | Blood serum | Slide agglutination assay | 2 |
| | Serum agglutination tests (SAT) for brucellosis | Serum | Antibody/antigen reaction | 2 |
| Plague | Fine needle aspiration (FNA) test for plague | Lymph node aspirates | Microscopy and culture | 5 |
| Leprosy | Microscopy for leprosy | Slit skin smear | Microscopy | 2 |
| | NAATs for leprosy | Skin biopsy from edges of active patches, whole blood samples | PCR | 6 |
| Virology | | | | |
| Disease Specific | | | | |
| HIV infection | Rapid tests for human immunodeficiency virus (HIV) antibody | Whole blood, Serum, plasma, buccal swabs | Lateral flow immunochromatography | 1 |
| | HIV/ Syphilis dual test | Whole blood, serum, plasma | Lateral flow immunochromatography | 2 |
| | Cluster of differentiation 4 (CD4) cell count | Whole blood | Flow cytometry, electrical impedance, LFA | 3 |
| | ELISA for HIV | Whole blood, serum | ELISA | 4 |
| | HIV NAATs/ viral load | Plasma, dried blood spots (DBS) | PCR | 3 |
| | HIV drug resistance | Plasma, dried blood spots (DBS) | Nucleic acid extraction (manual/automated), PCR (RT-PCR, nested PCR), quantification techniques (gel electrophoresis/ fluorometry/ spectrophotometry), sequencing | 6 |

| Test category | In vitro diagnostic test* | Specimen type | Test technique | LoU** |
|---|---|---|---|---|
| Hepatitis A | Hepatitis A rapid diagnostic test | Serum, whole blood | Lateral flow immunochro-matography | 3 |
| | Hepatitis A IgM/IgG ELISA | Serum, whole blood | ELISA | 4 |
| | NAATs for hepatitis A virus | Serum, whole blood, plasma | PCR | 5 |
| Hepatitis B | Hepatitis B surface antigen (HBsA-g)-RDT | Whole blood, plasma, serum | Lateral flow immunochro-matography | 2 |
| | NAATs for Hepatitis B | Serum, plasma (ethylene-diaminetetraacetic acid-EDTA) | PCR | 5 |
| | Hepatitis B surface antigen (HBsA-g)-ELISA | | ELISA | 4 |
| | Hepatitis B core antibody (HBcAb) | | ELISA | 4 |
| Hepatitis C | Hepatitis C anti-body-RDT | Whole blood, plasma, serum | Lateral flow immunochro-matography | 2 |
| | Hepatitis C virus antibody test | Serum, plasma | ELISA | 4 |
| | Hepatitis C NAATs | Serum, plasma | PCR/ELISA | 5 |
| Human Papil-loma virus infection | HPV DNA testing (NAATs) for cervical smears | Cervical swabs, Vaginal swabs | PCR | 3 |
| Oral/Genital herpes | Herpes simplex virus type 1 and type 2 NAATs | Blood, nasal swab, naso-pharyngeal swab, rectal swab | PCR | 5 |
| Coronavi-rus disease (COVID-19) | SARS-CoV-2 antigen test | Nasal swab, nasopharyn-geal swab | Lateral flow immunochro-matography | 2 |
| | SARS-CoV-2 NAATs | Nasopharyngeal swabs, nasal swabs, nasal wash/ aspirate, oropharyngeal swabs, sputum, bronchoal-veolar lavage (BAL) fluid | Reverse transcriptase-PCR | 4 |
| | SARS-CoV-2 ge-nome sequencing | | Genome sequencing | 6 |
| Influenza | Influenza multiplex NAATs | Nasopharyngeal swab, nasal swab, nasal wash/ as-pirate, oropharyngeal swab, throat swab | Reverse transcriptase-PCR | 6 |
| Measles | Measles NAATs test | Nasopharyngeal swab, throat swab, urine, blood | PCR | 6 |
| | Measles IgM/IgG ELISA test | Serum | ELISA | 6 |
| Rubella | Rubella IgM/ IgG antibody ELISA | Serum | ELISA | 6 |

1 Samples are either collected by providers or through self-collection before being transported to the level 4 health facility for DNA testing. Regarding this IVD are further enlisted in the accompanying KEDL 2023 Specifications Document.

| Test category | In vitro diagnostic test* | Specimen type | Test technique | LoU** |
|---|---|---|---|---|
| Mumps | Mumps IgM/ IgG ELISA test | Serum | ELISA | 6 |
| Rotavirus | Rapid test for rotavirus | Stool | Lateral flow immunochromatography | 2 |
| | NAATs for rotavirus | Stool | Reverse transcriptase-PCR | 5 |
| EBOLA virus Disease | NAATs for EBOLA | Whole blood, serum, plasma | Reverse transcriptase-PCR | 6 |
| Marburg virus disease | NAATs for Marburg virus | Whole blood, serum plasma, oral swabs, nasal swabs, semen, tissue | Reverse transcriptase-PCR | 6 |
| | IgM captured ELISA for Marburg virus | Serum, plasma, tissue | ELISA | 6 |
| Dengue | RDTs for dengue | Whole blood, serum, plasma | Lateral flow immunochromatography | 2 |
| | Dengue NAATs tests | Serum, plasma | Reverse transcriptase-PCR | 5 |
| | IgM, IgG ELISA for dengue | Serum, plasma | ELISA | 5 |
| Yellow fever | IgM/ IgG ELISA for yellow fever | Serum, plasma | ELISA | 6 |
| | NAATs for yellow fever | Whole blood, serum, plasma | Reverse transcriptase-PCR | 6 |
| West Nile fever | NAATs for West Nile fever | Whole blood, serum, plasma, CSF, tissue | Reverse transcriptase PCR | 6 |
| | West Nile fever IgG, IgM ELISA | Serum, CSF | ELISA | 6 |
| Zika Virus Disease | IgM, IgG ELISA antibodies to Zika virus | Serum, plasma | ELISA | 6 |
| | NAATs for Zika virus | Whole blood, plasma, serum, urine, CSF, semen, amniotic fluid, rectal swabs | Reverse transcriptase PCR | 6 |
| Rift valley fever | IgM/ IgG ELISA for Rift valley fever | Serum, plasma | ELISA | 6 |
| | NAATs for Rift valley fever | Whole blood, serum, plasma | Reverse transcriptase-PCR | 6 |
| Crimean Congo haemorrhagic fever | Crimean Congo haemorrhagic fever NAATs | Serum, whole blood, plasma | Reverse transcriptase PCR | 6 |
| | Crimean Congo haemorrhagic fever IgG, IgM ELISA | Serum, plasma | ELISA | 6 |
| Lassa fever | IgM, IgG ELISA for Lassa fever | Serum | ELISA | 6 |

| Test category | In vitro diagnostic test* | Specimen type | Test technique | LoU** |
|---|---|---|---|---|
| **Lassa fever** | NAATs for Lassa fever | Blood, urine, stool, swabs | Reverse transcriptase PCR | 6 |
| **Chikungunya** | IgG/IgM ELISA for chikungunya | Serum, plasma | ELISA | 6 |
| | NAATs for chikungunya | Whole blood, serum, plasma | Reverse transcriptase-PCR | 6 |
| **Mpox** | Mpox NAATs | Lesion swabs, lesion material | PCR | 6 |
| **Poliomyelitis** | Polio viral isolation in cell culture | Stool | Cell Culture | 6 |
| | NAATs for Polio virus PCR | Stool, serum, plasma, CSF | Reverse transcriptase-PCR | 6 |
| **Mycology** | | | | |
| **General** | Microscopy of skin scrapings | Skin scraping, nail sampling, hair follicle, skin snip smear | Microscopy | 3 |
| | Skin punch biopsy for skin diseases | Skin punch biopsy | Microscopy | 5 |
| | Fungal culture for skin diseases | Skin scraping, nail sampling, hair follicle, skin snip smear | Manual culture, mass spectrometry | 6 |
| Disease Specific | | | | |
| **Cryptococcal meningitis** | Cryptococcal antigen (CrAg) | Plasma, CSF, serum | Lateral flow immunochromatography | 3 |
| | Culture and antibiotic susceptibility testing for Cryptococcal meningitis | CSF | Culture and antimicrobial susceptibility testing | 4 |
| **Pneumonia** | NAATs for Pneumocystis jirovecii | BAL/sputum/ tracheal aspirate | PCR | 6 |
| **Aspergillosis** | Aspergillus IgG antibody | Serum | Immunofluorescence | 5 |
| | Aspergillus antigen test | Serum, CSF, BAL | Galactomannan (GM) antigen level via ELISA | 5 |
| | Culture for aspergillus | BAL, sputum, tracheal aspirate | Manual culture, mass spectrometry | 6 |
| **Parasitology** | | | | |
| **General** | Stool concentration for ova/ cyst (%) | Stool, rectal swabs | Microscopy | 2 |

| Test category | In vitro diagnostic test* | Specimen type | Test technique | LoU** |
|---|---|---|---|---|
| Disease Specific | | | | |
| Malaria | Malaria rapid tests | Blood | Immunochromatographic assay | 1 |
| | Blood smear for light microscopy for malaria | | Microscopy | 2 |
| | NAATs for malaria | | PCR | 6 |
| | Genome sequencing for malaria | | PCR | 6 |
| Schistosomiasis | Kato Katz test for schistosomiasis | Stool | Microscopy | 3 |
| | IgG/IgM ELISA for schistosomiasis | Blood | ELISA | 5 |
| | Urine microscopy for Schistosoma haematobium | Urine | Microscopy | 2 |
| African trypanosomiasis | Microscopic smear for African trypanosomiasis | Blood, spleen aspirations, skin scrapings | Microscopy | 3 |
| | IgG/ IgM ELISA for African trypanosomiasis | | ELISA | 4 |
| | Indirect-fluorescence test for African trypanosomiasis | | FM | 3 |
| Leishmaniasis | Rapid tests for leishmaniasis (recombinant k39 antigen test) | Blood, bone marrow, spleen aspirates | Immunochromatographic assay | 2 |
| | Smear microscopy-leishmaniasis | Bone marrow, blood, spleen aspirates, skin scrapings | Microscopy | 4 |
| | IgM, IgG for ELISA leishmaniasis | | ELISA | 5 |
| | NAATs for leishmaniasis | | PCR | 6 |
| | Direct fluorescence-leishmaniasis | | FM | 3 |
| Lymphatic Filariasis | Rapid diagnostic test | Whole blood, Serum | LFA | 2 |
| | Wet preparation & staining | Whole blood, urine, lymph node biopsy | Microscopy | 3 |
| | NAATs for lymphatic Filariasis | Whole blood, urine | PCR | 4 |
| Onchocerciasis | Skin snip biopsy | Skin | Microscopy | 4 |

| Test category | In vitro diagnostic test* | Specimen type | Test technique | LoU** |
|---|---|---|---|---|
| **Haematology** | | | | |
| **General** | Haemoglobin (Hb) | Whole blood | Haemoglobin meter | 2 |
| | Full haemogram | | Automated blood cells count | 3 |
| | Peripheral blood film examination | | Microscopy | 3 |
| | Reticulocyte count | | Manual reticulocyte count (microscopy) | 4 |
| | Erythrocyte sedimentation rate (ESR) | | Westergren Wintrobe<br>Electrical Impedence | 2 |
| | D-Dimer | Plasma (citrate) | Immunochromatographic assay, ELISA. immunoturbidimetry, latex agglutination | 4 |
| | Transferring, iron ferritin and TIBC | Serum | Spectrophotometry, immunoturbidimetry, immunoassay (ECLIA) | 4 |
| | Partial thromboplastin time (PTT), also known as activated partial thromboplastin time (APTT) | Plasma (citrate) | Chronometric, chromogenic and immunological principles | 4 |
| | Prothrombin time and international normalized ratio (PT/INR) | | | 4 |
| | Specific factor assay (factors VII, VIII, IX) | | | 5 |
| | Coombs (direct/indirect) | Whole blood/Serum | Antigen-antibody reaction | 3 |
| | ABO and Rh D grouping | | Antigen-antibody agglutination | 2 |
| | Bone marrow aspirate (BMA) | Bone marrow | Microscopy | 5 |
| Disease Specific | | | | |
| **Sickle cell** | Sickle cell testing | Whole blood | Microscopy, chromatography | 3 |
| | | | HB electrophoresis | 4 |

| Test category | In vitro diagnostic test* | Specimen type | Test technique | LoU** |
|---|---|---|---|---|
| **Blood Transfusion and Transplant Services Package (for Donor and Recipient)** | | | | |
| **General** | Blood grouping (ABO and Rh D, other blood types | Plasma and cells | Solid phase, column agglutination technology (gel testing), tube or microplates | 6 |
| | Full haemogram | Whole blood | Automated blood cell count, electric impedance, flow cytometry, spectrophotometry | 6 |
| | Antibody screening | Plasma | Solid phase, column agglutination technology (gel testing), tube | 6 |
| | A & B antibody titres | | Solid phase, column agglutination technology (gel testing), tube | 6 |
| | Haemoglobin estimation | Whole blood | Spectrophotometry, copper sulphate gravimetry | 6 |
| | NAATs for blood group genotyping | Serum | PCR | 6 |
| | Direct antiglobulin test (DAT), also known as direct Coombs test | Whole Blood (EDTA) | Solid phase, column agglutination technology (gel testing), tube | 6 |
| | Indirect antiglobulin test (IAT), also known as indirect Coombs test or red blood cell antibody screen | Plasma | Solid phase, column agglutination technology (gel testing), tube | 6 |
| | Coagulation tests | Plasma in sodium citrate | Chronometric, chromogenic and immunological principles | 6 |
| Disease Specific | | | | |
| **HIV infection** | HIV 1 & 2 | Serum, plasma | Chemiluminescent microparticle immunoassay, Electrochemiluminescence immunoassay (ECLIA), ELISA | 6 |
| **Hepatitis B** | HBs Ag | | | 6 |
| | HBc Ab (Core antibody) | | | 6 |
| **Hepatitis C** | HCV Ab | | | 6 |
| **Cytomegalovirus infection** | Cytomegalovirus test | Whole blood, plasma, serum | | 6 |

| Test category | In vitro diagnostic test* | Specimen type | Test technique | LoU** |
|---|---|---|---|---|
| **Epstein Barr virus infection** | Epstein Barr Virus (EBV) test | Whole blood, plasma, serum | Chemiluminescent microparticle immunoassay, **ECLIA, ELISA,** | 6 |
| **Syphilis** | Syphilis – Treponema pallidum test | Serum, plasma | Chemiluminescent microparticle immunoassay, **ELISA, Flocculation** | 6 |
| **Immunology** | | | | |
| **General** | Anticardiolipin antibody test | Serum, plasma | Immunochemistry, ELISA | 5 |
| | Specific IgE | Serum | Immunoassay | 5 |
| | Serum immunoglobulins (IgG, IgA & IgM) | | Immunofluorescence, ELISA | 5 |
| | Antinuclear antibodies test (ANA) | | Indirect Immunofluorescence, ELISA | 5 |
| | Anti-neutrophil cytoplasmic antibodies test (ANCA) | Serum, plasma | | 5 |
| | Extractable nuclear antigen antibodies (ENA) panel | | ELISA, Immunoblot | 5 |
| | Anti-cyclic citrullinated peptide test (ANTI-CCP) | | Immunofluorescence assay, ELISA | 5 |
| | Anti-double-stranded (ds) DNA | | ELISA, Indirect Immunofluorescence | 5 |
| Disease Specific | | | | |
| Streptococcal infection | Antistreptolysin O titre (ASOT) | Serum | Latex agglutination | 2 |
| Arthritis | Rheumatoid factor (RF) | Serum, plasma | Latex agglutination | 2 |
| **Clinical Chemistry** | | | | |
| General | Total cholesterol | Serum | Spectrophotometry or reflectance photometry | 4 |
| | Low-Density Lipoprotein (LDL) | | | 4 |
| | High-Density Lipoprotein (HDL) | | | 4 |
| | Triglycerides | | | 4 |
| | Troponin T/ I | | Enzyme immunoassay, Chemiluminescence | 5 |
| | Urinalysis | Urine | Lateral flow chromatography | 2 |
| | Blood Urea Nitrogen (BUN) | Serum, plasma, urine | Spectrophotometry (wet chem) or reflectance photometry (dry chem) Ion selective electrode (ISE) potentiometry | 4 |

| Test category | In vitro diagnostic test* | Specimen type | Test technique | LoU** |
|---|---|---|---|---|
| General | Creatinine | Serum, plasma, urine | Spectrophotometry (ret chem) or reflectance photometry (dry chem) ion selective electrode (ISE) potentionmetry | 4 |
| | Electrolytes (sodium, potassium, chloride, and bicarbonate) | Serum | | 4 |
| | Magnesium | | | 4 |
| | Phosphorous | | | 4 |
| | Total calcium | | | 4 |
| | Ionized calcium | | | 4 |
| | Vitamin B 12 | Urine | Urine lateral flow chromatography | 4 |
| | | Serum | Chemiluminescent microparticle or microparticle enzyme immunoassay | 4 |
| | Vitamin D (25-OH) | | Chemiluminescent or micro particle or microparticle enzyme Immunoassay | 4 |
| | Alanine aminotransferase (ALT) | Serum, plasma | Spectrophotometry (ret chem) or reflectance photometry (dry chem) | 4 |
| | Aspartate aminotransferase (AST) | | | 4 |
| | Alkaline phosphatase (ALP) | | | 4 |
| | Gamma-glutamyl transferase (GGT) | | | 4 |
| | Total bilirubin | | | 4 |
| | Direct bilirubin | | | 4 |
| | Albumin | | | 4 |
| | Lipase or amylase | Serum | Spectrophotometry or reflectance photometry | 4 |
| | Total protein | Serum, plasma / other serous fluids | Spectrophotometry (wet chem) or reflectance photometry (dry chem) | 4 |
| | Blood pH and gases | Whole blood in heparin | ISE potentiometry | 5 |
| | C-Reactive protein (CRP) | Serum | Spectrophotometry or enzyme immunoassay | 4 |
| | Whole blood lactate | Whole blood or plasma | Electrochemistry | 5 |
| | Blood glucose | Serum or plasma, CSF, & other serous fluids | Spectrophotometry or reflectance photometry | 4 |
| | Glucose-6- phosphate dehydrogenase (G6PD) | Whole blood | | 4 |

| Test category | In vitro diagnostic test* | Specimen type | Test technique | LoU** |
|---|---|---|---|---|
| | Procalcitonin | Serum | Enzyme immunoassay | 5 |
| | Uric acid | | Spectrophotometry or reflectance photometry | 4 |
| | Ketones | Urine | Lateral flow chromatography | 2 |
| | CSF/Urine protein (microalbumin) test | CSF / urine | Spectrophotometry or reflectance photometry | 4 |
| | Human chorionic gonadotropin (beta HCG)- Pregnancy testing | Urine | Lateral flow chromatography, Agglutination | 1 |
| | Human chorionic gonadotropin (beta HCG)- Fertility / tumour marker | Serum (frozen for delayed testing) | Enzyme immunoassay | 5 |
| | Thyroid-stimulating hormone (TSH) | | | 4 |
| | Free T3 | | | 4 |
| | Free T4 | | | 4 |
| | Estradiol | | | 5 |
| | Follicle stimulating hormone (FSH) | | | 5 |
| | Progesterone | | | 5 |
| | Prolactin | | | 5 |
| | Testosterone | | | 5 |
| | Sex hormone-binding globulin (SHBG) | | | 5 |
| | Cortisol (total) | | | 5 |
| Disease Specific | | | | |
| **Diabetes** | Blood glucose testing | Whole blood | Spectrophotometry | 1 |
| | Glucose tolerance test for diabetes mellitus | Urine | Lateral flow chromatography | 3 |
| | | Whole blood | | |
| | Glycocylated haemoglobin (HbA1C) test | | Spectrophotometry | 3 |
| | | | Enzyme immunoassay, boronate affinity | 4 |
| **Cancer** | Faecal Immunochemical test (FIT) | Stool | Radial immuno-diffusion assay FIT, immunohistochemistry | 4 |

| Test category | In vitro diagnostic test* | Specimen type | Test technique | LoU** |
|---|---|---|---|---|
| Cancer | BCR-ABL for cancer | Whole blood, bone marrow aspirates, trephine biopsy tissues | PCR | 4 |
| | Genetic testing for BRCA1 or BRCA2 mutation traits | | Genetic sequencing | 6 |
| | Cancer antigen 15-3 (CA 15-3) | Plasma, serum | Immunoassay | 5 |
| | Cancer antigen protein 125 (CA 125) | | Immunoassay | 5 |
| | Serum prostate-specific antigen (PSA) | | Immunoassay | 4 |
| | Beta Human Chorionic gonadotropin (HCG) | Serum | Immunoassay | 4 |
| | Faecal occult blood (FOB) | Stool | Lateral flow chromatographic immunoassay | 3 |
| | Alpha-fetoprotein (AFP) for cancer | Plasma, serum | Immunoassay | 4 |
| | Cancer antigen 19-9 (CA 19-9) | | Immunoassay | 5 |
| | Carcinoembryonic antigen (CEA) | | Immunoassay | 5 |
| | Calcitonin test | Serum (sodium or lithium heparin) | Quantitative chemiluminescent Immunoassay | 5 |
| | Beta- 2 microglobulin | Body fluids, serum, urine, or CSF- (rare cases) | ELISA - peroxidase conjugated competitive, ELISA Immunoturbidimetric assay | 5 |
| | Epidermal growth factor receptors (EGFR) | Serum/ tissue blocks | PCR, Genomic sequencing | 6 |
| | KRAS mutation analysis test | Tissue blocks/ | PCR, Genomic sequencing | 6 |
| | Lactate dehydrogenase (LDH) | Serum | Spectrophotometry (wet chem) or Reflectance photometry (dry chem) | 4 |
| | Bence jones proteins urine test | Urine | Electrophoresis, boiling method | 4 |
| | Flow cytometry antibodies Panel | Blood, bone marrow aspirates FNAs | Flow cytometry | 5 |

| Test category | In vitro diagnostic test* | Specimen type | Test technique | LoU** |
|---|---|---|---|---|
| **Histopathology and Cytology** | | | | |
| General | Histopathology examination | Surgical tissues, Biopsy tissues, trephine biopsies, bone marrow biopsies, Cadaveric tissues. | Decalcification, fixation, tissue processing, sectioning, routine staining, special staining, tissue microscopy, tissue/tissue block, slide archiving. | 4 |
| | Immunohistochemistry (IHC) | Gynae and non-gynae smears, body fluids like CSF, Effusions, urine, Tissue scrappings, excisional biopsies, incisional biopsy, core biopsies, formalin fixed tissue blocks. | Microscopy, peroxidase antigen Identification (immune labelling for: breast cancer, prostate cancer and lymphomas), Routine cytopathology and histopathology stains, histochemical stains Immunohistochemical testing (phenotyping). | 4 |
| | Cytopathology panel (smears, fine needle aspirates, fine cytology, fluids) | **Exfoliative cytology:** Gynaecological samples, respiratory cytology, urinary cytology, body fluid cytology, gastrointestinal cytology, discharge cytology, scrape cytology.<br><br>**Aspiration cytology:** Palpable lesion cytology, non-palpable/image guided cytology. | Microscopy, fluid cytology, pap stain, exfoliative cytology pap smear test-conventional, aspiration cytology (fine needle and fluids) ultrasound-guided biopsy. | 4 |
| | Post-mortem examination | Cadaveric tissues | Microscopy decalcification, fixation, tissue processing, sectioning, routine staining, special staining, tissue microscopy, tissue/tissue block, slide archiving, fluid cytology, pap stain, exfoliative cytology pap smear test- conventional, aspiration cytology (fine needle and fluids) | 5 |
| Disease Specific | | | | |
| Cancer | VIA VILI | Application of acetic acid/ iodine to cervix | Visual inspection | 2 |
| | Pap smear | Cervical swab | Papanicolaou stain | 4 |
| | Gastrointestinal H. Pylori infection | Gastric biopsy | H&E staining, Giemsa staining | 5 |
| | Fine needle aspirations (FNA) | Swellings, lumps aspirates | H&E staining, Papanicolaou's staining, gram stain, ZN staining, Romanowsky staining, molecular | 4 |
| | Basic panel for immunohistochemical testing for the diagnosis of cancer | Formalin fixed tissue blocks | Immunohistochemical testing | 6 |

| Test category | In vitro diagnostic test* | Specimen type | Test technique | LoU** |
|---|---|---|---|---|
| **Clinical and Forensic Toxicology** | | | | |
| General | Drug analysis | Blood, urine, saliva, stomach contents, liver, kidney, vitreous humour, urine, exhumation samples cloths | HPLC- GCMS, rapid immunoassays | 6 |
| | Pesticide analysis | Blood, urine, stomach content, liver, vomitus, food, water, soil, plant material | Gas chromatography- mass spectrometry, Ultraviolet–visible spectroscopy | 6 |
| | Heavy metal analysis | Blood, Urine, Stomach content, food, water, alcoholic beverages, non- alcoholic beverages, soil, plant material | Multi-Drug Test Panel (rapid test kits), Atomic absorption spectrometry (AAS), Inductively coupled plasma mass spectrometry (ICP-MS) | 6 |
| | Alcohol analysis | Blood, urine, stomach contents, vomitus, vitreous humour | Gas chromatography with headspace | 6 |
| | Carboxyhemoglobin/ Carbonmonoxide | Blood | Conway diffusion technique | 6 |
| **Forensic Biology** | | | | |
| General | DNA analysis for semen | **Sexual offences and homicide/infanticide:** Blood, high vaginal swabs, anal swabs, vulval swabs, blind virginal swabs, buccal swabs, combed and plucked pubic hair, combed and plucked head hair, fibres, foetus and foetal material, garments, hair.<br>**Human/ body identification and paternity tests:** Bones, fingernails, cartilages, blood, buccal swabs, fingernail scrapings. | Hair and fibre analysis through comparative microscopy, capillary electrophoresis. | 6 |
| **Food and Water Analysis** | | | | |
| General | Food adulterants | Food | Chromatography, screening, spectroscopy | 6 |
| | Food contaminants analysis | | Plate-based assay, spectrophotometry | 6 |
| | Food additives | | Chromatography | 6 |
| | Bacterial food analysis | | Culture | 6 |
| | Micronutrients analysis | | Spectrophotometry, titrimetric, volumetric analysis | 6 |
| | Water analysis (bacterial & chemical analysis) | Water | Spectrophotometry, culture | 6 |

# 4.0 Implementation Considerations

1. The implementation of the KEDL at national, county and sub-county levels should be considered in the context of the variability of health system resources, required staffing and infrastructure.[40]
2. Counties implementing the KEDL could adapt to the KEDL and prioritize essential IVDs according to their unique burden of disease profiles. All counties implementing the KEDL must assess the health system and societal factors such as acceptability and potential effects on equity.
3. Procurement officers, county officials and health care and laboratory managers may implement the KEDL based on the appropriate facility level requirements and available resources.
4. The MOH and DHPT encourage co-ordination in the implementation and monitoring of all essential Health Product and Technologies Lists (HPT lists). The KEDL 2023 should thus be implemented and monitored based on the a prioritized implementation plan (Annex 5) and monitoring & evaluation plan (Annex 6) template for all HPT Lists (KEDL, KEMSL). Monitoring will be in accordance with the principles of the Kenya Health Sector Monitoring and Evaluation plan[41] and WHO handbook for indicators for health systems.[42]
5. It is important to pursue digitization of laboratory services and its supply chain to facilitate monitoring on the implementation of the KEDL.

# 5.0 Limitations of the KEDL 2023

1. There were limited engagement meetings with stakeholders such as patient representatives and test manufacturers. Patient representatives would give more insight into test acceptability and equity concerns and test manufacturers' insights into local performance and potential costs. However, we believe validation of the KEDL by MoH officials and public consultation with relevant clinical and public health officials covered relevant information at this point. The TWG will consider extensive stakeholder engagements in the next KEDL update upon noting its implementation.
2. By adopting rapid review methods and searching for literature using the search engines PubMed and Google scholar, some research evidence published in other databases could have been missing.
3. For the evidence review, we did not use advanced GRADE methodology for guideline adaptation[35] and evidence to decision-making frameworks (EtD)[35 36] due to their complexity.[37] Utilizing the rigorous methods for many tests amidst limited time and resources for a TWG not trained in GRADE methodology was not feasible. Nonetheless, we inferred from principles and criteria of EtD frameworks and used simplified methods of EtD in selecting eligible tests in this KEDL.
4. We did not individually link each test in the KEDL to an individual medicine in the KEML using advanced methods[38] that recommend the consideration of levels of disease and health facility tiers in the linkage due to limited expertise and time for this. We nonetheless aligned the KEDL to the KEML by considering IVDs for clinical management that have an associated medicine category in Kenya's EML[14] and to the KEMSL by considering relevant supplies listed in the essential medical supplies list.

# 6.0 Suggestions for future research

1. More national evaluations of novel laboratories and point of care tests in line with emerging global and national threats such as Antimicrobial Resistance (AMR), emerging pandemics and non-communicable diseases.
2. Surveys, qualitative analysis and secondary analysis of the testing activities reported in the DHIS-2 could be done to explore the roles, purposes and utilities of tests in practice to understand reasons for variations and deviations in their use in government and private health facilities in Kenya. Variation in the roles and use of tests could be due to variation in disease burdens and health systems capacities, inconsistencies in testing scope and capacities within the same level of health care and inconsistency in diagnostic supplies in many settings leading tests to be used according to their availability rather than on their recommended role.[3 17]
3. To enable better uptake and impact of the EDL across different settings, implementation research is recommended to guide implementation strategies and tools.[43]
4. More primary research on the acceptability, feasibility, equity and cost requirements of various diagnostic tests are required to enable better decision-making about the appropriateness of tests across national and county levels in Kenya.
5. Finally, impact studies to evaluate the effect of the KEDL on availability and access to IVDs, on management practices and health outcomes would guide future updates and implementation planning of the essential list.

# 7.0 Funding and declaration of interests

The KEDL development process was funded by the Ministry of Health and FIND with CHAI being the implementation partner. FIND did not play a role in the design and development of the KEDL but provided guidance whenever requested. All KEDL development participants completed and signed conflict of interest forms. No conflicts of interest were declared by the secretariat, TWG and the evidence review team.

# 8.0 Accessing the guideline

The Kenya EDL 2023 can be accessed through:

1. The MOH website (https://www.health.go.ke/resources/guidelines-and-manuals/),
2. The MOH guideline, standards and policies portal (http://guidelines.health.go.ke/)
3. Contacting the NPHLS using the following email address; info@nphl.go.ke

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# Annexes

## Annex 1: List of Participants and Reviewers

### A. KEDL Technical Working Group

| Name | Designation | Location | Institution |
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| Joshua N. Muiruri | Sub-County Medical Laboratory Coordinator | Nyeri County | Nyeri Central Sub County |
| Stephen Ntuara | Laboratory Manager | National Government | National Spinal Injury Referral Hospital |
| Julius Okuku | Laboratory Manager | Kisumu County | Muhoroni County Hospital |
| Jacinta Nduku Sila | Laboratory manager | Machakos County | Masii Health Centre |
| Franklin Okemwa | Laboratory Manager | Kajiado County | Namanga Health Center |
| Ronald Juma | Deputy Laboratory Manager | Kisii County | Kisii County Referral hospital |
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| Name | Designation | Location | Institution |
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## B. List of Reviewers

| No. | Name | Organization/Affiliation |
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| | **External Reviewers** | |
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| 4 | Prof. Collins Ouma | Maseno University |
| 5 | Prof. Emily Rogena | Kenya Association of Clinical Pathologists |
| 6 | Prof. Geoffrey Omuse | Kenya Association of Clinical Pathologists |
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# Annex 2: List of priority diseases included in KEDL 2023

| Kenyan IDSR 2018 (Completed version) | Kenyan IDSR 2022 (ongoing/ developing version) | TWG Additions | Final list of priority diseases included in the KEDL 2023 |
|---|---|---|---|
| **Epidemic-prone diseases** | | | |
| Cholera | Cholera | Mpox | Cholera |
| Typhoid fever | Typhoid fever | Rubella | Typhoid fever |
| Dysentery | Dysentery (Shigella) | Mumps | Dysentery |
| Meningococcal meningitis | Bacterial meningitis | Rotavirus | Meningococcal meningitis |
| SARI | SARS | | COVID-19 |
| Measles* | SARIs | | Influenza |
| Yellow fever | Measles* | | Measles* |
| Other VHFs | Yellow fever | | Yellow fever |
| Anthrax | Ebola | | Ebola |
| Plague | Marburg | | Marburg |
| Brucellosis | Rift Valley Fever | | Rift Valley Fever |
| | Lassa | | Lassa |
| | Crimean Congo | | Crimean Congo |
| | West Nile Fever | | West Nile Fever |
| | Dengue | | Dengue |
| | Chikungunya | | Chikungunya |
| | Anthrax | | Anthrax |
| | Plague | | Plague |
| | Zika virus | | Brucellosis |
| | Maternal deaths** | | Zika virus |
| | Neonatal tetanus | | Dracunculiasis* |
| | Dracunculiasis* | | Malaria* |
| | Malaria* | | Mpox |
| | | | Rubella |
| | | | Mumps |
| | | | Rotavirus |
| **Diseases/ events/conditions of public health importance** | | | |
| Tuberculosis | Malaria* | Streptococcal infection (throat) | Tuberculosis |
| MDR/XDR Tuberculosis | MRD/XDR Tuberculosis | Hepatitis A | Streptococcal pneumonia |
| Childhood pneumonia | Severe pneumonia in under 5's | Peptic ulcers | Pneumocystis pneumonia |
| Malaria | Acute jaundice | Cryptococcal menin-gitis | Malaria |
| New AIDS cases | HIV/AIDS (new cases) | Skin diseases | HIV infection |
| STIs | STIs | Aspergillosis | Hepatitis B |
| Malnutrition <5years | Diarrhoea with dehydration in under 5's | Arthritis | Hepatitis C |
| Childhood diarrhoea | Schistosomiasis | Cytomegalovirus infection | Human papilloma virus |

| Kenyan IDSR 2018 (Completed version) | Kenyan IDSR 2022 (ongoing/ developing version) | TWG Additions | Final list of priority diseases included in the KEDL 2023 |
|---|---|---|---|
| Rabies | Trypanosomiasis* | Epstein Barr virus infection | Syphilis |
| Schistosomiasis | Diabetes mellitus (new cases) | Sickle cell disease | Gonorrhoea |
| Trachoma | Soil transmitted helminths | | Chlamydia |
| Cancers | Suicides | | Oral herpes |
| Neonatal deaths | Perinatal deaths | | Genital herpes |
| Maternal deaths | Maternal deaths | | Rabies (Human) |
| Hypertension | Non-neonatal tetanus | | Diarrhoeal diseases |
| Diabetes | Extreme malnutrition in under 5's | | Clostridium difficile infection |
| Acute jaundice | Injuries (road traffic accidents) | | Schistosomiasis |
| Adverse events following immunization (AEFI) | Hypertension | | African trypanosomiasis |
| Road traffic accidents | Epilepsy | | Soil transmitted helminths |
| | Adverse events following immunization (AEFI) | | Diabetes Mellitus |
| | | | Cancer |
| | | | Epilepsy |
| | | | Non-neonatal tetanus |
| | | | Streptococcal infection (throat) |
| | | | Hepatitis A |
| | | | Peptic ulcers |
| | | | Cryptococcal meningitis |
| | | | Skin diseases |
| | | | Aspergillosis |
| | | | Arthritis |
| | | | Cytomegalovirus infection |
| | | | Epstein Barr virus infection |
| | | | Sickle cell disease |
| **Diseases targeted for eradication or elimination** | | | |

| Kenyan IDSR 2018 (Completed version) | Kenyan IDSR 2022 (ongoing/ developing version) | TWG Additions | Final list of priority diseases included in the KEDL 2023 |
|---|---|---|---|
| Leprosy | Leprosy | | Leprosy |
| Poliomyelitis | Poliomyelitis | | Poliomyelitis |
| Leishmaniasis | Rabies* | | Leishmaniasis |
| Dracunculiasis/Guinea worm disease/ Serpent worm | Dracunculiasis | | Lymphatic filariasis |
| Neonatal tetanus | Neonatal tetanus | | Onchocerciasis |
| | Lymphatic filariasis | | Rabies* |
| | Onchocerciasis | | Human African Trypanoso-miasis* |
| | Trachoma | | Measles* |
| | Human African Trypano-somiasis* | | |
| | Measles* | | |
| | | | |

[1] Excluded because there is no associated in vitro diagnostic (IVD) test for the disease/event/condition.
*Multiple categorization (epidemic prone, public health, eradication)

# Annex 3: List of excluded IVDs from the KEDL after evidence review

| Disease/ Discipline | IVDs Excluded (n=18) | Reason for Exclusion |
|---|---|---|
| Immunology | Food allergy panel | The test is used to test multiple allergens but a similar test that performs the same function has already been included. |
| Brucellosis | Complement fixation test (CFT) | It requires additional equipment/reagents, and the test accuracy is low. |
| Rabies | Sellar staining | It requires a special stain, and it is a confirmatory test.<br>Additionally, diagnostics are not often used to guide treatment as patients reporting of bites by animals suspected of rabies are treated presumptively to avert disease progression to death. |
| | Immuno-chromatography | The test is done post-mortem and in veterinary labs as a confirmatory test.<br>Additionally, diagnostics are not often used to guide treatment as patients reporting of bites by animals suspected of rabies are treated presumptively to avert disease progression to death. |
| | Staining for Negri bodies | The test is done post-mortem and in veterinary labs as a confirmatory test.<br>Additionally, diagnostics are not often used to guide treatment as patients reporting of bites by animals suspected of rabies are treated presumptively to avert disease progression to death. |
| | PCR | The test is done post-mortem and in veterinary labs as a confirmatory test. Additionally, diagnostics are not often used to guide treatment as patients reporting of bites by suspected rabied animals are treated presumptively to avert disease progression to death. |
| Poliomyelitis | Blood antibody testing | Most samples are sent to KEMRI, so there are concerns about equity. Secondly, most patients already come to the hospital when the symptoms are presenting, thus diagnostic testing is not done. |
| Pancreas/GIT profile | Insulin | The test corresponds to a non-priority diseases based on Kenya's disease burden hence not essential. |
| | C-peptide | The test corresponds to a non-priority diseases based on Kenya's disease burden hence not essential. |
| | Faecal Calprotectin | The test corresponds to a non-priority diseases based on Kenya's disease burden hence not essential. |
| Leishmaniasis | Haemagglutination | The test is not widely used and therefore it's not essential. |
| Cardiovascular diseases | Homocysteine | It is a screening test but not compulsory for management. |
| | Lipoprotein A blood test | Tests for presence of lipoprotein that carry low-density cholesterol in the blood but similar tests that quantify low density cholesterol have been considered in the clinical chemistry discipline. |

| Disease/ Discipline | IVDs Excluded (n=18) | Reason for Exclusion |
|---|---|---|
| Respiratory Syncytial Virus infection | Respiratory Syncytial Virus (PCR) | Tests are expensive and probes are not easily available.<br>Additionally, it is offered mainly in research institutions and specialized laboratories. |
| Influenza & COVID | Influenza SARS-CoV-2 (Flu SC2) Assay (rtPCR) | Special reagents and equipment are needed which are costly. |
| COVID-19 | SARS-CoV-2 antibody test | The test is not approved in the country and thus should not be used as a screening test or for surveillance at the community level. |
| Cancer | Prostate Cancer Antigen 3 (PCA3) | It is reported that the test has poor performance, and the test is also expensive. |
| Influenza | Lateral flow assay | The test is not approved for use in the country. |

# Annex 4: List of included IVDs stratified by facility level

| Discipline/ Disease | | In vitro diagnostic test | Specimen type | Test technique |
|---|---|---|---|---|
| **Level 1** | | | | |
| **Virology** | HIV infection | Rapid tests for human immunodeficiency virus (HIV) antibody | Whole blood, serum, plasma, buccal swabs | Lateral flow immuno-chromatography |
| **Parasitology** | Malaria | Malaria rapid tests | Blood | Immunochromato-graphic assay |
| **Clinical Chemistry** | General | Human chorionic go-nadotropin (beta HCG)-Pregnancy testing | Urine | Lateral flow chroma-tography, Agglutination |
| | Diabetes | Blood glucose testing | Whole blood | Spectrophotometry, electrochemistry |
| **Level 2 and above tests recommended** | | | | |
| **Bacteriology** | Tuberculosis | Mycobacterium tuber-culosis test | Sputum, ascitic fluid, CSF, (SOTS), gastric lavage, autopsy | Acid-Fast Bacillus (AFB) microscopy: ZN/ fluorescence microscopy (FM) |
| | | Mycobacterium tuber-culosis deoxyribonu-cleic acid (DNA) test | Sputum | Loop-mediated iso-thermal amplification (LAMP) |
| | | TB LAM (Lipoarabino-mannan) | Urine | Lateral flow assay |
| | Syphilis | Venereal disease research laboratory (VDRL) for syphilis | Blood serum | Agglutination test |
| | Peptic ulcers | Helicobacter pylori antigen test | Stool | Immunochromato-graphic assay (Rapid test) |
| | Cholera | Cholera antigen detec-tion rapid test | Stool | Immunochromato-graphic assay (Rapid test) |
| | Typhoid fever | Salmonella antigen testing | Stool, whole blood | Immunochromato-graphic assay (Rapid test) |
| | Brucellosis | Rose Bengal (RBT) for brucellosis | Blood serum | Slide agglutination assay |
| | | Serum agglutination tests (SAT) for brucel-losis | Serum | Antibody/antigen reac-tion |
| | Leprosy | Microscopy for leprosy | Slit skin smear | Microscopy |

| Discipline/ Disease | | In vitro diagnostic test | Specimen type | Test technique |
|---|---|---|---|---|
| **Virology** | Hepatitis B | Hepatitis B surface antigen (HBsAg)-RDT | Whole blood, plasma, serum | Lateral flow immuno-chromatography |
| | Hepatitis C | Hepatitis C anti-body-RDT | Whole blood, plasma, serum | Lateral flow immuno-chromatography |
| | Human Pap-illomavirus infection | HPV DNA testing (NAATs) for cervical smears | Cervical swab, vaginal swab | PCR |
| | Rotavirus | Rapid test for rotavirus | Stool | Lateral flow immuno-chromatography |
| | Dengue | RDTs for dengue | Whole blood, serum, plasma | Lateral flow immuno-chromatography |
| | Coronavirus disease-2019 (COVID-19) | SARS-CoV-2 antigen test | Nasal swab, nasopha-ryngeal swab | Lateral flow immuno-chromatography |
| | HIV | HIV/ Syphilis dual test | Whole blood, serum, plasma | Lateral flow immuno-chromatography |
| **Parasitology** | General | Stool for ova/cyst | Stool, rectal swabs | Microscopy |
| | Malaria | Blood smear for light microscopy for malaria | Blood | Microscopy |
| | Schistosomi-asis | Urine for Schistosoma haematobium | Urine | Microscopy |
| | Leishmani-asis | Rapid tests for leish-maniasis (recombinant k39 antigen test)– leishmaniasis | Blood, bone marrow, spleen aspirates | Immunochromato-graphic assay |
| | Lymphatic Filariasis | Rapid diagnostic test | Whole blood, Serum | LFA |
| **Haematol-ogy** | General | Haemoglobin (Hb) | Whole blood | Haemoglobin meter |
| | | Erythrocyte sedimen-tation rate (ESR) | Whole blood | Westergren or win-trobe, Electrical Impe-dence |
| | | ABO and rhesus factor grouping | Whole blood, serum | Antigen-antibody ag-glutination |
| **Immunology** | Streptococ-cal infection | Antistreptolysin O titre (ASOT) | Serum | Latex agglutination |
| | Arthritis | Rheumatoid factor (RF) | Serum, plasma | Latex agglutination |
| **Clinical Chemistry** | General | Urinalysis | Urine | Lateral flow chroma-tography |
| | | Ketones | Urine | Lateral flow chroma-tography |
| **Cancer** | Cancer | VIA VILI | Application of acetic acid/ iodine to cervix | Visual inspection |

| Discipline/ Disease | | In vitro diagnostic test | Specimen type | Test technique |
|---|---|---|---|---|
| **Level 3 and above tests recommended** | | | | |
| **Bacteriology** | General | Microscopy, culture and identification of microbes | Stool, tissues, pus, urine, bronchial and abscess aspirates, body fluids, swabs, isolated bacterial colonies, sputum, (SOTS), CSF, central line catheter | Direct microscopy, Indian ink, gram stain, ZN /modified ZN stains, serotyping |
| | Tuberculosis | Mycobacterium tuberculosis deoxyribonucleic acid (DNA) test | Sputum | Nucleic acid amplification tests (NAATs) (chip-based) |
| | | | Sputum, ascitic fluid, gastric lavage, autopsy, stool, biopsy, FNA, bone marrow, pleural effusion | NAATs (cartridge-based) |
| | Pneumonia | Microscopy, culture/ identification and sensitivity for bacterial pneumonia | Blood, sputum bronchial wash, FNA, lower respiratory samples | Direct microscopy, Indian ink, gram stain, Ziehl Neelsen (ZN) /modified ZN stains, serotyping |
| | Gonorrhoea and Chlamydia | Microscopy, culture and antibiotic susceptibility testing for Gonorrhoea and Chlamydia | Urethral swabs, vaginal swabs, eye swabs, throat swabs | Direct microscopy, Indian ink, gram stain, Ziehl Neelsen (ZN) /modified ZN stains, serotyping |
| | Clostridium infection | Clostridium difficile antigen test | Stool | Immunochromatographic assay (Rapid test) |
| | Syphillis | Fluorescent treponemal antibody absorbed (FTA- ABS) for syphilis | Blood, serous fluid from syphilis lesions, other body fluids e.g. CSF | Fluorescent microscopy |
| **Virology** | HIV infection | Cluster of differentiation 4 (CD4) cell count | Whole blood | Flow cytometry, electrical impedance, LFA |
| | | HIV NAATs/ viral load | Plasma, dried blood spots (DBS) | PCR |
| | Hepatitis A | Hepatitis A rapid diagnostic test | Serum, whole blood | Lateral flow immunochromatography |
| | Human Papillomavirus infection | HPV DNA testing (NAATs) for cervical smears | Cervical swab, vaginal swab | PCR |
| **Mycology** | General | Microscopy of skin scrapings | Skin scraping, nail sampling, hair follicle, skin snip smear | Microscopy |
| | Cryptococcal meningitis | Cryptococcal antigen (CrAg) | Plasma, CSF, serum | Lateral flow immunochromatography |

| Discipline/ Disease | | In vitro diagnostic test | Specimen type | Test technique |
|---|---|---|---|---|
| **Parasitology** | African trypanosomiasis | Microscopic smear for African trypanosomiasis | Blood, spleen aspirates, skin scrapings | Microscopy |
| | | Indirect-fluorescence test for African trypanosomiasis | Blood, spleen aspirates, skin scrapings | FM |
| | Leishmaniasis | Direct fluorescence-leishmaniasis | Bone marrow, blood, spleen aspirates, skin scrapings | FM |
| | Schistosomiasis | Kato Katz test for schistosomiasis | Stool | Microscopy |
| | Lymphatic Filariasis | Wet preparation & staining | Whole blood, urine, lymph node biopsy | Microscopy |
| **Haematology** | General | Full haemogram | Whole blood | Automated blood cells count |
| | | Peripheral blood film examination | Whole blood | Microscopy |
| | | Coombs (direct/indirect) | Whole blood/Serum | Antigen-antibody reaction |
| | Sickle cell | Sickle cell testing | Whole blood | Microscopy, chromatography |
| **Clinical Chemistry** | Diabetes | Glucose tolerance test for diabetes mellitus | Urine | Lateral flow chromatography |
| | Diabetes | Glycocylated haemoglobin (HbA1C) test | Whole blood | Spectrophotometry |
| **Cancer** | Cancer | Faecal occult blood (FOB) | Stool | Lateral flow chromatographic immunoassay |
| **Level 4 and above tests recommended** | | | | |
| **Bacteriology** | General | Microscopy, culture and identification of microbes | Stool, tissues, pus, urine, bronchial and abscess aspirates, body fluids, swabs, isolated bacterial colonies, sputum, (SOTS), CSF, central line catheter | Culture (manual or automated methods) |
| | | Antimicrobial susceptibility tests | Microbial isolate | Fully automated/Kirby Bauer methods |
| | | Blood culture | Whole Blood | Culture (manual/ automation) |
| | Pneumonia | Microscopy, culture/ identification and sensitivity for bacterial pneumonia | Whole blood, sputum bronchial wash, lower respiratory samples | Culture and sensitivity |
| | Gonorrhoea and Chlamydia | Microscopy, culture and antibiotic susceptibility testing for Gonorrhoea and Chlamydia | urethral swabs, vaginal swabs, eye swabs, throat swabs | Culture and antimicrobial testing |
| | Cholera | Culture and antimicrobial susceptibility tests (AST) for cholera | Stool, rectal swab | Stool culture and antimicrobial testing |
| | | Serotyping-cholera | Cholera isolates | Slide agglutination |

| Discipline/ Disease | | In vitro diagnostic test | Specimen type | Test technique |
|---|---|---|---|---|
| **Bacteriology** | Typhoid fever | Salmonella culture and antimicrobial susceptibility tests | Stool, blood, bacterial isolates | Stool/blood isolates culture |
| | Dysentery | Culture and antimicrobial susceptibility tests for dysentery | Stool | Stool culture and antimicrobial Testing |
| | | Serotyping-Shigella | Shigella isolates | Slide agglutination |
| | Meningococcal meningitis | Culture and antimicrobial susceptibility testing for meningococcal meningitis | CSF | Culture and antimicrobial susceptibility testing |
| | | Serotyping for meningococcal meningitis | CSF | Meningococcal meningitis serotyping |
| **Virology** | HIV infection | ELISA for HIV | Whole blood, serum | ELISA |
| | Hepatitis B | Hepatitis B surface antigen (HBsAg)-ELISA | Serum, plasma (ethylene- diaminetetraacetic acid- EDTA) | ELISA |
| | | Hepatitis B core antibody (HBcAb) | Serum, plasma (ethylene- diaminetetraacetic acid- EDTA) | ELISA |
| | Hepatitis C | Hepatitis C virus antibody test (ELISA) | Serum, plasma | ELISA |
| | Hepatitis A | Hepatitis A IgM/ IgG ELISA | Serum, whole blood | ELISA |
| | Corona virus (Covid 19) | SARS-CoV-2 NAATs | Nasopharyngeal swabs, nasal swabs, nasal wash/ aspirate, oropharyngeal swabs, sputum, BAL fluid | Reverse Transcriptase-PCR |
| **Mycology** | Cryptococcal meningitis | Culture and antibiotic susceptibility testing for Cryptococcal meningitis | CSF | Culture and antimicrobial susceptibility testing |
| **Parasitology** | African trypanosomiasis | IgG/ IgM ELISA for African trypanosomiasis | Blood, spleen aspirates, skin scrapings | ELISA |
| | Leishmaniasis | Smear microscopy-leishmaniasis | Bone marrow, blood, spleen aspirates, skin scrapings | Microscopy |
| | Lymphatic filariasis | NAATs for lymphatic Filariasis | Whole blood, urine | PCR |
| | Onchocerciasis | Skin snip biopsy | Skin | Microscopy |
| **Haematology** | General | Reticulocyte count | Whole blood | Manual reticulocyte count (microscopy) |

| Discipline/ Disease | | In vitro diagnostic test | Specimen type | Test technique |
|---|---|---|---|---|
| **Haematology** | General | D-Dimer | Plasma (citrate) | Immunochromatographic assay, ELISA, immunoturbidimetry, latex agglutination |
| | | Transferrin, iron ferritin and TIBC | Serum | Spectrophotometry immunoturbidimetry, immunoassay (ECLIA) |
| | | Partial thromboplastin time (PTT), also known as activated partial thromboplastin time (APTT) | Plasma (citrate) | Chronometric, chromogenic and immunological principles |
| | | Prothrombin time and international normalized ratio (PT/INR) | Plasma (citrate) | Chronometric, chromogenic and immunological principles |
| | Sickle cell | Sickle cell testing | Whole blood | HB electrophoresis |
| **Clinical Chemistry** | General | Total cholesterol | Serum | Spectrophotometry or reflectance photometry |
| | | Low-Density Lipoprotein (LDL) | | Spectrophotometry or reflectance photometry |
| | | High-Density Lipoprotein (HDL) | | Spectrophotometry or reflectance photometry |
| | | Triglycerides | | Spectrophotometry or reflectance photometry |
| | | Blood urea nitrogen (BUN) | Serum, plasma, urine | Spectrophotometry (wet chem) or reflectance photometry (dry chem),ion selective electrode (ISE) potentiometry |
| | | Creatinine | | Spectrophotometry (wet chem) or reflectance photometry (dry chem) |
| | | Electrolytes (sodium, potassium, chloride, and bicarbonate) | Serum | Ion selective electrode (ISE) potentiometry |
| | | Magnesium | Serum | Ion selective electrode (ISE) potentiometry |
| | | Phosphorous | | Ion selective electrode (ISE) potentiometry |
| | | Total calcium | | Ion selective electrode (ISE) potentiometry |
| | | Ionized calcium | | Ion selective electrode (ISE) potentiometry |

| Discipline/ Disease | | In vitro diagnostic test | Specimen type | Test technique |
|---|---|---|---|---|
| **Clinical Chemistry** | General | Vitamin B 12 | Urine | Urine lateral flow chromatography |
| | | | Serum | Chemiluminescent or micro particle or Microparticle enzyme Immunoassay |
| | | Vitamin D (25-OH) | | Chemiluminescent or micro particle or Microparticle enzyme Immunoassay |
| | | Alanine aminotransferase (ALT) | Serum, plasma | Spectrophotometry (ret chem) or reflectance photometry (dry chem) |
| | | Aspartate aminotransferase (AST) | | Spectrophotometry (ret chem) or reflectance photometry (dry chem) |
| | | Alkaline phosphatase (ALP) | Serum, plasma | Spectrophotometry (ret chem) or reflectance photometry (dry chem) |
| | | Gamma-glutamyl transferase (GGT) | | Spectrophotometry (ret chem) or reflectance photometry (dry chem) |
| | | Total bilirubin | | Spectrophotometry (ret chem) or reflectance photometry (dry chem) |
| | | Direct bilirubin | | Spectrophotometry (ret chem) or reflectance photometry (dry chem) |
| | | Albumin | | Spectrophotometry (ret chem) or reflectance photometry (dry chem) |
| | | Lipase or amylase | Serum | Spectrophotometry or reflectance photometry |
| | | Total protein | Serum, plasma / other serous fluids | Spectrophotometry (wet chem) or reflectance photometry (dry chem) |
| | | C-Reactive protein (CRP) | Serum | Spectrophotometry or enzyme immunoassay |
| | | Blood glucose | Serum or plasma, CSF, & other serous fluids | Spectrophotometry or reflectance photometry |

| Discipline/ Disease | | In vitro diagnostic test | Specimen type | Test technique |
|---|---|---|---|---|
| **Clinical Chemistry** | General | Glucose-6- phosphate dehydrogenase (G6PD) | Whole blood | Spectrophotometry or reflectance photom-etry |
| | | Uric acid | Serum | Spectrophotometry or reflectance photom-etry |
| | | CSF/Urine protein (mi-croalbumin) test | CSF / urine | Spectrophotometry or reflectance photom-etry |
| | | Thyroid-stimulating hormone (TSH) | Serum (frozen for delayed testing) | Enzyme immunoassay |
| | | Free T3 | Serum (frozen for delayed testing) | Enzyme immunoassay |
| | | Free T4 | Serum (frozen for delayed testing) | Enzyme immunoassay |
| | Diabetes | Glycocylated haemo-globin (HbA1C) test | Whole blood | Enzyme immunoassay, boronate affinity |
| | Cancer | Faecal Immunochemi-cal Test (FIT) | Stool | Radial immuno-diffu-sion assay FIT, immu-nohistochemistry |
| | | BCR-ABL for cancer | Whole blood, bone marrow aspirates, trephine biopsy tis-sues. | PCR |
| | | Serum prostate-specif-ic antigen (PSA) | Plasma/ Serum | immunoassay |
| | | Beta Human Chorionic gonadotropin (HCG) | Serum | Immunoassay |
| | | Alpha-fetoprotein (AFP) for cancer | Plasma/serum | Immunoassay |
| | | Lactate dehydrogenase (LDH) | Serum | Spectrophotometry (wet chem) or Reflectance photometry (dry chem) |
| | | Bence jones proteins urine test | Urine | Electrophoresis, boil-ing method |
| **Histopa-thology and Cytopathol-ogy** | General | Histopathology exam-ination | Surgical tissues, biopsy tissues, tre-phine biopsies, bone marrow biopsies, cadaveric tissues. | Decalcification, fixa-tion, tissue processing, sectioning, routine staining, special stain-ing, tiisue microscopy, tissue block, slide archiving. |

| Discipline/ Disease | | In vitro diagnostic test | Specimen type | Test technique |
|---|---|---|---|---|
| **Histopathology and Cytopathology** | General | Immunohistochemistry (IHC) | Gynae and non-gynae smears, body fluids like CSF, effusions, urine, tissue scrappings, excisional biopsies, incisional biopsies, core biopsies, formalin fixed tissue blocks | Microscopy, peroxidase antigen identification (immune labelling for breast cancer, prostate cancer and lymphomas), toutine cytopathology and histopathology stains, histochemical stains, immunohistochemical testing (phenotyping) |
| | | Cytopathology panel (smears, fine needle aspirates, fine cytology, fluids) | **Exfoliative cytology:** Gynaecological samples, respiratory cytology, urinary cytology, body fluid cytology, gastrointestinal cytology, discharge cytology, scrape cytology<br>**Aspiration cytology:** Palpable lesion cytology, non-palpable/ image guided cytology | Microscopy, fluid cytology, pap stain, exfoliative cytology pap smear test, aspiration cytology (fine needle and fluids), ultrasound guided biopsy. |
| | Cancer | Pap smear | Cervical swab | Papanicolaou stain |
| | | Fine needle aspirates (FNA) | Swellings, lumps aspirates | H&E staining, Papanicolaou's staining, gram stain, ZN staining, Romanowsky staining, molecular |
| | | Faecal Immunochemical test (FIT) | Stool | Radial immuno-diffusion assay<br>FIT<br>immunohistochemistry |
| **Level 5 and above tests recommended** | | | | |
| **Bacteriology** | General | Antimicrobial susceptibility tests | Microbial aspirate | PCR for AMR |
| | | Microscopy, culture and identification of microbes | Stool, tissues, pus, urine, bronchial and abscess aspirates, body fluids, swabs, isolated bacterial colonies, sputum, (SOTS), CSF, central line catheter | PCR |
| | Tuberculosis | Mycobacterium tuberculosis DNA mutations associated with resistance test | Sputum, SOTS, culture isolates | 1st and 2nd line probe assay (LPA), PCR |
| | | Histological test for TB | Cadaveric tissue | Microscopy |
| | Pneumonia | Nucleic acid amplification tests (NAATs) for bacterial pneumonia | Bacterial isolates | PCR, sequencing |

| Discipline/ Disease | | In vitro diagnostic test | Specimen type | Test technique |
|---|---|---|---|---|
| **Bacteriology** | Syphilis | T. pallidum haemagglutination (TPHA) test for syphilis | Blood serum | Haemagglutination test |
| | | Nucleic acid amplification tests (NAATs)-PCR for syphilis | Blood serum | PCR |
| | Gonorrhoea and Chlamydia | Qualitative nucleic acid amplification test (NAAT) for Chlamydia trachomatis (CT) and Neisseria gonorrhoea (NG) infections | Urine, urethral swabs, endocervical swabs, vaginal swabs, rectal swabs, oropharyngeal swabs, Liquid cytology | PCR |
| | Clostridium infection | Nucleic acid amplification tests (NAATs) for clostridium difficile | Stool | PCR |
| | Cholera | Nucleic acid amplification tests (NAATs) for cholera | Cholera isolates | PCR, sequencing |
| | Typhoid fever | Nucleic acid amplification tests (NAATs) for salmonella | Bacterial Isolates and whole blood | PCR |
| | Meningococcal meningitis | Nucleic acid amplification tests (NAATs) for meningococcal meningitis (bacteria) | CSF | PCR |
| | Plague | Fine needle aspiration (FNA) test for plague | Lymph node aspirates | Microscopy and culture |
| **Virology** | Hepatitis B | Hepatitis B virus nucleic acid amplification tests (NAATs) -PCR | Serum, plasma (EDTA) | PCR |
| | Hepatitis C | Hepatitis C nucleic acid amplification tests (NAATs)- PCR | Serum, plasma | PCR/ELISA |
| | Hepatitis A | NAATs for hepatitis A virus | Serum whole blood, plasma | PCR |
| | Oral/Genital herpes | Herpes simplex virus type 1 and type 2 (HSV-1 & HSV- 2) NAATs | Blood, nasal swab, nasopharyngeal swab, rectal swab | PCR |
| | Rotavirus | NAATs for rotavirus | Stool | PCR |
| | Dengue | Dengue NAATs tests | Serum, plasma | RT-PCR |
| | Dengue | IgM, IgG, ELISA for dengue | Serum, plasma | ELISA |

| Discipline/ Disease | | In vitro diagnostic test | Specimen type | Test technique |
|---|---|---|---|---|
| **Mycology** | General | Skin punch biopsy for skin diseases | Skin punch biopsy | Microscopy |
| | Aspergillosis | Aspergillus IgG antibody | Serum | Immunofluorescence |
| | | Aspergillus antigen test | Serum, CSF, BAL | Galactomannan (GM) antigen level via ELISA |
| **Parasitology** | Schistosomiasis | IgG.IgM ELISA for schistosomiasis | Blood | ELISA |
| | Leishmaniasis | IgG, IgM Enzyme - linked immunosorbent assay (ELISA)- leishmaniasis | Blood, bone marrow, spleen aspirates, skin scrapings | ELISA |
| **Haematology** | General | Specific factor assay (factors VII, VIII, IX) | Plasma (citrate) | Chronometric, chromogenic and immunological principles |
| | | Bone marrow aspirate (BMA) | Bone marrow | Microscopy |
| **Immunology** | General | Anti-cardiolipin antibody test | Serum, plasma | Immunochemistry, ELISA |
| | | IgE for allergy (Specific IgE/ Total IgE) | Serum | Immunoassay |
| | | IgG, IgA, IgM tests | Serum | Immunofluorescence, ELISA |
| | | Antinuclear antibodies test (ANA) | Serum | ELISA, indirect immunofluorescence |
| | | Anti-neutrophilia cytoplasmic antibodies test (ANCA) | Serum, plasma | Indirect immunofluorescence (IIF), ELISA |
| | | Extractable nuclear antigen antibodies (ENA) panel | Serum, plasma | ELISA, immunoblot |
| | | Anti-cyclic citrullinated peptide test (ANTI-CCP) | Serum, plasma | Immunofluorescence assay, ELISA |
| | | Anti-double-stranded (DS) DNA | Serum, plasma | ELISA, indirect immunofluorescence |
| **Clinical Chemistry** | General | Troponin TnI | Serum | Enzyme immunoassay, chemiluminescence |
| | | Blood pH and gasses | Whole blood in heparin | ISE potentiometry |
| | | Whole blood lactate | Whole blood or plasma | Electrochemistry |
| | | Procalcitonin | Serum | Enzyme immunoassay |
| | | Human chorionic gonadotropin (beta HCG)- Fertility / tumour marker | Serum (Frozen for delayed testing) | Enzyme immunoassay |

| Discipline/ Disease | | In vitro diagnostic test | Specimen type | Test technique |
|---|---|---|---|---|
| **Clinical Chemistry** | General | Estradiol | Serum (Frozen for delayed testing) | Enzyme immunoassay |
| | | Follicle stimulating hormone (FSH) | Serum (Frozen for delayed testing) | Enzyme immunoassay |
| | | Progesterone | Serum (Frozen for delayed testing) | Enzyme immunoassay |
| | | Prolactin | Serum (Frozen for delayed testing) | Enzyme immunoassay |
| | | Testosterone | Serum (Frozen for delayed testing) | Enzyme immunoassay |
| | | Sex hormone-binding globulin (SHBG) | Serum (Frozen for delayed testing) | Enzyme immunoassay |
| | | Cortisol (total) | Serum (Frozen for delayed testing) | Enzyme immunoassay |
| **Cancer** | Cancer | Cancer antigen 15-3 (CA 15-3) | Plasma/serum | Immunoassay |
| | | Cancer antigen protein 125 (CA 125) | Plasma/serum | Immunoassay |
| | | Cancer antigen 19-9 (CA 19-9) | Serum/plasma | Immunoassay |
| | | Carcinoembryonic antigen (CEA) | Plasma/serum | Immunoassay |
| | | Calcitonin test | Serum (sodium or lithium heparin). | Quantitative Chemiluminescent Immunoassay |
| | | Beta-2 microglobulin | Body fluids, serum, urine, or CSF- (rare cases) | ELISA - peroxidase conjugated competitive, ELISA immunoturdimetric assay |
| | | Flow cytometry antibodies Panel | Blood, bone marrow aspirates FNAs | Flow cytometry |
| **Histopathology and cytopathology** | General | Post-mortem examination | Cadaveric tissues | Microscopy Decalcification, fixation, tissue processing, sectioning, routine staining, special staining, tissue microscopy, tissue/tissue block, slide archiving, fluid cytology, pap stain, exfoliative cytology pap smear test-conventional, aspiration cytology (fine needle and fluids) |
| | Cancer | Gastrointestinal H. Pylori infection | Gastric biopsy | H&E staining, Giemsa staining |

| Discipline/ Disease | | In vitro diagnostic test | Specimen type | Test technique |
|---|---|---|---|---|
| **Level 6 tests recommended** | | | | |
| **Bacteriology** | Tuberculosis | TB Whole Genome Sequencing (WGS)/Next Generation Sequencing (NGS) | Raw sputum, culture isolates, SOTS | Genome sequencing |
| | | Drug susceptibility testing of Mycobacterium tuberculosis | Sputum and SOTS | Drug susceptibility testing |
| | Anthrax | Culture and antimicrobial susceptibility tests for anthrax | Blood, Skin lesion swabs, Spinal fluid, Respiratory secretions | Anthrax culture and susceptibility testing |
| | | ELISA for anthrax | Blood | ELISA |
| | | Nucleic acid amplification tests (NAATs) for anthrax | Cutaneous lesion, lesion swab, blood, pleural fluid, ascitic fluid, sputum, and bacterial Isolates | PCR, sequencing |
| | | Gram stain microscopy for anthrax | Skin swabs | Microscopy |
| | Leprosy | NAATs for leprosy | Skin biopsy from edges of active patches, whole blood samples | PCR |
| **Virology** | HIV infection | HIV drug resistance | Plasma, DBS | Nucleic acid extraction (manual/automated), PCR (RT-PCR, nested PCR), quantification techniques (gel electrophoresis/ fluorometry/ spectrophotometry), sequencing |
| | Coronavirus disease (COVID-19) | SARS-CoV-2 genome sequencing | Nasopharyngeal swabs, nasal swabs, nasal wash/ aspirate, oropharyngeal swabs, sputum, BAL fluid | Genome sequencing |
| | Influenza | Influenza multiplex NAATs | Nasopharyngeal swab, nasal swab, nasal wash/aspirate, oropharyngeal swab, throat swab | Reverse transcriptase-PCR |
| | Measles | Measles NAATs test | Nasopharyngeal swab, throat swab, urine, blood | PCR |
| | | Measles IgM/IgG ELISA test | Serum | ELISA |
| | Rubella | Rubella IgM/ IgG antibody | Serum | ELISA |
| | Mumps | Mumps antibodies (IgG/ IgM) | Serum | ELISA |

| Discipline/ Disease | | In vitro diagnostic test | Specimen type | Test technique |
|---|---|---|---|---|
| **Virology** | Yellow fever | IgM/IgG ELISA for yellow fever | Serum, plasma | ELISA |
| | | NAATs for yellow fever | Whole blood, serum, plasma | RT-PCR |
| | Chikungunya | IgG/IgM ELISA for chikungunya | Serum, plasma | ELISA |
| | | NAATs for chikungunya | Whole blood, serum, plasma | RT-PCR |
| | EBOLA virus Disease | NAATs for EBOLA | Whole blood, serum, plasma | RT-PCR |
| | Rift valley fever | IgM/ IgG ELISA for RVF | Serum, plasma | ELISA |
| | | NAATs for RVF | Whole blood, serum, plasma | RT-PCR |
| | Marburg virus disease | NAATs for Marburg virus | Whole blood, serum plasma, oral swabs, nasal swabs, semen, tissue | Reverse transcriptase-PCR |
| | | IgM captured ELISA for Marburg virus | Serum, plasma, tissue | ELISA |
| **Virology** | West Nile fever disease | NAATs for West Nile fever | Whole blood, serum, plasma, CSF, tissue | Reverse transcriptase PCR |
| | | West Nile fever IgG, IgM ELISA | Serum, CSF | ELISA |
| | Zika virus disease | IgM, IgG ELISA antibodies to Zika virus | Serum, plasma | ELISA |
| | | NAATs for Zika virus | Whole blood, plasma, serum, urine, CSF, semen, amniotic fluid, rectal swabs | Reverse transcriptase PCR |
| | Crimean Congo hemorrhagic fever | Crimean Congo hemorrhagic fever NAATs | Serum, whole blood, plasma | Reverse transcriptase PCR |
| | | Crimean Congo hemorrhagic fever IgG, IgM ELISA | Serum, plasma | ELISA |
| | Lassa fever | IgM, IgG ELISA for Lassa fever | Serum | ELISA |
| | | NAATs for Lassa fever | Blood, urine, stool, swabs | Reverse transcriptase PCR |
| | Mpox | Mpox NAATs | Lesion swabs, lesion material | PCR |
| | Poliomyelitis | Polio viral isolation in cell culture | Stool | Cell Culture |
| | | NAATs for Polio virus PCR | Stool, serum, plasma, CSF | RT-PCR |

| Discipline/ Disease | | In vitro diagnostic test | Specimen type | Test technique |
|---|---|---|---|---|
| **Mycology** | General | Fungal culture for skin diseases | Skin scrapping, nail sampling, hair follicle, skin snip smear | Manual culture, mass spectrometry |
| | Pneumonia | Pneumocystis jirovecii nucleic acid amplification test (NAAT) | BAL/sputum/ tracheal aspirate | PCR |
| | Aspergillosis | Culture for aspergillosis | BAL, sputum, tracheal aspirate | Manual culture, mass spectrometry |
| **Parasitology** | Malaria | NAATs for malaria | Blood | PCR |
| | | Genome sequencing for malaria | Blood | PCR |
| | Leishmaniasis | NAATs for leishmaniasis | Blood, bone marrow, spleen aspirates, skin scrapings | PCR |
| **Histopathology and cytopathology** | General | Routine stains- Haematoxylin and eosin Special stains (histochemical stains)<br><br>Basic panel for immunohistochemical testing for the diagnosis of cancer | Gynae and non-gynae smears, body fluids like CSF, Effusions, urine, etc, Tissue scrappings, excisional biopsies, incisional biopsy, core biopsies, formalin fixed tissue blocks | Routine cytopathology and histopathology stains, histochemical stains Immunohistochemical testing (phenotyping) |
| | Pre-neoplastic and Neoplastic conditions | Genetic testing for BRCA1 or BRCA2 mutation traits. | Whole blood, saliva bone marrow aspirates, trephine biopsy, tissue blocks | Genetic sequencing |
| | | Epidermal growth factor receptors (EFGR)<br><br>KRAS mutation analysis test | Serum/tissue blocks | Genetic sequencing |
| **Blood transfusion and transplant services (for Donor & Recipient)** | General | Blood grouping (ABO and Rhesus factor (Rh) | Plasma, SER and Cells | Solid phase, column agglutination technology (gel testing), tube or microplates. |
| | | Full haemogram | Whole blood | Automated blood cell count, electric impedance, flow cytometry, spectrophotometry. |
| | | Antibody screening | Plasma | Solid phase, column agglutination technology (gel testing), tube. |

| Discipline/ Disease | | In vitro diagnostic test | Specimen type | Test technique |
|---|---|---|---|---|
| **Blood transfusion and transplant services (for Donor & Recipient)** | General | A & B antibody titres | Plasma | Solid phase, column agglutination technology (gel testing), tube |
| | | Haemoglobin estimation | Whole blood | Spectrophotometry, copper sulphate gravimetry. |
| | | NAATs for blood group genotyping | Serum | PCR |
| | | Direct antiglobulin test (DAT), also known as direct Coombs test | Whole Blood (EDTA) | Solid phase, column agglutination technology (gel testing), tube |
| | | Indirect antiglobulin test (IAT), also known as indirect Coombs test or red blood cell antibody screen. | Plasma | Solid phase, column agglutination technology (gel testing), tube |
| | | Coagulation tests | Plasma in sodium citrate | Chronometric, chromogenic and immunological principles. |
| | HIV infection | HIV 1&2 | Serum /plasma | Chemiluminescent Microparticle immunoassay, ELISA, ECLIA |
| | Hepatitis B | HBsAg | Serum /plasma | Chemiluminescent Microparticle immunoassay, ELISA, ECLIA |
| | | HBcAb (Core antibody) | Serum /plasma | Chemiluminescent Microparticle immunoassay, ELISA, ECLIA |
| | Hepatitis C | HCV Ab | Serum /plasma | Chemiluminescent Microparticle immunoassay, ELISA, ECLIA |
| | Cytomegalovirus infection | Cytomegalovirus test | Whole Blood/plasma/ serum | Chemiluminescent Microparticle immunoassay, ELISA, ECLIA |
| | Epstein Barr virus infection | Epstein Barr Virus test | Whole blood/plasma/ serum | Chemiluminescent Microparticle immunoassay, ELISA, ECLIA |
| | Syphilis | Syphilis – Treponema pallidum test | Serum, plasma | Chemiluminescent Microparticle immunoassay, ELISA, Flocculation |

| Discipline/ Disease | | In vitro diagnostic test | Specimen type | Test technique |
|---|---|---|---|---|
| **Clinical Chemistry** | Cancer | Genetic testing for BRCA1 or BRCA 2 mutation traits | Whole blood, bone marrow aspirates, trephine biopsy tissues | Genetic sequencing |
| | | Epidermal growth factor receptors (EGFR) | Serum/tissue blocks | PCR, Genomic sequencing |
| | | KRAS mutation analysis test | Tissue blocks | PCR, Genomic sequencing |
| **Clinical and Forensic toxicology** | General | Drug analysis | Blood, urine, saliva, stomach contents, liver, kidney, vitreous humour, urine, exhumation samples cloths | HPLC- GCMS, rapid immunoassays |
| | | Pesticide analysis | Blood, urine, stomach content, liver, vomitus, food, water, soil, plant material | Gas chromatography-mass spectrometry, Ultraviolet–visible spectroscopy |
| | | Heavy metal analysis | Blood, Urine, Stomach content, food, water, alcoholic beverages, non- alcoholic beverages, soil, plant material | Multi-Drug Test Panel (rapid test kits), Atomic absorption spectrometry (AAS), Inductively coupled plasma mass spectrometry (ICP-MS) |
| | | Alcohol analysis | Blood, urine, stomach contents, vomitus, vitreous humour | Gas chromatography with headspace |
| | | Carboxyhemoglobin/ Carbonmonoxide | Blood | Conway diffusion technique |
| **Forensic Biology** | General | DNA analysis for semen | **Sexual offences and homicide/infanticide:** Blood, high vaginal swabs, anal swabs, vulval swabs, blind virginal swabs, buccal swabs, combed and plucked pubic hair, combed and plucked head hair, fibres, foetus and foetal material, garments, hair<br>**Human/ body identification and pertanity tests:** Bones, fingernails, cartilage, blood, buccal swabs, fingernail scrapings | Hair and fibre analysis through comparative microscopy, capillary electrophoresis |

| Discipline/ Disease | | In vitro diagnostic test | Specimen type | Test technique |
|---|---|---|---|---|
| **Food and water analysis** | General | Food adulterants | Food | HPLC-GCMS, Rapid immuno test strips, chromatography, screening, spectroscopy |
| | | Food contaminants analysis | Food | Plate-based assay, spectrophotometry |
| | | Food additives | Food | Chromatography |
| | | Bacterial food analysis | Food | Culture |
| | | Micronutrients analysis | Food | Spectrophotometry, titrimetric, volumetric analysis |
| | | Water analysis (bacterial & chemical analysis) | Water | Spectrophotometry, culture |

# Annex 5: Dissemination and implementation plan template

| Kenya Essential HPT Lists Dissemination & Implementation Framework | | | | | | | |
|---|---|---|---|---|---|---|---|
| **S/ No** | **Activity** | **Activity narrative** | **Target group** | **Output** | **Indicator** | **Timeframe** | **Responsible Person** |
| 1. | Designing and Printing of the Essential HPT Lists (KEML, KEDL, KEMLS) | Essential HPT Lists to be printed for dissemination | MOH, Counties, partners, private sector actors, FBO, professional bodies | Essential HPT Lists printed | Printed Essential HPT Lists | By July 2023 | MOH & Partners |
| 2. | Launch of the finalized Essential HPT Lists (KEML, KEDL, KEMLS | National launch of the Essential HPT Lists by MOH | MOH, Counties, regulatory bodies, Kenya Medical Supplies Agency, MEDS, Professional Associations, health research institutions, development & implementing partners, FBO, public and private sector players | Launch of Essential HPT Lists | Launched Essential HPT Lists | By August 2023 | MOH & Partners |
| 3. | Develop essential HPT lists sensitization package and dissemination plan | Have a standard dissemination package and plan for use by all counties and partners | MOH, Counties, FBO, Partners, training Institutions, professional associations | Sensitization package Dissemination plan | Sensitization package Dissemination plan | July 2023 | MOH & Partners |
| 4. | Disseminate the Essential HPT Lists to counties and to different institutions/ stakeholders | Dissemination will ensure the Essential HPT Lists are accessed and available to all relevant stakeholders for utilization | MOH, Counties, Partners, Institutions | Dissemination report (s) | No. of persons by institution essential HPT list disseminated to | By October 2023 (and Continuous) | MOH, Partners |
| 5. | Link Essential HPT Lists with KEMSA & other procurement systems, IFMIS, Donations portal | Linking the Essential HPT Lists with KEMSA & other procurement, donations and financial systems will ensure standardization of procurement processes and adherence to standard treatment guidelines/essential list | National and County Governments, KEMSA, MEDS, Manufacturers, Suppliers, Partners, Donors | Essential HPT Lists linked with procurement, financial systems, donations portal | Synchronized procurement systems in tandem with the Essential HPT Lists | By November 2023 | MoH, KEMSA, National Treasury |
| 6. | Develop a standardized Checklist or digital platform for monitoring implementation of Essential HPT Lists at all levels of care | The standardized checklist will provide a platform for monitoring implementation of Essential HPT Lists at all levels of care | National and County MOH, Implementing and development partners, the public, regulatory bodies, KEMSA, MEDS, Professional Associations, health research institutions, public, private & other sector players | Standardized checklist developed | Checklist available | Continuous | MOH, Counties, Institution Facilities offering health services |
| 7. | Conduct support supervision to monitor implementation of the Essential HPT Lists | Support supervision to monitor implementation of KEDL | County Health Teams, Health Facility Management Teams | Biannual assessments conducted | No. of assessments done in a year | Biannually | MOH, Counties, Health Facilities |

# Annex 6: Indicators to Monitor and Evaluate KEDL 2023

| S/ No. | Indicator | Indicator Definition | Data Source | Frequency | Responsible Person |
|---|---|---|---|---|---|
| **Core indicator (To be monitored using routinely available data and during site visits/surveys)** | | | | | |
| 1. | Proportion of available tracer essential HPT (medicines, medical & diagnostic supplies) in health facilities | % of tracer essential HPT available in facilities per month | DHIS-2, Facility inventory data, MoH 647 report, LMIS | Monthly | MoH, Counties, health facilities |
| **Additional indicators** | | | | | |
| **Indicators that can be monitored using routinely available data** | | | | | |
| 1. | Percentage of facilities that experienced stock outs of tracer HPT (medicines, medical & diagnostic supplies) at any point, within a defined period (month) | % of facilities with stock out of tracer essential HPT within the month | DHIS-2, Facility inventory data, MoH 647 report, LMIS | Monthly | MoH, Counties, health facilities |
| 2. | Percentage of facilities stocked according to plan for tracer essential HPT | Facilities with no under- or overstocks based on average consumption for tracer HPT | DHIS-2, Facility inventory data, MOH 647 report, LMIS | Quarterly | MoH, Counties, health facilities |
| 3. | % of tracer essential HPT ordered by health facilities from KEMSA (or another private supplier) over a defined period that are supplied according to quantities requested | Order fill rate by quantity per commodity | Facility order/ report, KEMS LMIS | Quarterly | Counties, health facilities, KEMSA |
| 4. | Proportion of HPT stocked in the facility based on the essential HPT Lists (medicines, medical & diagnostic supplies) | No. of HPT in stock based on essential HPT lists | Facility inventory data, essential HPT lists | Quarterly | Counties, health facilities |
| 5. | Value (in Ksh.) of tracer essential HPT at risk of expire within the next 6 months | Value of tracer essential HPT at risk of expiry in the next 6 months | DHIS-2, Facility inventory data, MoH 647 report, LMIS | Monthly | Counties, health facilities |
| 6. | Value (in Ksh.) of tracer essential HPT expired in the last 6 months | Value of tracer essential HPT that have expired in the last 6 months | DHIS-2, Facility inventory data, MoH 647 report, LMIS | Monthly | Counties, health facilities |

| S/ No. | Indicator | Indicator Definition | Data Source | Frequency | Responsible Person |
|---|---|---|---|---|---|
| **Indicators that can be tracked during surveys/site visits** | | | | | |
| 1. | Percentage of facilities with a stock out of any tracer HPT (medicines, medical & diagnostic supplies) on day of site visit | No. of facilities with stock- out of any tracer HPT on the day of the site visit | Facility inventory data | Annually | MOH, Counties, health facilities |
| 2. | The average number of times each tracer HPT (medicines, medical & diagnostic supplies) was out of stock in the past 6 months | No. of times each tracer HPT was stocked out in the past 6 months | Facility inventory data | Biannually | MOH, Counties<br>health facilities |
| 3. | Value of stock for a tracer HPT (medicines, medical & diagnostic supplies) that is unusable due to expiration or damage | Value of unusable stock for tracer HPT at the facility | Facility records | Biannually | MOH, Counties, health facilities |
| 4. | Percentage of laboratory equipment down time that led to non-utilization of reagents | Lab equipment down-time logs | Facility records, medical equipment logs | Biannually | MOH, Counties, health facilities |
| 5. | Proportion of prescriptions with one or more antibiotics prescribed | % of prescriptions with one or more antibiotics prescribed at the facility's outpatient departments | Survey, support supervision, Prescriptions, facility registers | Quarterly | Counties, health facilities |
| 6. | Proportion of medicines prescribed by generic name | % of medicines prescribed by generic name | Survey, Prescriptions, facility registers | Quarterly | MOH, Counties, health facilities |
| 7. | Proportion of reserve antibiotics prescribed at level 4 or lower levels | % of Antibiotics under Reserve classification prescribed in level 4 or lower levels | Routine Reports, Surveys, prescriptions | Quarterly | MOH, Counties, health facilities |

REPUBLIC OF KENYA

MINISTRY OF HEALTH