



TECHNICAL REPORT

HIV DIAGNOSTIC TESTS IN LOW- AND MIDDLE-INCOME COUNTRIES: FORECASTS OF GLOBAL DEMAND FOR 2021–2025

DECEMBER 2021

HIV DIAGNOSTIC TESTS IN LOW- AND MIDDLE-INCOME COUNTRIES: FORECASTS OF GLOBAL DEMAND FOR 2021–2025

DECEMBER 2021

HIV diagnostic tests in low- and middle-income countries: forecasts of global demand for 2021–2025

ISBN 978-92-4-004226-1 (electronic version)

ISBN 978-92-4-004227-8 (print version)

© World Health Organization 2022

Some rights reserved. This work is available under the Creative Commons Attribution-NonCommercial-ShareAlike 3.0 IGO licence (CC BY-NC-SA 3.0 IGO; <https://creativecommons.org/licenses/by-nc-sa/3.0/igo>).

Under the terms of this licence, you may copy, redistribute and adapt the work for non-commercial purposes, provided the work is appropriately cited, as indicated below. In any use of this work, there should be no suggestion that WHO endorses any specific organization, products or services. The use of the WHO logo is not permitted. If you adapt the work, then you must license your work under the same or equivalent Creative Commons licence. If you create a translation of this work, you should add the following disclaimer along with the suggested citation: “This translation was not created by the World Health Organization (WHO). WHO is not responsible for the content or accuracy of this translation. The original English edition shall be the binding and authentic edition”.

Any mediation relating to disputes arising under the licence shall be conducted in accordance with the mediation rules of the World Intellectual Property Organization (<http://www.wipo.int/amc/en/mediation/rules/>).

Suggested citation. HIV diagnostic tests in low- and middle-income countries: forecasts of global and regional demand for 2021–2025. Geneva: World Health Organization; 2022. Licence: CC BY-NC-SA 3.0 IGO.

Cataloguing-in-Publication (CIP) data. CIP data are available at <http://apps.who.int/iris>.

Sales, rights and licensing. To purchase WHO publications, see <http://apps.who.int/bookorders>. To submit requests for commercial use and queries on rights and licensing, see <https://www.who.int/copyright>.

Third-party materials. If you wish to reuse material from this work that is attributed to a third party, such as tables, figures or images, it is your responsibility to determine whether permission is needed for that reuse and to obtain permission from the copyright holder. The risk of claims resulting from infringement of any third-party-owned component in the work rests solely with the user.

General disclaimers. The designations employed and the presentation of the material in this publication do not imply the expression of any opinion whatsoever on the part of WHO concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted and dashed lines on maps represent approximate border lines for which there may not yet be full agreement.

The mention of specific companies or of certain manufacturers' products does not imply that they are endorsed or recommended by WHO in preference to others of a similar nature that are not mentioned. Errors and omissions excepted, the names of proprietary products are distinguished by initial capital letters.

All reasonable precautions have been taken by WHO to verify the information contained in this publication. However, the published material is being distributed without warranty of any kind, either expressed or implied. The responsibility for the interpretation and use of the material lies with the reader. In no event shall WHO be liable for damages arising from its use.

Design and layout by Brainagent

CONTENTS

CONTENTS	iii
LIST OF FIGURES	iv
LIST OF TABLES	iv
ACKNOWLEDGEMENTS	v
ABBREVIATIONS AND ACRONYMS	vi
EXECUTIVE SUMMARY	vii
1. INTRODUCTION	1
2. METHODS	2
2.1 CURRENT DEMAND	2
2.2 PROJECTIONS BY THE CLINTON HEALTH ACCESS INITIATIVE	2
2.3 CONSOLIDATED FORECAST	4
3. RESULTS	5
SUMMARY	10

LIST OF FIGURES

Fig. 1. Demand for CD4 count tests, 2020–2025	5
Fig. 2. Demand for viral load tests, 2020–2025	6
Fig. 3. Demand for early infant diagnosis tests, 2020–2025	7
Fig. 4. Demand for rapid diagnostic tests, 2014–2025	8
List of tables	
Table 1. Distribution of rapid diagnostic tests used in 2019 and 2020	9

ACKNOWLEDGEMENTS

WHO, UNAIDS and Avenir Health are grateful to the Clinton Health Access Initiative (CHAI) for the successful collaboration on this project and appreciate the effort of all interested experts to reach agreement to develop and produce one single consolidated forecast merging CHAI forecasts and other projections developed by WHO, UNAIDS and Avenir Health.

WHO, UNAIDS and Avenir Health extend their gratitude to the people who reviewed this report and to the comments of the diagnostic meeting participants during plenary discussions.

WHO thanks everyone who contributed to this product, especially **Daniel Low-Beer, Meg Doherty, Ren Minghui** and WHO staff members and partners who participated in the joint WHO/UNAIDS consultation with diagnostics companies.

WHO expresses its special thanks to **John Stover** (Avenir Health), **Zack Panos** and **Jessica Fox** (Clinton Health Access Initiative), **Peter Ghys** and **Deepak Mattur** (UNAIDS) **Lorenzo L. Witherspoon** (UNITAID) and **Boniface Dongmo Nguimfack** .

ABBREVIATIONS AND ACRONYMS

ART	antiretroviral therapy
CHAI	Clinton Health Access Initiative
UNAIDS	Joint United Nations Programme on HIV/AIDS

EXECUTIVE SUMMARY

This report provides projections of the future demand for HIV diagnostic tests through 2025. These projections are intended to inform advocacy for scaling up access to diagnostics to achieve the UNAIDS 95–95–95 targets for HIV treatment access and viral load suppression. The projections will also be useful for producers so that they can plan for adequate supply and to procurement organizations in planning future funding and long-term purchase plans.

The projections rely on data from several sources, including country reports to the Global AIDS Monitoring system, purchases reported to the Global Price Reporting Mechanism and forecasts and historical testing volumes provided by the Clinton Health Access Initiative (CHAI) for countries with a high burden of HIV.

This report presents consolidated estimates relying on detailed country-specific analysis conducted by CHAI for 15–24 countries with a high burden of HIV and extrapolations of past trends for the other countries based on country reports to Global AIDS Monitoring.

The main results are as follows.

- **Rapid diagnostic tests.** The demand for professional rapid diagnostic tests may be nearing saturation. The market may still grow over the next six years but at a slow rate.
 - HIV self-testing is likely to have a larger role in determining the need for treatment (and prevention) interventions.
- **Viral load.** Demand for viral load tests continues to grow rapidly and could reach nearly 30 million by 2024 as more countries adopt viral load testing for routine monitoring that may be further enabled by use of viral load point-of-care technologies and dried blood spots.
- **CD4 tests.** Conversely, demand for CD4 tests for routine monitoring is declining since most countries have adopted routine viral load testing for treatment monitoring.
 - However, there will continue to be a need for everyone starting treatment to receive CD4 testing to identify people with advanced HIV disease.
 - Additionally, CD4 for routine monitoring will be needed for people with limited access to viral load testing.
- **early infant diagnosis tests:** Demand for early infant diagnosis tests will likely grow as point of care testing continues to scale up and countries adopt nucleic acid testing at 9 months per the WHO's guidelines.

1. INTRODUCTION

The objective of this report is to project future demand for HIV diagnostics through 2025. These forecasts are intended to inform advocacy for scaling up access to diagnostics to achieve the UNAIDS 95–95–95 targets for HIV treatment access. The forecasts may also be useful for producers so that they can plan for adequate supply and to procurement organizations in planning future funding and long-term purchase plans.

The key sources of data on diagnostics for this report are:

- an annual WHO survey of low- and middle-income countries on HIV treatment and diagnostic tests with data from 2012 through 2018 plus country reports to the Global AIDS Monitoring system for 2019 and 2020;
- the WHO Global Price Reporting Mechanism;
- data on past use and forecasted testing volumes developed by the Clinton Health Access Initiative (CHAI) for countries with a high burden of HIV; and
- the UNAIDS Global AIDS Response Progress Reporting system for HIV testing;

To inform these projections, data were also used on the number of people receiving antiretroviral therapy (ART) by country annually through 2020 from Global AIDS Monitoring and projections for the use of ART through 2025 based on the UNAIDS Global Strategy 2021–2026, which includes the 95–95–95 targets.¹

¹The 95–95–95 targets are that by 2025, 95% of all people living with HIV know their HIV status, 95% of the people who know their HIV-positive status are accessing treatment and 95% of the people receiving treatment have suppressed viral loads.

2. METHODS

The consolidated forecast combines information on past and current demand from the WHO antiretroviral medicine and diagnostic use survey, detailed forecasts for countries with a high burden of HIV prepared by CHAI and linear and logarithmic extrapolations of past demand for countries not covered by CHAI. Each of these is explained below.

2.1. Current demand

The WHO antiretroviral medicine and diagnostic use survey and country reports to Global AIDS Monitoring provided data for 2014 through 2020. Not all countries reported in all years. The numbers of countries reporting by year from 2014 to 2020 are 138, 47, 60, 34, 51, 96 and 77, respectively. Overall, 110 countries reported data in at least two years. For the 33 countries not reporting in 2020, an estimate was made based on linear regression to the data reported from 2014 to 2019. For countries without data from 2020 and less than two data points in previous years, the estimate for 2020 was based on the number of people receiving ART and the ratio of tests to people receiving ART from all reporting countries. The ratios were 0.25 tests per person receiving ART for CD4 tests, 0.65 for viral load and 1.09 for early infant diagnosis.

2.2. Projections by CHAI

CHAI's HIV diagnostics forecasts project the total anticipated demand (tests run) for CD4 count, early infant diagnosis and viral load from 2020 to 2025. The forecasts use a bottom-up approach to estimate the demand in countries with a high HIV burden.² The data for these countries has been obtained from annual data requests to country teams and publicly available sources. The diagnostics forecasts are updated at least annually using new service delivery statistics and programme plans from CHAI country teams.

The methods for each of the market forecasts for CD4 count, early infant diagnosis and viral load vary based on the state of the market and the types of data available for analysis. For all forecasts, the historical numbers of people receiving ART have been obtained from the figures reported in the UNAIDS

²For viral load testing, the following 18 countries were included in CHAI's forecast: Cameroon; Democratic Republic of the Congo; Eswatini; Ethiopia; India; Kenya; Lesotho; Malawi; Mozambique; Myanmar; Nigeria; Rwanda; Senegal; South Africa; Uganda; United Republic of Tanzania; Zambia; Zimbabwe. CHAI's CD4 forecast used the same countries except for Democratic Republic of the Congo, Rwanda and Senegal (15 countries total). For early infant diagnosis testing, the following 24 countries were included in CHAI's forecast: Angola; Botswana; Brazil; Burundi; Cameroon; Côte d'Ivoire; Democratic Republic of the Congo; Eswatini; Ethiopia; Ghana; India; Kenya; Lesotho; Malawi; Mozambique; Nigeria; Rwanda; Senegal; South Africa; Thailand; Uganda; United Republic of Tanzania; Zambia; and Zimbabwe.

AIDSinfo database (<http://aidsinfo.unaids.org>). For future growth in the number of people receiving ART, CHAI assumes that the number of people receiving treatment will increase linearly at the same rate as the trend observed in the last four years and will plateau as universal access approaches. CHAI publishes their estimates for generic-accessible low- and middle-income countries in aggregate annually in their HIV market report.³

CD4 testing forecast by CHAI

In generating this forecast, data on historical CD4 tests performed are collected from CHAI country teams or publicly available reports. If no historical data on the tests performed are available, procurement data are used. Historical compound annual growth rates are applied to fill in gaps if neither testing nor procurement data are available for the baseline year.

Forecasted demand is estimated by applying historical compound annual growth rates to baseline year data and constrained by the calculated need or country targets (whichever is more conservative).

Early infant diagnosis forecast by CHAI

CHAIs forecast for early infant diagnosis draws on several data points for historical early infant diagnosis testing volumes, including data from public reports and testing dashboards, annual data from CHAI country teams and the UNAIDS AIDSinfo database.

To estimate future demand, the three-year compound annual growth rate for each country is applied to baseline year data.

Estimated future demand is also affected by potential adoption of birth and non-prevention of mother-to-child transmission entry point testing as reported by CHAI country teams.

At the country level, the projected demand is constrained by the estimated testing need. When the projected number of early infant diagnosis tests based on linear extrapolation exceeds the theoretical need, the latter is used instead.

CHAI forecast for viral load testing

CHAI has developed a viral load testing forecast based on historical and hypothetical growth analogues. Demand has been calculated based on the predicted viral load testing coverage for a country in a given year multiplied by the estimated need.

Countries have been mapped to historical or hypothetical growth analogues based on their current viral load testing coverage and expectations for future scaling up.

³2021 HIV market report. Boston: Clinton Health Access Initiative; 2021 (<https://3cdmh310dov3470e6x160esb-wpengine.netdna-ssl.com/wp-content/uploads/2021/10/2021-CHAI-HIV-Market-Report.pdf>, accessed 10 December 2021).

2.3. Consolidated forecast

The consolidated forecast combines the CHAI forecast with extrapolations for the remaining countries from Avenir Health and the WHO survey. The CHAI CD4 forecast accounts for 73% of the people receiving ART in low- and middle-income countries; the CHAI early infant diagnosis forecast accounts for 90% of pregnant women receiving ART globally; and the CHAI viral load testing forecast accounts for 75% of the people receiving ART in low- and middle-income countries.

For all countries not included in the CHAI forecast, the projections from Avenir were used. The projections were made as a linear extrapolation of the trend from 2011 to 2020. For all countries, demand in 2021 was assumed to be equal to 2020 to recognize the conflicting forces of continued growth in need for testing with the disruptions in testing services caused by COVID-19. Demand in 2022–2025 was projected as a linear extrapolation of the historical growth rate for each country.

2.4. The 95–95–95 treatment targets

In 2021, UNAIDS proposed a new target for scaling up treatment: the 95–95–95 treatment targets. The targets envision that, by 2025:

- 95% of the people living with HIV know their HIV status;
- 95% of the people who know their HIV-positive status are accessing treatment; and
- 95% of the people receiving treatment have suppressed viral loads.

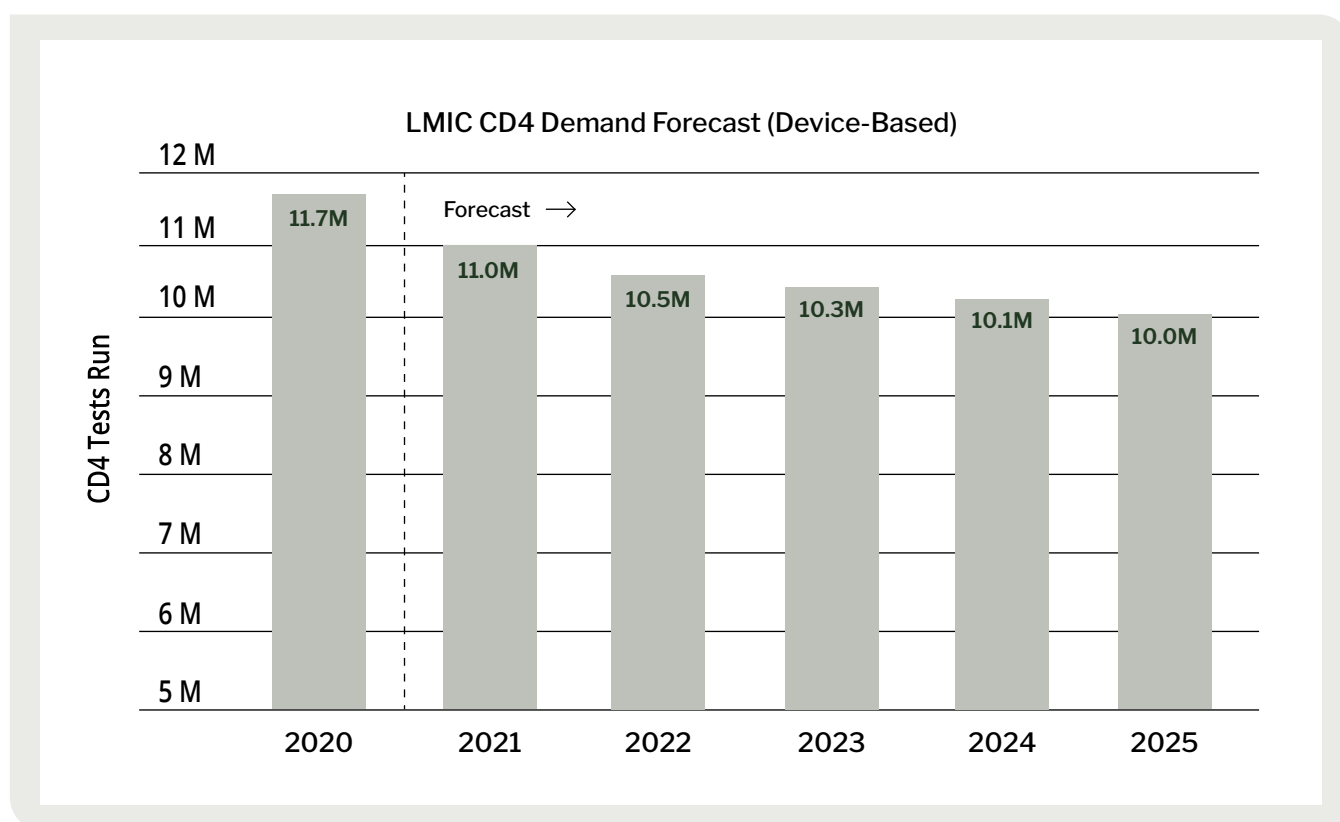
These targets were developed as part of the UNAIDS Global AIDS Strategy 2021–2026, which calls for achieving 95–95–95 in all countries and all populations by 2025.

3. RESULTS

3.1. CD4 tests

Fig. 1 shows estimates of future demand for CD4 tests. The forecast indicates a gradual decline in demand for CD4 tests as countries switch to viral load monitoring to about 10.0 million by 2025. However, the forecast shows that substantial CD4 volumes will still be needed, especially to identify people initiating treatment with advanced HIV disease.

Fig. 1. Forecast for device-based CD4 demand for low- and middle-income countries CD4 tests performed

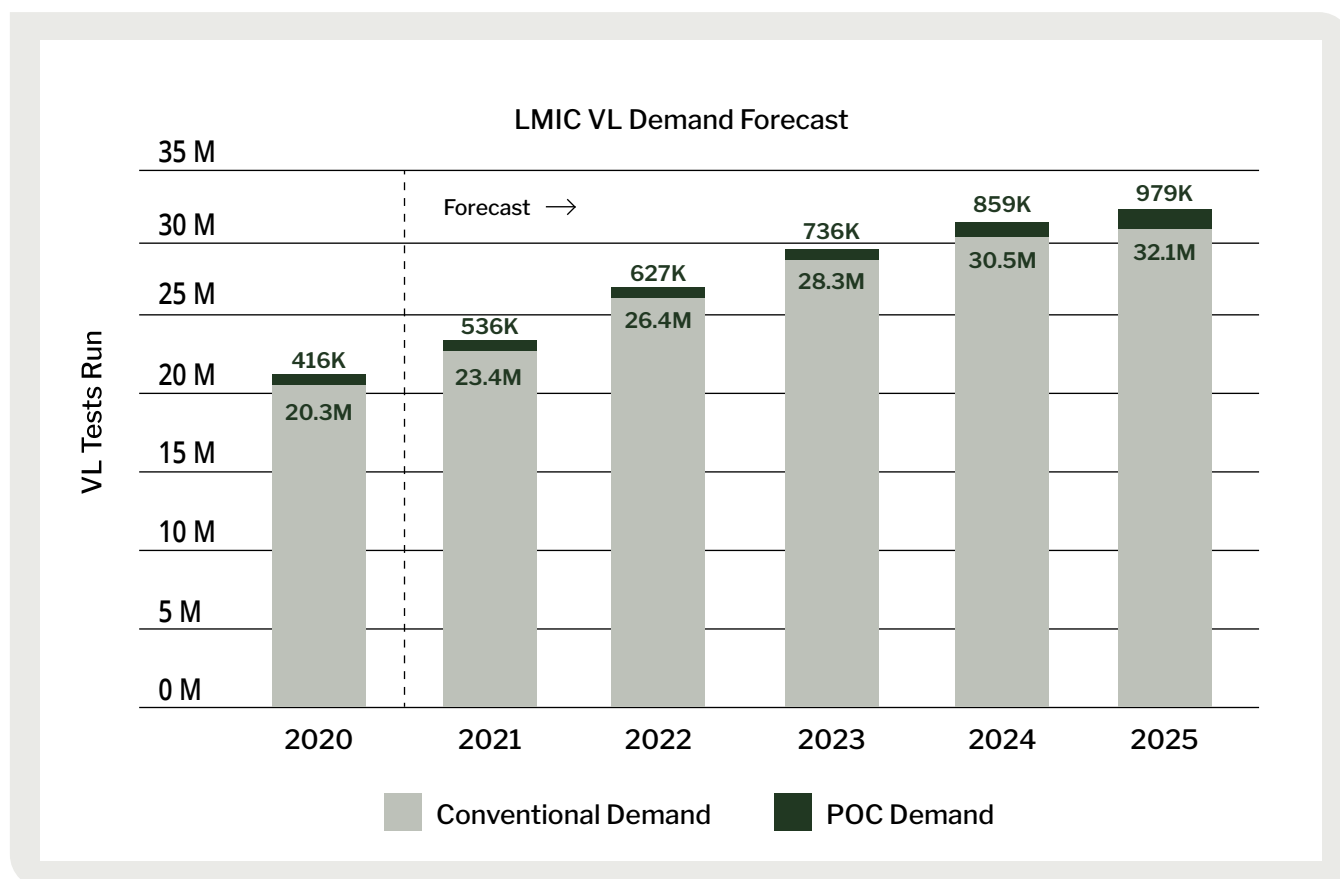


3.2. Viral load tests

Fig. 2 shows the projected demand for viral load tests. Demand is expected to increase to reach about 30 million viral load tests in 2024 as the number of people receiving ART increases and as more countries adopt routine viral load testing for patient monitoring.

The dark blue bars show estimated conventional laboratory-based demand and the light blue bars show estimated point-of-care demand.

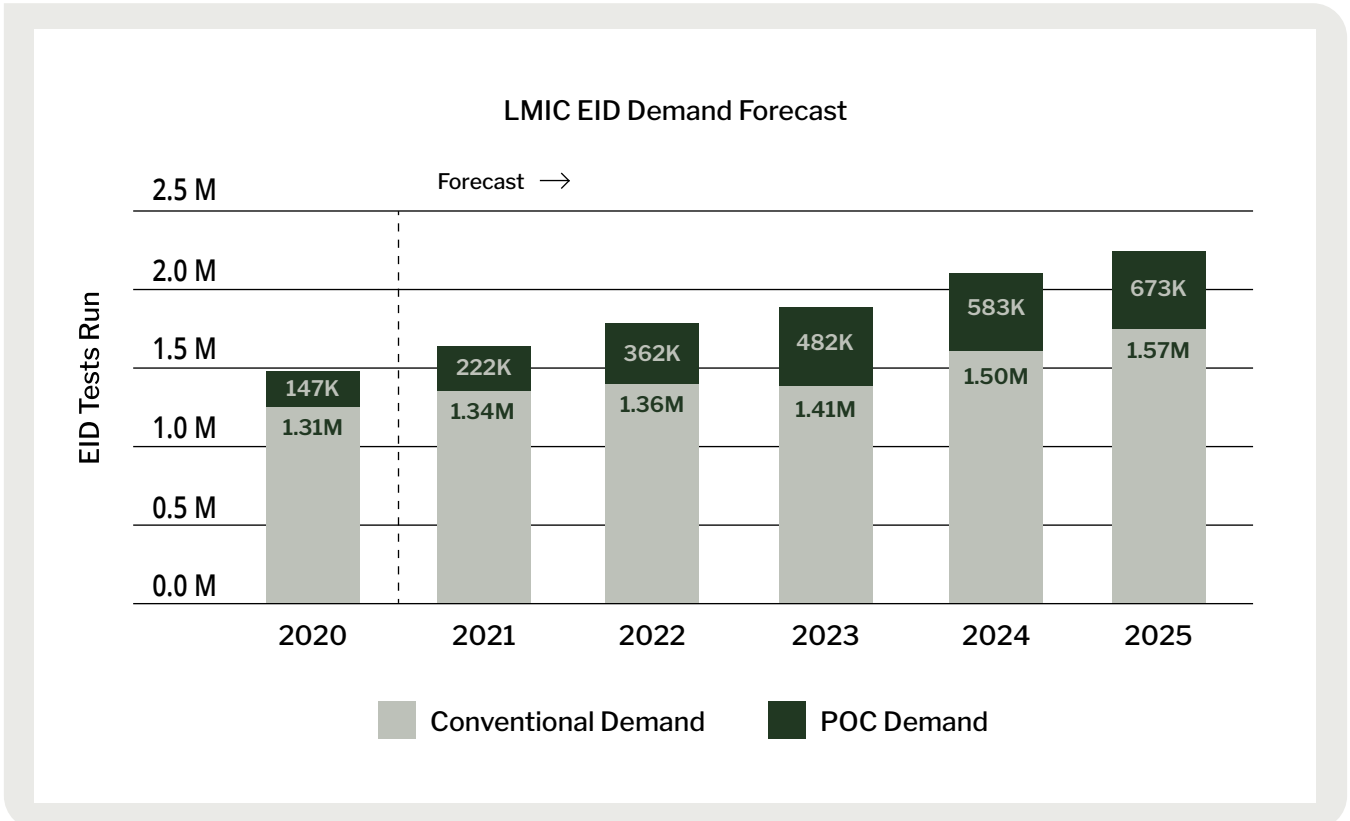
Fig. 2. Forecast for viral load testing demand for low- and middle-income countries



3.3. Early infant diagnosis tests

Fig. 3 shows the forecasted demand for early infant diagnosis tests through 2025. The projection assumes that programmes will expand their use of early infant diagnosis in accordance with WHO guidelines. Some countries are already adopting testing at birth as well as testing at non-prevention of mother-to-child transmission entry points. The dark blue columns estimate conventional laboratory-based demand and the light blue columns estimate point-of-care demand, which is expected to continue to scale up in the coming years.

Fig. 3. Forecast for early infant diagnosis demand for low- and middle-income countries



3.4. HIV testing

Fig. 4 shows the trends in the uptake for rapid diagnostic tests. The data on the use of rapid diagnostic tests were collected globally from country-specific reports from the 2014 through 2020. The projection is made by linear extrapolation for each of 110 countries reporting data. The country projections are aggregated to produce the total.

Fig. 4. Forecast for demand for rapid diagnostic tests and ELISA for low- and middle-income countries

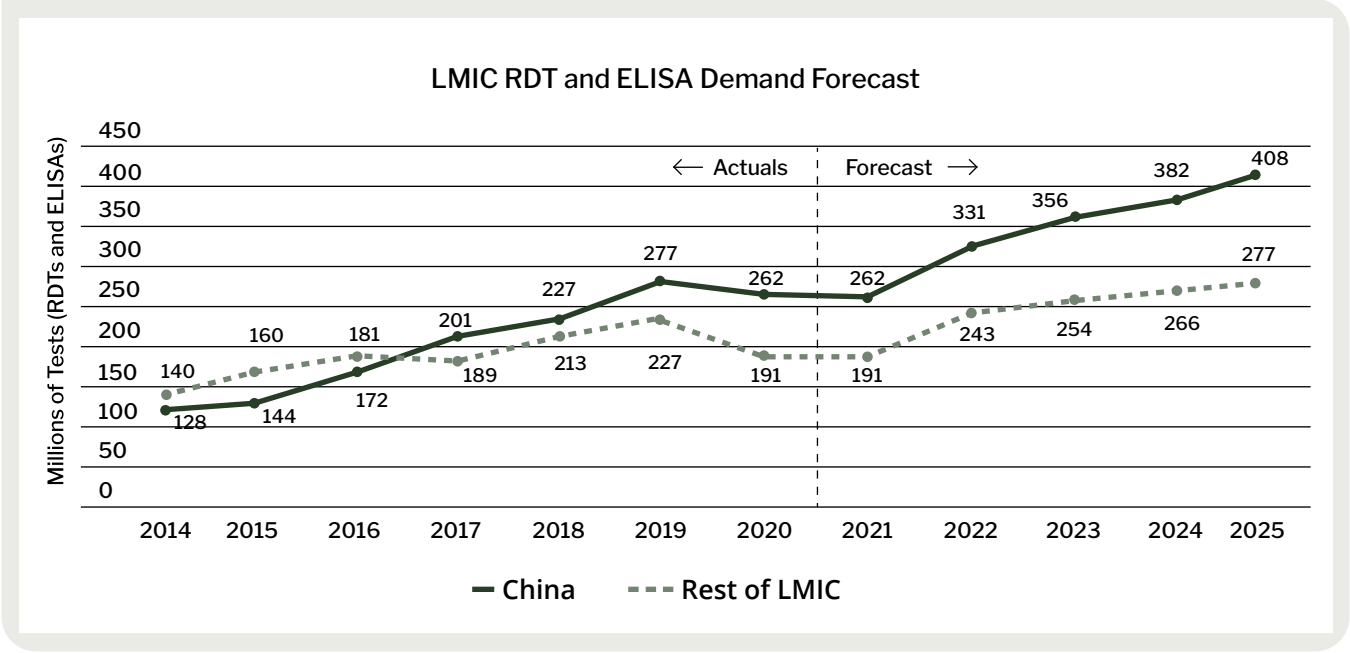


Table 1 shows the distribution of the demand for rapid tests in 2019 and 2020. The largest market is in China, followed by India, South Africa, Nigeria, and Mozambique. Note that most countries experienced a decline in testing volumes from 2019 to 2020 presumably due to COVID-19 associated disruptions. For the 68 countries reporting in both 2019 and 2020, 29% reported an increase from 2019 to 2020, 21% reported no change and 50% reported a decline.

Table 1. Distribution of rapid diagnostic tests used in 2019 and 2020

Country	2019	2020	% Change
China	277	262	-5%
India	51.2	38.8	-24%
South Africa	18.1	15.1	-16%
Nigeria	7.1	8.5	+20%
Mozambique	8.8	7.9	-10%
United Republic of Tanzania	10.6	7.8	-26%
Ethiopia	8.0	7.6	-6%
Turkey	10.3	7.1	-31%
Uganda	8.0	6.2	-21%
Zambia	5.8	5.6	-4%
Kenya	8.8	5.2	-41%
Rest of LMICs	87.5	80.2	-8%

SUMMARY

Summary of projected demand of diagnostic tests, 2020–2025

Type of test	Modality	2020	2021	2022	2023	2024	2025
CD4 tests	Total	6 377 000	5 869 000	5 560 000	5 428 000	5 339 000	5 052 000
Viral load tests	Conventional	20 346 000	23 420 000	26 360 000	28 330 000	30 514 000	32 068 000
	Point-of-care	416 000	536 000	627 000	736 000	859 000	979 000
	Total	20 762 000	23 956 000	26 987 000	29 066 000	31 373 000	33 047 000
Early infant diagnostic test	Conventional	1 312 000	1 337 000	1 358 000	1 405 000	1 495 000	1 567 000
	Point-of-care	147 000	222 000	362 000	482 000	583 000	673 000
	Total	1 459 000	1 559 000	1 720 000	1 887 000	2 078 000	2 240 000
HIV tests	China	262 000 000	262 000 000	331 000 000	356 000 000	382 000 000	408 000 000
	Rest of the low- and middle-income countries	191 000 000	191 000 000	243 000 000	254 000 000	266 000 000	277 000 000

- The demand for professional rapid diagnostic tests outside China may be nearing saturation – the market may still grow over the next six years but at a slow rate.
- HIV self-testing is likely to start having a more prominent role in determining the need for treatment (and prevention) interventions among HIV-negative people.
- **Viral load.** Demand for viral load tests continues to grow rapidly and could reach nearly 30 million by 2024 as more countries adopt viral load testing for routine monitoring that may be further enabled by the use of viral load point-of-care technologies and dried blood spots.
- **CD4 tests.** Conversely, demand for CD4 tests for routine monitoring is declining since most countries have adopted routine viral load for treatment monitoring.
 - However, there will continue to be a need for everyone starting treatment to receive CD4 testing to identify people with advanced HIV disease.
 - Additionally, CD4 for routine monitoring will be needed for people with limited access to viral load.
- **Early infant diagnosis tests.** Demand for early infant diagnosis tests will likely grow as point-of-care testing continues to scale up and countries adopt nucleic acid testing at nine months in accordance with the WHO guidelines.

For more information, contact:

World Health Organization
Department of HIV/AIDS
20, avenue Appia
1211 Geneva 27
Switzerland

E-mail: hiv-aids@who.int

www.who.int/hiv

