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| **REVISION 1 (23 June 2025) of the CEI has been issued to:**  **1. extend the closing date to 2 July 2025**  **2. revised the delivery timelines in Section III**  **Revisions in the CEI are made in ‘RED’ Colour** |

Call for Expression of Interest (CEI): HPV laboratory-based screening tests

**Invitation to manufacturers of HPV laboratory-based screening tests to submit an expression of interest for financial support to improve affordability of primary screening with HPV tests in low- and middle-income countries (LMICs).**

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| **Release Date** | **14 May 2025** |
| **Closing Date** | **25 June 2025 2 July 2025** |
| **Reference** | **MGL CEI 2025 - HPV laboratory-based screening tests** |
| **Submission** | [submissions@medaccess.org](mailto:submissions@medaccess.org) |

**DISCLAIMER**

This CEI is issued by MedAccess for planning purposes in respect of their market shaping activities only. MedAccess shall not be under any obligation to purchase or procure any of the services or products or provide any financial tools or volume guarantee (“VG”) to a Respondent and the issuing of this CEI shall not be deemed to be a commitment by MedAccess or to enter into commercial or other business relations.

Any information submitted in response to this CEI is provided to MedAccess on a voluntary basis. MedAccess may use the information provided by respondents to the CEI (“Respondent(s)”) to support strategic decisions, understand demand for the product and planning within their portfolio, or for their own internal purposes, including but not limited to, the design of future CEIs or other solicitations. Subject to the confidentiality undertakings set out in Section IV below, MedAccess may share such information with its potential market- shaping partners collaborating with MedAccess such as the Clinton Health Access Initiative (“Partners”), and MedAccess and its Partners may use the information with a view to assess suitability of a VG or another innovative financial tool.

All Respondents are solely responsible for their costs and expenses incurred in connection with the CEI including the preparation and submission of responses and participation in all future stages of this process. Under no circumstances will MedAccess be liable for any costs or expenses borne by a Respondent or any of its supply chain, partners or advisors in this process.

# Introduction

[MedAccess](https://medaccess.org/) Guarantee Ltd (“MedAccess”) is a social finance company established with the intention of making medical supplies more widely available at lower prices in underserved markets, specifically through the provision of financial tools to pharmaceutical companies.

Established in November 2017, MedAccess is a wholly-owned subsidiary of the British International Investment (“BII”), the UK’s Development Finance Institution and wholly owned by the UK Government. MedAccess has executed thirteen transactions to date supporting access to HIV, TB, malaria, COVID-19, NCD and Nutrition commodities.

# Purpose and Eligibility Criteria

HPV is a common sexually transmitted infection that affects the skin, genital area, and throat. While the immune system clears most HPV infections, high-risk HPV types can persist and cause abnormal cell development, which may progress to cancer.[[1]](#footnote-2) Research suggests that HPV causes more than 95% of cervical cancers, as well as the majority of other less common cancers affecting men and women including anal, vulvar, vaginal, mouth, throat and penile cancers.[[2]](#footnote-3) Despite being entirely preventable, cervical cancer still causes approximately 350,000 deaths each year, with 94% of these occurring in low- and middle-income countries (LMICs).[[3]](#footnote-4)

In 2020, the World Health Organisation (“WHO”) launched an initiative to eliminate cervical cancer by 2030. This initiative includes the 90-70-90 targets, which aim for 70% of women to undergo high performance screening tests at least twice in their lifetime. High performance tests are defined as those matching or exceeding the accuracy of HPV laboratory-based screening tests, as noted in the WHO’s Target Product Profile. The Target Product Profile can be found here ([click here](https://iris.who.int/bitstream/handle/10665/379099/9789240100275-eng.pdf)).[[4]](#footnote-5)

Manufacturers of HPV laboratory-based screening tests have worked with LMICs to make the tests available. Several challenges continue to hinder the widespread adoption of screening in LMICs resulting in limited scale-up. Current screening coverage averages just 19%, compared to 63% in high-income countries across all screening methods—not only high-precision tests.[[5]](#footnote-6)

MedAccess aims to explore whether volume guarantees, combined with implementation support in key markets, can enable manufacturers of HPV laboratory-based screening tests to reduce prices and improve affordability and access in LMICs. This Expression of Interest (EOI) invites manufacturers to submit proposals (using the form in the Appendix) outlining the product price they could offer across LMICs if they received support in the form of volume guarantees, implementation support, or other financing mechanisms. We are particularly interested in proposals that can leverage existing systems placed under the HIV programme and are compatible with HPV laboratory-based screening tests.

This invitation applies only to manufacturers whose products:

* are WHO pre-qualified; or
* Currently under review by the WHO prequalification of In Vitro Diagnostics Programme; or
* Approved by a Stringent Regulatory Authority; and
* Operate in a Polymerase Chain Reaction (“PCR”) or Transcription Mediated Amplification (“TMA”) system.

We are currently exploring a multi-year partnership that includes a volume guarantee from MedAccess and implementation support from partners. We are seeking proposals that bundle instrument, test and services costs into a single “all- inclusive price”. Please refer to Appendix D for an overview of components to include. In the section, please indicate the all-inclusive price per test you could offer in LMICs if you received a volume guarantee and implementation support.

# Submission Instructions

All EOIs must be submitted in English using the form provided in the Appendix and be signed (electronically or otherwise) by the authorised representative of the Respondent. Interested manufacturers should complete and return the Appendix form electronically to [submissions@medaccess.org](mailto:submissions@medaccess.org) by 25 June 2025 2 July 2025 with ‘MGL CEI 2025 – HPV laboratory-based screening tests – EOI: [name of the company]’ in the email subject line. MedAccess may request additional information to supplement or verify the information provided in the EOI, arrange interviews with the manufacturer and/or visit the manufacturer’s premises and facilities, if it deems necessary. MedAccess and its Partners may conduct high-level introductory calls with shortlisted Respondents.

The receipt timestamp is the date and time the submission has been received, as indicated by the log files of the email received. It is the sole responsibility of Respondent to ensure that the EOI and related documents are received on or before the prescribed deadline.

# Confidentiality

Information provided by the Respondent will be received by MedAccess and shared with its Partners including Clinton Health Access Initiative.  All information will be used for assessment purposes. Any information submitted in the EOI that needs to be treated as “confidential” should be clearly marked as such on the completed form by the Respondent. Where MedAccess and the Respondent have a non-disclosure agreement (“NDA”) in place, information marked confidential will be treated as Confidential Information in accordance with the terms of such NDA. Otherwise, when information is marked confidential, MedAccess will take all reasonable measures to keep the information confidential and will not share it with other entities or individuals outside MedAccess and its advisors without the respondent’s written authorization. This confidentiality commitment shall not apply if the information concerned, or any part of it: (a) was known to MedAccess prior to any disclosure by the Respondent; or (b) was in the public domain at the time of disclosure by the Respondent; or (c) becomes part of the public domain through no fault of MedAccess; or (d) becomes available to MedAccess from a third party who is not in breach of any legal obligation of confidentiality to the Respondent. If processing the EOI involves the recording and processing of personal data (such as name, address), such data will be processed pursuant to MedAccess’ privacy policy, which is available at <https://medaccess.org/privacy-policy/> . Information relating to the examination, clarification, and evaluation of EOI shall not be disclosed to other Respondents or any other persons not officially concerned with such process.

# Appendix: Manufacturer Proposal

**A. Company and Product Information**

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| **Table 1: Company and Product Information** | |
| **Company Name** | *[Company name]* |
| **Contact Point** | *[Name, title, email address, contact number]* |
| **WHO Pre-Qualification Date [or expected date]/ Other regulatory approvals** | *If WHO PQ obtained: [Approval date and WHO reference number]*  *If WHO PQ in progress: [dossier submission date, dossier type (product review or change notification)]* |
| **Manufacturing location(s) of HPV assay (reagents and consumables)** | *[Site Name, Address]* |
| **Production capacity and maximum production capacity** | *[Production capacity allocated per year for: instruments, HPV assays, and all necessary components for testing]*  *[Maximum production capacity allocated per year for: instruments, HPV assays, and all necessary components for testing]* |
| **Quality approvals** | *[e.g., ISO certification]* |

**B: HPV Assay and Instrument information**

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| **Table 2: Assay and Instrument information** | |
| **Screens** | *[DNA or mRNA]* |
| **Assay** | *[Product Name and Code (where applicable)]* |
| **HPV analyte type** | *[Genotypes tested; Extended genotyping]* |
| **Target population** | *[Target population]* |
| **Specimen type** | *[List of accepted samples]* |
| **Shelf life (of assay)** | *[Total product shelf life]* |
| **Relative clinical sensitivity** | *[XX%]* |
| **Relative clinical specificity** | *[XX%]* |
| **Kit size** | *[# assays per kit]* |
| **Storage conditions for Reagents & Consumables** | *[Temperature, storage requirements]* |
| **Instrument** | *[Product Name(s) and Code(s) where applicable; including any instruments that will supersede existing instrument and expected timelines to replace instruments in country]* |
| **Additional equipment** | *[Additional equipment and sample processing required to run HPV test. Please leave blank if not required]* |
| **Instrument compatible assays** | *[e.g., HIV, HBV, HCV, STIs etc.,]* |
| **Time to first result** | *[Time from sample processing to first result by instrument]* |
| **Throughput** | *[Tests conducted per 8-hour work shift by instrument]* |
| **Workflow requirements** | *[Overview of workflow, resources (physical and human) and steps required to run a test]* |
| **Self-sampling** | *[Self-sampling product if commercially available and if not available, expected timelines to launch self-sampling product including timelines to register product and conduct country validations]*  *[If self-sampling product is commercially available, please include supporting Instructions for Use and technical information]* |

**C: Information on key markets**

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| **Table 3: Key market information** | | | | | | |  |
|  | **Number of operational systems that can be used for HPV tests** | **Plans to introduce new or replacement systems** | **Average spare system capacity in current instruments (in the last 12 months)[[6]](#footnote-7)** | **Please provide details of any country specific or access programme commitments[[7]](#footnote-8)** | **Please provide details for any tenders for HPV you have recently submitted to or plan to submit** | **Please provide details of % of HPV test sales that are direct and distributor led.** | **What incoterms are in place for this country?** |
|  | *[# systems]* | *[# new systems to be introduced across a 2 year period]* | *[% average spare system capacity across all systems]* | *[Access incentives]* | *[Details of tender; timelines of tender]* | *[Direct: XX%; Distributor: XX%]* | *[Input country incoterms]* |
| **Rwanda** |  |  |  |  |  |  |  |
| **South Africa** |  |  |  |  |  |  |  |
| **Tanzania** |  |  |  |  |  |  |  |
| **Zambia** |  |  |  |  |  |  |  |
| **Zimbabwe** |  |  |  |  |  |  |  |
| **Botswana** |  |  |  |  |  |  |  |
| **Ghana** |  |  |  |  |  |  |  |
| **Kenya** |  |  |  |  |  |  |  |
| **Mozambique** |  |  |  |  |  |  |  |
| **Nigeria** |  |  |  |  |  |  |  |
| ***Other (please input below)[[8]](#footnote-9)*** |  |  |  |  |  |  |  |
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**D: Price volume matrix and all-inclusive model components (without and with a volume guarantee)**

Instructions for Table 4 and Table 5: Please input the components you currently include in your “all-inclusive price per test” as per your commercial plan in Table 4 and any other components in Table 5. For example, if you do not offer an all-inclusive price, please only complete the “Reagent and Consumable price per test ($)” in Table 4 and input other components in Table 5.

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| **Table 4:** **Price volume matrix without a volume guarantee (as per current commercial plan)** | | | | |
| **Target LMICs** | *[LMICs included in price volume matrix]* | | | |
| **Annual Sales Volume (tests completed for target LMICs)** | **Reagent and Consumable price per test ($)** | **Instrument price per test ($)**  **Note:** If only existing instruments are leveraged, the instrument price per test would be $0.[[9]](#footnote-10) | **Service and maintenance price per test ($)** | **Sample collection per test ($)** |
| **Included in all-inclusive model?** | *[Yes/ No]* | *[Yes/ No]* | *[Yes/ No]* | *[Yes/ No]* |
| **250,000** | *[$XX]* | *[$XX]* | *[$XX]* | *[$XX]* |
| **500,000** | *[$XX]* | *[$XX]* | *[$XX]* | *[$XX]* |
| **1,000,000** | *[$XX]* | *[$XX]* | *[$XX]* | *[$XX]* |
| **1,250,000** | *[$XX]* | *[$XX]* | *[$XX]* | *[$XX]* |
| **[Other]** | *[$XX]* | *[$XX]* | *[$XX]* | *[$XX]* |

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| **Table 5: Price volume matrix without a volume guarantee: Components not included in all-inclusive model** | |
| **Target LMICs** | *[LMICs included in price volume matrix]* |
| **Cost component** | **Price ($)**  **Note:** Only complete for components not included in all-inclusive model in table 4. |
| **Instrument** | *[Price per system]* |
| **Service and maintenance** | *[Price per system, account or appliable unit]* |
| **Samplecollection** | *[Price per test]* |
| ***Other (please input below)*** | *[Price per unit]* |
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Instructions for Table 6 and Table 7: Please input the components that will be included in your “all-inclusive price per test” if MedAccess is able to offer volume guarantee support in Table 6 and any other components in Table 7. For example, if the all-inclusive price with MedAccess’ support includes Reagent and Consumables, Service and Maintenance, Instrument and Sample collection costs, please do not input these components in Table 7.

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| **Table 6:** **Price volume matrix with a volume guarantee[[10]](#footnote-11)** | | | | |
| **Target LMICs** | *[LMICs included in price volume matrix]* | | | |
| **Annual Sales Volume (tests completed for target LMICs)** | **Reagent and Consumable Price per test ($)** | **Instrument price per test ($)**  **Note:** If only existing instruments are leveraged, the instrument price per test would be $0. | **Service and maintenance price per test ($)** | **Sample collection per test ($)** |
| **Included in all-inclusive model?** | *[Yes/ No]* | *[Yes/ No]* | *[Yes/ No]* | *[Yes/ No]* |
| **250,000** | *[$XX]* | *[$XX]* | *[$XX]* | *[$XX]* |
| **500,000** | *[$XX]* | *[$XX]* | *[$XX]* | *[$XX]* |
| **1,000,000** | *[$XX]* | *[$XX]* | *[$XX]* | *[$XX]* |
| **1,250,000** | *[$XX]* | *[$XX]* | *[$XX]* | *[$XX]* |
| **[Other]** | *[$XX]* | *[$XX]* | *[$XX]* | *[$XX]* |

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| **Table 7: Price volume matrix with a volume guarantee: Components not included in all-inclusive model** | |
| **Target LMICs** | *[LMICs included in price volume matrix]* |
| **Cost component** | **Price ($)**  **Note:** Only complete for components not included in all-inclusive model in table 6. |
| **Instrument** | *[Price per system]* |
| **Service and maintenance** | *[Price per system, account or appliable unit]* |
| **Sample collection** | *[Price per test]* |
| ***Other (please input below)*** | *[Price per unit]* |
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**E: Additional questions (optional)**

Please answer as many questions as possible and relevant in the questionnaire.

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| **Table 8: Additional questions** | | |
| **Instruments** | Could you provide details of any existing Service Level Agreements (SLAs) including parties involved and details of the SLA? | *[Parties involved and services included in SLA]* |
| What challenges do you anticipate with integrating HPV testing on HIV platforms? | *[Anticipated challenges]* |
| **Sales** | Could you share your historical sales data for 2021–2024, including the following:  How many HPV tests were sold? Which geographies and countries purchased these tests? What proportion of total sales was public vs. private? What proportion of total public sales was funded by the US government? | *[Number of tests sold, Country, Purchaser]* |
| **Partnerships and programmes** | Could you provide information on any existing partnerships with global health organisations or initiatives that are supporting efforts to further enable access to HPV testing? | *[Details of partners and scope of partnership]* |
| **Private sector** | How critical is private sector purchasing in achieving sales targets for HPV testing? | *[Assessment of role of private sector in achieving sales targets]* |
| |  | | --- | |  |   If information is available, how are tests currently being paid for in the private sector (e.g., out-of-pocket payments, national health insurance, government subsidies)? | *[Number of tests sold, Country, Purchaser]* |
| If different from the prices listed in Appendix D, could you provide the price range for HPV tests? | *[Price range, components included in prices]* |

**F: Additional Comments**

*[Space to provide any further commentary (e.g. interest in and motivation for working with MedAccess, past experience implementing similar partnerships)].*

1. There are 14 types of HPV that are considered high risk for cervical cancer. Two of these types, HPV 16 and HPV 18, cause ~70% of all cervical cancer cases. [↑](#footnote-ref-2)
2. UNICEF. 2024. 5 fast facts about HPV and cervical cancer. Published online at unicef.org. Accessed: November 2024 ([link](https://www.unicef.org/stories/fast-facts-hpv-cervical-cancer)) [↑](#footnote-ref-3)
3. The Cancer Atlas. 2024. Sub-Saharan Africa cervical cancer. Published online at canceratlas.cancer.org. Accessed: December 2024 ([link](https://canceratlas.cancer.org/the-burden/sub-saharan-africa/)) [↑](#footnote-ref-4)
4. Target product profiles for human papillomavirus screening tests to detect cervical pre-cancer and cancer. Accessed: January 2025 ([link](https://iris.who.int/bitstream/handle/10665/379099/9789240100275-eng.pdf)) [↑](#footnote-ref-5)
5. Z Petersen et al. 2022. Barriers to uptake of cervical cancer screening services in low- and middle-income countries: a systematic review. Published online at pmc.ncbi.nlm.nih.gov. Accessed: November 2024 ([link](https://pmc.ncbi.nlm.nih.gov/articles/PMC9716693/#CR4)) [↑](#footnote-ref-6)
6. Assumes an 8-hour work shift. [↑](#footnote-ref-7)
7. This could include volume or price commitments to the market or specific agreements with Ministries of Health. [↑](#footnote-ref-8)
8. Please add any other priority markets you wish to include in Sub-Saharan Africa, Asia Pacific and Latin America. [↑](#footnote-ref-9)
9. At this stage this will only be used to indicate the ability to utilise existing systems for tests. We understand that if HPV tests are run on existing systems, there may be a need to include an instrument price per test, which will be determined during proposition diligence. [↑](#footnote-ref-10)
10. The proposed pricing with a volume guarantee is not final and is up for further discussion and negotiation at a later stage. [↑](#footnote-ref-11)