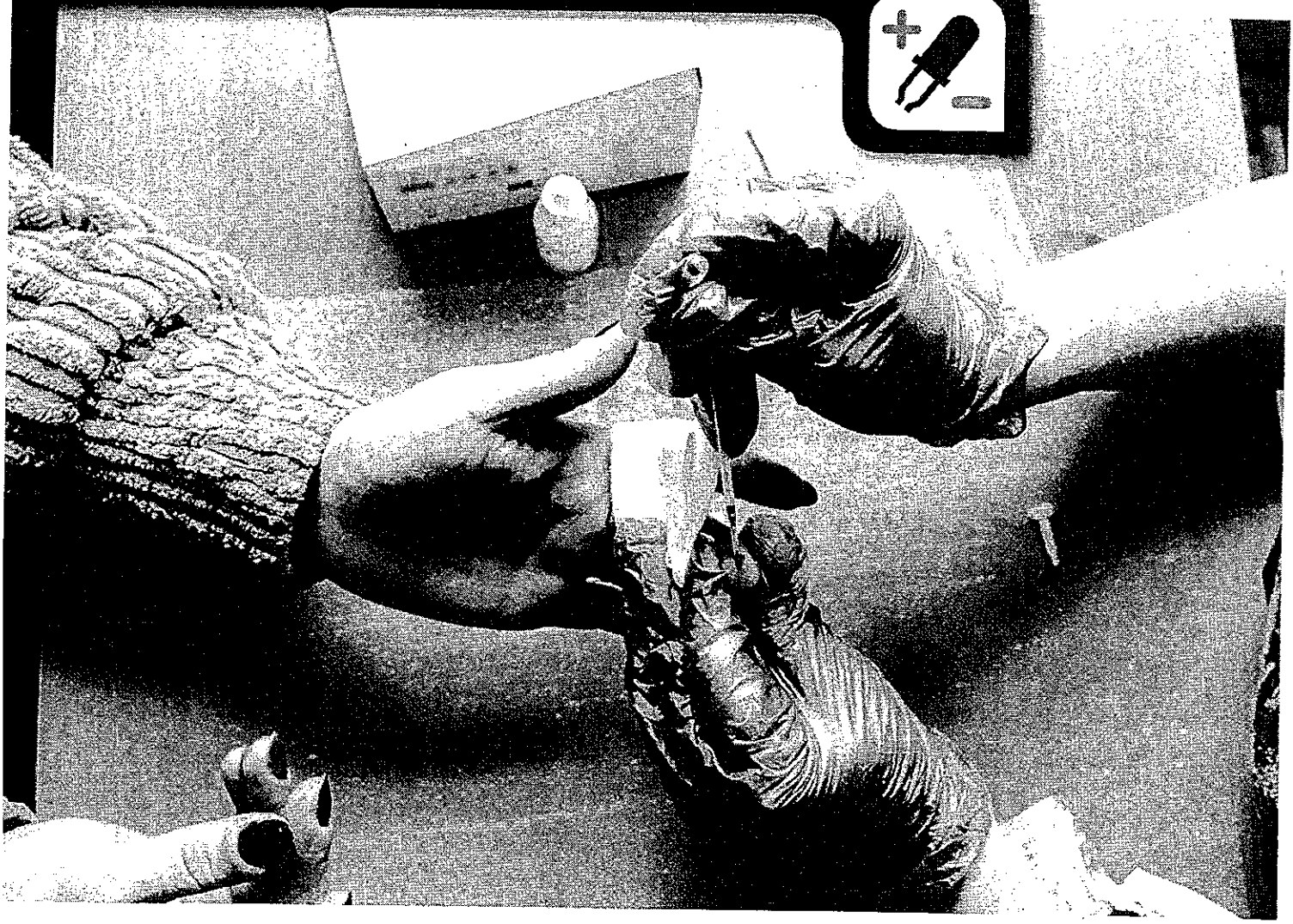
POLICY BRIEF

WHO RECOMMENDS COUNTRIES MOVE AWAY FROM THE USE OF WESTERN BLOTTING AND LINE IMMUNOASSAYS IN HIV TESTING STRATEGIES AND ALGORITHMS

NOVEMBER 2019



World Health Organization

The World Health Organization (WHO) recommends replacing western blotting and line immunoassays with simpler tests in HIV testing services. These simpler tests include rapid diagnostic tests (RDTs) that can be used at the point-of-care, and enzyme immunoassays (EIAs). These tests get results to the client faster, produce accurate results more often, cost less, can be performed by various cadres of health providers, and can thus facilitate greater access and uptake of HIV testing services among those who need it most.

NEW

WHO Recommendation

Western blotting and line immunoassays should not be used in HIV testing strategies/algorithms.

(strong recommendation, low quality evidence).

Rationale for the new recommendation

Globally one in five people with HIV still do not know their status. Many people with HIV who do not know their status are from key populations and other vulnerable groups that often find it difficult to access health services, including HIV testing. Further efforts are needed to expand HIV testing services for these populations and others. At the same time, testing itself should be optimized to produce quick and reliable results.

Worldwide, most people are diagnosed with HIV using testing strategies that include RDTs only. However, in some countries western blotting and line immunoassays, which are longstanding laboratory-based technologies, are still used as the second or third test in national testing algorithms to confirm HIV infection. This is common in a number of countries within the European region and other high-income settings as well as in parts of the South-East Asia, Western Pacific and Eastern Mediterranean regions. In these regions, knowledge of HIV status is generally low, hampering uptake of antiretroviral therapy (ART) among people with HIV or prevention services for those at high ongoing risk.

Moving away from western blotting and rolling-out HIV rapid diagnostic testing algorithms in Kyrgyzstan

In 2016, Kyrgyzstan revised their national HIV testing policy and included a simplified HIV testing strategy aligned with WHO recommendations. Through this policy, western blotting was phased out across the country, and replaced with testing strategies/algorithms using a combination of HIV rapid diagnostic tests (RDTs) and enzyme immunoassays (EIAs). Because of this shift, HIV testing is being integrated into primary care, as well as in community settings.

Since the introduction of this new strategy, the turnaround time between testing and receiving final HIV diagnoses reduced from 4-6 weeks to 1-2 weeks. Cost of HIV testing services reported by the national programme have also considerably decreased.

Continued efforts are needed to provide fast and accurate diagnoses so more people with HIV can access treatment, and those who are HIV negative can benefit from prevention services.

Source: Republican AIDS Centre of Kyrgyzstan, WHO Regional Office for Europe, 2019.

Disadvantages of western blotting and line immunoassays

For western blotting/line immunoassays, specimens are collected in a health facility by venepuncture, processed and then sent to a laboratory, where highly skilled staff perform the test. The laboratory then sends the test results to the referring facility, which contacts the client, so they can deliver the result.

Compared with RDTs, which provide same-day diagnosis, it takes longer to provide the final HIV status to the client with testing strategies or algorithms that include western blotting/line immunoassays. Interpretation of the test result and final HIV status with western blotting/line immunoassays can also be complex. Indeterminate results are common, leaving affected clients without a definitive diagnosis and the need to return for retesting.

HIV testing services delivered with western blotting/line immunoassays will not be able to increase access to and uptake of HIV treatment and prevention services among those in greatest need. The time to conduct western blotting/line immunoassays, interpret the results and to return test results to clients is resource intensive, from both a cost and human resource perspective. These same factors also lead to delayed or no ART initiation resulting in lost to follow-up along the testing and treatment pathway.

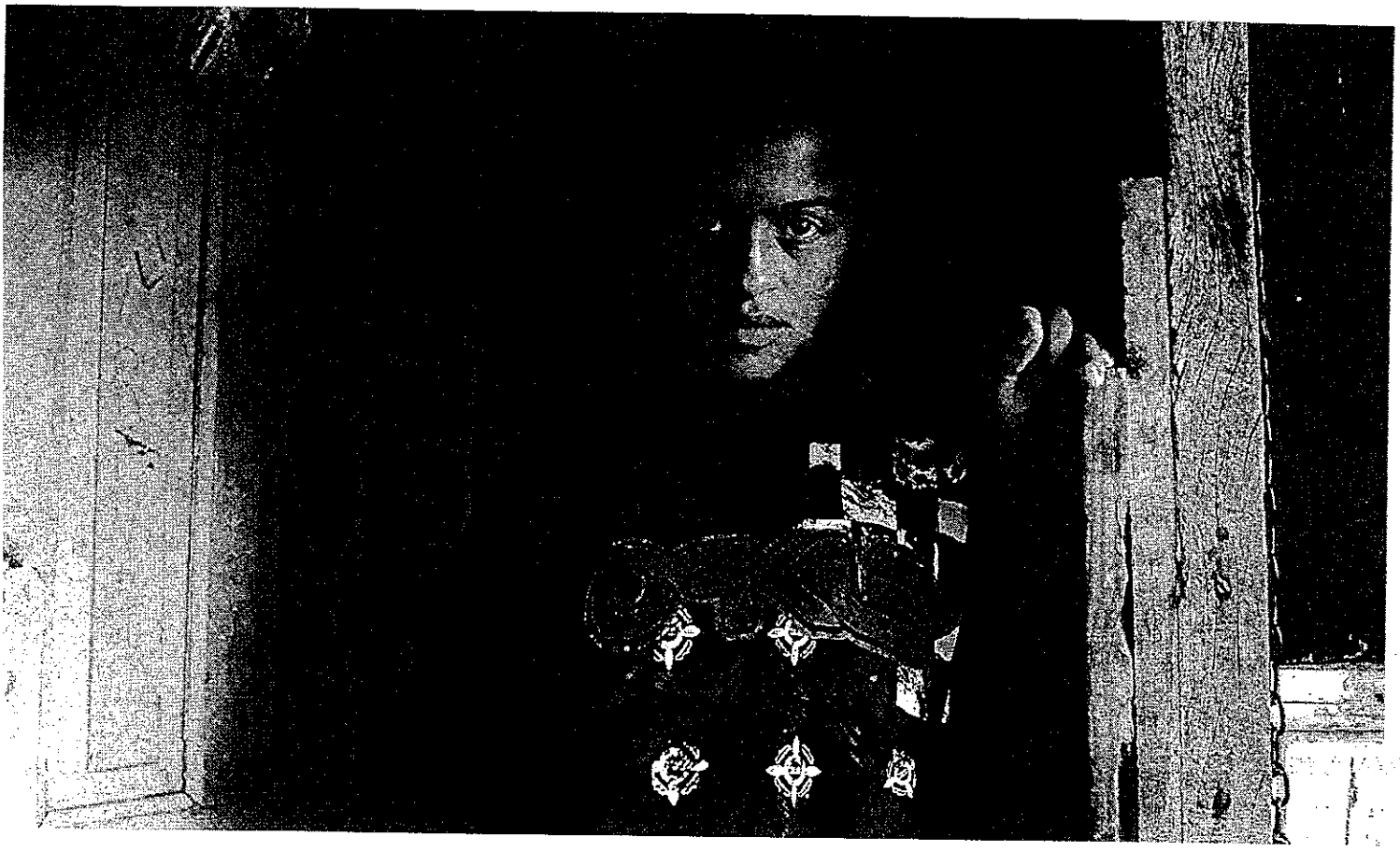
Evidence favours discontinuation of western blotting/line immunoassays for HIV diagnosis

WHO commissioned a systematic review to compare testing strategies that include western blotting/line immunoassays with those that only use a combination of HIV RDTs and/or EIAs. The review found similar accuracy (sensitivity and specificity), but that testing algorithms with western blotting/line immunoassays led to more HIV-indeterminate results, requiring more clients to return for retesting 14 days later. Nearly half of all indeterminate results identified were among people with HIV, and therefore they were unable to start ART quickly.

A client's perspective on western blotting

I took a rapid [HIV] test and it turned out to be reactive. The counselor explained I had to take a "western blot" test [to confirm my diagnosis], which is only available at the hospital. It took five weeks to get the final results and it was a nightmare, I even regretted taking the HIV test!

Source: Association de Lutte Contre le Sida (ALCS), Morocco



For those with conclusive test results, whether positive or negative, including western blotting led to longer turnaround time between testing and receiving a final HIV diagnosis, increased loss to follow-up and delayed linkage to treatment.

Testing strategies that included western blotting/line immunoassays were **costlier** and **less preferred** by both clients and providers. Use of HIV RDTs and EIAs alone were strongly preferred as they were accurate, convenient and enabled clients to get their results faster.

Based on this evidence, WHO recommended against the use of western blotting/line immunoassays in routine HIV testing services. **Countries should move away from western blotting or line immunoassays.**

Use of testing strategies that do not include western blotting/line immunoassays is highly feasible and already implemented in most settings. Testing strategies that only include RDTs require less infrastructure and can be performed by various cadres of health workers, including trained lay providers and community health workers. The switch to non-western blot/line immunoassay containing strategies can facilitate immediate initiation of ART and streamline the offer of pre-exposure prophylaxis (PrEP), as well as support the expansion and decentralization of HIV testing services including community-based testing. This is also likely lead to greater equity and uptake among people with HIV who do not know their status.

Many countries have made the shift away from western blotting/line immunoassays, a few of them in recent years. The countries where western blotting/line immunoassays remain the standard of care should plan to make the switch. These countries may need support to make the transition to updated testing strategies/ algorithms and to select replacement assays. Reviewing and selecting assays to take the place of western blotting/line immunoassays requires time and resources in the short term but will achieve greater impact for clients and reduce future costs.

Implementation considerations

- Many HIV RDTs or EIAs can replace western blotting and line immunoassays. The critical task is to verify that the new test selected works well in combination with the other two tests in the algorithm. Most important is to maximize the specificity of the products chosen as the second and third tests in a strategy/algorithm. Countries should review and consider products listed by WHO prequalification: https://www.who.int/diagnostics_laboratory/evaluations/pq-list/hiv-rdts/public_report/en/.
- The move away from western blotting/line immunoassays will facilitate task sharing with health providers, as well as community workers, enabling more people in need of HIV testing to be served with fewer resources. Efforts will be needed to support and reorient the role of laboratories, so they can take on broader roles around supportive supervision and other aspects of quality assurance.
- The transition away from western blotting/line immunoassays will require national policy change and training of staff. These changes should be linked to broader efforts to scale-up rapid ART initiation and access to HIV prevention services. Consultation with communities and other stakeholders will be critical.
- Promoting, and providing messages to communities, on the shift to faster, more accurate test results may help to increase demand for HIV testing services, particularly among key populations and populations where the burden of undiagnosed HIV is the greatest.

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主旨：有關貴公司所詢醫療器材伯瑞金能滋愛滋病毒確認檢驗試劑組（衛部醫器輸字第029600號）相關健保給付疑義，復如說明，請查照。

說明：

一、依貴公司107年5月7日伯瑞字第1070501號函辦理。

二、查全民健康保險醫療服務給付項目及支付標準（以下稱支付標準）中HIV抗體檢驗項目為編號14075C「HIV-I抗體檢查(西方墨點法)」及14076C「HIV-II抗體檢查(西方墨點法)」，其檢驗原理與貴公司所詢試劑所用之免疫層析試驗不同，建議貴公司可依新增診療項目相關程序，請本保險特約醫事服務機構、相關醫學會或相關單位提出申請。

三、新增公告前，本保險特約醫事服務機構可依支付標準總則五規定：「各保險醫事服務機構實施本標準未列項目，應就適用之類別已列款目中，按其最近似之各該編號項目所訂點數申報，惟新療法須經保險人報由中央主管機關核定後實施」申報。

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