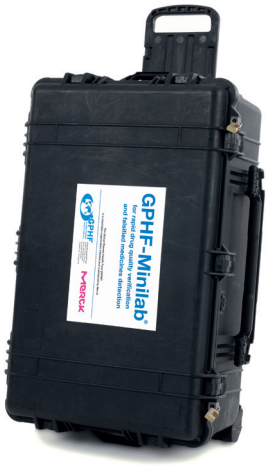
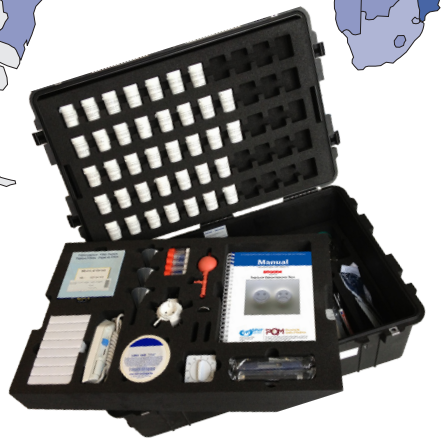
Global use of GPHF-Minilabs for the detection of falsified and substandard medicines





Africa	
Djibouti	1
South Africa	1
Swaziland	1
Benin	2
Cape Verde	2
Congo PR	2
Guinea-Equatorial	2
Lesotho	2
Namibia	2
Botswana	3
Chad	3
Gambia	3
Ivory Coast	3
Mauritania	3
Sudan	3
Central African Republic	4
Eritrea	4
Gabun	4
Guinea-Bissau	4
Zimbabwe	4
South Sudan	5
Togo	5
Somalia	6
Burkina Faso	7
Malawi	7
Niger	7
Burundi	9
Guinea-Conakry	11
Liberia	11
Sierra Leone	11
Uganda	12
Rwanda	13
Zambia	14
Senegal	17
Mali	18
Mozambique	19
Kenya	20
Cameroon	21
Angola	22
Madagascar	24
Ethiopia	27
Ghana	36
Congo DR	37
Tanzania	57
Nigeria	65
	534

Asia	
Georgia	1
Mongolia	1
Sri Lanka	1
Tadzhikistan	1
Uzbekistan	1
West Bank & Gaza	1
Bhutan	2
Maldives	2
Kyrgyztan	3
Nepal	3
Kazakhstan	5
Bangladesh	12
Thailand	16
India	17
Pakistan	18
Cambodia	19
Afghanistan	23
Myanmar	26
Laos	29
Vietnam	62
	243

America	
Belize	1
Grenada	1
Guatemala	1
St. Lucia	1
Virgin Islands (brit.)	1
Brazil	2
Nicaragua	2
Surinam	2
Venezuela	3
Ecuador	4
Bolivia	5
Peru	6
Guyana	6
Haiti	7
USA*	9
Colombia	11
	62

Pacific	
Fiji Islands	1
Samoa	1
Timor Leste	1
Australia*	2
Taiwan*	3
China*	4
Papua New Guinea	9
Indonesia	20
Philippines	29
	70

Europe	
Belgium*	1
Great Britain*	1
Italy*	1
Netherlands*	1
Norway*	1
Spain*	1
Switzerland*	2
Germany*	8
Russia*	9
	25

1
2-3
4-9
10-19
≥ 20

Global
934

The GPHF-Minilab™

A mini-laboratory developed by the Global Pharma Health Fund (GPHF) to boost the medicines testing capacity at healthcare providers in developing countries. Focus on priority essential medicines, for example antiinfectives. Non-sophisticated, affordable and fit for use in the field. Supplied over 900 times to 99 countries. Minilabs save lives. For more, go to **www.gphf.org**.

GPHF
GLOBAL PHARMA HEALTH FUND E.V.

A charitable organisation voluntarily supported by Merck KGaA Darmstadt (Germany)

* For training and demonstration purposes only | Latest update January 2022

GPHF-Minilab Project

Proliferation of falsified medicines constitutes serious health hazards. The World Health Organization (WHO) estimates that a disturbing proportion of more than 10% of all medicines offered in low and middle income countries are either fake or of deficient quality already.

To prevent falsified and substandard anti-infective medicines infiltrating drug supply organisations and priority disease programmes in malaria, TB and HIV/AIDS endemic countries, the Global Pharma Health Fund (GPHF) in Frankfurt, a charity voluntarily supported by Merck KGaA Darmstadt (Germany), set out to develop and supply at low cost the GPHF-Minilab™, a mini-laboratory mainly based on thin layer chromatography for rapid drug quality verification and easy detection of falsified and poor quality medicines where the contents are different, much higher or lower than indicated. Test protocols advise to start with a physical inspection to verify label claims on product identity and source. Physical inspection could include a check on total tablet and capsule weight as well as a simplified disintegration test to screen for obvious deficiencies on drug release. The screening methods presented are semi-quantitative only and cannot replace fully-fledged laboratory testing. Any deficiencies observed on drug identity, content and release must be confirmed by compendial tests prior to legal actions.

The screening methods are non-sophisticated and inexpensive. The Minilab provides manuals with appropriate test protocols to safeguard correct sample treatment and interpretation of assay readings on each individual compound. The tests can be performed outside a laboratory environment and do not need to be carried out by fully-fledged qualified pharmacists, chemists, but by those having some understanding of analytical chemistry, for example medical or pharmaceutical technicians. Training is not essential but may help operators to understand the concept of rapid screening better, refresh laboratory practice hardly used in the past and build confidence in assay generation, reading and interpretation. Beyond the Minilab itself, such a training will help staff to recognize and conduct the principles of good sample collection, laboratory practices and data reporting.

GPHF-Minilabs contain the essential lab ware, chemicals and reference samples. The use of solvents has been driven to its sheer minimum. Supplies include sufficient quantities in order to perform about a thousand assays while ensuring that the total material costs for one test run do not exceed four Euros. One heavy-duty flight case contains the essential components - a full range of glassware for sample extraction, preparation, pipetting and spotting, chromatographic plates, developing and detection chambers, UV lamps with different wavelengths, a hot plate, storage containers and an electronic pocket balance. Even pens and pencils are included. Of particular importance are a full collection of reference agents for 102 active pharmaceutical ingredients and a set of manuals providing simple test protocols. Written in a non-scientific format and rich in illustrations, the manuals read more like a cooking recipe than an instruction booklet. They are also available in French and Spanish.

Since 24 years, GPHF-Minilabs are assisting health authorities, programmes and facilities in various countries and regions to protect patients against counterfeit and substandard medicines threatening the health of millions of people living in developing nations. Overall, more than 900 Minilabs have been supplied across 99 countries already. There, they help to boost medicines testing capacity. Funding and implementation facilities were so far the United Nation family (UNICEF, UNODC, WHO, RBM), the Global Fund (AMFm), the United States (USP/PQM, USAID), Great Britain (PATHS2), Switzerland (SCIH), Belgium (BTC) and Germany (GIZ/PTB). Faith-based organisations are procuring GPHF-Minilabs frequently on behalf of the Ecumenical Pharmaceutical Network (EPN) for own health services and partner hospitals as beneficiaries in Africa. In various health sectors across the globe, more than 20.000 samples have been screened with the GPHF-Minilab in the recent past. From this, one thousand samples have been identified of being fake or of extreme poor quality. Minilab data on falsified antimalarial and antibacterial medicines with no active principle have prompted several WHO Medical Product Alerts already.

GPHF
GLOBAL PHARMA HEALTH FUND E.V.

Global Pharma Health Fund
Frankfurt, Germany
Tel.: +49-69-46939-662
Fax: +49-69-46939-852
info@gphf.org · www.gphf.org

MERCK

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