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LOGISTICS FACT SHEETS: GPHF-Minilab[®] and CD4 Machines (FACSCCount[™] and Guava Easy CD4[™])



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DELIVER
No Product? No Program. Logistics for Health

DELIVER

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Implemented by John Snow, Inc. (JSI), (contract no. HRN-C-00-00-00010-00) and subcontractors (Manoff Group, Program for Appropriate Technology in Health [PATH], and Crown Agents Consultancy, Inc.), DELIVER strengthens the supply chains of health and family planning programs in developing countries to ensure the availability of critical health products for customers. DELIVER also provides technical management of USAID's central contraceptive management information system.

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Abstract

The lab fact sheets provide information about two types of CD4 machines (FACSCount[™] and Guava Easy CD4[™]) and the GPHF-Minilab[®].

DELIVER

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LOGISTICS FACT SHEETS: CD4 MACHINES AND GPHF-MINILAB[®]

FACSCOUNT[™]



MANUFACTURER INFO

BD Biosciences
2350 Qume Drive
San Jose, CA 95131-1807
USA
Tel: +1-877-232-8995
www.bdbiosciences.com

Technical Assistance
BD East Africa Ltd
Africa Re Centre,
Hospital Rd., Upper Hill
P. O. Box 76613-00508
Nairobi, Kenya
Tel: 254-20-2738339
Fax: 254-20-2738342

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MATERIALS PROVIDED WITH START-UP PACKAGE

- dedicated instrument system for CD4, CD8, and CD3 absolute counting
- automated analysis software (available for CD4/CD8 or only CD4)
- coring station
- electronic pipette
- workstation for holding blood samples and supplies during sample and control preparation
- spares kit containing replacement parts and consumables.

OPTIONS

- barcode reader

MATERIALS NOT PROVIDED WITH START-UP PACKAGE

- vortex mixer

MATERIALS REGULARLY CONSUMED

- FACS Flow (Catalog No. 342003)
- FACS Clean (Catalog No. 340345)
- FACS Rinse (Catalog No. 340346)
- FACS Control Kit (Catalog No. 340166)
- pipette tips
- K₃ or K₂ EDTA BD Vacutainer[™] brand blood collection tubes
- disposable gloves
- chlorine bleach
- distilled water
- biosafety materials.

PRECISION/REPORTABLE RANGE

- <10% coefficient of variation for:
CD4 results between 50 and 2,000
CD8 results between 100 and 2,000
CD3 results between 100 and 3,500.

RESULTS PROVIDED

- CD4 absolute count
- CD8 absolute count
- CD3 absolute count
- CD4/CD8 ratio
- CD4/CD3 ratio (if using single tube CD4 software/reagents)
- (no CD4 percentage capability).

TIME TO RESULT

- 70 minutes (5 minutes for preparation, 60 minutes for incubation, 5 minutes for instrument run)
- maximum sample throughput:
 - >15 patients/hour for CD4 ≥ 400 (fewer patients/hour with lower CD4 count)
 - >30 patients/hour for CD4 ≥ 400 (if only using single tube for CD4)
- maximum samples per run: 1.

SPACE REQUIREMENTS

Instrument:

- Width: 43.2 cm (17 in)
- Height: 38.1 cm (15 in)
- Depth: 55.9 cm (22 in)
- Weight: 25.9 kg (57.1 lbs) (when fluid reservoirs are empty).

Workstation:

- Width: 48.3 cm (19 in.)
- Height: 9.1 cm (3.6 in.)
- Depth: 18.5 cm (7.3 in.)

REGULATORY STATUS

- Approved by FDA for in vitro diagnostic
- Single tube for CD4: for export only, not for sale or distribution in U.S.

REAGENT AND QUALITY CONTROL COMMODITY INFORMATION

Reagents (2 reagent kits are available):

- CD4/CD8 reagent kit
 - Includes: premeasured CD4/CD3 reagent tubes, premeasured CD8/CD3 reagent tubes, counting beads, tube caps, and fixative
 - Available in 50 tests/kit
 - Two premeasured reagent tubes and counting beads required per test (CD4/CD3 and CD8/CD3)
- Single tube CD4 reagent kit
 - Includes: premeasured CD4/CD3 reagent tubes, counting beads, tube caps, and fixative
 - Available in 50 tests/kit
 - One premeasured reagent tube and counting beads required per test (CD4/CD3)

Quality controls:

- Control bead kit (use daily)
 - Includes: zero, low, medium and high concentrations of control beads
 - Available in 25 runs/kit
 - Two reagent pairs (4 tubes for CD4 and CD8, 3 tubes for single tube CD4) plus control beads required per control run

COST

- Instrument: \$27,000*
- Reagents:
 - CD4/CD8: \$6/test*
 - Single Tube CD4: \$4.50/test*
- Quality Controls: \$7-8.80/run,* depending on volume (slightly cheaper for single tube CD4)
 - * Average price in Africa. Excludes freight, duties, taxes, and distribution.

SHELF LIFE

Reagents

- 15 months from manufacture
- Reagents are guaranteed to have 6 months shelf life when leaving San Jose, Puerto Rico, and 5 months when arriving in Africa.

Quality controls

- 18 months from manufacture
- Reagents are guaranteed to have 7 months shelf life when leaving San Jose, Puerto Rico, and 6 months when arriving in Africa.

STORAGE REQUIREMENTS

Conditions for reagents and quality controls:

- 2–8°C (36–46°F)

Packaging:

- Reagents
 - Width: 18.7 cm (7.4 in.)
 - Height: 18.4 cm (7.3 in.)
 - Depth: 10.3 cm (4.1 in.)
- Quality Controls
 - Width: 18.7 cm (7.4 in.)
 - Height: 4.3 cm (1.7 in.)
 - Depth: 12.7 cm (5 in.)

SAMPLE INFORMATION

Blood stability:

- 48 hours after drawn if stored at room temperature

Sample stability:

- 48 hours after preparation when stored at room temperature

Blood sample volume required:

- 100 µL (50 µL for single tube CD4)

OPERATIONAL CONSIDERATIONS

- Software and reagents are available for single tube CD4 tests (CD4/CD3 only) to reduce cost; software for CD4/CD8 capability and for CD4-only capability cannot run concurrently.
- Includes 1 day of onsite installation and training.
- Includes computer-based training and user's guide.
- Strong technical support, including an Africa-based technical assistance unit.
- Regional workshops on good laboratory practice are offered.
- Minimum order of 20 kits offers the best value for shipping, but there is no required minimum order.
- One year warranty (costing \$5,000) includes two preventative maintenance visits and two urgent repair visits.
- Additional visits are invoices for travel costs only; defective parts replaced free of charge.
- This technology does not offer CD4 percentage.

LOGISTICS FACT SHEETS: CD4 MACHINES AND GPHF-MINILAB®

GUAVA EASYCD4™



MANUFACTURER INFO

Guava Technologies
25801 Industrial Boulevard
Hayward, CA 94545
USA

Customer Service Department:
Tel: +1-510-576-1400 (overseas)
+1-866-448-2827 (U.S. toll free)
Fax: +1-510-576-1500

Field Office
Kenya
Guava Technologies
Vision Plaza, 2nd Floor
Suite 18, Mombasa Road
P.O. Box 8545-00200
Nairobi
Tel: +254-20-828-893

MATERIALS PROVIDED

- Guava Personal Cell Analyzer (PCA™) with laptop, connections, and software
- 100 test kit reagents for CD4
- 100 test kit reagents for CD8
- 500 microcentrifuge tubes (1.5 mL) and matching caps
- 1 bottle of instrument cleaning solution (100 mL) (~6 months supply)
- Guava Check beads (~3–4 months supply)
- 1 extra flow cell (microcapillary flow cell)
- tool for cleaning and tool for removing the flow cell
- user's guide
- plastic cover for system and laptop keyboard
- 2–3 days of training from a field representative.

MATERIALS NOT PROVIDED

- pipettes (p20 and p200) and matching pipette tips
- vortex mixer
- test tube racks
- UPS and/or surge protector.

MATERIALS REGULARLY CONSUMED

- CD4 and CD8 reagents
- caps and tips
- microcentrifuge tubes
- cleaning solution

- disposable gloves
- chlorine bleach
- distilled water
- biosafety materials.

INSTRUMENT/ TECHNOLOGY COST

- \$35,000

PRECISION/ REPORTABLE RANGE

- <10% CV

SPACE REQUIREMENTS

Instrument:

- Area: 0.12 m² (1 ft x 1 ft)
- Height: 0.45–0.6 m (1.5–2 ft)
- Weight: <16 kg (35 lbs)

Working Space:

- 24-in.-wide countertop

TIME TO RESULT

- 35–40 minutes: 5-minute preparation, two 15-minute incubation periods
Sample preparation time depends on the number of samples. The maximum number of samples/day is 100–150.

RESULTS PROVIDED

- CD3/CD4 absolute
- CD3/CD8
- (CD4 percentage capability currently in trials)

REGULATORY STATUS

- FDA submission process has begun.

REAGENT INFORMATION

Number of reagents:

- 2 kits (CD4 and CD8)
- CD4 Kit: Anti-human CD4, Anti-human CD3, Antibody Dilution Buffer, Guava IX Lysing Solution
- CD8 Kit: Anti-human CD8, Anti-human CD3, Antibody Dilution Buffer, Guava IX Lysing Solution

Reagent cost:

- \$1*/test
* Average price in Africa. Excludes freight, duties, taxes, and distribution.

SHELF LIFE

- 12 months from manufacture
Reagents are never sent with less than 3 months shelf life and usually arrive in country with an average of 6 months shelf life.

Storage Requirements

Conditions

- 2–8°C (36–46°F)

Packaging

- The 2 reagent kits are available in 100-test, 500-test, or 1,000-test kits.
- The reagents are sent in plastic bags with minimal storage requirements.
- There is no minimum or maximum order quantity.

SAMPLE INFORMATION

- Blood collected by venipuncture should be stained within 24 hours of collection for optimal results.
- Unstained anticoagulated blood should be maintained at 20–25°C.
- Samples should be analyzed within 24 hours of staining.

Sample stability

- 48 hours after preparation when stored at room temperature.

Blood sample volume required

- minimum 10 µL whole blood.

QUALITY CONTROL

COMMODITY INFORMATION

Number of runs

- 50 tests/kit
- Generally, Guava Check should be run daily.

Control run cost

- \$3/test (\$150/kit)

Shelf Life

- 12 months from manufacture
Reagents are never sent with less than 3 months shelf life and usually arrive in country with an average of 6 months shelf life.

STORAGE REQUIREMENTS

Conditions

- 2–8°C (36–46°F)

Packaging

- 3.5 in. x 3.5 in. x 6 in.

LOGISTICS FACT SHEETS: CD4 MACHINES AND GPHF-MINILAB[®]

GPHF-MINILAB[®]



BRAND AND MANUFACTURER

Sales Information

German Pharma Health Fund e.V.
(GPHF)

Postfach 15 23, 61405 Oberursel nr.
Frankfurt, Germany

Tel.: +49-6171-50399-0

Fax: +49-6171-50399-20

Email: info@gphf.org

Website: www.gphf.org

Supplier

Technologie Transfer Marburg e.V.
(TTM)

Auf der Kupferschmiede 1, 35091
Coelbe, Germany

Tel.: +49-6421-87373-0

Fax: +49-6421-87373-7

Email: ttm@ttm-germany.de

For technical questions about
equipment and testing procedures and
references from current users:

Dr. Richard W. O. Jähnke

German Pharma Health Fund e.V.
(GPHF)

Postfach 15 23, 61405 Oberursel nr.
Frankfurt, Germany

Tel.: +49-6171-50399-0

Fax: +49-6171-50399-20

Email: info@gphf.org

KIT INFORMATION

Counterfeiting of pharmaceuticals and the proliferation of substandard drugs constitute a serious health risk, especially in the developing world where drug quality control systems are not always readily available. Experts assume that currently as much as 7 percent of the world's total pharmaceutical sales is counterfeited or of substandard quality.

The GPHF-Minilab[®]* is a mini-laboratory used in developing countries by medical store and hospital managers, drug inspectors, and other authorities to detect counterfeit and substandard pharmaceuticals and to provide basic quality control of drugs.

* Developed by the German Pharma Health Fund (GPHF), a nonprofit organization that promotes pilot projects for the improvement of health services in developing countries.

DRUGS AND CATEGORIES

Analgesics (pain relievers)

Acetylsalicylic Acid, Metamizole,
Paracetamol

Antiasthmatics

Aminophylline, Salbutamol

Antibiotics

Amoxicillin, Ampicillin, Cefalexin, Chloramphenicol, Ciprofloxacin, Cloxacillin, Cotrimoxazole, Erythromycin, Metronidazole, Phenoxymethylpenicillin, Tetracycline

Antidiabetic

Glibenclamide

Antifungal

Griseofulvin

Anthelmintic

Mebendazole

Antimalarials

Amodiaquine, Artemether, Artesunate, Lumefantrine, Chloroquine, Mefloquine, Primaquine, Quinine, Sulfadoxine/Pyrimethamine

Antiretrovirals (ARVs)*

Didanosine, Indinavir, Lamivudine, Nevirapine, Stavudine, Zidovudine

* On special request only and at additional cost

Antituberculosis

Ethambutol, Isoniazid, Pyrazinamide, Rifampicin

Diuretic

Furosemide

Steroid

Prednisolone

CURRENTLY USED IN

Latin America & the Caribbean

- Bolivia
- Colombia
- Grenada
- St. Lucia
- Venezuela
- Brazil
- Ecuador
- Guyana
- Surinam

Africa

- Cameroon
- Eritrea
- Ghana
- Kenya
- Mali
- Niger
- Senegal
- Sudan
- Togo
- Congo
- Gabon
- Guinea
- Liberia
- Mozambique
- Nigeria
- Sierra Leone
- Tanzania
- Zimbabwe

Asia

- Afghanistan
- Cambodia
- Georgia
- Indonesia
- Nepal
- Pakistan
- Sri Lanka
- Vietnam
- Bangladesh
- China
- India
- Myanmar
- Laos
- Philippines
- Thailand

Middle East

- Palestine

TESTING PROCEDURES

Visual Inspection Test

A comparison of solid dosage forms, including the packaging material, in order to rapidly reject crudely presented formulations. The test includes a search for deficiencies in the labeling, packaging, and dosage forms in comparison with the descriptions given in the GPHF-Minilab® manual included in the start-up package.

Disintegration Test

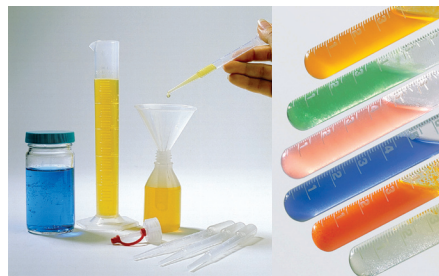
This test requires that all instantly soluble tablets and capsules disintegrate in water at a certain temperature within a designated timeframe, as specified in the main manual. This is a simple test for preliminary assessments of deficiencies related to drug solubility and availability. All instantly soluble tablets and capsules must pass the Disintegration Test. The manual included in the GPHF-Minilab® start-up package provides a detailed description of this test.

Color Reaction Test

A simplified test for a quick color check of any drug present against a standard in order to verify the drug's identity. A sample of the drug is crushed and mixed with the appropriate reagents to create a color reaction. The color is verified using the reference standards given in the GPHF-Minilab® manual on color reactions. If the drug fails this step, it is recommended to reject the drug and conserve resources by not conducting the TLC testing below.

Thin Layer Chromatography (TLC) Test

A semi-quantitative test against a standard to check the amount of active ingredient present to verify a drug's potency. This test requires one whole unit of an oral solid dosage to be dissolved in a known volume of extraction solution. The sample solution is applied to a thin layer chromatoplate (supplied in the GPHF-Minilab® start-up package), allowed to develop for 15 minutes in a solvent, dried using a hot plate, analysed using an ultra-violet (UV) lamp, and finally stained with iodine to detect any spots failing to appear in the UV detection. Detailed instructions for the analysis of each drug are given in the GPHF-Minilab® main manual on TLC.



SUPPLY CHAIN IMPLICATIONS

	Color Reaction Kit	TLC Kit
Equipment Included in Kit	rulers, thermometer, timer, labeling tape and pen, hot plate, sample preparation equipment (test tubes, test tube rack, mixing beakers, scalpel/blade, spatula, filter paper, tweezers, scissors, pestle, funnel, pipettes, pipette rack)* universal pH indicator testing paper, dropping bottle and sealer cap, glass stirring rod, measuring cylinders, glass bottles with closures, transfer pipettes, micro-spoon, adapter plug, alcohol lamp, methylated spirit (alcohol) - 1 L, safety spectacle, test-tube brush	aluminum foil, glass bottles with closures, pumpette, pencil, pencil sharpener, Merck TLC aluminum plates, TLC developing chamber, iodine staining chamber, battery-powered UV lamps of various preset wavelengths with replacement batteries, authentic secondary reference standards (ARV secondary reference standards supplied on request)
Reagents and Solvents Included in Start-up Package	acetone (1 L); glacial acetate acid (1 L); methanol (1 L); ninhydrin (10 g); sulfuric acid 96% (1 L)* copper (II) acetate, monohydrate (100 g) 4-(dimethylamino)-benzaldehyde (25 g) fast red TR salt (10 g) ferric (II) chloride tetrahydrate (50 g) ferric (III) chloride solution 10% (0.25 L) formaldehyde 37% (50 mL) hydrochloric acid solution 36% (1 L) hydrogen peroxide solution 30% (1 L) phenol crystals (or liquid phenol) (100 g) potassium dichromate (50 g) sodium hydroxide pellets (500 g)	ammonia solution 25-26% (50 mL) disodium or tripotassium edetate (50 g) ethylacetate (1 L) glacial acetic acid (1 L) hydrochloric acid solution 32-36% (1 L) iodine (50 g) magnesium chloride hexahydrate (100 g) methanol (1 L) ninhydrin (10 g) toluene (1 L)
	Capacity sufficient for 3,000 color reaction runs	Capacity sufficient for 1,000 TLC runs
Packaging and Shipping Information	1 protective case (black with pre-formed dividers/pockets) 62 x 50 x 22 cm 14 kg	1 protective case (black with pre-formed dividers/pockets, wheels and extension handle) 83 x 52 x 29 cm 23 kg
	Start-up package: reagents and solvents 20–22 boxes (approx. 50 kg)	
	Approximately 90 kg as ready-packed palette for worldwide delivery by air (40 kg for suitcases and 50 kg for reagents)	
	Order will be shipped within 3 weeks from when order is received and the invoice is settled.	
Shelf Life	5 years for reagents and solvents in their original packaging.	<ul style="list-style-type: none"> • 2 years for authentic secondary reference standards. • Less than 2 years for authentic secondary reference standards for ARVs.
Storage Conditions	<ul style="list-style-type: none"> • Store at room temperature, avoiding direct sunlight. • No special storage required for the quantities of chemicals supplied. 	
Installation and Use	<ul style="list-style-type: none"> • Can be used outdoors and indoors. • Can be mounted on a bench top or office table. • Fits all electrical sockets and voltages. • Sufficient air ventilation needed, e.g., fan and open window, when using indoors. • Requires access to running water for cleaning equipment. 	

* Included in both the Color Reaction Kit and the TLC Kit.

ESTIMATED PRICE

Minilab Start-up Package¹

- 3,100 €
- U.S.\$3,760 without optional features

Transport to Country²

- 800 ± 100 €
- U.S.\$970 ± U.S.\$120

Transport in Country

- 120 €
- U.S.\$145

Duties

- 1000 €
- U.S.\$1,213

Total

- 4,750 € (about 5 €/assay)
- U.S.\$5,760 about U.S.\$6/assay

One Week Training

- 450 €/person
- U.S.\$546/person

Travel Expenses³

- 2,500 €
- U.S.\$3,032

Resupply of Reagents & Solvents⁴

- Minimum order: 10 €
- U.S.\$12

¹ Price valid until Dec. 31, 2005.

² U.S.\$ value as of June 23, 2005.

³ Price of transport and duties varies by destination.

⁴ Price lists are available from the supplier.

OPTIONAL FEATURES

(with minimal increase in weight and volume)

- Authentic secondary reference standards for ARVs. Cost: approximately 7 € (U.S.\$8.50) for each ARV secondary reference standard.

Note: As of May 2004, there is a donated stock of these materials, so this cost is only for additional packaging and handling fees for each tube (containing 20 samples of authentic reference tablets/capsules). Cost for stock falling below a shelf life of 6 months is negotiable. If this donated stock is not available, the actual market value of the ARV drug will be applicable.

- Small battery-driven pocket balance with a precision of 0.01 g for testing the quality of bulk drug substances, uniformity of tablet and capsule mass, and easy preparation of test solutions. Cost: 160 € (U.S.\$194).

LIMITATIONS

- Reagents are supplied separately and need an adequate amount of storage space, although there are no special storage requirements for the chemicals.

TRAINING

Training on the Minilab's operational procedures is offered locally, or in Germany by the:

- Medical Mission Institute Würzburg, mi-appro@mailuni-wuerzburg.de
- German Medical Aid Organization medeor, info@medeor.org
- GPHF-Minilab[®] Project Manager, info@gphf.org.

For more information, please visit
<http://www.deliver.jsi.com>.

The author's views expressed in this publication do not necessarily reflect the views of the United States Agency for International Development or the United States Government.

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