

# Identification and Specification of Laboratory Items



Ludo Scheerlinck  
MSc, MBA, MPH  
Technical Officer, Medical & Laboratory  
UNICEF Supply Division, Denmark

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# Identification and Specification of Laboratory Items

1. Context and Identification
2. Specifications



# Identification and Specification of Laboratory Items

- For public procurement importance of correct identification and specification can not be over emphasized.
- First - Strict focus on **Clinical Laboratory**. Challenging to refuse involvement in other labs in need of supplies.
- Broadly two groups of lab items (i) RDTs (ii) Equipment & Renewable are procured.
- For procurement of (i) we rely on WHO work in the area of specifications and prequalification.

# Identification and Specification of Laboratory Items

- Review of program areas based on MTSP 06-09.
- Identification of all clinical laboratory activities required to support each program at primary and secondary level.
- Identification of all essential items for each activity.
- Summary result: a for UNICEF-programs tailor made list of approx. 300 lab items. (Grouped: Equipment, Renewable, Reagents, Blood Transfusion)
- Generic specifications were developed for each, allowing public tendering in line with UN Rules.

# Identification and Specification of Laboratory Items

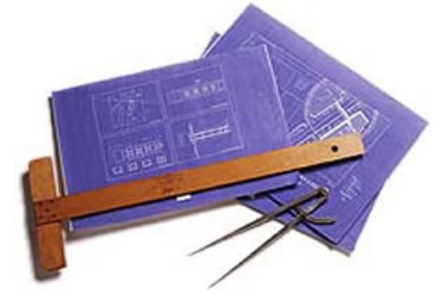
Essential Lab Items	Lab Item 01	Lab Item 02	Lab Item 03	Lab Item 04	Lab Item 05	Lab Item 06	Lab Item 07	Lab Item 08	Lab Item 09	Lab Item 10	Lab Item 11	Lab Item 12	Lab Item 13	Lab Item 14
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## Programs With Clinical Lab Services Component

Malaria treatment for children & pregnant women.	Activities (x,y,z)	X	X			X	X		X					X
Monitoring, disease and nutritional surveillance and surveys.	Activities (x,y,z)			X										X
Treatment of children infected HIV/AIDS for secondary & opportunistic infections.	Activities (x,y,z)	X	X		X					X				
Community-integrated management of neonatal and Childhood Illnesses.	Activities (x,y,z)	X				X		X	X	X	X	X	X	
Community-based care & support of HIV/AIDS affected children.	Activities (x,y,z)	X	X	X			X						X	X
Provision essential health & nutrition resources & commodities community level.	Activities (x,y,z)			X				X	X					
Scaling up actions to strengthen local basic service providers	Activities (x,y,z)		X		X	X	X					X		

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# Identification and Specification of Laboratory Items

- Guiding notes and publications from WHO. Supplemented with those from partner organizations: CDC, MSF etc
- Field experience of our Technical Capacity: environment, practice and procedures, products, logistics, etc.
- Frequent end-user fit-for-purpose surveys.
- Market research: products and suppliers.
- Examples of UNICEF/SD generic specifications:

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## **Distillation unit, 2 L/h, with tank**

- Automatic water purification system.
- Operates from raw potable feed water 2 to 6 bar, 4 to 35 C
- Output conductivity, approx: 2  $\mu$ S, at 20 C
- Tank capacity, approx: 4 L
- Unit indicates power on/off, standby and/or in process, tank level.
- Thermostatic control as well as overheat protection
- Free-standing or wall mounted, supplied with necessary fixing materials for wall mount.
- Power requirements: 220 V / 50 Hz
- Power consumption: 1500 W
- To be supplied with:  
Spare set of deionization, adsorption and filtration cartridges.
- Supplied with:  
Instructions for use, for preventive maintenance and troubleshooting

## **Analyser, haematology, 18 parameter**

- Determination of 18 parameter, with 3-part differential, for routine haematology
- Open system, automatic
- Sample size, approx: 30  $\mu$ l
- Throughput 50 samples per hour
- Determination of:  
Red blood cell (RBC), White blood cell (WBC), Haemoglobin (HGB), Haematocrit (HCT), Mean cell volume (MCV), Mean cell haemoglobin (MCH), Red cell distribution (RDW-SD and RDW-CV), Platelets (PLT), Platelet distribution (PDW-SD and PDW-CV), Mean platelet volume (MPV), differential leucocytes (LYM, LYM%, MID, MID%, GRA, GRA%).
- Sample ID, date and time are reported with test results
- Supplied complete with dedicated data analysis and data management software
- Results are reported on external inkjet printer
- Casing, corrosion proof material such as plastic or epoxy coated steel
- With built-in RS232 or equivalent, allowing data transfer.
- Power requirements: 220 V / 50 Hz
- Power consumption: 400 W
- Supplied with:  
UPS of sufficient size to ensure uninterrupted sample testing in case of power variations or power interruption.
- Supplied with:  
Instructions for use, for preventive maintenance and troubleshooting in E/F/S

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## **Paper, dry blood spot, box/100**

- Dry blood spot (DBS) card with bar coding
- Collects blood and preserves proteins for future nucleic acid analysis
- 5 distinct spots
- Stability min 18 months for DNA
- Box of 100

## **Tube, capillary, heparin, box/1000**

- Capillary glass tube
- Heparin coated
- Diameter, approx: 1.1 to 1.2 mm
- Length, approx: 75 mm
- Packaging tropical, per 100
- Packed per 100 tubes
- Box 10 packs of 100

## **Tube, vacuum, EDTA, 6 ml, box/100**

- Blood collection
- Capped with vacuum seal
- Plastic
- Box of 100

## **Lancet, safety, 1.8 mm, box/200**

- Instant trigger launches spring-based needle
- Needle, approx: 1.8 mm
- Single-use disposable
- Mechanism prevents reuse
- Clean packed in box of 200

## **Flask, volumetric, set/7**

- Heat-resistant glass
- Set with following sizes:
  - 3 x 100 ml
  - 2 x 250 ml
  - 1 x 500 ml
  - 1 x 1000 ml
- Graduated

## **Bottle, 30 ml, set/6**

- Colourless glass
- Screw-top with dropper pipette
- Leak-proof stopper
- Supplied as a set of 6

## **Jar, Coplain, staining**

- Fits slide of 26 x 76 mm
- Capacity: 10 slides
- Slides extend above the opening, allowing manipulation without forceps
- Screw cap with metal foiled lining withstanding stain and organic solvents

## **Slide, microscope, box/100**

- Thickness: 1.0 - 1.2 mm
- Size: 76 x 26 mm
- Colourless glass
- Clinical grade, non-corrosive, clean washed and polished
- Free from nicks and scratches.
- Dimensions and optical properties conform ISO 8037 (part 1 and 2)
- Packed fibre-free
- Box of 100

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<p><b>Stain, Gram, set</b></p> <ul style="list-style-type: none"> <li>• Gentian Violet Crystal (1 x 250 ml)</li> <li>• Lugol Iodine (1 x 250 ml)</li> <li>• Differentiator, ethanol (1 x 250 ml)</li> <li>• Safarine (1 x 250 ml)</li> <li>• Supplied as a set</li> </ul>
<p><b>Stain, Ziehl Neelson, set</b></p> <ul style="list-style-type: none"> <li>• Carbol fuchsin (1 x 250 ml)</li> <li>• Acid alcohol, 1 % HCl in 70 % alcohol (1 x 250 ml)</li> <li>• Methylene blue 0.1 % aqua (1 x 250 ml)</li> <li>• Supplied as a set</li> </ul>
<p><b>Stain, Geimsa, solution, bot/500 ml</b></p> <ul style="list-style-type: none"> <li>• Solution</li> <li>• Bottle of 500 ml</li> </ul>
<p><b>Stain, Field A, solution, bot/500 ml</b></p> <ul style="list-style-type: none"> <li>• Solution</li> <li>• Bottle of 500 ml</li> </ul>
<p><b>Stain, Field B, solution, bot/500 ml</b></p> <ul style="list-style-type: none"> <li>• Solution</li> <li>• Bottle of 500 ml</li> </ul>

<p><b>Blood bag, single, 450ml, box/36</b></p> <ul style="list-style-type: none"> <li>• Anticoagulant CPDA-1</li> <li>• Fit with 16 G needle</li> <li>• With in-line closure device</li> <li>• Provided with writable label</li> <li>• Box of 36</li> </ul>
<p><b>Plate, matching/grouping, box/5</b></p> <ul style="list-style-type: none"> <li>• Plastic plate provides 12 recessed wells</li> <li>• Used for blood grouping and cross matching</li> <li>• Size wells, approx: diameter 20 mm, depth 3 mm</li> <li>• Reusable polystyrene</li> <li>• Wells marked with Anti-A, Anti-B, Anti-AB and Anti-D, 8 unmarked</li> <li>• Size plate, approx: 180 x 50 x 5 mm</li> <li>• Box of 5</li> </ul>
<p><b>Refrigerator, blood bag, 50 units</b></p> <ul style="list-style-type: none"> <li>• Refrigerator for storage of whole blood or red cell packs</li> <li>• Compression type with forced air cooling</li> <li>• Stainless steel structure, stainless steel lining</li> <li>• Gross volume, approx: 200 L</li> <li>• Storage capacity, approx: 50 blood bags of 450 ml</li> <li>• Easily adjustable shelves</li> <li>• Internal lighting</li> <li>• One lockable glass door, with sensor</li> <li>• Refrigerant CFC free</li> <li>• Electronic temperature control, range: 2 to 6 C (minimal graduation: 1 C)</li> <li>• External display with actual interior temperature</li> <li>• Operating ambient temperature: + 10 to 43 C</li> <li>• Hold-over time: minimum 30 min (full load at + 4 C to rise above 6 C)</li> <li>• Cool-down time: maximum 13 hrs (full load at + 25 C to cool below 6 C)</li> <li>• Digital temperature recording device, accuracy: 0.1 C</li> <li>• Electronic thermostat with audio &amp; visual alarm system</li> <li>• Battery back-up for electronic audio &amp; visual alarm system</li> <li>• Fitted with ball bearing swivel castors</li> <li>• Compliant with WHO minimal performance specification BTS/RF.1</li> <li>• Meeting quality standard ISO 8187 / EN 28187</li> <li>• Meeting safety standards: EMI 89/336EEC, 73/23/EEC and 93/68/EEC code AB1</li> <li>• Power requirements: 220 V / 50 Hz</li> <li>• Power consumption, approx: 400W</li> <li>• Supplied with: <ul style="list-style-type: none"> <li>UPS</li> <li>Instructions for use, for preventive maintenance and troubleshooting in E/F/S</li> </ul> </li> </ul>

# Identification and Specification of Laboratory Items

## **CD4 [abs, %] counter, CyFlow SL\_3, with starter kit**

- Absolute and percentage CD4 counter, CyFlow SL\_3, with starter kit.
- Manufacturer's product reference: Partec CY-S-1023
- Bench top flow based fluorescence-activated cell sorter
- Volumetric, provides absolute T-lymphocyte counts per unit of volume.
- Enumerates CD3, CD4 and/or CD8 cells: approximately ranges 50 to 2500 cells/ul.
- On same platform, provides CD4 percentage versus total T-lymphocytes.
- Sample volume, for analysis: approximately 50 ul whole blood.
- With external computer, software and colour printer.
- Report with among others: date/time/batch, patient ID, CD4 absolute cells/ul, ratios CD3/CD4/CD8 and CD4 versus total T-lymphocytes
- Micro-computer with memory stores/retrieves measured results per patient ID.
- Alphanumeric display informs about device status and on-going analysis.
- Energy requirements: 100 to 240 V AC, or 12 V DC (battery)
- Consumption: approximately 200 W

### Supplied with:

- 1 x Set of micropipettes
- 1 x Instruction manual in 3 languages (English, French and Spanish)
- 1 x Service manual in 3 languages (English, French and Spanish)
- 1 x UPS, 500 VA / 300 W
- 1 x Transportation box/suitcase
- 1 x Starter Kit, (package of consumables for 300 CD4 tests), contents:
- 1 x Caps for sample tubes, 1000 pcs
- 1 x Inline filter for sheath container, 10 pcs
- 1 x Tubing replacement set for flow cuvette
- 1 x Tubing replacement set for sheath/waste container
- 1 x Replacement tubing for BioSafety pump
- 1 x (S0001241) CyFlow SL\_3, Easycount kit, 100 tests
- 2 x (S0001250) CyFlow, Easycount kit, 100 tests
- 1 x (S0001251) CyFlow, Sample tube, 3.5ml/BOX-500
- 1 x (S0001252) CyFlow, Count check bead, 2x25ml, 50 tests
- 1 x (S0001253) CyFlow, Decontamination solution, 250ml
- 1 x (S0001254) CyFlow, Cleaning solution, 250ml
- 1 x (S0001255) CyFlow, Hypochlorid solution, 250ml
- 1 x (S0001256) CyFlow, Pipette tip, 2-200ul/BOX-1000
- 1 x (S0001257) CyFlow, Pipette tip, 50-1000ul/BOX-1000

WARNING: The starter kit contents products with SHORT SHELF LIFE and storage 2-8 dea C.

## **Quantities and products required for 200 tests during 3 months:**

- 1 x S0001241 CyFlow SL\_3, Easycount kit, 100 tests (ref 05-8405)
- 1 x S0001250 CyFlow, Easycount kit, 100 tests (ref 05-8401)
- 1 x S0001251 CyFlow, Sample tube, 3.5ml/BOX-500 (ref 04-2000)
- 1 x S0001252 CyFlow, Countcheckbead, 2x25ml, 50tst (ref 05-4011)
- 1 x S0001253 CyFlow, Decontamination sol., 250ml (ref 04-4010)
- 1 x S0001254 CyFlow, Cleaning solution, 250ml (ref 04-4009)
- 4 x S0001255 CyFlow, Hypochloride solution, 250ml (ref 04-4012)
- 1 x S0001256 CyFlow, Pipette tip, 2-200ul/BOX-1000 (ref 04-6-1510)
- 1 x S0001257 CyFlow, Pipettetip, 50-1000ul/BOX-1000 (ref 04-6-1530)

# Identification and Specification of Laboratory Items

- In the specifications we invariably insist on, and verify adherence to, applicable international quality standards:

- > Supplier:

- Accredited quality management system according ISO 9001:2000 or ISO 13485:2003.

- > Its products:

- Certified according CE MDD 92/43 or CE IVDD 98/79.

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THANK YOU ...



FOR YOUR ATTENTION !

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