

Crown Agents Ukraine - General Procurement Notice – addendum 10

Requirements for Programme 4 – Test-systems for HIV Diagnostics

International non-proprietary name	Form of presentation	Estimated Demand, 100%	Estimated Quantity under the Assets Allocated
Mother to Child HIV Transmission Preventative Tools			
ELISA Test System (reagent kit) for simultaneous detection of HIV-1 p24 antigen and antibodies to HIV ½	test	111,840	111,840
Rapid (express) tests to detect HIV ½ antibodies	- " -	18,550	18,550
Reagents and Consumables Compatible with the Architect i1000sr Device			
ARCHITECT HIV Ag/Ab Combo Reagent Kit, 100 tests, or equivalent	kit	420	420
ARCHITECT HIV Ag/Ab Combo Calibrator, or equivalent	- " -	3	3
ARCHITECT HIV Ag/Ab Combo Controls, 4 control kit, or equivalent	- " -	7	7
ARCHITECT Concentrated Wash Buffer (4 x 975 ml vials), or equivalent	package	29	29
ARCHITECT Pre-Trigger Solution (4 x 975 ml vials), or equivalent	- " -	4	4
ARCHITECT Trigger Solution (4 x 975 ml vials), or equivalent	- " -	4	4
ARCHITECT Reaction Vessel, 4,000 pieces per package, or equivalent	- " -	8	8
ARCHITECT Sample Cup, 1,000 pieces per package, or equivalent	- " -	11	11
ARCHITECT Septum, 200 pieces per package, or equivalent	- " -	4	4
ARCHITECT Replacement Cap, 100 pieces per package, or equivalent	- " -	2	2
ARCHITECT Probe Conditioning Solution (4 x 25 ml vials), or equivalent	- " -	2	2
Reagents and Consumables Compatible with Cobas e411 and e601 Devices			
Test for HIV-1 and HIV-1/2 generic antibody detection, 100 tests	package	459	459
Elecsys HIV combi PT, Elecsys HIV Duo and Elecsys HIV Ag quality control test, or equivalent	- " -	62	62
Universal Diluent, 2 x 16 ml vials, or equivalent	- " -	3	3
System solution for electrochemical signal generation in Elecsys, Cobas e immunoanalyzers, 6 x 380 ml vials, or equivalent	- " -	87	87

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Detector block cleaning solution, Elecsys, Cobas e, 6 x 380 ml vials, or equivalent	- " -	136	136
ISE Cleaning Solution/Elecsys SysClean, 5 x 100 ml vials, or equivalent	- " -	10	10
Cobas e 411/Elecsys 2010 Assay Tip, 3,600 pieces, or equivalent	- " -	46	46
Cobas e 411/Elecsys 2010 Assay Cup, 3,600 pieces, or equivalent	- " -	17	17
Elecsys Sys Wash solution, 500 ml, or equivalent	- " -	16	16
Service Calibration Solution, Elecsys, Cobas e, 2 x 50 ml vials, or equivalent	- " -	12	12
Control Solution, Elecsys, Cobas e, 3 x 40 ml vials, or equivalent	- " -	13	13
Elecsys, Cobas e, SAP Test, 250 tests, or equivalent	- " -	9	9
Sample cup, 5,000 pieces	- " -	11	11
ProCell M Kit, or equivalent	- " -	29	29
CleanCell M Elecsys, Cobas e, or equivalent	- " -	29	29
PreClean M, Wash Solution, or equivalent	- " -	14	14
ProbeWoshe M, Cleaning Solution or equivalent	package	20	20
Cobas e 601/Cobas e 602 Cup, E170 modules, or equivalent	- " -	2	2
<i>Measures for Conducting Confirmatory Tests for HIV-Antibody Detection</i>			
ELISA Test System (kit) for simultaneous detection of HIV-1 p24 antigen and antibodies to HIV ½	test	12,672	12,672
ELISA Test System (kit) for HIV ½ antibodies detection	- " -	23,616	23,616
ELISA Test System (kit) for HIV-1 and HIV-2 antibodies detection	- " -	14,976	14,976
Test system (kit) for HIV immunological diagnosis through the use of the immunoblotting method	- " -	540	540
Test system (kit) for HIV-1 p24 antigen quantitative detection	- " -	3,552	3,552
Test system (kit) for confirming the presence of HIV-1 p24 antigen	- " -	1,440	1,440
<i>CD4 Count Test: in HIV-Positive Pregnant Women; for ART Follow-Up; for Dispensary Patients</i>			
<i>Reagents and Consumables Compatible with Beckman Coulter FC 500, EPICS XL and DxFLC Flow Cytometers</i>			
CYTO-STAT triCHROME CD45-FITC/CD4-RD1/CD3-PC5, 50 tests, or equivalent	vial	38	38

International non-proprietary name	Form of presentation	Estimated Demand, 100%	Estimated Quantity under the Assets Allocated
COULTER CLENZ, Cleaning Agent, 5 l, or equivalent	package	4	4
ISOFLOW, Sheath Fluid, 10 l, or equivalent	- " -	6	6
IMMUNOPREP, Reagent System, 100 tests, or equivalent	- " -	6	6
IMMUNOPREP, Reagent System, 300 tests, or equivalent	package	5	5
Flow-Check, Fluorosphere, 3 x 10 ml vials, or equivalent	- " -	4	4
Flow-Count, Fluorosphere, 200 tests, or equivalent	vial	11	11
Test tube (12 x 75 mm), blue, 250 pieces, or equivalent	package	9	9
IMMUNO-TROL Cells, low, 2 x 3 ml vials	- " -	4	4
DxFLEX, Sheath Fluid, 10 l, or equivalent	- " -	0	0
CONTRAD 70, Cleaning Agent, 1 l, or equivalent	- " -	0	0
CytoFLEX Daily QC, Fluorosphere, 2 ml, or equivalent	- " -	0	0
<i>Reagents and Consumables Compatible with the Becton Dickinson FACSCalibur Flow Cytometer</i>			
BD TriTEST™ Reagent for CD3/CD4/CD45 detection, labelled FITC/PE/PerCP with BD TruCount™ tubes, 50 tests, or equivalent	- " -	0	0
BD FACS Flow, Sheath Fluid, 20 l, or equivalent	- " -	0	0
BD FACS Clean, Cleaning Solution, 5 l, or equivalent	- " -	0	0
BD FACS Rinse, Detergent Solution, 5 l, or equivalent	- " -	0	0
CaliBRITE™ 3 beads unlabelled, labelled FITC, PerCP, PE-labelled beads to adjust the instrument settings, 25 tests, or equivalent	kit	0	0
BD FACS™ Lysing Solution, 100 ml, or equivalent	vial	0	0
BD™ Multi-Check CD4, low control, 1 x 2.5 ml vial, or equivalent	- " -	0	0
<i>Reagents and Consumables Compatible with the Beckman Coulter AQUIOS CL Flow Cytometer</i>			
AQUIOS Tetra-1 Panel, 50 tests, or equivalent	vial	1,596	1,596
AQUIOS Sheath Solution, 10 l, or equivalent	package	482	482
AQUIOS Immuno-Trol Cells, 30 tests, or equivalent	- " -	96	96
AQUIOS Immuno-Trol Low Cells, 30 tests, or equivalent	- " -	96	96
AQUIOS Sodium Hypochlorite Solution, 4 x 50 ml vials, or equivalent	- " -	31	31

International non-proprietary name	Form of presentation	Estimated Demand, 100%	Estimated Quantity under the Assets Allocated
AQUIOS Cleaning Agent, 0.5 l, or equivalent	- " -	547	547
AQUIOS Lysing Reagent Kit, 100 tests, or equivalent	kit	706	706
AQUIOS 96-Well Plate, 50 plate kit, or equivalent	package	26	26
<i>Reagents and Consumables Compatible with the BD Biosciences BD FACSPresto Device</i>			
BD FACSPresto™ Cartridge Package (BD FACSPresto™ Cartridges; BD™ 100 µl disposable pipettes), 100 cartridges per package, or equivalent	- " -	79	79
Viral Load Tests: In HIV-Positive Pregnant Women; for ART Follow-Up; in Dispensary Patients			
<i>Reagents and Consumables Compatible with the Abbott m2000sp Device and Abbott RealTime m2000rt Amplifier</i>			
Reagent kit for sample preparation, 96 tests	package	343	343
Abbott Real-Time HIV-1 Calibrator Kit, or equivalent	- " -	13	13
Abbott Real-Time HIV-1 Controls, or equivalent	package	79	79
Reagent kit for amplification	- " -	343	343
Adhesive cover	- " -	13	13
Optical 96-well reaction plate	- " -	29	29
Pipette tip, 1,000 µl	- " -	141	141
Reaction vessel, 5 ml	- " -	20	20
Reagent vessel, 200 ml	- " -	38	38
96-well deep plate	- " -	46	46
Tube with a cap, 1.5 ml ASPS	- " -	52	52
Pipette tip, 200 µl	- " -	13	13
Master Mix Tube, or equivalent	- " -	10	10
Filter Tip, 1,000 µL, sterile	tray	713	713
Tube, 4.5 ml, 75 x 12 mm, PP	package	37	37
Filter Tip, 200 µL, sterile	tray	155	155
Tip without a filter, 1,000 µL, sterile	- " -	65	65
Biohazard waste bag	package	13	13
<i>Reagents and Consumables Compatible with the AmpliPrep/Cobas Device</i>			
COBAS® AmpliPrep HIV-1 Test, version 2.0, 48 tests, or equivalent	- " -	0	0
Cobas AmpliPrep/Cobas TaqMan, wash reagent, 5.1 l, or equivalent	- " -	0	0
K-Tip, 12 x 36 pieces, or equivalent	- " -	0	0
K-Tube Rack, 12 x 96 pieces, or equivalent	- " -	0	0
S-Tube Input + Barcode Flips, 12 x 24 pieces, or equivalent	- " -	0	0

International non-proprietary name	Form of presentation	Estimated Demand, 100%	Estimated Quantity under the Assets Allocated
Specific Sample Processing Unit (SPU), 12x24 pieces, or equivalent	- " -	0	0
Reagents and Consumables Compatible with the iQ5 Amplifier with Real Time Fluorescent Signal Detection ("Fluorescence Detection in Real-Time" – "FRT" Format)			
Real-Time Reagent kit for HIV-1 quantitative detection RNA – "FRT", 100 tests, or equivalent	kit	0	0
Filter Tip, 1,000 µL, sterile	tray	0	0
Filter Tip, 200 µL, sterile	- " -	0	0
Tip without a filter, 1,000 µL, sterile	- " -	0	0
Tip without a filter, 200 µL, sterile	- " -	0	0
Microtube, 1.5 ml	piece	0	0
0.2 ml Thin Wall PCR Tube, flat cap	- " -	0	0
0.2 ml Thin Wall PCR Tube, convex cap	- " -	0	0
Reagents and Consumables Compatible with the COBAS 4800 PCR Detection System			
Quantitative test for nucleic acid detection in the Cobas® 4800 System (HIV-1), or equivalent	package	126	126
Cobas® HBV/HCV/HIV-1 Control Kit, 10 kits, or equivalent	- " -	17	17
Filter CORE TIPS, 3,840 pieces, or equivalent	- " -	51	51
AD-Plate, 0.3 ml, 50 pieces, or equivalent	- " -	6	6
Reagent Vessel, 50 ml, 200 pieces	- " -	4	4
Reagent Vessel, 200 ml, 100 pieces	- " -	6	6
Extraction Plate, 2.0 ml, 40 pieces, or equivalent	- " -	6	6
Cobas 4800 Wash Buffer, 960 tests, or equivalent	- " -	18	18
Cobas 4800 Sample Prep Kit, 960 tests, or equivalent	- " -	18	18
Cobas 4800 Lysis Kit, 960 tests, or equivalent	- " -	18	18
Small waste bag (25 pieces per package)	package	3	3
Large waste bag (50 pieces per package)	- " -	6	6
Waste dish (10 pieces per package)	- " -	7	7
Cobas 4800 Spec Dil Kit, 240 tests, or equivalent	- " -	4	4
Reagents and consumables compatible with the GeneXpert Analyzer			
GeneXpert Xpert HIV-1/VL Assay, 10 Cartridges with Sample Reagent, 1 kit, or equivalent	package	1,422	1,422
Preventive Measures for Mother-to-Child HIV Transmission (Test Systems for Newborns Delivered by HIV-Positive Women)			
Reagents and Consumables for the "Rotor-Gene 6000TM" or "iQ5" Amplifier with Real Time Fluorescent Signal Detection ("Fluorescence Detection in Real-Time" – "FRT" Format)			

International non-proprietary name	Form of presentation	Estimated Demand, 100%	Estimated Quantity under the Assets Allocated
Real-Time Reagent Kit for HIV-1 proviral DNA FRT-detection, 100 tests per kit, or equivalent	kit	3	3
Tip without a filter, 1,000 µL, sterile	tray	0	0
Filter Tip, 1,000 µL, sterile	- " -	47	47
Tip without a filter, 200 µL, sterile	- " -	6	6
Microtube, 1.5 ml	piece	1,161	1,161
0.2 ml Thin Wall PCR Tube, flat cap	- " -	1,161	1,161
Filter Tip, 200 µL, sterile	tray	11,800	11,800
<i>Reagents and Consumables Compatible with the Abbott m2000sp Device and Abbott Real-Time m2000rt Amplifier</i>			
Abbott RealTime HIV-1 Qualitative Amplification Reagent Kit, or equivalent	package	8	8
Abbott RealTime HIV-1 Qualitative Control Kit, or equivalent	- " -	3	3
Abbott mSample Preparation System DNA, 96 tests, or equivalent	package	8	8
Pipette Tip, 1,000 µl	- " -	4	4
Pipette Tip, 200 µl	- " -	1	1
Reaction Vessel, 5 ml	- " -	1	1
Reagent Vessel, 200 ml	- " -	2	2
Optical 96-well reaction plate	- " -	2	2
96-well deep plate	- " -	2	2
Adhesive cover	- " -	1	1
Master Mix Tubes, or equivalent	- " -	1	1
Biohazard waste bag	- " -	1	1
Filter Tip, 1,000 µL, sterile	tray	20	20
Tube, 4.5 ml, 75 x 12 mm, PP	package	1	1
Filter Tip, 200 µL, sterile	tray	49	49
Tube with a cap, 1.5 ml ASPS	package	1	1
Abbott mSample/ Preparation System RNA Bulk Lysis Buffer Kit, or equivalent	- " -	6	6
Test-tube with a cap, 50 ml, 25 pieces per tray, or equivalent	- " -	25	25
<i>Reagents and Consumables Compatible with the AmpliPrep/Cobas Device</i>			
COBAS® AmpliPrep, version 2.0, 48 tests, or equivalent	package	0	0
Cobas AmpliPrep/Cobas TaqMan, Wash Reagent, 5.1 l, or equivalent	- " -	0	0
COBAS® AmpliPrep/COBAS® TaqMan® Specimen Pre-Extraction Reagent (SPEX), 5 x 78 ml vials, or equivalent	- " -	0	0

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K-Tip, 12 x 36 pieces, or equivalent	- " -	0	0
K-Tube Rack, 12 x 96 pieces, or equivalent	package	0	0
S-Tube Input + Barcode Flips, 12 x 24 pieces, or equivalent	- " -	0	0
Specific Sample Processing Unit (SPU), 12 x 24 pieces, or equivalent	- " -	0	0
COBAS® TaqMan®, Kit CAP/CTM Spec Pre-extract GPR, or equivalent	- " -	0	0
<i>Reagents and Consumables Compatible with the COBAS 4800 Analyzer for Proviral DNA Detection in Dried Blood Spot Specimens</i>			
Quantitative test for nucleic acid detection in the Cobas® 4800 System (HIV-1), or equivalent	package	9	9
Cobas® HBV/HCV/HIV-1 Control Kit, or equivalent	- " -	5	5
Cobas 4800, 240 test, KIT COBAS 4800 SAMPLE PREP 2 240T CE-IVD, or equivalent	- " -	5	5
Cobas 4800, 240 test, KIT, Cobas 4800 SYS WASH BUFFER 240T IVD, or equivalent	- " -	5	5
Cobas 4800, 240 test, KIT COBAS 4800 LYSIS 2 240T CE-IVD, or equivalent	- " -	5	5
Cobas® 4800/6800/8800, Cobas® Specimen Pre-Extraction Reagent, or equivalent	- " -	3	3
Extraction plate, 2 ml, or equivalent	- " -	2	2
AD-plate, 0.3 ml, or equivalent	- " -	2	2
HIGH VOL. CO-RE TIPS, FILTER, or equivalent	- " -	4	4
Reagent reservoir 200 ml, or equivalent	- " -	2	2
Reagent reservoir 50 ml, or equivalent	package	2	2
Small waste bag, (25/box)	- " -	1	1
<i>Reagents and consumables compatible with the GeneXpert Analyzer</i>			
GeneXpert Xpert HIV-1 Qual, 10 Cartridges with Sample Reagent, 1 Unit, or equivalent	- " -	533	533
<i>Consumable Kit Required for Preparation of a Single Dried Blood Spot (DBS) Specimen in Children Born from HIV-Infected Mothers for Early HIV Diagnostics within the First 48 Hours of Birth</i>			
Filter paper for DBS preparation, 100 pieces per package	- " -	38	38
Clipped bag, small	piece	3,420	3,420
Clipped bag, large	- " -	3,370	3,370
Humidity indicator card, 50 pieces per package	package	72	72
Auto-lancet (scarifier), 200 pieces per package	- " -	29	29
Sanitiser (an alcohol wipe, 60 x 30 mm), 100 pieces per package	- " -	53	53
Nitrile non-powdered gloves, 100 pieces per package	- " -	62	62

International non-proprietary name	Form of presentation	Estimated Demand, 100%	Estimated Quantity under the Assets Allocated
Silica gel, 2g, sachet	- " -	4,335	4,335
Laboratory Monitoring of HIV Resistance to ART			
ViroSeq HIV-1 Genotyping System v 2.0, or equivalent	package	0	0
PCR Cleanup Kit	kit	0	0
Sequencing Consumable Kit, or equivalent	- " -	0	0
BigDye Terminator Sequencing Standard Kit, or equivalent	package	0	0
POP-6 Polymer	- " -	0	0
10 x Concentrated Genetic Analyzer Buffer	package	0	0
96-Well Plate Cover	- " -	0	0
Hi-Di Formamide, 25ml	- " -	0	0
Microtube, 1.5 ml	piece	0	0
Filter Tip, 20 µL, sterile	tray	20	20
Filter Tip, 1,000 µL, sterile	- " -	0	0
0.2 ml Thin Wall PCR Tube, flat cap	piece	0	0
Filter Tip, 200 µL, sterile	tray	0	0
Thin Wall PCR Tube, 0.2 ml, 8 per strip	strip	0	0
Thin Wall PCR Cap, 0.2 ml, 8 per strip	- " -	0	0
External and Internal Quality Control Measures for HIV/AIDS Laboratory Testing			
Standard control (qualification) serum panels containing (in various concentrations) and non-containing HIV antibodies	vial	0	0
Control serum samples containing HIV antibodies (for internal laboratory quality control)	- " -	610	610
Standard serum samples containing HIV-1 p24 antigen (for internal laboratory quality control)	- " -	156	156
HIV DBS Control Kit (HIVDBSEP01-C) (HIV DNA)	package	12	12
HIV-1 Control Panel (HIVRNAEP01-C) (HIV RNA)	- " -	25	25
External Quality Assurance Services (EQAS®) HIV-Hepatitis Program), 12 x 2 ml, or equivalent	- " -	29	29
Closed Blood Sampling Systems for Immunological and Virological Studies in HIV-infected patients			
Closed blood sampling system (Vacutainer K3EDTA Tubes, holders, needles)	kit	74,800	74,800
Closed blood sampling system (Vacutainer K2EDTA Tubes, holders, needles)	- " -	53,400	53,400