

**Diagnostic market analysis:  
HIV simple/rapid, enzyme immunoassay (EIA)  
and supplemental tests: available data and  
implications for future funding**

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## TABLE OF CONTENTS

<b>PURPOSE OF THIS DOCUMENT .....</b>	<b>6</b>
<b>EXECUTIVE SUMMARY .....</b>	<b>7</b>
Top-line trends in available procurement data for HIV simple/rapid tests .....	8
Top-line trends in available procurement data for HIV EIA tests .....	9
Top-line trends in available procurement data for HIV supplemental tests .....	9
Suggestions for use of available procurement data to inform future funding and procurement strategy .....	10
Suggestions to improve data collection .....	11
Suggestions for further data analysis.....	12
<b>INTRODUCTION .....</b>	<b>20</b>
<b>AVAILABLE TECHNOLOGIES .....</b>	<b>21</b>
Overview .....	21
HIV simple/rapid tests.....	21
HIV enzyme immunoassays (EIA) .....	21
HIV supplemental tests .....	22
<b>PROCUREMENT DATA .....</b>	<b>24</b>
Key funding and procurement agencies .....	24
Data availability and critical gaps.....	24
Overview of procurement data for HIV simple/rapid, EIA, and supplemental tests.....	28
Procurement data for HIV simple/rapid tests.....	31
Procurement data for HIV EIA tests .....	47
Procurement data for HIV supplemental tests .....	55
<b>DISCUSSION AND NEXT STEPS .....</b>	<b>61</b>
Use of available procurement data to inform future funding and procurement strategy.....	61

Areas for improvement in data collection .....	62
Areas for further analysis or consideration in future procurement .....	64
<b>REFERENCES .....</b>	<b>65</b>

## **PURPOSE OF THIS DOCUMENT**

The purpose of this document is to characterize the market for diagnostic products for the detection of HIV, with a focus on HIV simple/rapid, enzyme immunoassay (EIA), and supplemental tests. This document is intended to provide:

- An overview of technologies that were purchased during the time period analyzed in the report;
- Analysis of available procurement data and information gaps; and
- Discussion of issues related to market dynamics for HIV simple/rapid, EIA, and supplemental tests

This document was prepared based on market data available in the timeframe required, and is intended as a basis for discussion. Due to critical gaps in the available data, it is recommended that this market analysis be updated as and when additional or improved data are available.

## EXECUTIVE SUMMARY

Key trends in the market for HIV simple/rapid, EIA, and supplemental diagnostic products include:

- Procurement primarily of HIV simple/rapid tests (vs. other formats), with over 43 million HIV simple/rapid tests procured in 2010 by agencies for which data were available;
- An increasingly consolidated market for HIV simple/rapid tests, in part due to recent mergers and acquisitions;
- A range of ex-works prices by destination country and by means of procurement (agency; direct vs. indirect procurement; supplier, agent or intermediary);
- For HIV simple/rapid tests, a decrease in the weighted average ex-works price, despite increases in minimum and maximum prices per test, indicating a shift towards procurement of less expensive tests; and
- For HIV EIA and supplemental tests, an increase in the weighted average ex-works price, indicating price increases and/or a shift towards procurement of more expensive tests.

These trends, expanded and detailed in this report, provide context to inform UNITAID funding priorities, ensuring maximum market impact. Because UNITAID's contribution to scaling up access to treatment for HIV/AIDS for people in low- and middle-income countries hinges on increased access to quality diagnostics, it is critical to understand current diagnostic market dynamics and recent trends to optimize ongoing and future investment in national HIV programmes, including the treatment of HIV/AIDS in these countries.

Patients who are not diagnosed cannot access treatment. Point-of-care diagnostics play a critical role in bringing testing and counseling closer to the community. As such, point-of-care diagnostics provide the entry point for access to treatment to HIV infected patients. It should be noted that provision of a reliable HIV serostatus result to an individual requires at least two, sometimes three, consecutive rapid tests. This point is important for correctly interpreting market dynamics and recent trends. Future funding priorities should be informed by a clear picture of what tests are currently procured and how they are used.

This report reviews available sources of procurement data to characterize the current market for HIV simple/rapid, enzyme immunoassay (EIA), and supplemental tests, and analyses the current market structure, relevant trends, and implications for UNITAID. Based on the data available in the timeframe required for preparation of this document, several areas are flagged for discussion.

## Top-line trends in available procurement data for HIV simple/rapid tests

The procurement data indicate:

- HIV simple/rapid test procurement is well established and, according to available data at the time of analysis, constitutes almost 96% of the procurement value for HIV simple/rapid, EIA and supplemental tests. (It should be noted, though, that Global Fund principle recipients are not required to report information on non-rapid tests to the Global Fund Price and Quality Reporting [PQR] mechanism; other sources should be consulted if a more exhaustive analysis of weight by product category is to be conducted).
- Over 43 million HIV simple/rapid tests were procured in 2010, with most significant procurement volumes reported by SMCS and UNICEF (Table 1).
- In 2010, the weighted average ex-works price of HIV simple/rapid tests ranged from \$0.47 to \$3.64 per test. The weighted average price decreased 7% from 2008 to 2010, despite increases in minimum and maximum prices per test (Table 2), indicating a shift toward procurement of less expensive tests.
- The market is highly consolidated, dominated by Inverness Medical Innovations (now Alere), with market-leading product Determine™ HIV-1/2 accounting for 83.8% of the reported 2010 procurement volume.
- The market recently has become increasingly consolidated through mergers and acquisitions, as well as through more organic changes in market share, such as product growth (Figure 1). For example, Inverness Medical Innovations owns 75% of Standard Diagnostics<sup>1</sup>, the third leading manufacturer of HIV simple/rapid tests and producer of the SD BIOLINE HIV 1/2 3.0 test. In addition, Orgenics, reported as the fifth leading manufacturer of HIV simple/rapid tests (with products including DoubleCheckGold™ HIV1&2, DoubleCheckGold™ Ultra HIV1&2, ImmunoComb® II HIV 1&2 BiSpot and ImmunoComb HIV 1&2 TriSpot Ag-Ab), is part of Inverness Medical Innovations (now Alere). This trend may render the market more vulnerable to supply disruptions or lack of price competition.
- Country-specific analysis of available HIV simple/rapid test procurement data reported at the ex-works level shows that Determine™ HIV-1/2 was the most procured test in 2010, representing >90% of the tests procured (by volume) in 50% of the countries for which data were available (Figure 2).
- Ex-works prices vary by destination country. For example, the 2010 weighted average ex-works price of Determine™ HIV-1/2 ranged from \$0.69 in Benin to \$1.47 in Mauritius

<sup>1</sup> Inverness Takes Standard Diagnostics Stake to 75 Percent, MassDevice – Medical Device Industry News. 31 March 2011. Available at: <http://www.massdevice.com/news/inverness-takes-standard-diagnostics-stake-75-percent>.



(22% difference between least and most expensive countries; and from 7% less to 39% greater than the weighted average price of \$0.80 per test).

- Ex-works prices also vary depending on means of procurement (e.g. directly from the manufacturer vs. from suppliers, agents, or intermediaries). For example, the 2010 ex-works price for Determine™ HIV-1/2 ranged from \$0.65 to \$1.08 (i.e., from 19% less to 34% greater than the weighted average price of \$0.80 per test), depending on how it was procured.

### **Top-line trends in available procurement data for HIV EIA tests**

HIV EIA tests are procured in much smaller volumes in low- and middle-income countries than HIV simple/rapid tests, accounting for <4% of the total procurement value of HIV simple/rapid, EIA and supplemental tests, based on available data. In addition, the market for EIA tests is more diverse: data include both HIV antibody-only tests and combined HIV antigen-antibody EIAs. EIA procurement data indicate:

- Over 1.3 million HIV EIA tests were procured in 2010, with >60% of volumes reported by SMCS (Table 3).
- In 2010, the weighted average ex-works price of HIV EIA tests ranged from \$0.17 to \$2.18 per test. The minimum price per HIV EIA test decreased 15% between 2008 and 2010, and the maximum price per test rose 17% between 2008 and 2010. The weighted average price increased 38% during this time, indicating price increases and/or a shift towards procurement of more expensive tests (Table 4).
- Manufacturer market share shows a more fragmented market for HIV EIA tests than for HIV simple/rapid tests. Several manufacturers play an important role in this market, including bioMérieux, Bio-Rad, Abbott, Siemens and Diasorin (Figure 3). Key bioMérieux products include Vironostika® HIV Uni-Form II Ag/Ab (the market-leading product, representing 28.0% of reported 2010 procurement by value and 16.9% of reported 2010 procurement by volume) and Vironostika® HIV Uni-Form II Plus O (18.7% by value, 12.9% by volume).

### **Top-line trends in available procurement data for HIV supplemental tests**

HIV supplemental tests, like HIV EIA tests, are procured in much smaller volumes than HIV simple/rapid tests, and the market is less well characterized (e.g., Global Fund PQR data do not cover HIV supplemental tests [Table 8]). HIV supplemental test procurement data indicate:

- Fewer than 10,000 HIV supplemental tests were procured in 2010, with most significant procurement volumes reported by SMCS (Table 5).

- In 2010, the weighted average ex-works price of HIV supplemental tests ranged from \$5.61 to \$32.05 per test. The minimum price per HIV supplemental test decreased 65% between 2008 and 2010, and the maximum price per test rose 39% between 2008 and 2010. The weighted average price increased 25% during this time, indicating price increases and/or a shift towards procurement of more expensive tests (Table 6).
- Manufacturer market share shows a more evenly distributed market for HIV supplemental tests, although this may be due in part to lack of data. MP Biomedicals, Maxim Biomedical, and Innogenetics are the only manufacturers for which procurement data were reported in 2009, but Orgenics (Inverness) and Bio-Rad re-emerged as additional manufacturers in this market in 2010 (Figure 4).

## **Suggestions for use of available procurement data to inform future funding and procurement strategy**

Available procurement data can be used to characterize the market, with market trends used to inform future funding and procurement strategy.

### ***1. Leverage information on price variation by country and by test to improve cost-effectiveness of procurement***

Trend analysis indicates variation in the weighted average price of HIV simple/rapid tests (>200% difference between countries, not accounting for differences in selected tests; 22% difference between countries for Determine™ HIV-1/2, the most-procured product). These wide ranges illustrate the potential for improved procurement value. For example, a country achieving lower prices could be used as a benchmark for negotiating lower prices for other countries.

### ***2. Account for market consolidation in procurement decisions to balance competition with market stability***

Healthy competition among manufacturers should be encouraged, but too much disruption in supply could compromise patient outcomes. For example, a sudden change in the most commonly used product could be problematic if there is a lack of familiarity with new tests, a lack of appropriate laboratory infrastructure or required materials, or if new tests are ill-suited for a particular setting. The balance between competition and market stability depends on market dynamics for each test type.

As outlined in this report, the HIV simple/rapid test market is highly consolidated. Future procurement decisions in this market could encourage competition and availability of better products at the lowest possible price. Market analysis also indicates a shift towards procurement of more expensive HIV EIA and supplemental tests, despite greater price competition. While this could be driven by a number of factors (e.g., increased use of 4<sup>th</sup>

generation HIV EIA tests), future procurement decisions in this market could consider this information in assessing cost-effectiveness of product selection.

## **Suggestions to improve data collection**

Data for HIV simple/rapid tests are generally well reported, but key gaps discussed in this report could be addressed to improve the quality and completeness of data to better inform future procurement. In addition, reporting of procurement of HIV EIA and supplemental tests, while much smaller in volume and value than that of HIV simple/rapid tests, could be improved.

### ***3. Include data from country tenders***

Some countries procure HIV diagnostics directly by issuing national tenders (e.g., Brazil, India, and South Africa). The value and volume of direct procurement by countries is not included in this report, but would be expected to be significant. Gaining access to these data would allow for a more comprehensive overview.

### ***4. Support improved accuracy of GPRM data***

The GPRM database compiles transaction-level procurement data from a wide range of agencies, and therefore could be a valuable resource for future market analysis. However, the quality of the data reported requires improvement, as concurrence of GPRM and original source data was found to be poor (refer to Section 6 of this report). Funding bodies should mandate reporting of procurement transactions and encourage more transparent data verification.

### ***5. Address potential overlap in Global Fund PQR and UNICEF***

To better characterize the purchases that the Global Fund PQR data reflect and to limit the potential for overlap, Global Fund should be encouraged to identify more clearly which parties are responsible for reporting data (e.g. Global Fund itself, its principal recipients [e.g., UNDP], or procuring bodies [e.g., UNICEF]).

### ***6. Encourage more complete reporting in Global Fund PQR***

Procurement data for HIV EIA and supplemental tests are less fully and accurately reported than for simple/rapid tests. To create a full picture of international procurement for HIV diagnostics, reported categories should be expanded to include HIV EIA and supplemental tests.

### ***7. Address inconsistent or insufficient data entry***

In much of the data, the manufacturer and/or product description was observed to be incorrect or incomplete. Drop-down lists could be used to encourage correct data entry.

**8. Account for funding timeframe in reporting procurement data**

Procurement funds are often disbursed at a single point in time for projects spanning several years. This can present difficulties for analyzing year-on-year trends in the data, and thus forecasting demand. Information on project duration should be included in reporting requirements, allowing comparison across years and funding bodies.

**Suggestions for further data analysis**

Further analysis in the following areas could be valuable in the future, to take advantage of improved data availability and/or to complement funding for future procurement:

**9. Further analyse direct-from-manufacturer procurement to procurement through suppliers, agents, or intermediaries to assess potential for improved cost-effectiveness**

Initial analysis has been performed to assess differences in price for products obtained by agencies using direct procurement versus procurement through suppliers, agents or intermediaries. With a more complete dataset, in-depth analysis of price and order patterns could be performed to inform efforts to improve cost-effectiveness of procurement.

**10. Consider activities needed to complement procurement of HIV simple/rapid, EIA and supplemental tests**

Improvements in appropriate use and counseling maximize the public health impact of improved test pricing and availability. For example, simple/rapid tests often do not include positive and negative controls. These may be available from the manufacturer, but are sold separately (in part due to their differing shipping and storage requirements). Funding agencies could earmark a portion of procurement funds for positive and negative controls, thereby enhancing the value of their investments.

In summary, HIV serological and supplemental test procurement is well established, and the market – particularly for HIV simple/rapid tests – is well characterized. Top-line trends in test availability and pricing can be used to inform procurement decisions, for example, in striking a balance between fostering healthy competition and avoiding supply disruptions, or in negotiating lower prices for tests. With modest effort, the quality and completeness of data can be improved, allowing for further analysis to optimize the cost-effectiveness of procurement.

Tables and figures referenced in executive summary

**Table 1. Overview of available data on procurement of HIV simple/rapid tests**

Simple/ rapid tests	Total value (USD)			Volume (total number of tests)			Weighted average price per test (USD)		
	2008	2009	2010	2008	2009	2010	2008	2009	2010
GFATM	1,287,150	12,144,408	3,127,507	1,470,601	12,422,941	3,743,089	0.96	0.98	0.92
GFATM - pending verif.	2,816,330	4,150,873	4,633,207	N/A	N/A	N/A	N/A	N/A	N/A
SCMS	21,547,000	22,083,329	18,020,619	26,695,265	26,229,025	20,182,375	1.25	1.48	1.14
UNICEF	10,518,230	9,008,879	13,813,076	11,307,384	10,572,240	17,120,896	1.17	1.16	1.05
UNITAID	2,244,393	32,016	1,059,786	3,364,650	49,300	1,464,433	1.10	0.72	1.07
WHO	606,042	562,250	433,022	495,090	615,300	490,840	1.20	1.08	1.00
<b>Total</b>	<b>36,202,815</b>	<b>43,830,882</b>	<b>36,454,010</b>	<b>43,332,990</b>	<b>49,888,806</b>	<b>43,001,633</b>	<b>1.14</b>	<b>1.23</b>	<b>1.05</b>

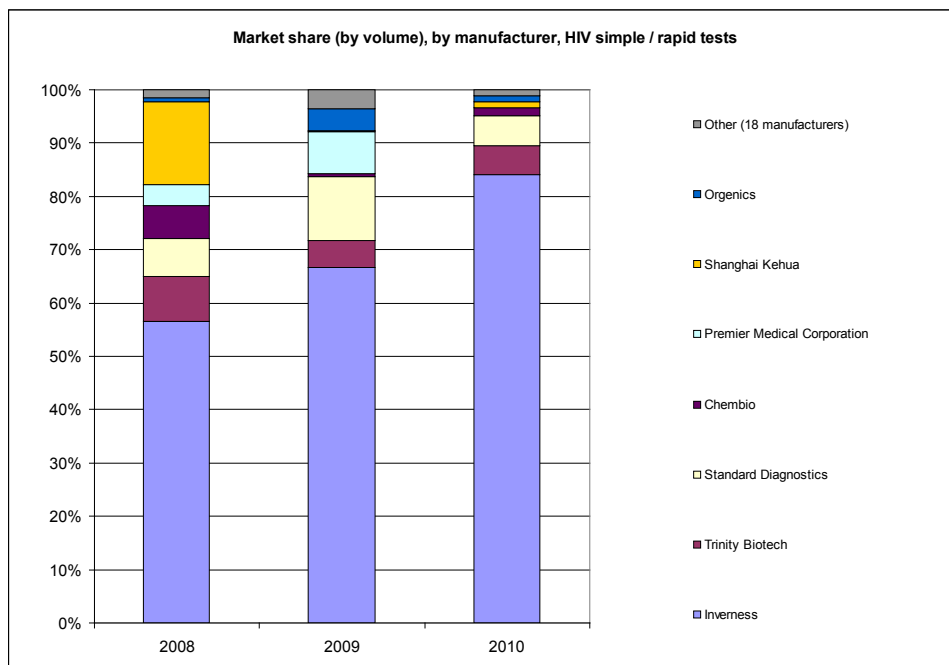
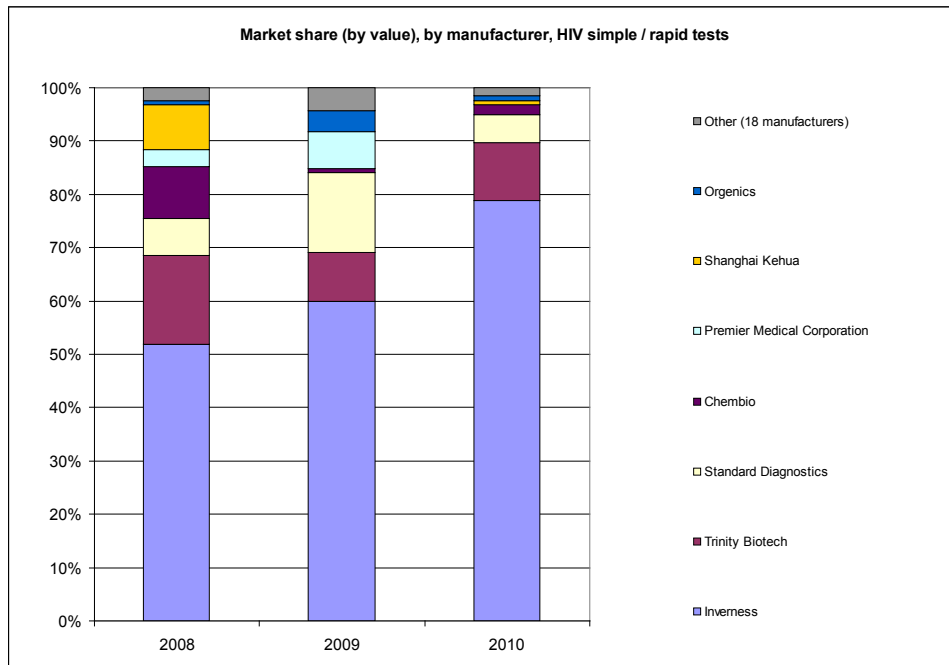
Note: Refer to Table 8 for important comments on limitations of data availability. "GFATM - pending verification" refers to data tagged by Global Fund as requiring clarification and not resolved as of June 2011. Overall weighted average price excludes "GFATM - pending verification" data.

N/A: Not available

**Table 2. Price trends for HIV simple/rapid tests based on available procurement data reported at the ex-works level**

Parameter	2008	2009	2010	% change
Minimum price/test (USD)	0.39	0.38	0.47	21%
Maximum price/test (USD)	3.60	3.63	3.64	1%
Weighted average price/test (USD)	1.14	1.23	1.05	-7%

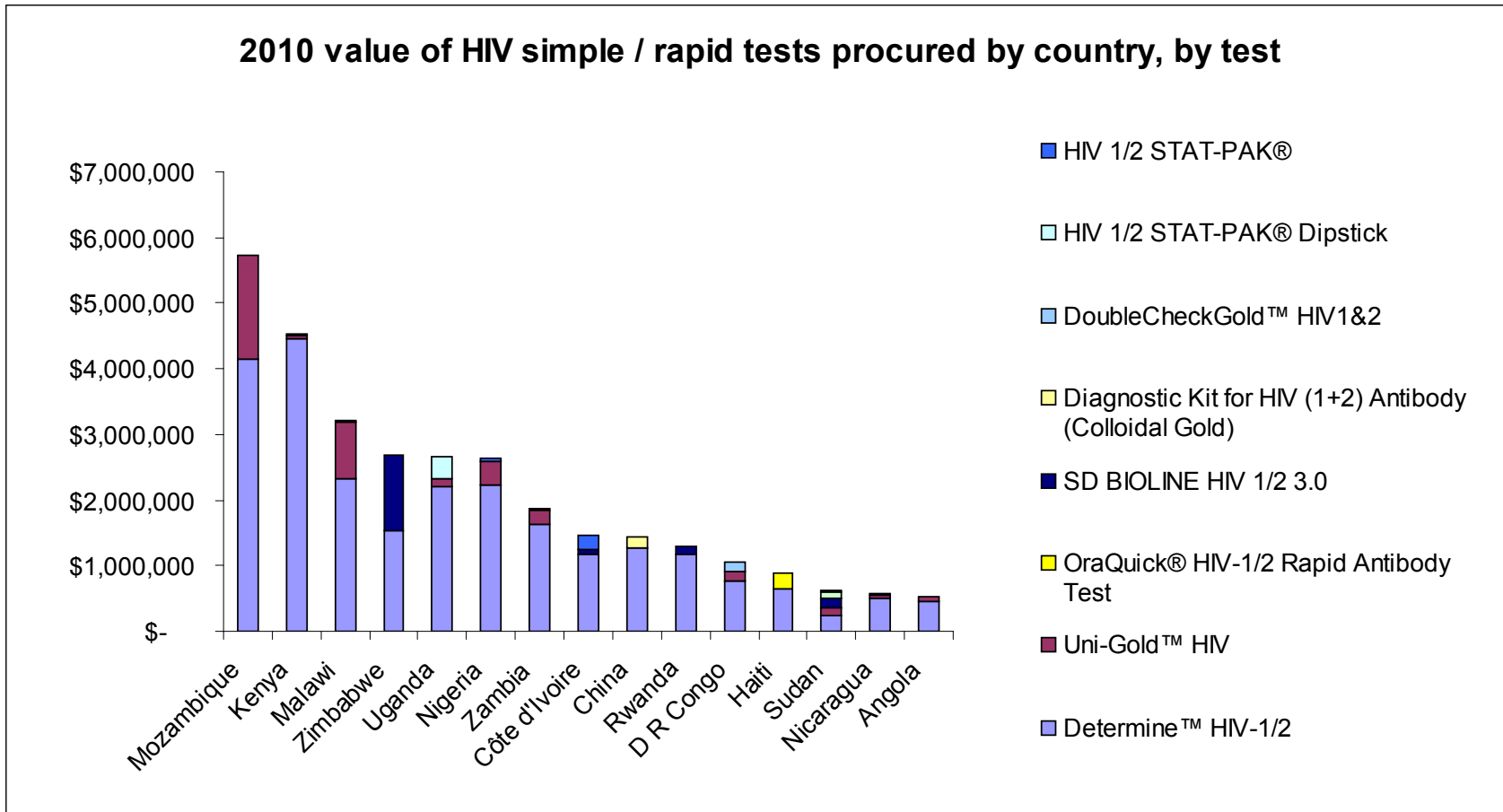
**Figure 1. Manufacturer market share of HIV simple/rapid tests, by value and volume (available data, 2008-2010, reported at the ex-works level)**



Note: Charts reflect reported data. Note: Organics is part of Inverness Medical Innovations. Inverness owns 75% of Standard Diagnostics and, in turn, is now part of Alere.<sup>2</sup>

<sup>2</sup> Inverness Takes Standard Diagnostics Stake to 75 Percent, *MassDevice – Medical Device Industry News*. 31 March 2011. Available at: <http://www.massdevice.com/news/inverness-takes-standard-diagnostics-stake-75-percent>.

Figure 2. 2010 value of HIV simple/rapid tests procured by country, by test (available data, 2009-2010, reported at the ex-works level)



**Table 3. Overview of available data on procurement of HIV EIA tests**

EIA tests	Total value (USD)			Volume (total number of tests)			Weighted average price per test (USD)		
	2008	2009	2010	2008	2009	2010	2008	2009	2010
GFATM	1,710	6,836	549	1,728	5,760	384	0.99	1.21	1.43
GFATM - pending verif.	6,763	125,151	134,350	N/A	N/A	N/A	N/A	N/A	N/A
SCMS	328,485	801,112	1,305,071	188,160	344,704	890,488	1.80	3.49	1.75
UNICEF	506,277	466,426	138,005	888,864	641,184	345,600	0.84	1.12	0.90
UNITAID	N/A	N/A	1,990	N/A	N/A	1,152	N/A	N/A	1.73
WHO	116,982	121,824	60,035	126,912	140,736	62,592	0.96	0.85	1.16
<b>Total</b>	<b>953,454</b>	<b>1,396,199</b>	<b>1,505,650</b>	<b>1,205,664</b>	<b>1,132,384</b>	<b>1,300,216</b>	<b>1.04</b>	<b>1.45</b>	<b>1.43</b>

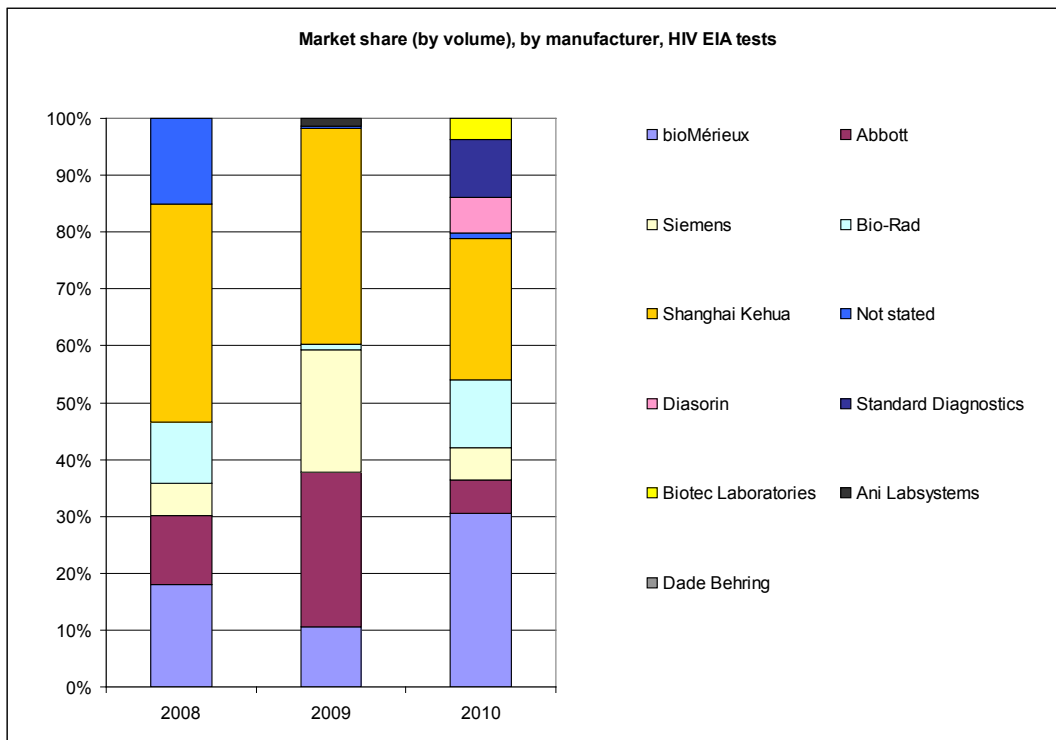
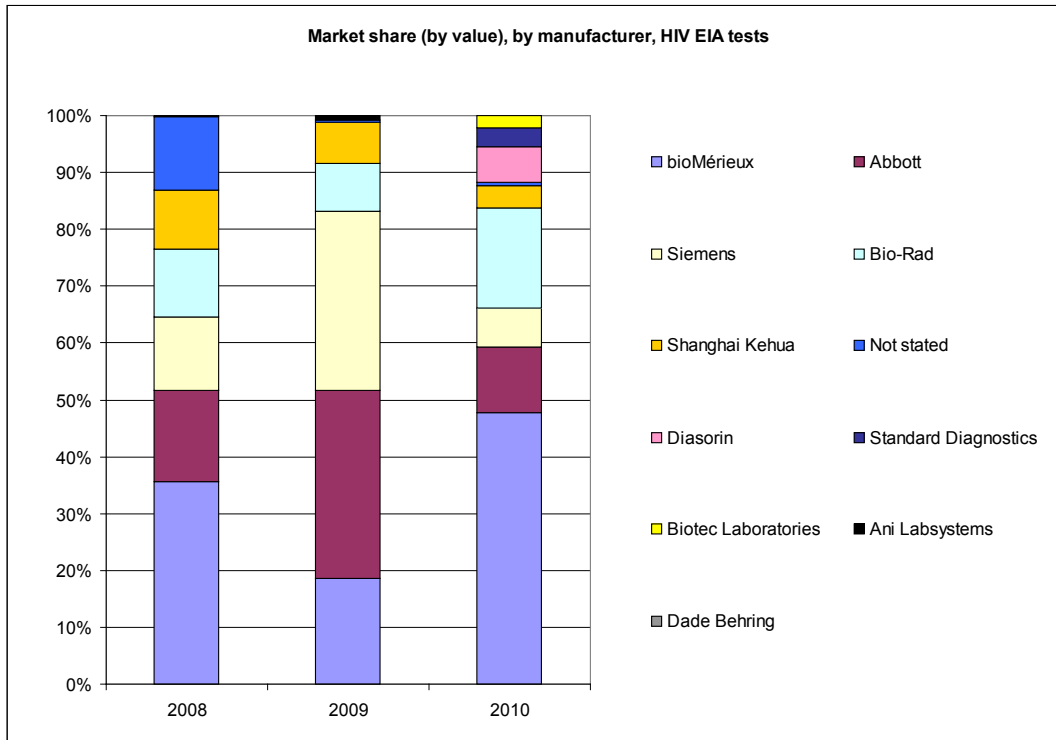
Note: Refer to Table 8 for important comments on limitations of data availability. "GFATM - pending verification" refers to data tagged by Global Fund as requiring clarification; yet to be resolved as of June 2011. Overall weighted average price excludes "GFATM - pending verification" data. N/A: not available.

**Table 4. Price trends for HIV EIA tests based on available procurement data reported at the ex-works level**

Parameter	2008	2009	2010	% change
<b>Minimum price/test (USD)</b>	0.20	0.17	0.17	-15%
<b>Maximum price/test (USD)</b>	1.86	2.03	2.18	17%
<b>Weighted average price/test (USD)</b>	1.04	1.45	1.43	38%



**Figure 3. Manufacturer market share of HIV EIA tests, by value and volume (available data, 2008-2010, reported at the ex-works level)**



*DiaSorin acquired the product range from Abbott GmbH in April 2010.*

**Table 5. Overview of available data on procurement of HIV supplemental tests**

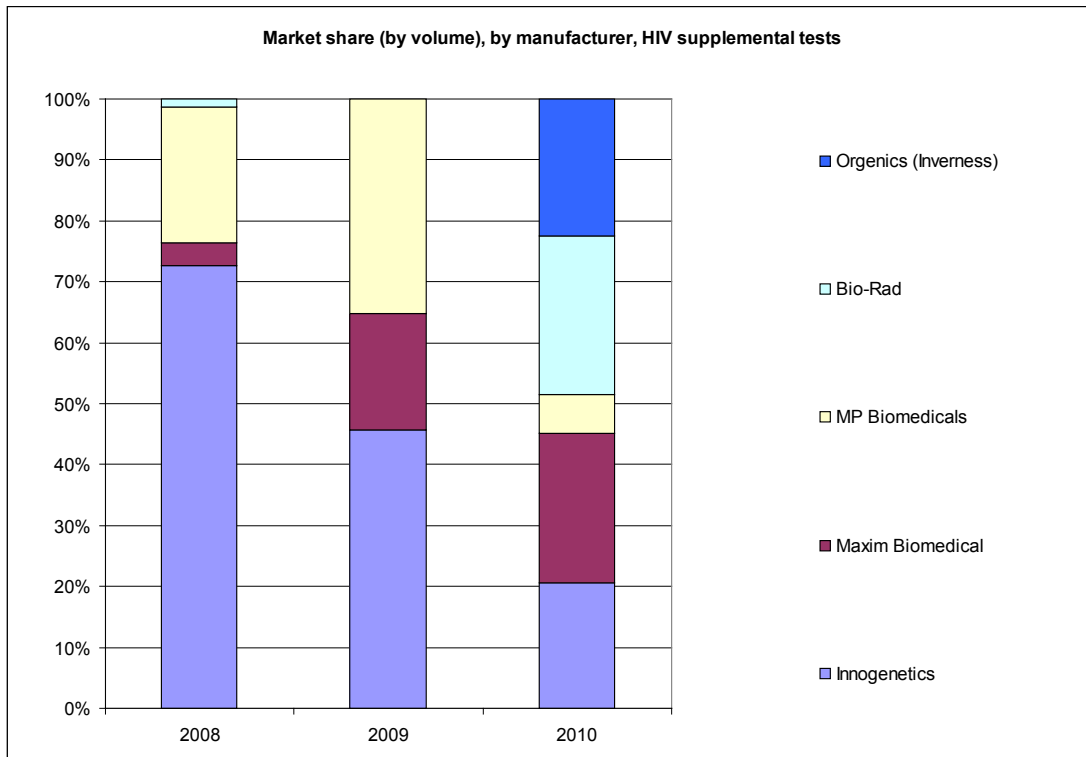
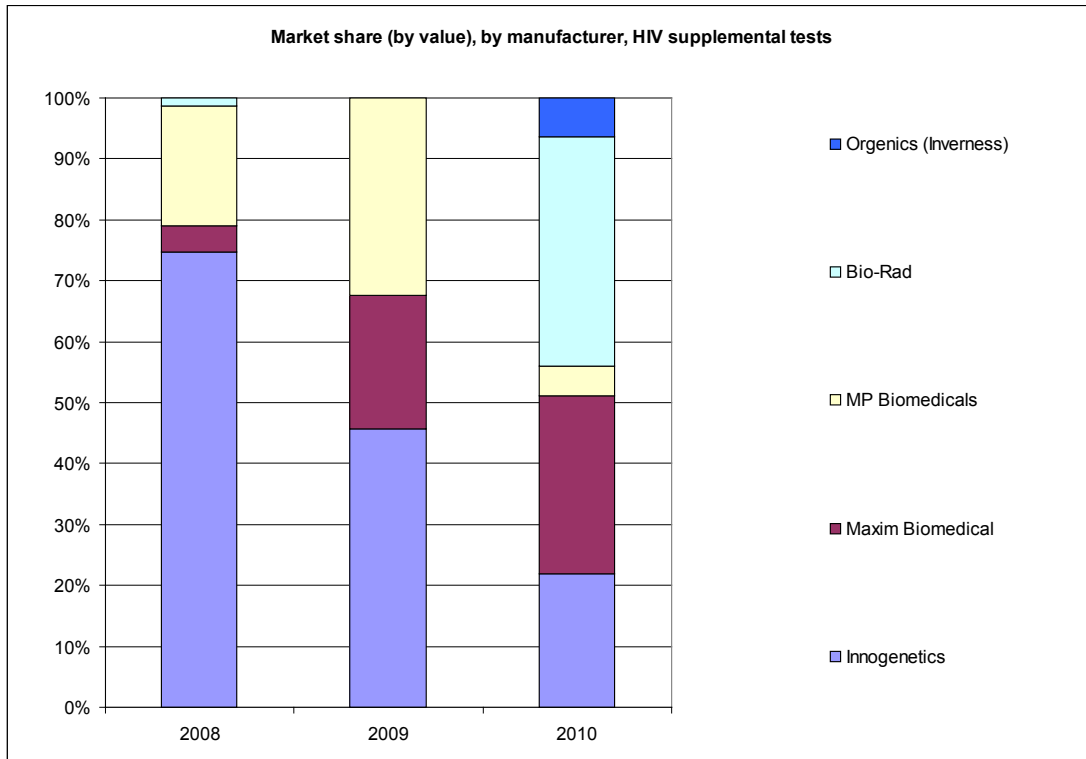
Supplemental tests	Total value (USD)			Volume (total number of tests)			Weighted average price per test (USD)		
	2008	2009	2010	2008	2009	2010	2008	2009	2010
GFATM	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
GFATM - pending verif.	N/A	9,226,024	6,281	N/A	N/A	N/A	N/A	N/A	N/A
SCMS	28,502	53,499	138,027	1,100	2,192	6,800	25.19	27.17	26.69
UNICEF	147,131	N/A	44,387	7,550	3,908	2,370	18.60	16.39	17.17
WHO	3,373	0	0	252	0	0	13.57	N/A	N/A
<b>Total</b>	<b>179,005</b>	<b>53,499</b>	<b>182,414</b>	<b>8,902</b>	<b>6,100</b>	<b>9,170</b>	<b>19.24</b>	<b>18.96</b>	<b>24.07</b>

Note: Refer to Table 8 for important comments on limitations of data availability. "GFATM - pending verification" refers to data tagged by Global Fund as requiring clarification; yet to be resolved as of June 2011. Overall weighted average price excludes "GFATM - pending verification" data. N/A: not available.

**Table 6. Price trends for HIV supplemental tests based on available procurement data reported at the ex-works level**

Parameter	2008	2009	2010	% change
<b>Minimum price/test (USD)</b>	15.84	15.78	5.61	-65%
<b>Maximum price/test (USD)</b>	23.00	23.00	32.05	39%
<b>Weighted average price/test (USD)</b>	19.24	18.96	24.07	25%

**Figure 4. Manufacturer market share of HIV supplemental tests, by value and volume (available data, 2008-2010, reported at the ex-works level)**



## INTRODUCTION

By the end of 2009, nearly 5.2 million HIV-infected patients from low- and middle-income countries were receiving antiretroviral (ARV) drugs.<sup>3</sup> Current WHO guidelines (2010) promote HIV diagnosis and earlier initiation of ARV treatment.<sup>4</sup> HIV serological tests, including simple/rapid, enzyme immunoassay (EIA), and supplemental, or confirmatory, tests, play a critical role in identifying patients who are infected with HIV, and thus are the gateway to treatment.

HIV diagnosis can be performed using HIV simple/rapid, EIA and supplemental tests. According to UNAIDS-WHO recommendations (1997),<sup>5</sup> selection of the most appropriate testing strategy, including the choice of particular test(s), depends on:

- Test objective (transfusion/transplant safety, surveillance, or diagnosis of HIV infection);
- Sensitivity and specificity of the test; and
- Prevalence of HIV infection in the population being tested.

Individuals are informed of their positive serostatus based on the combined results of at least two or three consecutive HIV tests. As a result, countries need a greater volume of the first-line HIV rapid test, as only the reactive specimens are further investigated with second-line and possibly third-line HIV rapid tests. This approach ensures a positive predictive value of 99% while reducing cost.

<sup>3</sup> UNAIDS/WHO. Global Report: UNAIDS report on the global AIDS epidemic 2010.

<sup>4</sup> WHO. Antiretroviral therapy for HIV infection in adults and adolescents: recommendations for a public health approach. 2010 (revised).

<sup>5</sup> WHO. Joint United Nations Programme on HIV/AIDS (UNAIDS) – WHO Revised recommendations for the selection and use of HIV antibody tests. Weekly Epidemiological Record. March 1997; 12(72):81-88.

## AVAILABLE TECHNOLOGIES<sup>6</sup>

### Overview<sup>7</sup>

The diagnosis of HIV infection is usually made on the basis of the detection of antibodies to HIV. Serological tests for detecting antibodies to HIV are generally classified as screening or supplemental tests (sometimes referred to as confirmatory tests). First-line tests can provide the presumptive identification of antibody-positive (and/or HIV antigen) specimens, and supplemental tests are used to confirm whether specimens found reactive with a particular screening test contain antibodies specific to HIV and/or HIV antigen. That is, at least two to three tests are required to give an individual a positive HIV test result.

### HIV simple/rapid tests<sup>8</sup>

A variety of simple, instrument-free tests are now available, including agglutination, immunofiltration (flow-through tests), immunochromatographic (lateral-flow tests) and dipstick tests. Specimens and reagents are often added to the test device by means of a disposable transfer pipette. A reactive result is indicated by the appearance of a colored band/line or dot, or by an agglutination pattern. Most of these tests can be performed in less than 20 minutes and are therefore called rapid tests. Other simple tests are less rapid and their procedures require 30 minutes to 2 hours. The results are read visually. In general, these are most suitable for use in testing and counselling centres and laboratories that have limited facilities and process low numbers of specimens daily.

### HIV enzyme immunoassays (EIA)<sup>9</sup>

The most widely used screening tests are enzyme immunoassays (often referred to as EIAs or ELISAs) as they are the most appropriate for screening large numbers of specimens on a daily basis, e.g. blood donations and surveillance. The earliest tests used purified HIV lysates (1<sup>st</sup> generation), and often lacked sensitivity and specificity. Improved tests based on recombinant proteins and/or synthetic peptides, which also enabled the production of combined HIV-1/HIV-2 assays, became rapidly available (2<sup>nd</sup> generation). The so-called 3<sup>rd</sup> generation or sandwich EIAs, which use labelled antigen as conjugate, are extremely sensitive and have reduced the window period considerably. Enhanced EIAs have been developed that detect both antibody to HIV and HIV-1 antigen (4<sup>th</sup> generation) leading to earlier

<sup>6</sup> This section is an excerpt from a WHO report produced by the Diagnostics and Laboratory Technology team. HIV assays: Operational characteristics. Report 16, Rapid assays. 2010. Please refer to the original report for further information, including detailed operational characteristics of the HIV rapid tests evaluated.

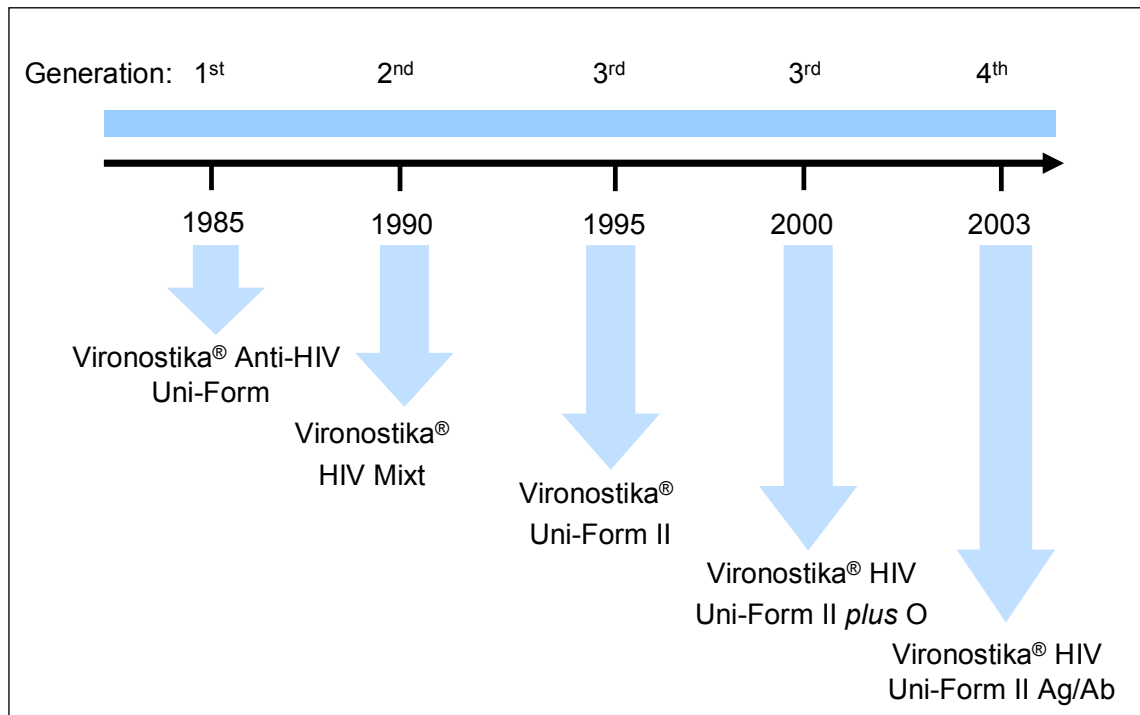
<sup>7</sup> WHO. HIV assays: Operational characteristics. Report 16, Rapid assays. 2010.

<sup>8</sup> *Ibid.*

<sup>9</sup> *Ibid.*

detection of HIV infection and further reducing the window period.<sup>10</sup> Figure 5 illustrates the evolution of Vironostika® HIV EIAs as an example.

**Figure 5. The evolution of HIV EIAs: Vironostika® as an example**



Note: Each generation offered improvements in specificity and sensitivity.

### HIV supplemental tests<sup>11</sup>

When a single screening test is used for testing in a population with a very low prevalence of HIV infection, the probability that a person is infected when a positive test result is obtained (i.e., the positive predictive value) is very low, since the majority of people with positive results are not infected. This problem occurs even when a test with high specificity is used. Accuracy can be improved if a second supplemental test is used to retest all those specimens found reactive by the first test. The negative predictive value will generally always approach near to 100%, irrespective of prevalence. A third test may also be required to elucidate the correct status.

Until 2000, the most commonly used supplemental test was the Western blot (WB). However, its use has proven to be very expensive and can, under some conditions, produce a relatively large number of indeterminate results. Similar tests, generically called line immunoassays (LIAs), based on recombinant proteins and/or synthetic peptides capable of detecting antibodies to specific HIV-1 and/or HIV-2 proteins, have been developed. Examples of this technology include

<sup>10</sup> Duong LT, Laperche S, Brennan C, et al. Evaluation of the sensitivity and specificity of six HIV combined p24 antigen and antibody assays. *Journal of Virological Methods*, 122:185-194, 2004.

<sup>11</sup> WHO. HIV assays: Operational characteristics. Report 16, Rapid assays. 2010.

the INNO-LIA™, Pepti-LAV, and RIBA™ assays. In general, these tests produce fewer indeterminate results as compared to WB, but are also more expensive.

The WHO Diagnostics and Laboratory Technology team provides technical information on individual HIV tests on the basis of:

- General and operational characteristics
- Comparison of the assays under evaluation with reference assays
- Detailed operational aspects
- Technician's appraisal of the test kit
- Ease of performance
- Technical suitability for use in small laboratories
- Results on commercial seroconversion panels

Refer to HIV performance evaluation reports<sup>12</sup> for more information: [http://www.who.int/diagnostics\\_laboratory/publications/evaluations/en/index.html](http://www.who.int/diagnostics_laboratory/publications/evaluations/en/index.html).

<sup>12</sup> WHO. HIV assays: Operational characteristics. Report 16, Rapid assays. 2010.

## PROCUREMENT DATA

### Key funding and procurement agencies

A substantial number of HIV simple/rapid, EIA, and supplemental tests for use in low- and middle-income countries are procured with donor funding. Procurement can be either direct (at country level) or through procurement agencies. This report is limited to donor funded procurement and does not include other procurement performed through direct funding by countries.

A range of other international agencies (e.g., MSF, MSH, IDA, World Bank, UNOPS, etc.) also procure or fund procurement of HIV simple/rapid, EIA, and supplemental tests but are not included in this study.

The activities of the agencies included in this study are summarized in Table 7.

**Table 7. Agencies funding and/or procuring HIV simple/rapid, EIA, and supplemental tests included in this study**

Agency	Activity
<b>Global Fund to Fight AIDS, Tuberculosis, and Malaria</b>	<ul style="list-style-type: none"> <li>• <i>Public-private partnership that funds procurement of HIV simple/rapid, EIA, and supplemental tests as part of its HIV/AIDS grant portfolio</i></li> <li>• <i>Principal recipients (PRs) of Global Fund grant (e.g., UNDP) in turn procure via UNICEF or other procurement agency</i></li> </ul>
<b>Supply Chain Management System (SCMS)</b>	<ul style="list-style-type: none"> <li>• <i>Procurement collaboration funded as part of the US President's Emergency Plan for AIDS Relief (PEPFAR)</i></li> <li>• <i>Procures for a range of programmes via in-country representatives (direct-from-manufacturer or via distributor) and other procurement service agents (e.g., Crown Agents)</i></li> <li>• <i>Can procure ART, HIV diagnostics, laboratory supplies and equipment, and other HIV/AIDS-related items; aligns with USAID waiver list and WHO requirements</i></li> </ul>
<b>The United Nations Children's Fund (UNICEF)</b>	<ul style="list-style-type: none"> <li>• <i>Agency focused on four aspects of HIV/AIDS: prevention, care, treatment and protection</i></li> <li>• <i>Identifies procurement and supply as one of its core cross-cutting issues</i></li> <li>• <i>Procures directly for UNICEF country programmes, and also acts as a procurement agent</i></li> </ul>
<b>UNITAID</b>	<ul style="list-style-type: none"> <li>• <i>Supports procurement efforts for HIV/AIDS, malaria and tuberculosis, with a particular focus on leveraging price reductions and scaling up access to treatment in low-income countries</i></li> </ul>
<b>WHO</b>	<ul style="list-style-type: none"> <li>• <i>Supports procurement with technical guidance, including bulk procurement list/prequalification information</i></li> <li>• <i>Also procures for countries (albeit in lower quantities in recent years)</i></li> </ul>

### Data availability and critical gaps

Table 8 summarizes procurement data availability for HIV simple/rapid, EIA, and supplemental tests and identifies critical gaps in available information.



**Table 8. Summary of procurement data availability for HIV simple/rapid, EIA, and supplemental tests for agencies included in this report**

Agency	Data source	Simple/rapid	EIA	Supplemental	Comments	Critical gaps
Global Fund	PQR <sup>13</sup>	60% of data (by 2010 value) pending verification as of June 2011	Very limited data reported	Very limited data reported	<ul style="list-style-type: none"> <li>98% of reported data (by 2010 value) is for simple/rapid tests as this is the only required category of products for reporting within diagnostics category</li> <li>For diagnostic tests, only HIV and malaria rapid tests should be reported in the PQR</li> <li>See comment in text regarding poor agreement with GPRM data</li> </ul>	<ul style="list-style-type: none"> <li>HIV EIA and supplemental tests are not reported</li> <li>Verification needed for 60% of simple/rapid data entries</li> </ul>
SCMS	Supplied by SCMS	Data reported			<ul style="list-style-type: none"> <li>Data supplied on request; cleaned to align with other sources</li> <li>See comment in text regarding poor agreement with GPRM data</li> </ul>	<ul style="list-style-type: none"> <li>Not applicable</li> </ul>
UNICEF	Supplied by UNICEF				<ul style="list-style-type: none"> <li>Reported at ex-works level</li> <li>Data supplied on request; cleaned to align with other sources</li> <li>See comment in text regarding possibility of overlap with Global Fund PQR for HIV simple/rapid tests</li> <li>See comment in text regarding poor agreement with GPRM data</li> </ul>	<ul style="list-style-type: none"> <li>Not applicable</li> </ul>
UNITAID	GPRM <sup>14</sup>				<ul style="list-style-type: none"> <li>UNITAID mandates that grant recipients report procurement in GPRM</li> </ul>	<ul style="list-style-type: none"> <li>GPRM data for procurement funded by other bodies are incomplete and/or inaccurate; see comment in text</li> </ul>
WHO	GSM <sup>15</sup>				<ul style="list-style-type: none"> <li>Reported at ex-works level</li> </ul>	<ul style="list-style-type: none"> <li>Not applicable</li> </ul>

<sup>13</sup> The Global Fund to Fight AIDS, Tuberculosis and Malaria. Price & Quality Reporting (PQR) – Procurement and Supply Management. April 2011. Available at: <http://www.theglobalfund.org/en/procurement/pqr/>.

<sup>14</sup> WHO. Global Price Reporting Mechanism. April 2011. Available at: <http://www.who.int/hiv/amds/gprm/en/>.

<sup>15</sup> WHO. Global Management System (GSM). April 2011. Available at: <http://intranet.who.int/sites/gsm>. Only accessible with a WHO login.

Additional global issues considered in analysis of the data are as follows:

#### *Country bidding procedures*

Some countries procure HIV diagnostics directly via bidding procedures initiated by the countries themselves (e.g., Brazil, India, South Africa), even if funding is sometimes provided by an agency external to the country. The value and volume of direct procurement by countries with domestic funds is not reflected in this report, which gathered available procurement data from the sources outlined in Table 8.

#### *Accuracy of GPRM data*

The Global price reporting mechanism (GPRM) is a web-based database, managed by the AIDS medicines and diagnostics service (AMDS), which collates transaction-level procurement data from a wide range of agencies.<sup>16</sup> The database is intended for reporting of transaction prices and quantities for HIV, malaria and tuberculosis drugs and commodities.

Concurrence of GPRM and original source data was occasionally problematic at the time of analysis (June 2011), with some rows in the GPRM data already represented in original source data. Some data was duplicative. GPRM data were removed from the core data set where more reliable data could be obtained directly from the source (e.g., UNICEF, SCMS, Global Fund).

#### *Potential overlap in Global Fund PQR and UNICEF*

The Price and Quality Reporting (PQR) tool is a web-based system, managed by the Global Fund, that collects transaction-level procurement data from principal recipients of Global Fund grants.

In some circumstances, the principal recipient of a Global Fund grant (e.g., UNDP) in turn procures via UNICEF or another body. For this reason, there is the potential for some overlap in data reported for HIV simple/rapid tests by Global Fund PQR and UNICEF. However, both data sources were included in the core dataset analysed, as in addition to its role as a procurement agent for diagnostics on behalf of UNDP for Global Fund, UNICEF procures directly for countries and UNICEF in-country programmes.

<sup>16</sup> For example, the Clinton Health Access Initiative (CHAI), the Crown Agent, the Global Drug Facility (GDF), GFATM, the Global Malaria Programme (GMP), the International Dispensary Association (IDA HIV/AIDS), USAID/Deliver, Mission Pharma, Management Sciences for Health (MSH), the Partnership for Supply Chain Management (PFSCMS), the United Nations Development Programme (UNDP), UNFPA, UNICEF, UNITAID and the WHO/Contracting and Procurement Service (WHO/CPS)

*Use of ex-works data for price analysis*

International commercial (INCO) terms, published by the International Chamber of Commerce (ICC), define the terms of shipment (e.g., buyer and seller responsibilities for transaction costs) for international procurement. For example, ex-works data describe procurement transactions in which the buyer acquires the goods at the site of manufacturer (or other named place) and then assumes risk and responsibility from that point, including all transaction costs (loading, transportation costs, etc.). Data reported as Cost, Insurance and Freight (CIF) or Carriage and Insurance Paid To (CIP), on the other hand, describe shipping procurement transactions in which the seller assumes more of the responsibility and risk – i.e., for transportation costs, insurance, and freight to the named destination port.

All available procurement data are presented in overview charts for each type of test (e.g., Figure 6 and Figure 7). For further analysis, however, only data reported at the ex-works level were used. This allowed a like-for-like comparison – e.g., of weighted average prices. Refer to Table 9 for an overview of ex-works data as a percentage of total data by value.

**Table 9. Ex-works data as a percentage of total data by value**

Test type	2008	2009	2010
HIV simple/rapid	98.9%	100%	99.6%
HIV EIA	77.6%	53.1%	70.3%
HIV supplemental	96.5%	95.9%	95.3%

Due to the high level of procurement of HIV simple/rapid tests relative to HIV EIA and supplemental tests, detailed analysis of procurement by test, by country, was of interest (e.g., Figure 10 through Figure 13). As data reported at the ex-works level accounted for >98% of available data for HIV simple/rapid tests by value, the ex-works data can be considered an accurate reflection of the total. Detailed analysis by test, by country, was not performed for HIV EIA tests because ex-works data in this case was less representative of total data. Detailed analysis by test, by country, was not performed for HIV supplemental tests due to relatively low levels of procurement. It was assumed that Global Fund PQR reports ex-works price based on the following statement in the user guide: “Global Fund PQR specifies that total cost of product should NOT include freight, shipping, and handling fees – these costs should be specified separately by user inputting data”.<sup>17</sup>

<sup>17</sup> The Global Fund to Fight AIDS, Tuberculosis and Malaria. A Quick Guide to the Global Fund’s Price and Quality Reporting System (PQR), Revision 0.3, November 2010. Available at: [http://www.theglobalfund.org/documents/psm/PSM\\_PQRQuick\\_Guide\\_en.pdf](http://www.theglobalfund.org/documents/psm/PSM_PQRQuick_Guide_en.pdf).

### *Inconsistencies in manufacturer listed for a particular product*

In much of the data, verification of the manufacturer<sup>18</sup> was required. Inconsistencies in the manufacturer listed for a particular product were common, due to apparent data entry errors or change or geographical distinction in ownership of a particular test. For example:

- Inverness Medical Innovations (now Alere) bought the Determine™ product range from Abbott in 2008, although Abbott retained rights to sale and distribution via Abbott access programmes. Some data sources continued to list Determine™ products as manufactured by Abbott after this divestment.
- Similarly, DiaSorin acquired the Murex product range from Abbott in 2010.
- Clearview® COMPLETE HIV1/2 is made by Chembio in the USA. Inverness Medical Innovations (now Alere) has rights for sale and use in USA, under the brand Clearview® COMPLETE HIV1/2. Chembio has rights for rest of world, under the brand Chembio SureCheck® HIV 1/2.

## **Overview of procurement data for HIV simple/rapid, EIA, and supplemental tests**

Table 10 contains an overview of available data for procurement of HIV simple/rapid, EIA, and supplemental tests, including the value of products procured by test type for each source.

<sup>18</sup> NB: throughout this report, shortened names for manufacturers have been used for ease of reading, e.g., “Chembio” instead of “Chembio Diagnostic Systems, Inc.”

**Table 10. Overview of available data on procurement of HIV simple/rapid, EIA, and supplemental tests**

	Total value (USD)			Volume (total number of tests)			Weighted average price per test (USD)		
	2008	2009	2010	2008	2009	2010	2008	2009	2010
<b>Simple/rapid tests</b>									
GFATM	1,287,150	12,144,408	3,127,507	1,470,601	12,422,941	3,743,089	0.96	0.98	0.92
GFATM - pending verif.	2,816,330	4,150,873	4,633,207	N/A	N/A	N/A	N/A	N/A	N/A
SCMS	21,547,000	22,083,329	18,020,619	26,695,265	26,229,025	20,182,375	1.25	1.48	1.14
UNICEF	10,518,230	9,008,879	13,813,076	11,307,384	10,572,240	17,120,896	1.17	1.16	1.05
UNITAID	2,244,393	32,016	1,059,786	3,364,650	49,300	1,464,433	1.10	0.72	1.07
WHO	606,042	562,250	433,022	495,090	615,300	490,840	1.20	1.08	1.00
<b>Total</b>	36,202,815	43,830,882	36,454,010	43,332,990	49,888,806	43,001,633	N/A	N/A	N/A
<b>EIA tests</b>									
GFATM	1,710	6,836	549	1,728	5,760	384	0.99	1.21	1.43
GFATM - pending verif.	6,763	125,151	134,350	N/A	N/A	N/A	N/A	N/A	N/A
SCMS	328,485	801,112	1,305,071	188,160	344,704	890,488	1.80	3.49	1.75
UNICEF	506,277	466,426	138,005	888,864	641,184	345,600	0.84	1.12	0.90
UNITAID	N/A	N/A	1,990	N/A	N/A	1,152	N/A	N/A	1.73
WHO	116,982	121,824	60,035	126,912	140,736	62,592	0.96	0.85	1.16
<b>Total</b>	953,454	1,396,199	1,505,650	1,205,664	1,132,384	1,300,216	N/A	N/A	N/A

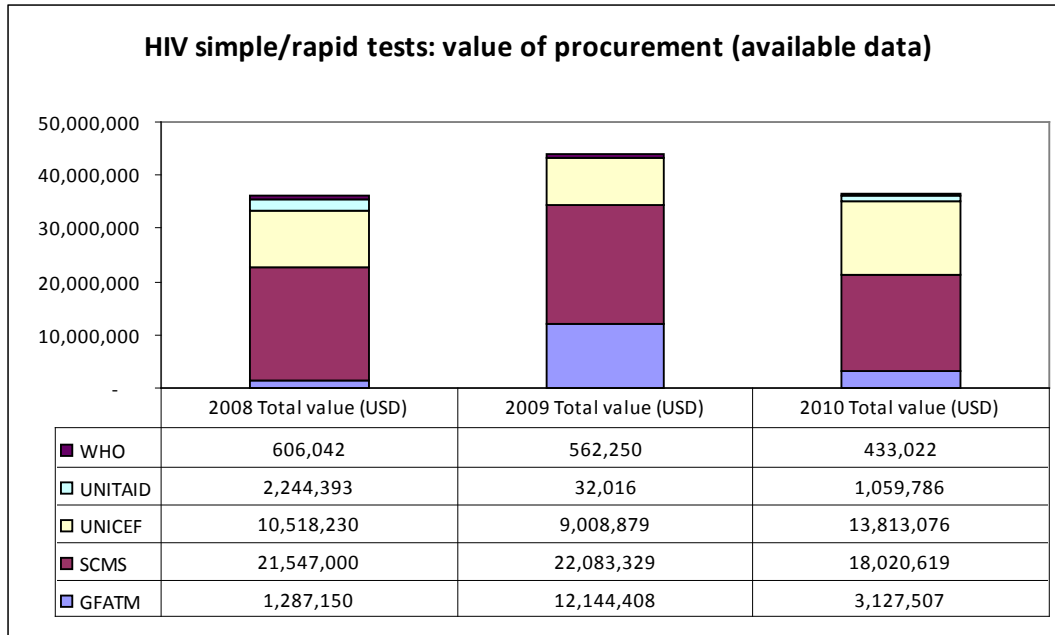
<b>Supplemental tests</b>	2008	2009	2010	2008	2009	2010	2008	2009	2010
GFATM	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
GFATM - pending verif.	N/A	9,226,024	6,281	N/A	N/A	N/A	N/A	N/A	N/A
SCMS	28,502	53,499	138,027	1,100	2,192	6,800	25.19	27.17	26.69
UNICEF	147,131	N/A	44,387	7,550	3,908	2,370	18.60	16.39	17.17
WHO	3,373	0	0	252	0	0	13.57	N/A	N/A
Total	179,005	53,499	182,414	8,902	6,100	9,170	N/A	N/A	N/A

*Note: Refer to Table 8 for important comments on limitations of data availability. "GFATM - pending verification" refers to data tagged by Global Fund as requiring clarification; yet to be resolved as of June 2011. N/A: not available.*

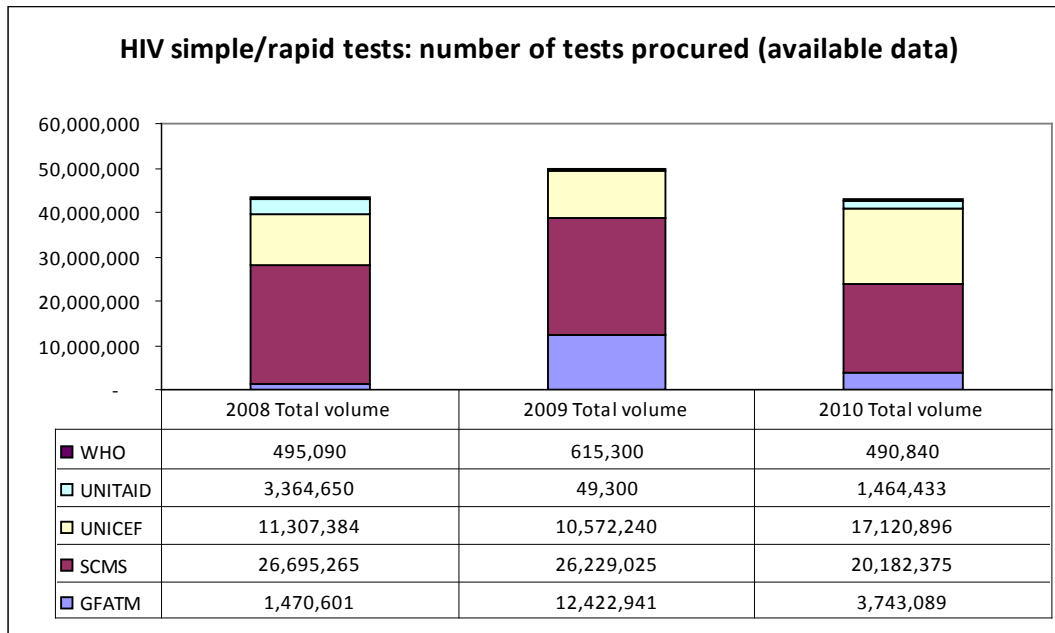
### Procurement data for HIV simple/rapid tests

Procurement volumes for HIV simple/rapid tests far outstrip those of other types of HIV diagnostic tests. The total of all available procurement data for HIV simple/rapid tests is shown in Figure 6 and Figure 7.

**Figure 6. Value of HIV simple/rapid test procurement (based on available data)**



**Figure 7. Volume of HIV simple/rapid test procurement (based on available data)**



*Note: Figure 7 is based on available data only. Refer to Table 8 for detail on available data, including notes on important gaps.*

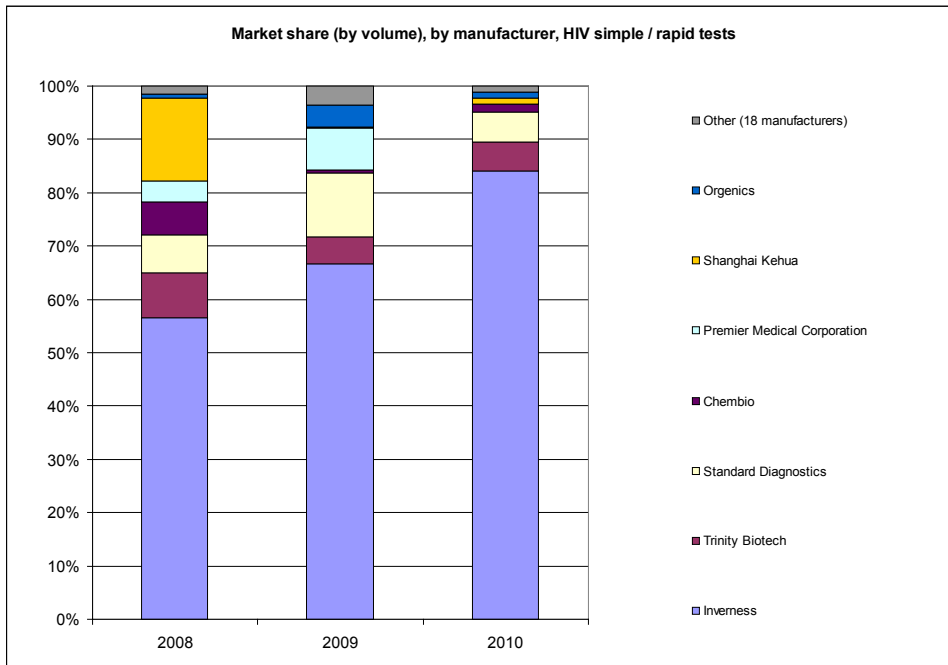
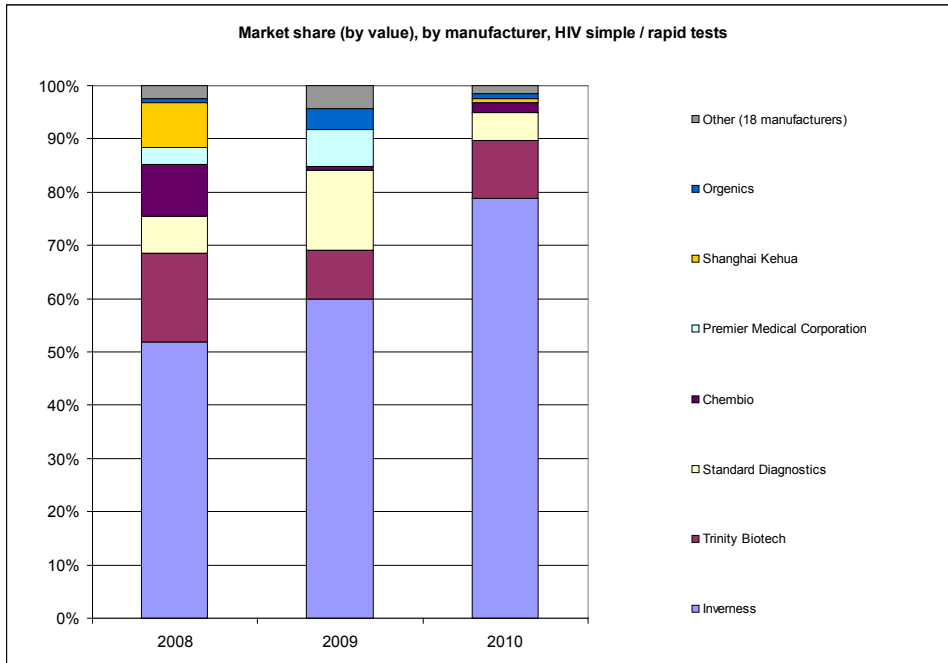
Based on available HIV simple/rapid test procurement data reported at the ex-works level, manufacturer market share (by value and volume) shows a market dominated by Inverness Medical Innovations (now Alere), with market-leading product Determine™ HIV-1/2 representing 78.6% of the reported 2010 procurement value and 83.8% of the reported 2010 procurement volume. Trinity Biotech and Standard Diagnostics play secondary roles in this market, with products Uni-Gold™ HIV (Trinity Biotech; 10.9% of value, 5.6% of volume) and SD BIOLINE HIV 1/2 3.0 (Standard Diagnostics; 5.2% of value, 5.5% of volume).

Inverness Medical Innovations also owns 75% of Standard Diagnostics, **Error! Bookmark not defined.** the third leading manufacturer of HIV simple/rapid tests. Organics, reported as the fifth most important manufacturer of HIV simple/rapid tests, is part of Inverness Medical Innovations (now Alere). Thus, the market is becoming increasingly consolidated through mergers and acquisitions, as well as through more organic changes in market share, such as product growth. Refer to



Figure 8 and Figure 9 for presentation of HIV simple/rapid tests market share by manufacturer and product, respectively. Refer to Table 11 for tabulated data on 2010 market-leading HIV simple/rapid tests.

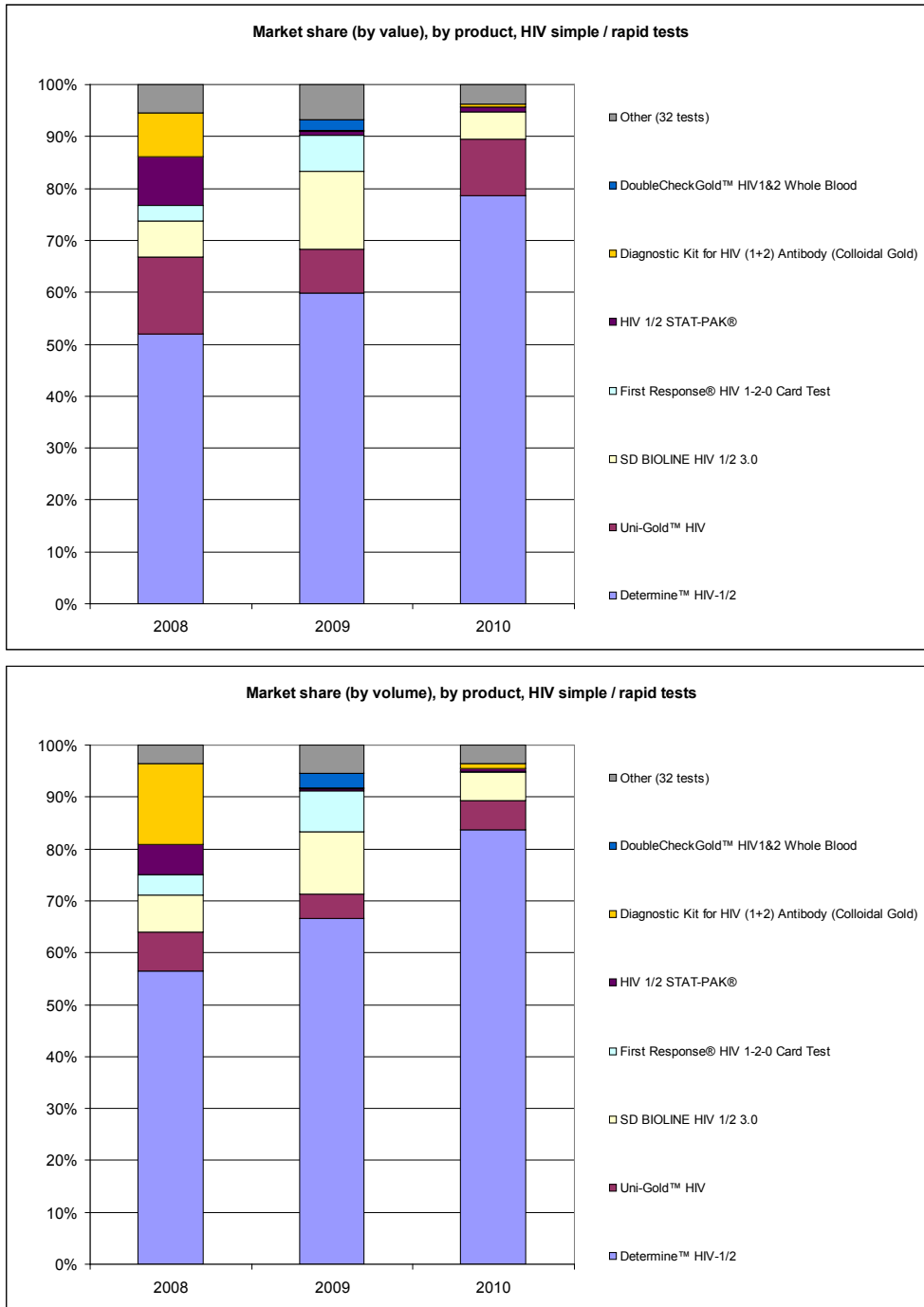
**Figure 8. Manufacturer market share of HIV simple/rapid tests, by value and volume (available data, 2008-2010, reported at the ex-works level)**



Note: Charts reflect reported data. Note: Organics is part of Inverness Medical Innovations. Inverness Medical Innovations also owns 75% of Standard Diagnostics.<sup>19</sup> Inverness Medical Innovations, in turn, is now part of Alere.

<sup>19</sup> Inverness Takes Standard Diagnostics Stake to 75 Percent, MassDevice – Medical Device Industry News. 31 March 2011. Available at: <http://www.massdevice.com/news/inverness-takes-standard-diagnostics-stake-75-percent>.

**Figure 9. Product market share of HIV simple/rapid tests, by value and volume (available data, 2008-2010, reported at the ex-works level)<sup>20</sup>**



<sup>20</sup> Based on available data only. Refer to Table 8 for detail on available data, including notes on important gaps.

Table 11. 2010 market-leading HIV simple/rapid tests based on available procurement data reported at the ex-works level<sup>21</sup>

Test	Manufacturer	2010 volume (number of tests)	2010 value (USD)	2010 price (weighted average) (USD)	2010 market share (volume)	2010 market share (value)
Determine™ HIV-1/2	Inverness	6,008,200	28,518,872	0.81	83.8%	78.6%
Uni-Gold™ HIV	Trinity Biotech	2,405,860	3,965,200	1.63	5.6%	10.9%
SD BIOLINE HIV 1/2 3.0	Standard Diagnostics	2,350,710	1,903,470	0.82	5.5%	5.2%
HIV 1/2 STAT-PAK® Dipstick	Chembio	448,020	358,143	0.79	1.0%	1.0%
HIV 1/2 STAT-PAK®	Chembio	206,760	286,622	1.41	0.5%	0.8%
OraQuick® HIV-1/2 Rapid Antibody Test	OraSure Technologies	68,400	242,050	3.64	0.2%	0.7%
Diagnostic Kit for HIV (1+2) Antibody (Colloidal Gold)	Shanghai Kehua	447,900	216,156	0.47	1.0%	0.6%
ADVANCED QUALITY™ Rapid Anti-HIV(1&2) Test	InTec Products	344,080	188,881	0.71	0.8%	0.5%
DoubleCheckGold™ HIV1&2	Orgenics	211,700	165,873	0.81	0.5%	0.5%
DoubleCheckGold™ Ultra HIV1&2	Orgenics	184,800	134,524	0.84	0.4%	0.4%
Determine™ HIV-1/2 Ag/Ab Combo	Inverness	108,200	99,480	0.97	0.3%	0.3%
SERODIA® -HIV 1/2	Fujirebio	45,960	51,423	1.11	0.1%	0.1%
ImmunoComb® II HIV 1&2 BiSpot	Orgenics	25,416	44,660	1.78	0.1%	0.1%
Not stated	Other	28,000	33,546	1.15	0.1%	0.1%
First Response® HIV 1-2-0 Card Test	Premier Medical Corp.	45,540	29,928	0.70	0.1%	0.1%

<sup>21</sup> Based on available data only. Refer to Table 8 for detail on available data, including notes on important gaps.

Based on available HIV simple/rapid test procurement data reported at the ex-works level, the minimum price per test rose 21% between 2008 and 2010, and the maximum price per test rose 1% between 2008 and 2010. The weighted average price, on the other hand, decreased 7% during this time, indicating a shift towards procurement of less expensive tests. Refer to Table 12 for a summary of price trends for HIV simple/rapid tests.

**Table 12. Price trends for HIV simple/rapid tests based on available procurement data reported at the ex-works level**

Parameter	2008	2009	2010	% change
Minimum price/test (USD)	0.39	0.38	0.47	21%
Maximum price/test (USD)	3.60	3.63	3.64	1%
Weighted average price/test (USD)	1.14	1.23	1.05	-7%

Country-specific analysis of available HIV simple/rapid test procurement data reported at the ex-works level shows that Determine™ HIV-1/2 was the most procured test across markets in 2010, and made up >90% of the tests procured (by volume) in 50% of the countries for which data were available (refer to Figure 10 and Figure 11). It should be noted that, in some cases, a national tender may be issued only for the test used as 1st line, with 2nd or 3rd line tests procured through the local market. This may explain the apparent total dominance of one test in a particular market (e.g., Determine™ HIV-1/2 in Kenya).

The weighted average ex-works price of HIV simple/rapid tests varies greatly by country. Figure 12 presents the ten countries where HIV simple/rapid tests are procured at the highest price per test; Figure 13 presents the ten countries with the lowest price per test. Both Figure 12 and Figure 13 are based on available data, which are limited in some cases and should be interpreted with caution (e.g., < \$10,000 worth of HIV simple/rapid tests were procured in 2010 for the following countries: Syrian Arab Republic, Mauritius, Egypt, Paraguay, Solomon Islands, West Bank and Gaza Strip, Jordan, Romania, Libya, Albania, Spain, Democratic People's Republic of Korea). In addition, there are many potential reasons for price variation (e.g., differences in supplier, selection of test[s] for a particular country) that cannot be analysed on the basis of procurement data alone.

The weighted average ex-works price of specific HIV simple/rapid products also varies by country. The range of 2010 country prices for leading HIV simple/rapid tests Determine™ HIV-1/2, Uni-Gold™ HIV, and SD BIOLINE HIV 1/2 3.0 are shown in Figure 14, Figure 15 and Figure 16, respectively. As shown in Figure 14, the 2010 weighted average ex-works price of Determine™ HIV-1/2, the most-procured product, averaged \$0.80 across countries and ranged from \$0.69 in Benin to \$1.47 in Mauritius, representing a 22% difference between countries with the lowest and highest prices. As shown in Figure 15, the 2010 weighted average ex-works price of Uni-Gold™ HIV averaged \$1.63 across countries and ranged from \$1.53 in Sierra Leone to \$1.76 in Yemen and Malawi (a 22% difference). As shown in Figure 16, the 2010 weighted average ex-works price of SD BIOLINE HIV 1/2 3.0 averaged \$0.82 across countries and ranged from \$0.78 in Togo and the Philippines to \$1.50 in Honduras (a 94% difference).

Figure 10. 2010 value of HIV simple/rapid tests procured by country, by test (available data reported at the ex-works level)

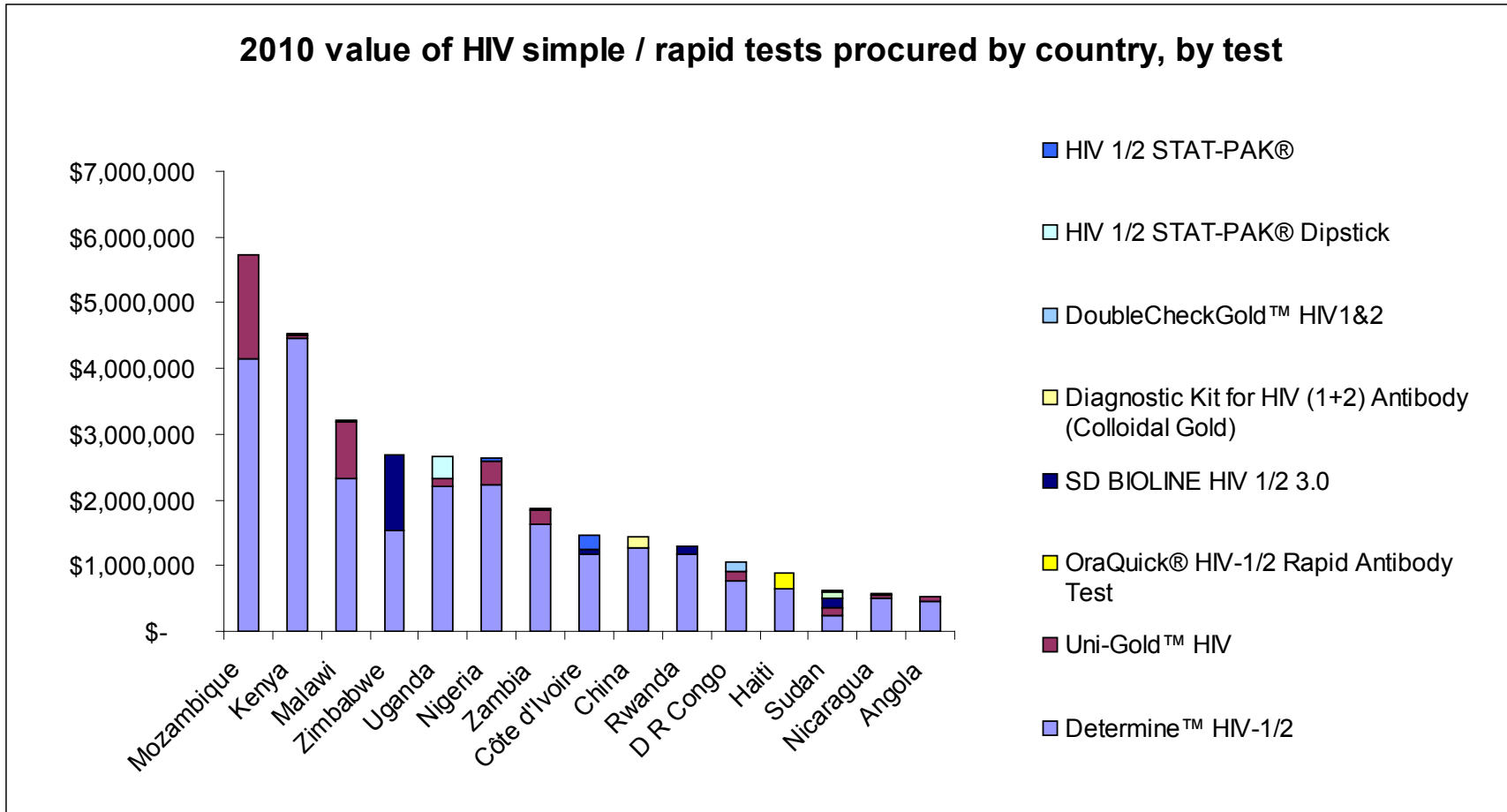
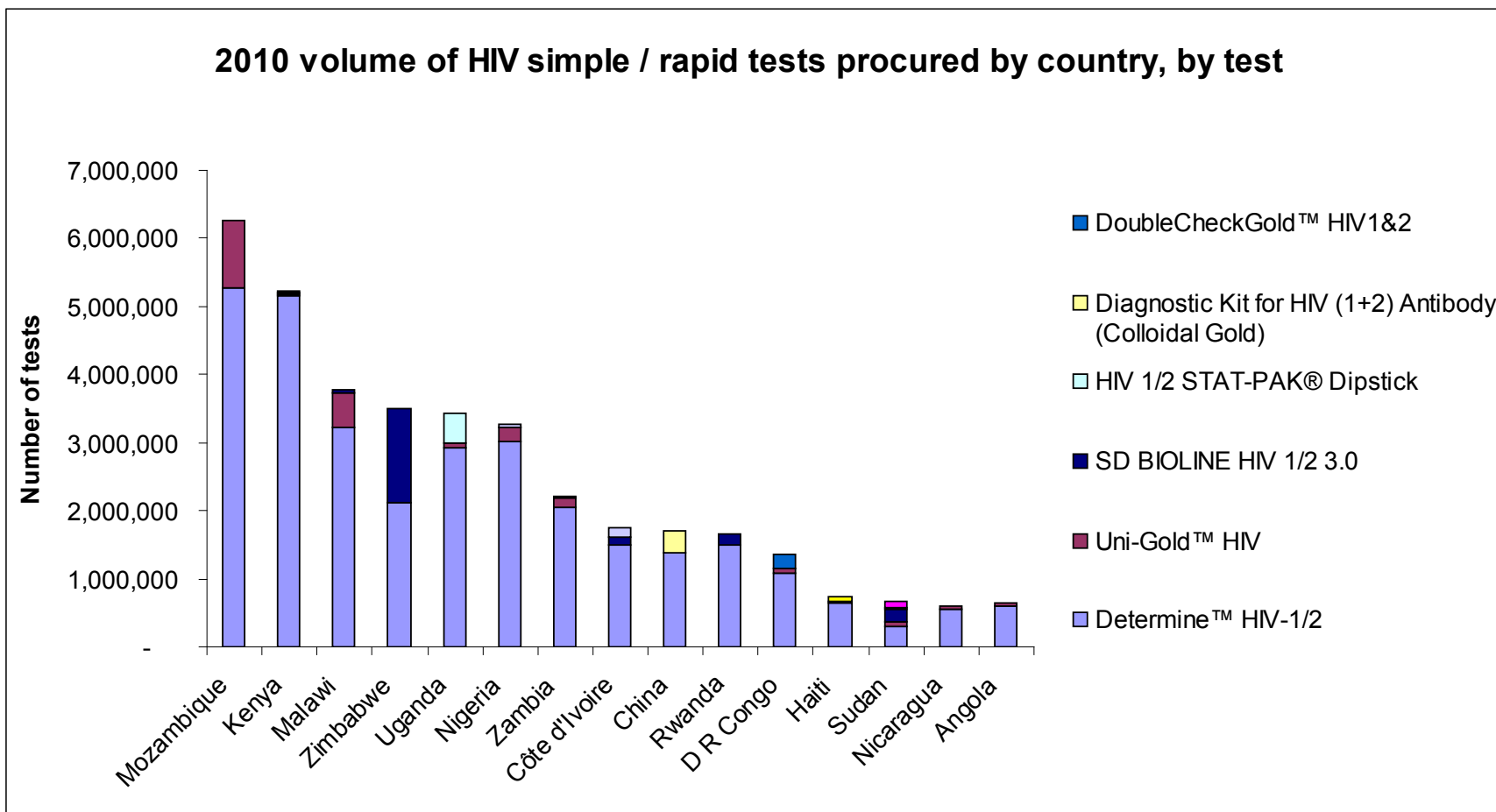
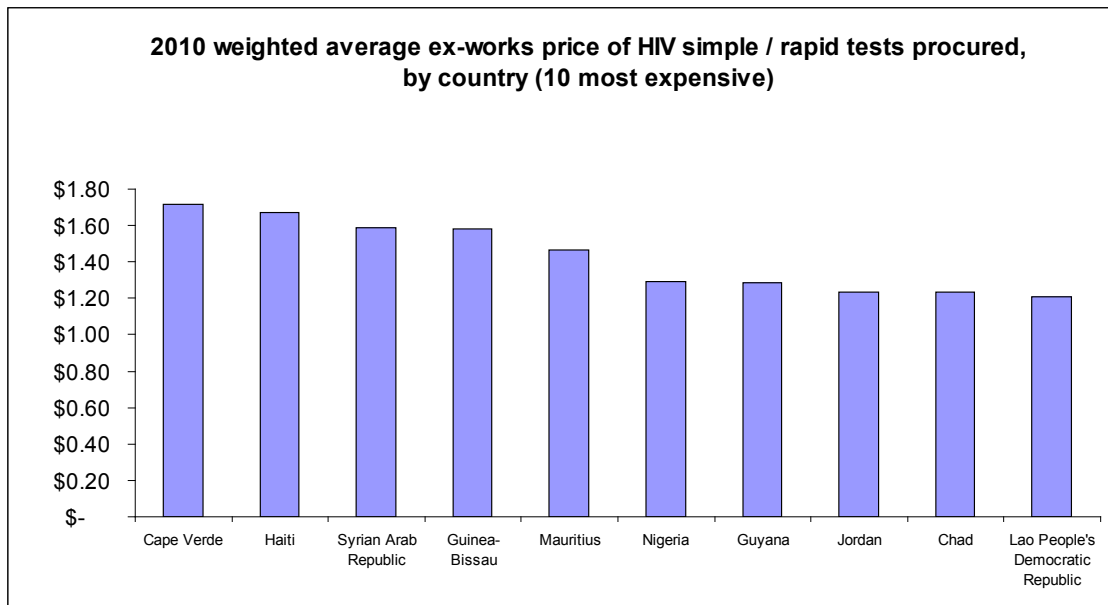


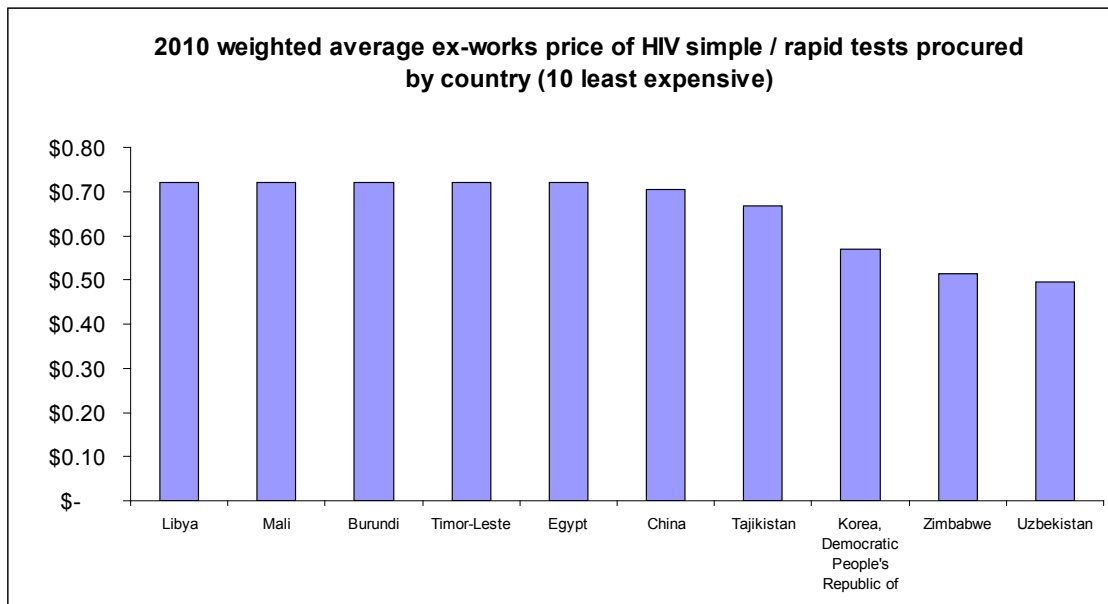
Figure 11. 2010 volume of HIV simple/rapid tests procured by country, by test (available data reported at the ex-works level)



**Figure 12. 2010 weighted average price of HIV simple/rapid tests procured by country, 10 most expensive (available data, 2010, reported at the ex-works level)<sup>22</sup>**



**Figure 13. 2010 weighted average price of HIV simple/rapid tests procured by country, 10 least expensive (available data, 2010, reported at the ex-works level)<sup>23</sup>**



<sup>22</sup> Data are limited in some cases and should be interpreted with caution (e.g., < \$10,000 worth of HIV simple/rapid test procurement in 2010 for: Syrian Arab Republic, Mauritius, Egypt, Paraguay, Solomon Islands, West Bank & Gaza Strip, Jordan, Romania, Libya, Albania, Spain, Democratic People's Republic of Korea). There are also many potential reasons for price variation (e.g., differences in supplier, selection of test(s)) that cannot be analysed on the basis of procurement data alone.



Figure 14. 2010 weighted average price of Determine™ HIV-1/2 (available data, 2010, reported at the ex-works level)

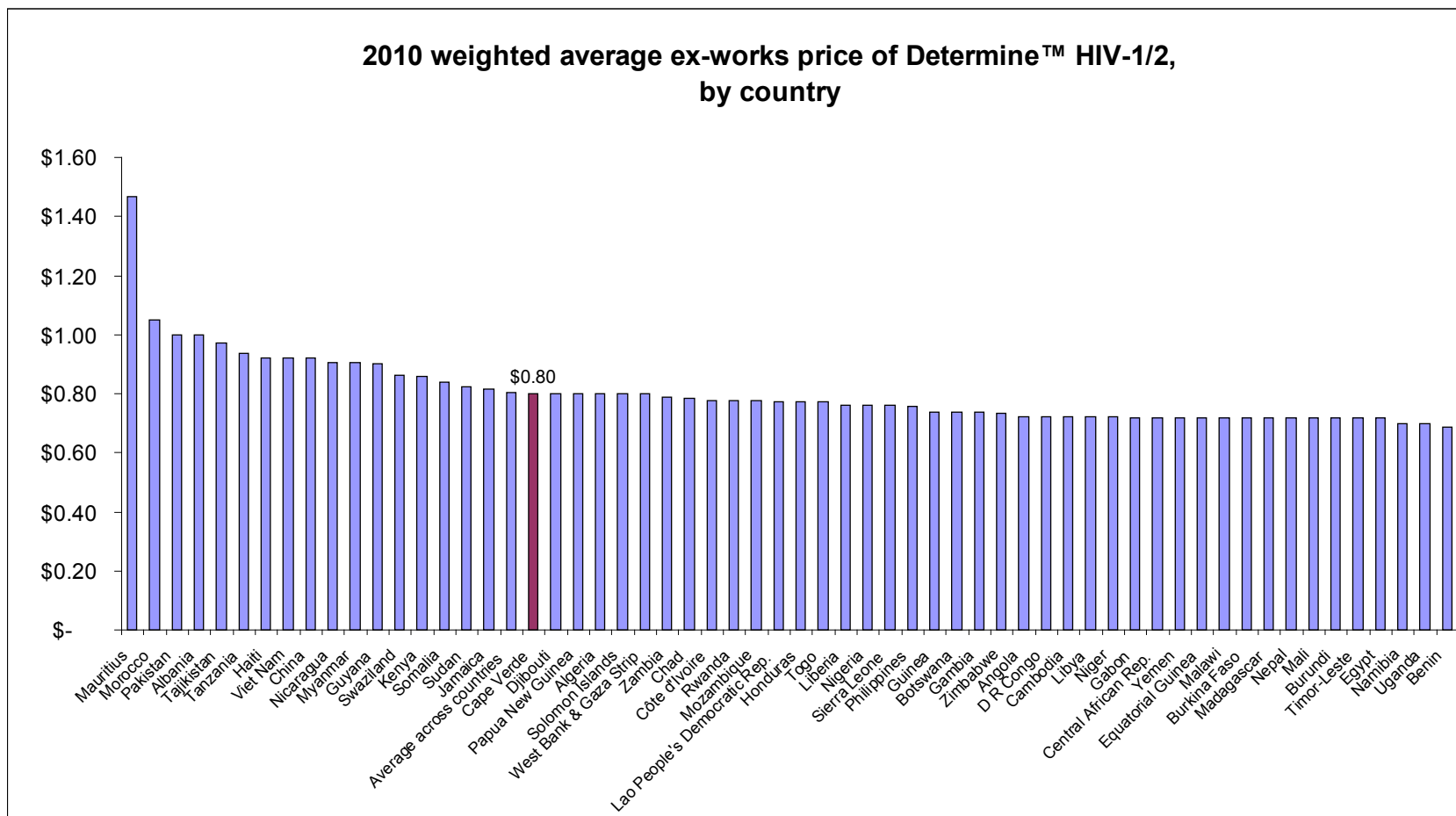
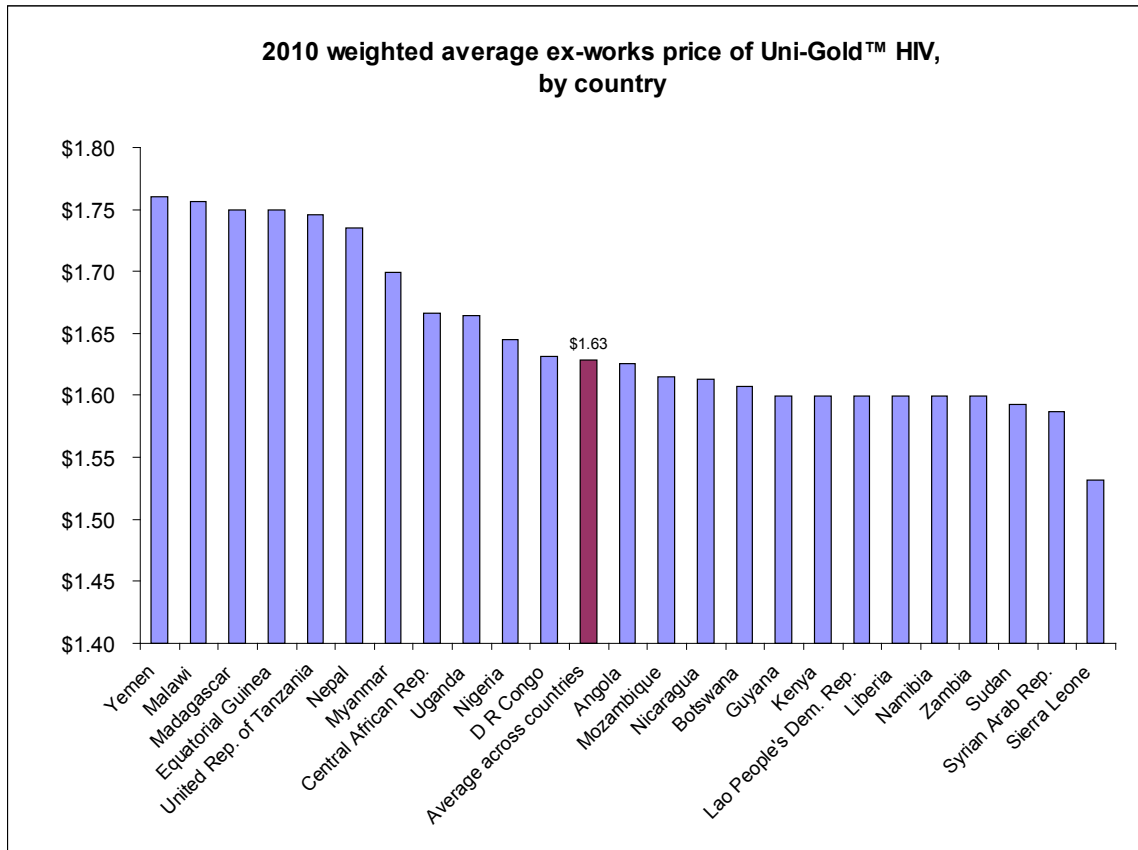
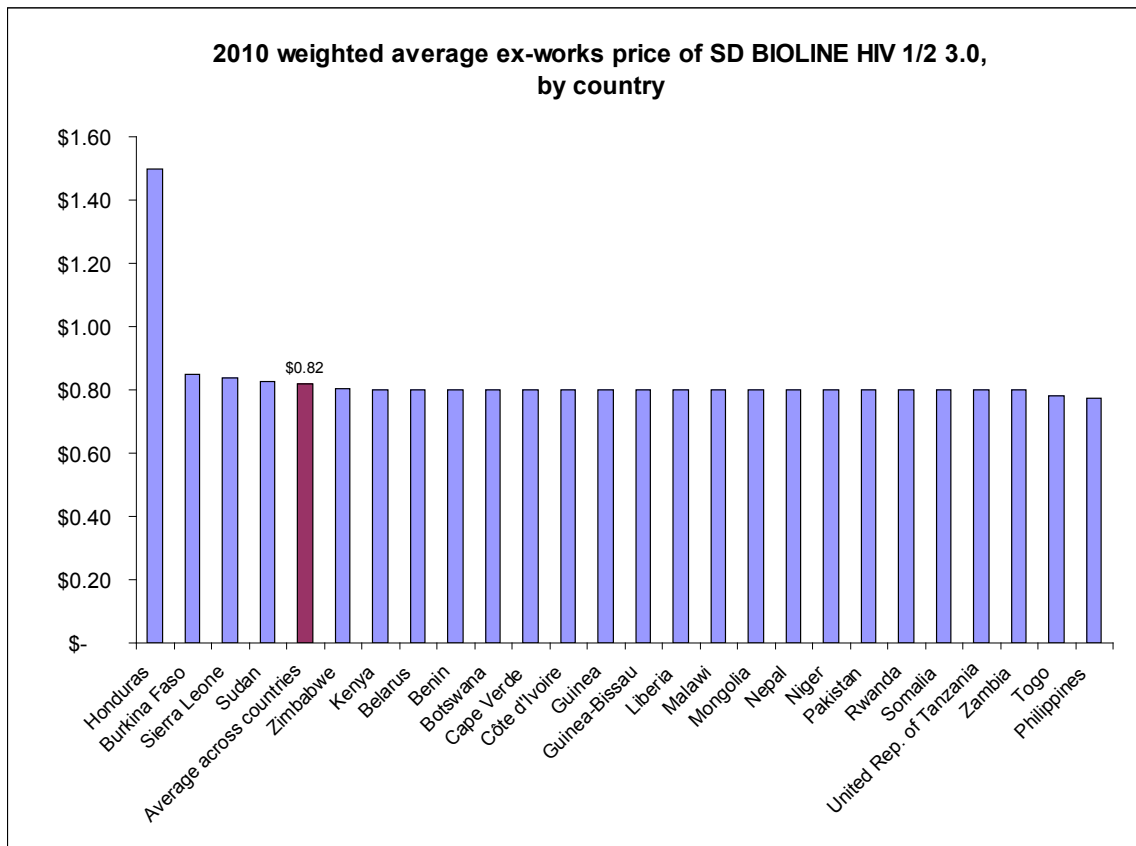


Figure 15. 2010 weighted average price of Uni-Gold™ HIV (available data, 2010, reported at the ex-works level)



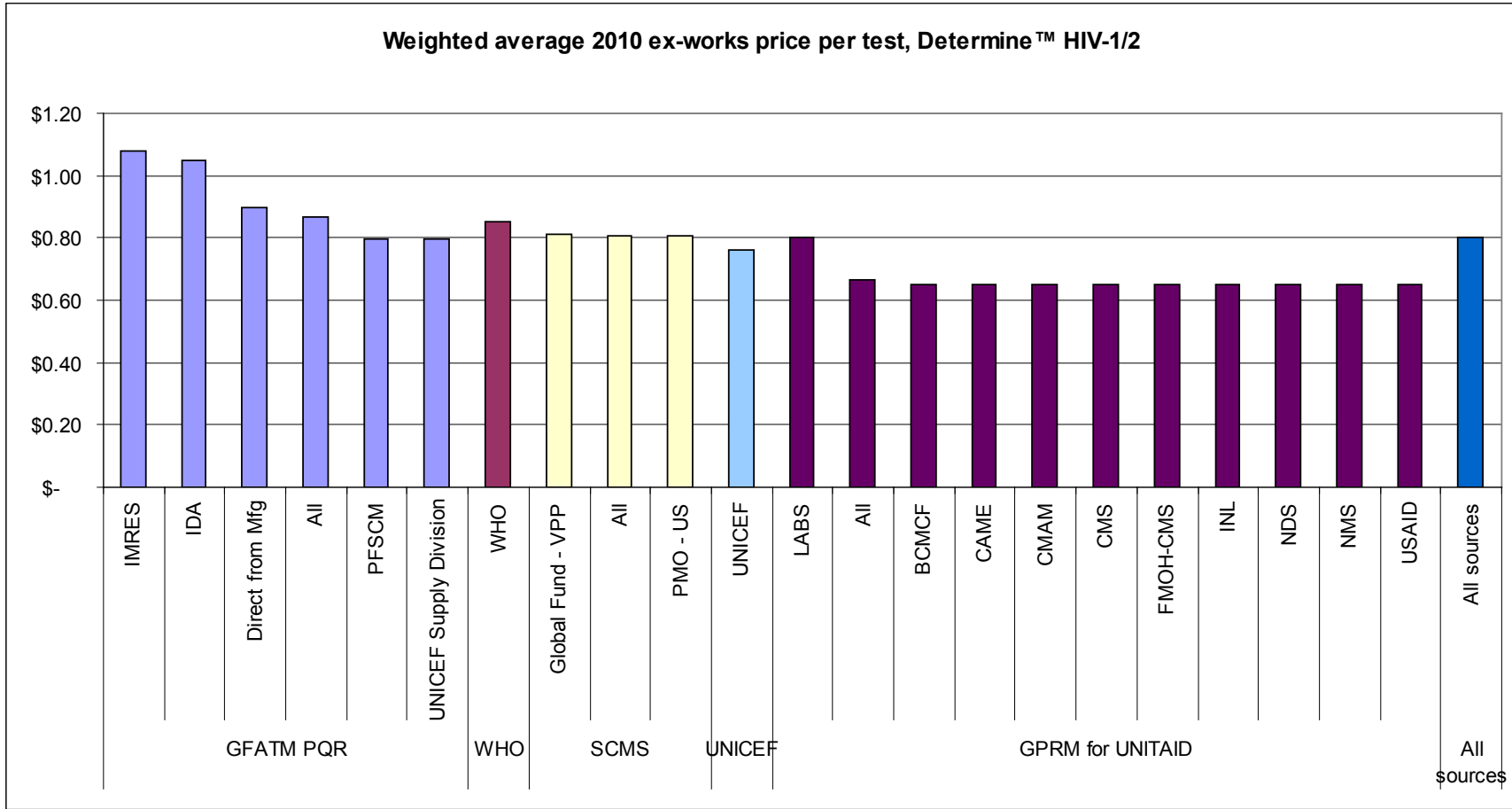
**Figure 16. 2010 weighted average price of SD BIOLINE HIV 1/2 3.0 (available data, 2010, reported at the ex-works level)**



Controlling for price differences among tests, analysis can reveal price differences between products procured directly from the manufacturer, and those procured through suppliers, agents, or intermediaries. This analysis is limited by the current dataset (for example, verification for 60% of simple/rapid data entries available from the Global Fund PQR database was pending as of June 2011). However, for directional purposes only, indicative analyses for leading HIV simple/rapid tests Determine™ HIV-1/2, Uni-Gold™ HIV and SD BIOLINE HIV 1/2 3.0 are shown in Figure 17, Figure 18 and Figure 19. The 2010 ex-works price for Determine™ HIV-1/2, for example, ranged from \$0.65 to \$1.08 (i.e., from 19% less to 34% greater than the weighted average price of \$0.80 per test).

Once a more complete dataset is available, data could be further analysed to detect and examine differences (e.g., in price or order patterns) between direct and indirect procurement, and between suppliers, agents or intermediaries involved in indirect procurement, and other procurement circumstances and patterns (e.g., delivery times required, volumes, competitive versus non-competitive procurement, etc).

Figure 17. Weighted average 2010 ex-works price per test, Determine™ HIV-1/2, by agency and reported means of procurement (available data reported at the ex-works level)



PFSCM: Partnership for Supply Chain Management, Inc.; VPP: Voluntary pooled procurement.

Figure 18. Weighted average 2010 ex-works price per test, Uni-Gold™ HIV, by agency and reported means of procurement (available data reported at the ex-works level)

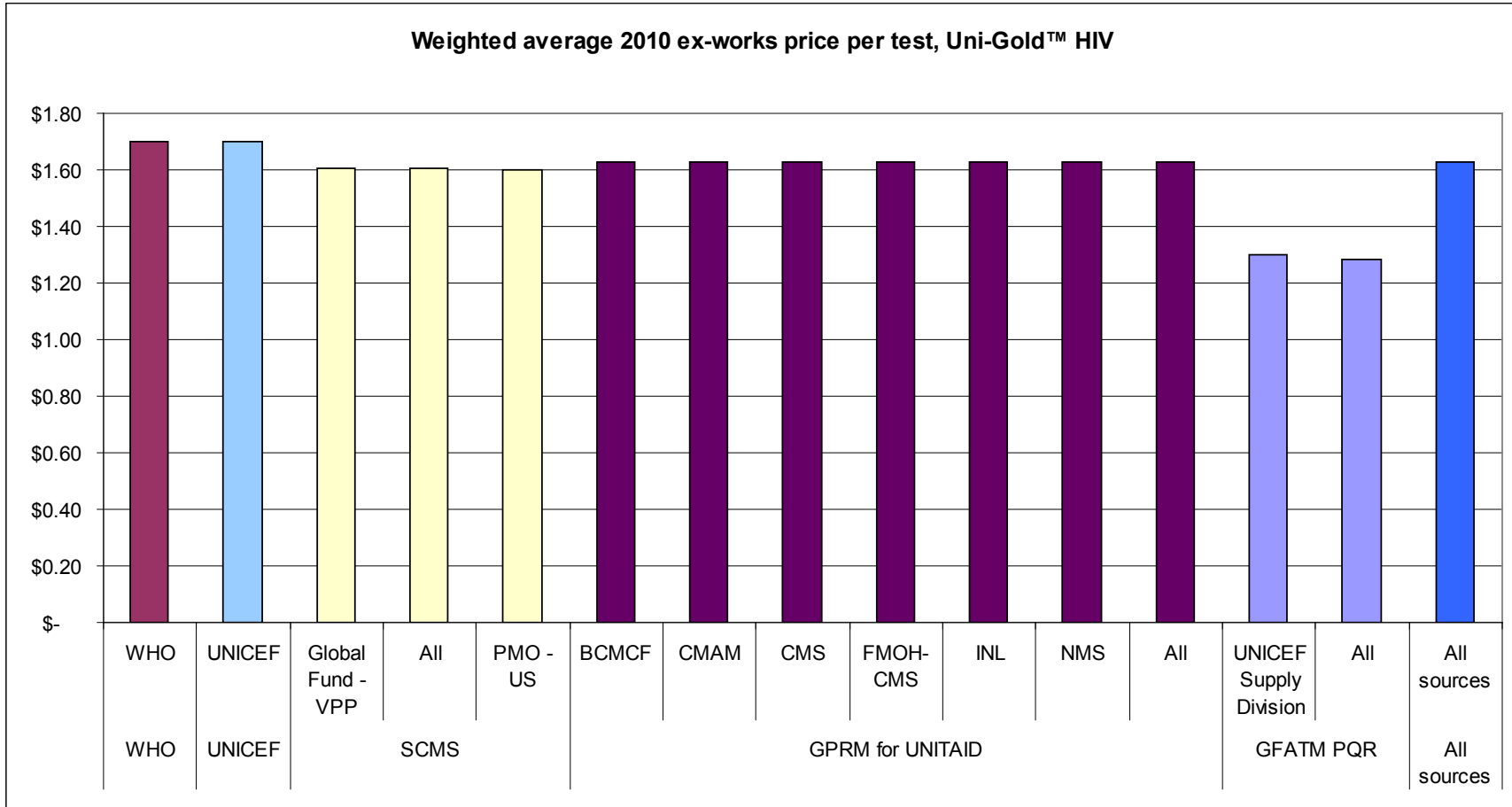
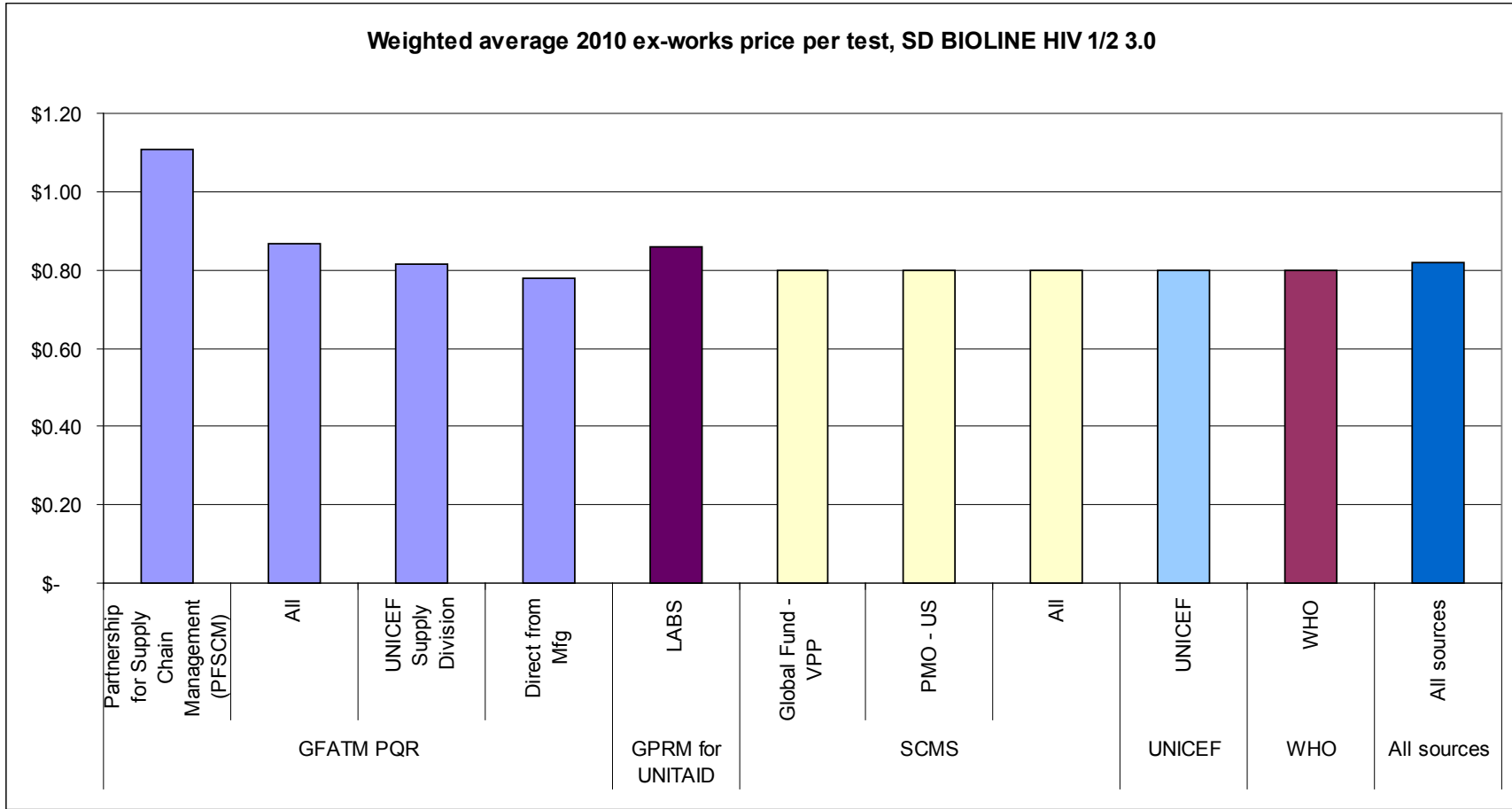


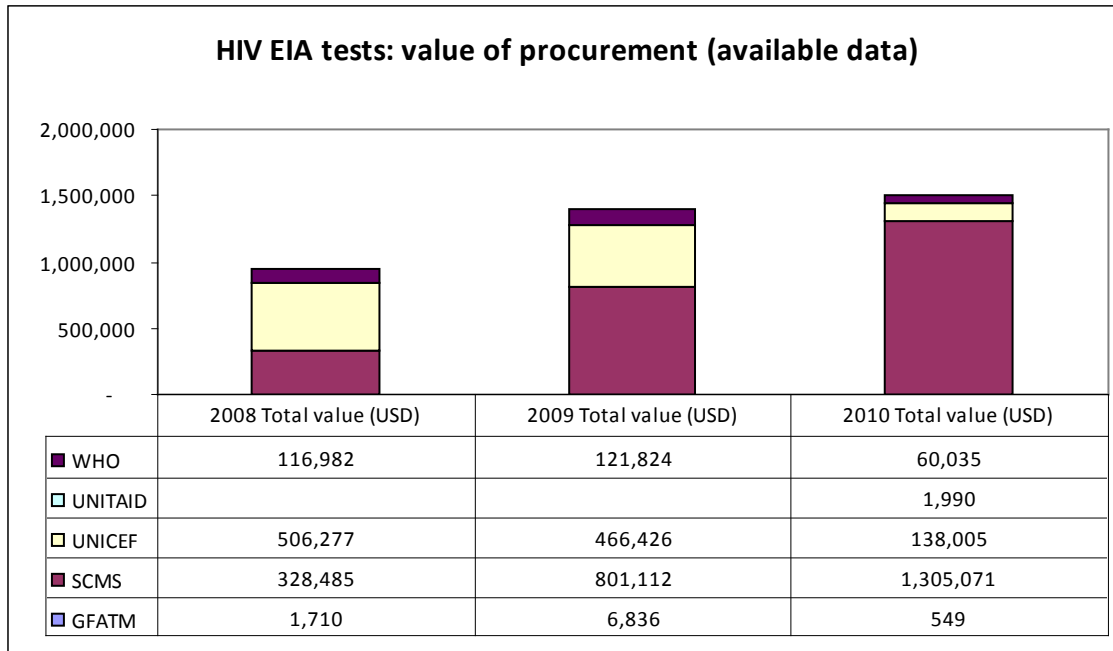
Figure 19. Weighted average 2010 ex-works price per test, SD BIOLINE HIV 1/2 3.0, by agency and reported means of procurement (available data reported at the ex-works level)



## Procurement data for HIV EIA tests

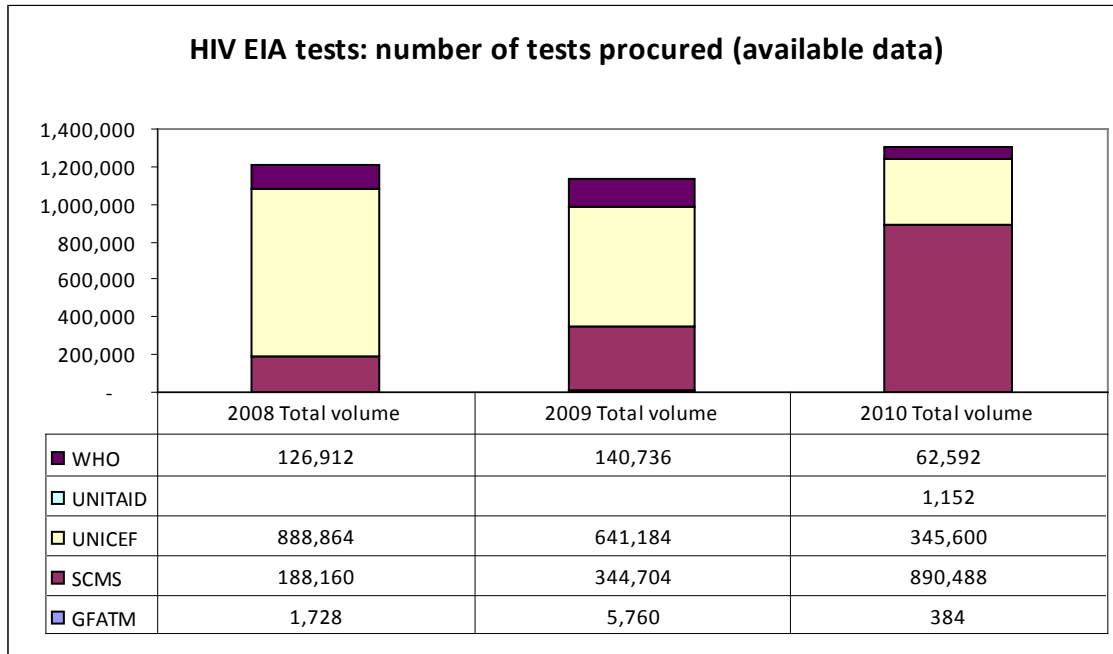
Procurement data for HIV EIA tests are less fully and accurately reported than for simple/rapid tests. Refer to Table 8 for important comments on limitations of data availability. The total of all available procurement data for HIV EIA tests is shown in Figure 20 and Figure 21.

**Figure 20. Value of HIV EIA test procurement (based on available data)<sup>23</sup>**



<sup>23</sup> Based on available data only. Refer to Table 8 for detail on available data, including notes on important gaps.

Figure 21. Volume of HIV EIA test procurement (based on available data)<sup>24</sup>



Based on available HIV EIA test procurement data reported at the ex-works level, the minimum price per test decreased 15% between 2008 and 2010, and the maximum price per test rose 17% between 2008 and 2010. The weighted average price increased 38% during this time, indicating a shift towards procurement of more expensive tests. This may partly reflect evolution of available technology – e.g., increased use of 4<sup>th</sup> generation tests. Refer to Table 13 for a summary of price trends for HIV EIAs. Refer to

<sup>24</sup> Based on available data only. Refer to Table 8 for detail on available data, including notes on important gaps



Table 14 for more detail on generation and price for each of the market-leading tests, and to Figure 24 for 2010 weighted average ex-works price by test (3<sup>rd</sup> vs. 4<sup>th</sup> generation).

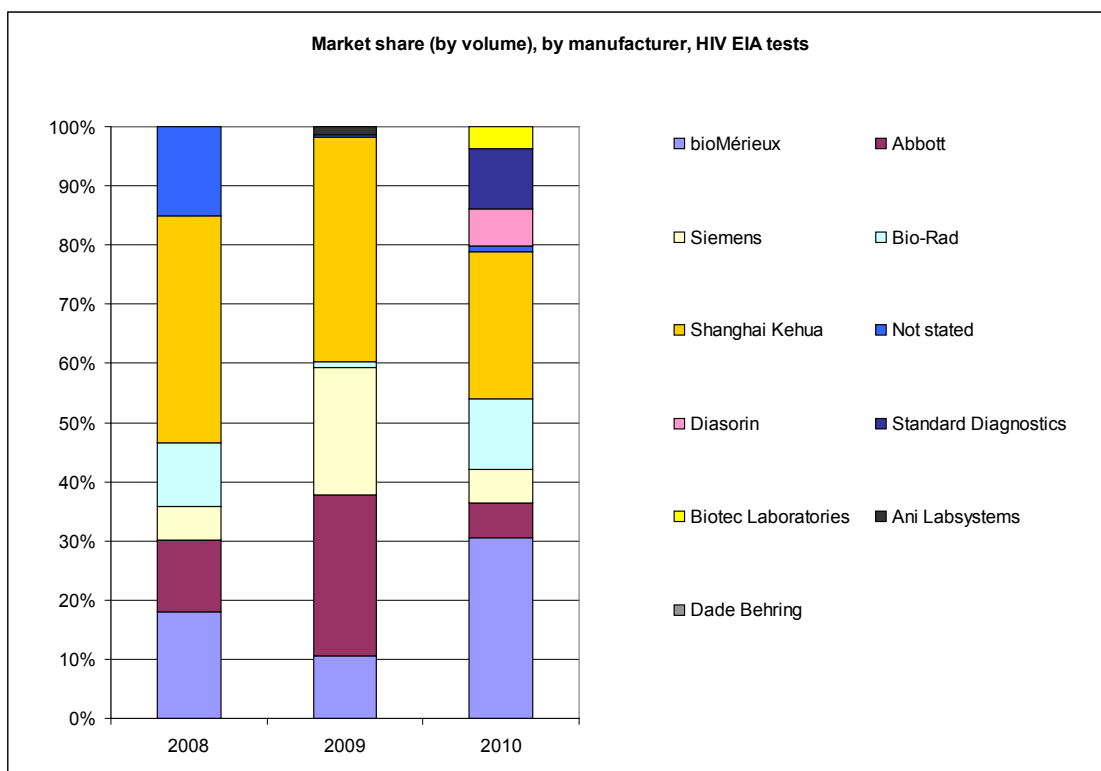
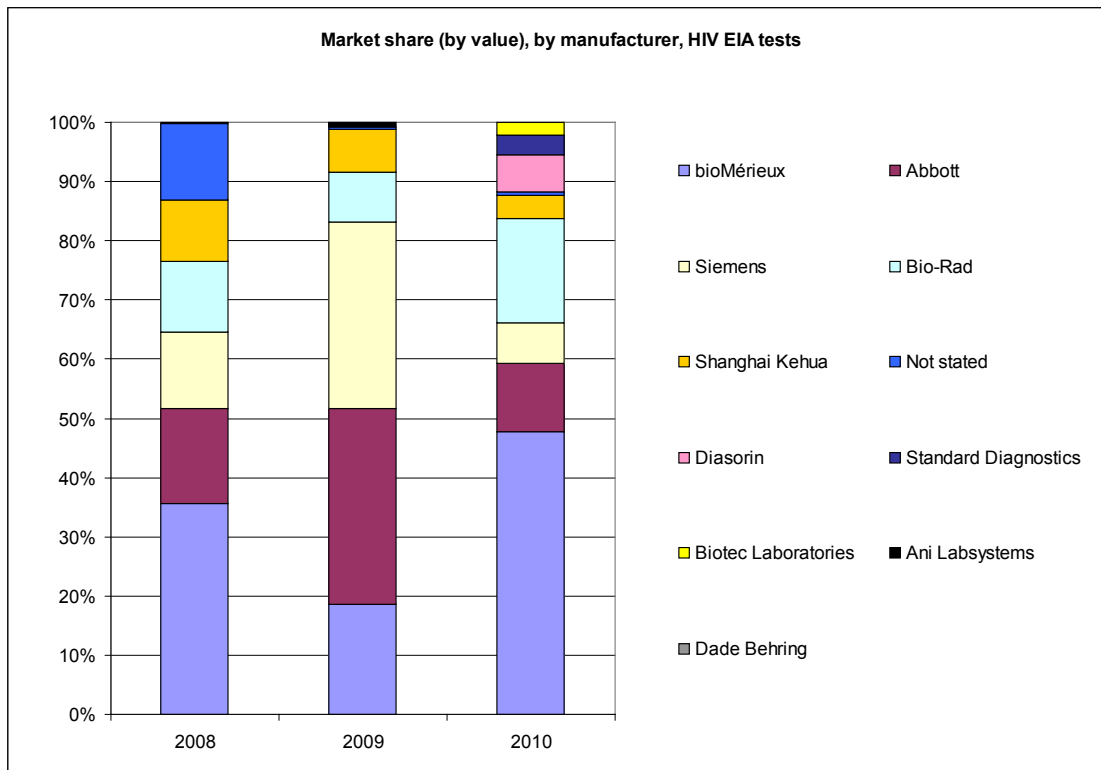
**Table 13. Price trends for HIV EIA tests based on available procurement data reported at the ex-works level**

Parameter	2008	2009	2010	% change
Minimum price/test (USD)	0.20	0.17	0.17	-15%
Maximum price/test (USD)	1.86	2.03	2.18	17%
Weighted average price/test (USD)	1.04	1.45	1.43	38%

An analysis of manufacturer market share by value and volume shows a more fragmented market for HIV EIA tests than for HIV simple/rapid tests. Several manufacturers play an important role in this market, with bioMérieux, Bio-Rad, Abbott, Siemens and Diasorin together accounting for almost 90% of the value of 2010 procurement reported at the ex-works level. Key bioMérieux products include Vironostika® HIV Uni-Form II Ag/Ab (market-leading product, with 28.0% of the reported 2010 procurement by value and 16.9% by volume) and Vironostika® HIV Uni-Form II Plus O (18.7% by value, 12.9% by volume). Other products with significant market share based on 2010 procurement reported at the ex-works level include: Genscreen™ Ultra HIV Ag-Ab (Bio-Rad; 16.4% by value, 11.2% by volume); Murex HIV Ag/Ab Combination (with Abbott as reported manufacturer: 11.7% by value, 5.8% by volume; with Diasorin as reported manufacturer; 5.2% by value, 5.8% by volume). Shanghai Kehua product ANTI-HIV 1 + 2 Antibodies ELISA Diagnostics Kit – a 3<sup>rd</sup> generation test – represented 25.0% of the reported 2010 procurement by volume but only 4.0% by value, reflecting its much lower average price compared to other HIV EIA tests. Refer to Figure 22 and Figure 23 for HIV EIA tests by manufacturer and product market share, respectively. Refer to

Table 14 for tabulated data on 2010 market-leading HIV EIA tests.

**Figure 22. Manufacturer market share of HIV EIA tests, by value and volume (available data, 2008-2010, reported at the ex-works level)**



Note: DiaSorin acquired the product range from Abbott GmbH in April 2010.  
N/S: Not stated.

Figure 23. Product market share of HIV EIA tests, by value and volume (available data, 2008-2010, reported at the ex-works level)<sup>25</sup>



Note: Murex HIV Ag/Ab Combination listed separately; reported separately as manufactured by Abbott or Diasorin (DiaSorin acquired the product range from Abbott GmbH in April 2010).

<sup>25</sup> Based on available data only. Refer to Table 8 for detail on available data, including notes on important gaps

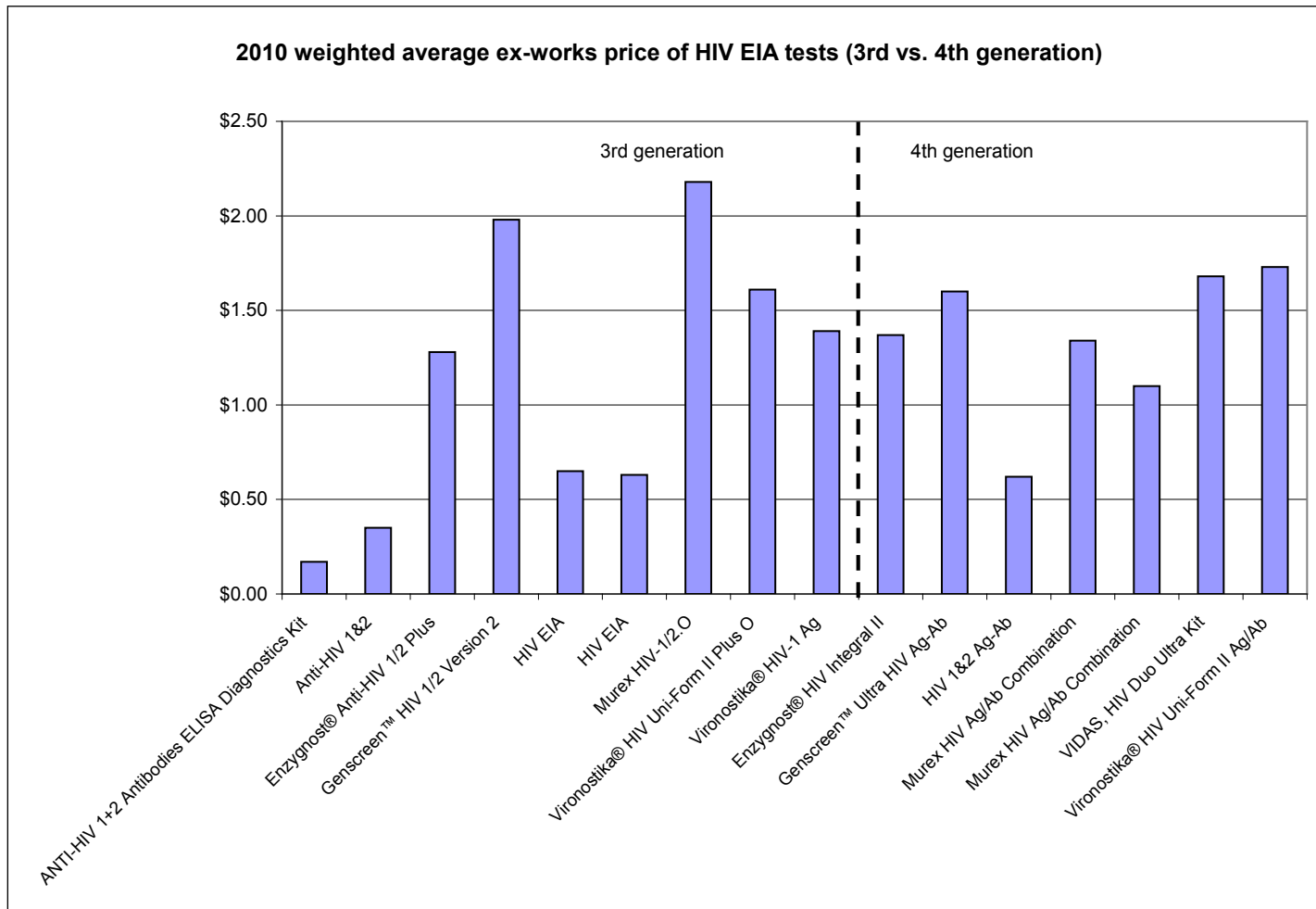
Table 14. 2010 market-leading HIV EIA tests based on available procurement data reported at the ex-works level <sup>26</sup>

Test	Generation	Manufacturer	2010 volume (number of tests)	2010 value (USD)	2010 price (weighted average) (USD)	2010 market share (volume)	2010 market share (value)
Vironostika® HIV Uni-Form II Ag/Ab	4 <sup>th</sup>	bioMérieux	168,960	295,817	1.73	16.9%	28.0%
Vironostika® HIV Uni-Form II Plus O	3 <sup>rd</sup>	bioMérieux	128,832	198,258	1.61	12.9%	18.7%
Genscreen™ Ultra HIV Ag-Ab	4 <sup>th</sup>	Bio-Rad	111,744	173,225	1.60	11.2%	16.4%
Murex HIV Ag/Ab Combination	4 <sup>th</sup>	Abbott	58,080	123,371	1.34	5.8%	11.7%
Murex HIV Ag/Ab Combination	4 <sup>th</sup>	Diasorin	58,560	54,528	1.10	5.8%	5.2%
Enzygnost® Anti-HIV 1/2 Plus	3 <sup>rd</sup>	Siemens	43,584	52,082	1.28	4.4%	4.9%
ANTI-HIV 1 + 2 Antibodies ELISA Diagnostics Kit	3 <sup>rd</sup>	Shanghai Kehua	250,080	42,514	0.17	25.0%	4.0%
Anti-HIV 1&2	3 <sup>rd</sup>	Standard Diagnostics	100,032	35,011	0.35	10.0%	3.3%
HIV 1&2 Ag-Ab	4 <sup>th</sup>	Biotec Laboratories	37,152	23,027	0.62	3.7%	2.2%
Enzygnost® HIV Integral II	4 <sup>th</sup>	Siemens	14,976	19,696	1.37	1.5%	1.9%
Genscreen™ HIV 1/2 Version 2	3 <sup>rd</sup>	Bio-Rad	6,240	12,350	1.98	0.6%	1.2%
Murex HIV-1/2.O	3 <sup>rd</sup>	Diasorin	4,800	10,450	2.18	0.5%	1.0%
HIV EIA	3 <sup>rd</sup>	Not stated	9,600	6,269	0.65	1.0%	0.6%
Vironostika® HIV-1 Ag*	3 <sup>rd</sup> *	bioMérieux	4,992	6,045	1.39	0.5%	0.6%
VIDAS, HIV Duo Ultra Kit	4 <sup>th</sup>	bioMérieux	2,688	4,525	1.68	0.3%	0.4%
HIV EIA	3 <sup>rd</sup>	Ani Labsystems	960	604	0.63	0.1%	0.1%

\*Ag detection only.

<sup>26</sup> Based on available data only. Refer to Table 8 for detail on available data, including notes on important gaps

Figure 24. 2010 weighted average price of HIV EIA tests based on available procurement data reported at the ex-works level<sup>27</sup>



<sup>27</sup> Based on available data only. Refer to Table 8 for detail on available data, including notes on important gaps.

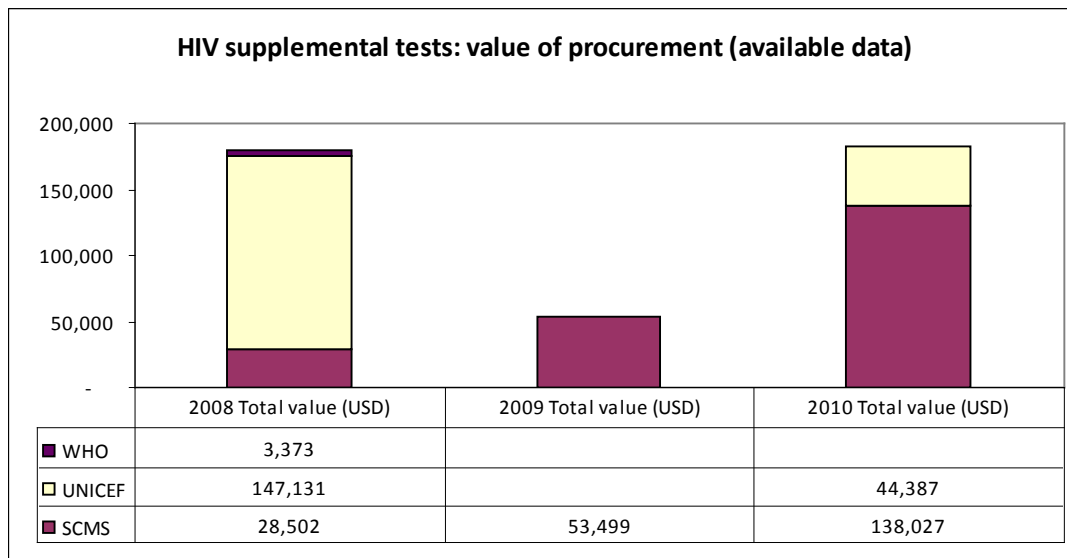
## Procurement data for HIV supplemental tests

As for HIV EIA tests, procurement data for HIV supplemental tests are less fully and accurately reported than for simple/rapid tests. Refer to Table 8 for important comments on limitations of data availability. The total of all available procurement data for HIV supplemental tests is shown in

Figure 25 and

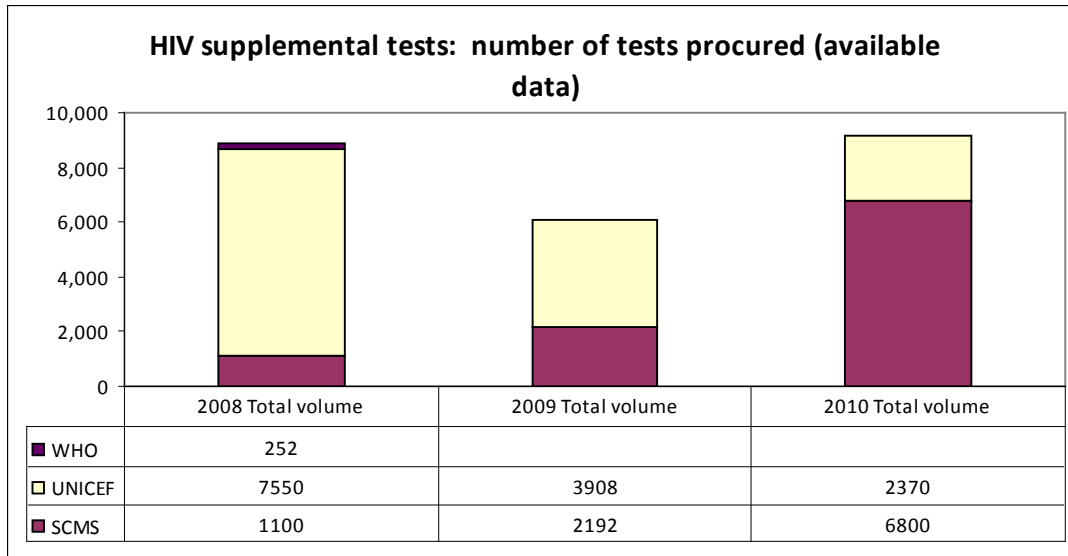
Figure 26.

**Figure 25. Value of HIV supplemental test procurement (based on available data)<sup>28</sup>**



**Figure 26. Volume of HIV supplemental test procurement (based on available data)<sup>29</sup>**

<sup>28</sup> Based on available data only. Refer to Table 8 for detail on available data, including notes on important gaps.



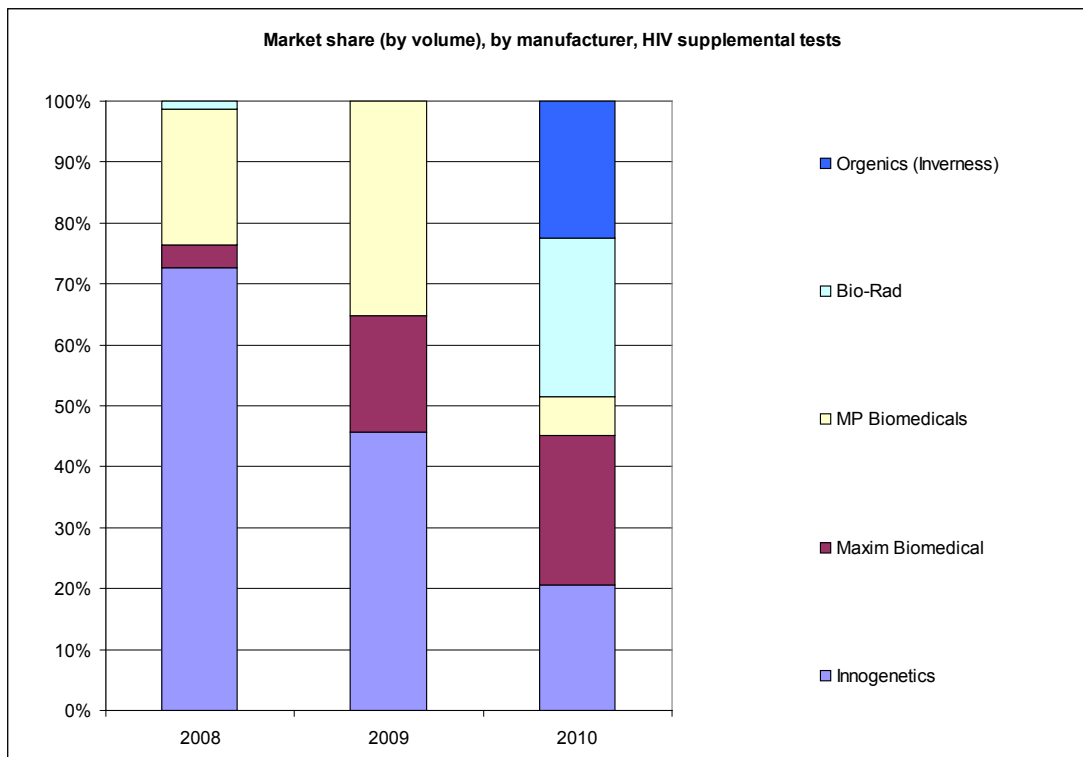
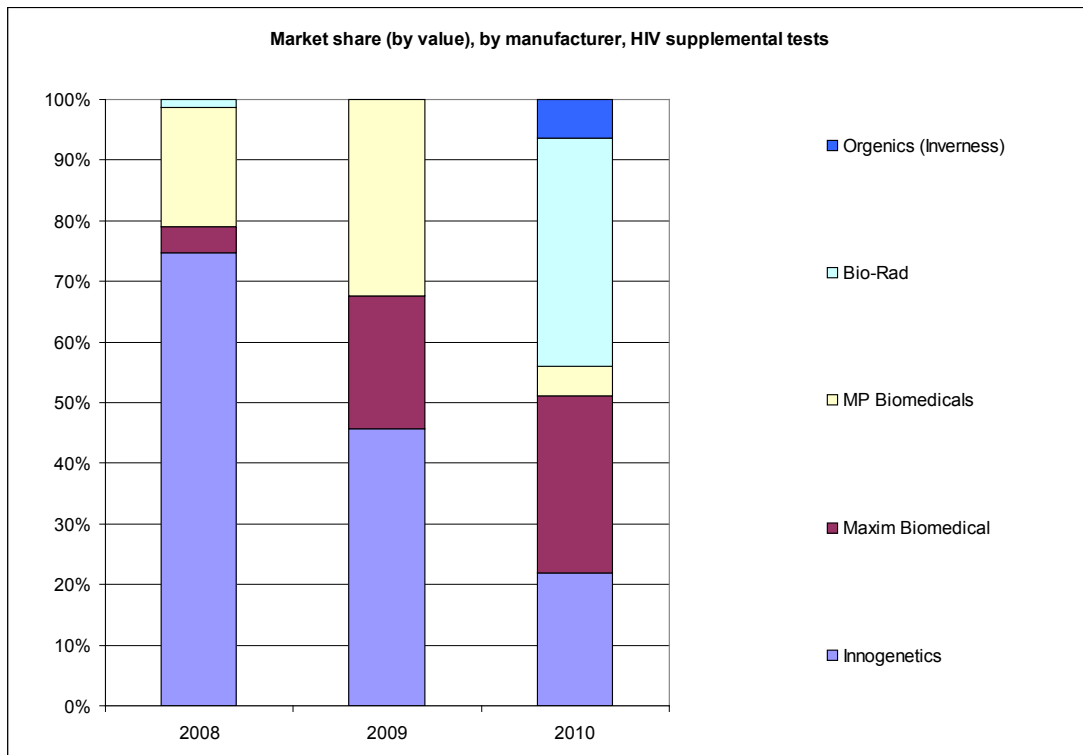
Manufacturer market share by value and volume based on test kit procurement reported at the ex-works level shows a consolidated market for HIV supplemental tests kits, although this may be due in part to incompleteness of data. MP Biomedicals, Maxim Biomedical, and Innogenetics are the only manufacturers for which procurement data were reported in 2009, but Orgenics (Inverness) and Bio-Rad re-emerged as additional manufacturers in this market in 2010.

Market-leading products by both value and volume based on test kit procurement reported at the ex-works level include: Cambridge Biotech HIV-1 Western Blot (Maxim Biomedical), INNO-LIA HIV I/II Score (Innogenetics), and Pepti-LAV 1|2 Assay (Bio-Rad). Orgenics (Inverness) product ImmunoComb II CombFirm HIV 1&2, with procurement reported in 2010 only, represented only 6.4% of the 2010 market by value, but 22.5% of the 2010 market by volume. This product, with a weighted average 2010 ex-works price of \$5.61 per test – 77% below the weighted average ex-works price of \$24.07 for all HIV supplemental tests kits – is a notable exception in the shift towards procurement of more expensive tests, noted above.

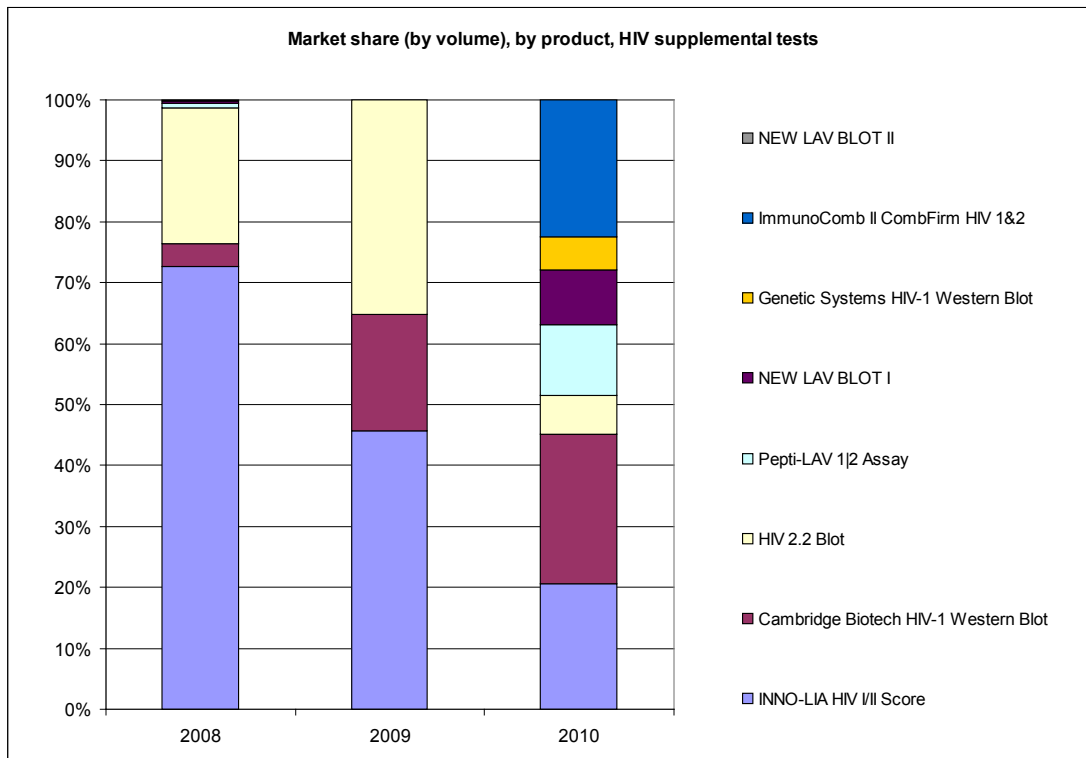
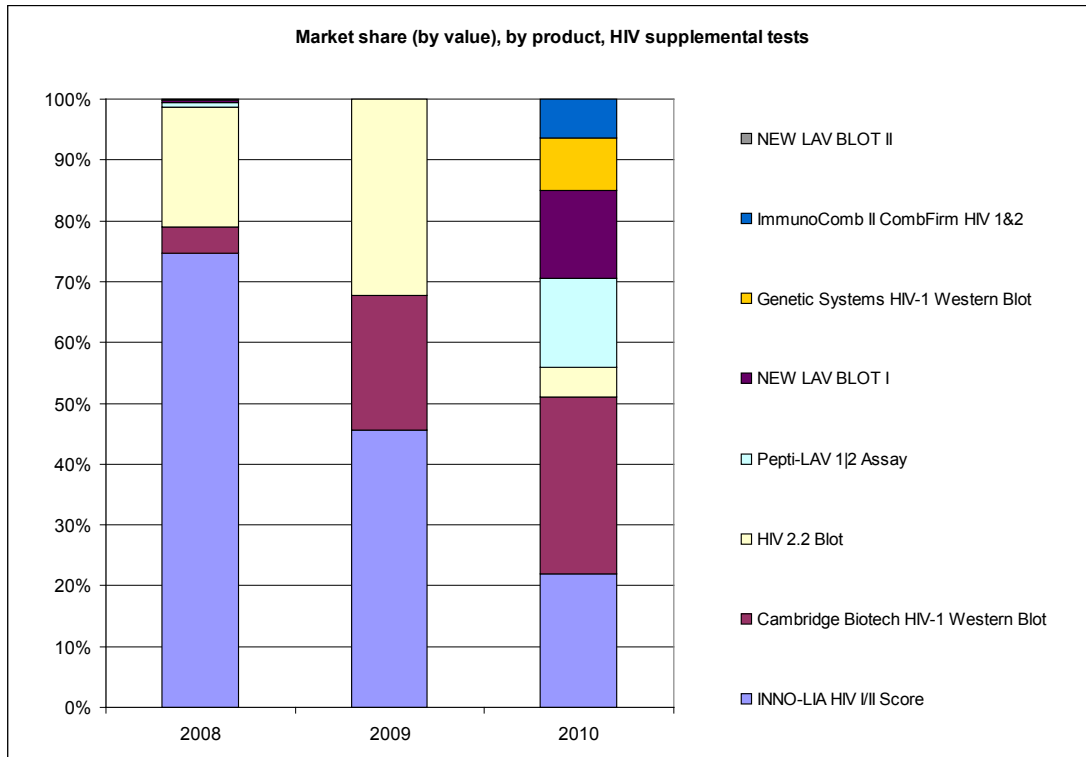
Refer to Figure 27 and Figure 28 for the market share of HIV supplemental tests, by manufacturer and product, respectively. Refer to Table 15 for tabulated data on 2010 market-leading HIV supplemental tests.



**Figure 27. Manufacturer market share of HIV supplemental tests, by value and volume (available data, 2008-2010, reported at the ex-works level)**



**Figure 28. Product market share of HIV supplemental tests, by value and volume (available data, 2008-2010, reported at the ex-works level)**



**Table 15. 2010 market-leading HIV supplemental tests based on available procurement data reported at the ex-works level**<sup>29</sup>

Test	Manufacturer	2010 volume (number of tests)	2010 value (USD)	2010 price (weighted average) (USD)	2010 market share (volume)	2010 market share (value)
<b>Cambridge Biotech HIV-1 Western Blot</b>	Maxim Biomedical	2,160	50,758	23.44	24.5%	29.2%
<b>INNO-LIA HIV I/II Score</b>	Innogenetics	1,820	38,106	21.62	20.7%	21.9%
<b>Pepti-LAV 1 2 Assay</b>	Bio-Rad	1,020	25,255	24.76	11.6%	14.5%
<b>NEW LAV BLOT I</b>	Bio-Rad	792	25,181	32.05	9.0%	14.5%
<b>Genetic Systems HIV-1 Western Blot</b>	Bio-Rad	480	15,000	31.25	5.4%	8.6%
<b>ImmunoComb II CombFirm HIV 1&amp;2</b>	Orgenics (Inverness)	1,980	11,110	5.61	22.5%	6.4%
<b>HIV 2.2 Blot</b>	MP Biomedicals	558	8,448	21.77	6.3%	4.9%

<sup>29</sup> Based on available data only. Refer to Table 8 for detail on available data, including notes on important gaps.

Based on available HIV supplemental test procurement data reported at the ex-works level, the minimum price per test kit decreased 65% between 2008 and 2010, and the maximum price per test kit rose 39% between 2008 and 2010. The weighted average price increased 25% during this time, indicating a shift towards procurement of more expensive tests. Refer to Table 16 for a summary of price trends for HIV supplemental test kits.

**Table 16. Price trends for HIV supplemental tests based on available procurement data reported at the ex-works level**

<b>Parameter</b>	<b>2008</b>	<b>2009</b>	<b>2010</b>	<b>% change</b>
<b>Minimum price/test (USD)</b>	15.84	15.78	5.61	-65%
<b>Maximum price/test (USD)</b>	23.00	23.00	32.05	39%
<b>Weighted average price/test (USD)</b>	19.24	18.96	24.07	25%

## DISCUSSION AND NEXT STEPS

Based on the procurement data discussed in this document, several areas can be flagged for discussion. First, top-line procurement trends highlight implications for future funding. Second, data collection may be improved. Finally, this analysis points to areas for further research or consideration in future procurement.

### Use of available procurement data to inform future funding and procurement strategy

Available procurement data may be used to characterize the market, with market trends used to inform future funding and procurement strategy.

#### *#1: Leverage information on price variation by country and by test to improve cost-effectiveness of procurement*

Trend analysis indicates a wide variation in weighted average price per HIV simple/rapid test. Based on available data for 2010 reported at the ex-works level:

- As shown in Figure 13, the countries with the highest procurement prices were Cape Verde and Haiti (weighted average price of approximately \$1.70 per HIV simple/rapid test); the lowest price per test was observed in Uzbekistan (\$0.50 per test). This wide variation (>200%), however, does not account for differences in products selected.
- As shown in Figure 14, the 2010 weighted average ex-works price of Determine™ HIV-1/2, the most-procured product, averaged \$0.80 across countries and ranged from \$0.69 in Benin to \$1.47 in Mauritius (22% difference between countries procuring at the lowest vs. highest prices). As shown in Figure 15, the 2010 weighted average ex-works price of Uni-Gold™ HIV averaged \$1.63 across countries and ranged from \$1.53 in Sierra Leone to \$1.76 in Yemen and Malawi (a 15% difference). As shown in Figure 16, the 2010 weighted average ex-works price of SD BIOLINE HIV 1/2 3.0 averaged \$0.82 across countries and ranged from \$0.78 in Togo and the Philippines to \$1.50 in Honduras (a 94% difference).
- The most expensive test across all countries for which procurement data were available, the OraQuick® HIV-1/2 Rapid Antibody Test, had a weighted average price of \$3.64. The least expensive test across all countries, Diagnostic Kit for HIV (1+2) Antibody (Colloidal Gold), had a weighted average price of \$0.47.

These wide ranges illustrate the potential for improved procurement efficiencies. For example, the price paid in one country could be used as a benchmark for achieving lower prices in others. The influences underlying lower prices should be determined, with learning applied globally to increase procurement efficiencies. Further analysis could be performed to compare the effectiveness of existing procurement

practices (e.g., by examining the weighted average price of tests procured directly from the manufacturer or in-country supplier vs. via procurement agencies).

## *#2: Account for market consolidation in procurement decisions to balance competition with market stability*

Competition among manufacturers is key and should be encouraged, while avoiding disruption in supply that could compromise patient outcomes. For example, a sudden change in the most commonly used product could be problematic if there is a lack of familiarity with new tests, a lack of appropriate laboratory infrastructure or required materials, or if new tests are ill-suited for a particular setting. Sudden increase of required quantities for a given product can affect the quality of production if not adequately planned. The balance between competition and market stability depends on market dynamics for each test type.

- The HIV simple/rapid test market was dominated by Inverness Medical Innovations (now Alere) during the period considered in this study, with market-leading product Determine™ HIV-1/2 representing 78.6% (by value) and 83.8% (by volume) of 2010 procurement. Orgenics, the fourth leading manufacturer, is also part of Inverness Medical Innovations (now Alere). Thus, the market risks becoming increasingly consolidated through mergers and acquisitions. Future procurement decisions could encourage a more diversified product selection to encourage competition among manufacturers.<sup>30</sup>
- The HIV EIA test market is more fragmented than that for HIV simple/rapid tests. In addition, based on available data for both HIV EIA and supplemental tests, the range of ex-works prices widened, but the weighted average price increased by 38% between 2008 and 2010. This indicates a shift towards procurement of more expensive HIV EIA and supplemental tests, despite greater price competition between tests. While this could be driven by a number of factors (e.g., increased use of 4th generation HIV EIA tests), future procurement decisions could consider this information in assessing cost-effectiveness of product selection.

## **Areas for improvement in data collection**

Data for HIV simple/rapid tests are generally well reported, but key gaps discussed in this report could be addressed to improve the quality and completeness of data to better inform future procurement. In addition, reporting of procurement of HIV EIA and supplemental tests, while much smaller in volume and value than that of HIV simple/rapid tests, could be improved. Findings focus on improvement of data collection:

<sup>30</sup> It should be noted that in some cases, a tender (for international procurement) may be issued only for the test used as 1st-line. Tests for use in 2nd or 3rd line may be procured through the local market. As a result, the market may be less consolidated than it appears based only on analysis of international procurement data.

### *#3: Include data from country tenders*

Some countries procure HIV diagnostics directly by issuing tenders that are not reported in global databases if domestically funded (e.g., Brazil, India, and South Africa). The value and volume of direct procurement by countries is not included in this report, but would be expected to be significant. Gaining access to these data would allow for a more comprehensive overview.

### *#4: Support improved accuracy of GPRM data*

The GPRM database compiles transaction-level procurement data from a wide range of agencies, and therefore can serve as a valuable resource for future market analysis. However, as noted in Section 6 of this report, data quality can be improved. Funding agencies should mandate reporting of procurement transactions. In addition, bodies reporting into GPRM could encourage more effective verification of entered data (e.g., an internal screening mechanism with unverified data flagged, as done for Global Fund PQR).

### *#5: Encourage other categories of product to be reported in Global Fund PQR*

Procurement data for HIV EIA and supplemental tests are less fully and accurately reported than for simple/rapid tests. For example, the Global Fund PQR database compiles data for the following categories of products: bednets, condoms, malaria/HIV rapid diagnostic tests, anti-retrovirals, anti-malaria medicines, and anti-TB medicines. Guidance to users of PQR notes that for diagnostic tests, only HIV and malaria rapid tests should be reported in the PQR. To create a full picture of international procurement for HIV diagnostics, categories reported should be expanded to include HIV EIA and supplemental tests (as well as other HIV tests, such as CD4 and virological technologies).

### *#6: Address inconsistent or insufficient data entry*

In much of the data, verification of the manufacturer was required. Inconsistencies in the manufacturer listed for a particular product were common, due to apparent data entry errors or change or geographical distinction in ownership of a particular test. For continued analysis of market dynamics – particularly of manufacturer market share – bodies reporting procurement data should take care to report the current manufacturer.

Similarly, product descriptions vary, and sometimes do not include enough information to identify a unique product. For example, data entered for "DoubleCheckGold" may refer to DoubleCheckGold™ HIV1&2, DoubleCheckGold™ HIV1&2 Whole Blood, or DoubleCheckGold™ Ultra HIV1&2. For both manufacturer and product description, drop-down lists could be used to encourage correct data entry.

### *#7: Account for funding timeframe in reporting procurement data*

As for other types of diagnostics, procurement funds for HIV simple/rapid, EIA, and supplemental tests are often disbursed at a single point in time. With the exception of annual tenders, these disbursements often fund projects that span several years. This can present difficulties in analysis of year-on-year

trends in the data, and thus forecasting demand. Inclusion of information on the duration of the project funded could be useful in comparing procurement trends across years and funding bodies.

## **Areas for further analysis or consideration in future procurement**

The analysis in this report focuses on top-line market trends based on available data. Further analysis in the following areas could be valuable in the future, to take advantage of improved data availability and/or to complement funding for future procurement:

*#9: Compare direct-from-manufacturer procurement to procurement through suppliers, agents, or intermediaries to assess potential for improved cost-effectiveness*

As mentioned above, some sources from which data were obtained report transaction-level procurement data from principal recipients of grants. That is, for each transaction, it was noted whether the product was procured directly from the manufacturer, or the name of the supplier/agent/intermediary, if relevant. Initial analysis has been performed to assess differences in price for products obtained by agencies using direct procurement versus procurement through suppliers, agents or intermediaries. However, a significant portion of the data is lacking or pending verification (e.g., 60% of simple/rapid data Global Fund PQR entries are currently flagged as 'pending verification'), hindering further analysis. With a more complete dataset, in-depth analysis of price and order patterns could be performed to inform efforts to improve cost-effectiveness of procurement.

*#10: Consider activities needed to complement procurement of HIV simple/rapid, EIA and supplemental tests*

Improvements in appropriate use and counseling maximize the public health impact of market impact on test pricing and availability. For example, simple/rapid tests often do not include positive and negative controls. These may be available from the manufacturer, but are sold separately (in part due to their differing shipping and storage requirements). Funding agencies could earmark a portion of procurement funds for positive and negative controls, thereby enhancing the value of their investments.

In summary, HIV serological and supplemental test procurement is well established, and the market – particularly for HIV simple/rapid tests – is well characterized. Top-line trends in test availability and pricing can be used to inform procurement decisions, for example, in striking a balance between fostering healthy competition and avoiding supply disruptions, or in negotiating lower prices for tests. With modest effort, the quality and completeness of data can be improved, allowing for further analysis to optimize the cost-effectiveness of procurement.



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