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**AAPD 07-05 “USAID List of Approved HIV/AIDS Test Kits” is archived. The information has been incorporated into ADS 312. See Addition Help document ADS 312sae, Section IV.A.2. and the “Resources” section of GH/OHA/SCM’s webpage (<https://www.usaid.gov/what-we-do/global-health/hiv-and-aids/technical-areas/supply-chain-hiv-and-aids-essential-health>) for the USAID List of Approved HIV/AIDS Rapid Test Kits.**



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## Acquisition & Assistance Policy Directive (AAPD)

From the Director, Office of Acquisition & Assistance Issued: August 29, 2007

**AAPD 07 - 05**

### USAID List of Approved HIV/AIDS Test Kits

Subject Category: Assistance, Acquisition Management  
Type: Policy and Procedure

AAPDs provide information of significance to all agency personnel and partners involved in the Acquisition and Assistance process. Information includes (but is not limited to): advance notification of changes in acquisition or assistance regulations; reminders; procedures; and general information. Also, AAPDs may be used to implement new requirements on short-notice, pending formal amendment of acquisition or assistance regulations.

AAPDs are EFFECTIVE AS OF THE ISSUED DATE unless otherwise noted in the guidance below; the directives remain in effect until this office issues a notice of cancellation.

This AAPD:  Is New  Replaces/ Amends CIB/AAPD No: 05-01

<p>Applicable to:</p> <p><input checked="" type="checkbox"/> Existing awards; <input type="checkbox"/> Modification required</p> <p><input type="checkbox"/> No later than</p> <p><input type="checkbox"/> As noted in guidance below</p> <p><input checked="" type="checkbox"/> RFPs/RFAs issued on or after the effective date of this AAPD; all other Pending Awards, i.e., 8(a), sole source, IQC</p> <p><input type="checkbox"/> Other or N/A</p>	<p>Precedes change to:</p> <p><input type="checkbox"/> AIDAR Part(s) Appendix</p> <p><input checked="" type="checkbox"/> USAID Automated Directives System (ADS) Chapters 303</p> <p><input type="checkbox"/> Code of Federal Regulations</p> <p><input type="checkbox"/> Other</p> <p><input type="checkbox"/> No change to regulations</p>
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Signature on File

Michael F. Walsh, Director

## **AAPD 07- 05 USAID List of Approved HIV/AIDS Test Kits**

### **PURPOSE:**

1. This AAPD replaces AAPD 05-01.
2. The USAID List of Approved HIV/AIDS Test Kits has been updated.
3. AA/M no longer approves test kits; the authority has been delegated to Director of the Office of HIV/AIDS, Bureau for Global Health (GH/OHA). GH/OHA establishes the technical requirements and issues technical guidance for test kits.
4. The List, technical requirements, technical guidance and technical points of contact are at [http://www.usaid.gov/our\\_work/global\\_health/aids/TechAreas/scms/scms.html](http://www.usaid.gov/our_work/global_health/aids/TechAreas/scms/scms.html)
5. This AAPD confirms that source/origin waivers and OAA “restricted commodity” approvals under ADS 312.5.3c are not required for the test kits on the list.

**ACTION REQUIRED:** COs/AOs, in coordination with Cognizant Technical Officers (CTOs), amend current agreements and include language in new agreements to implement the AAPD, as appropriate.

**BACKGROUND:** HIV/AIDS rapid test kits are considered pharmaceuticals by USAID. USAID contracts and agreements have provisions that require a source/origin waiver for HIV/AIDS rapid test kits that are manufactured outside the United States. They also require a “restricted commodity” approval for HIV/AIDS rapid test kits that are not approved by the Federal Drug Administration (FDA).

On January 11, 2001, the Administrator authorized the procurement of non-US HIV/AIDS rapid test kits provided they met certain technical requirements. In an Action Memorandum dated September 26, 2006, the Administrator modified the basis for the waiver and delegated the authority to approve test kits to the Director of the Office of HIV/AIDS, Bureau for Global Health. As a result of the Administrator’s waiver, no further source/origin waivers or restricted commodity approvals are needed. A Contracting/Agreement Officer can give consent to proceed with the procurement of any of the HIV/AIDS rapid test kits on the USAID list.

GH/OHA has established a website for List of HIV/AIDS rapid test kits and the technical and documentation requirements and has recently updated the technical and documentation requirements. They are no longer in the AAPD. Firms and individuals seeking USAID approval of an HIV/AIDS rapid test kit to add to the List of HIV/AIDS Rapid Test Kits should refer to that website.

### **GUIDANCE:**

- A.** The “USAID List of Approved HIV/AIDS Test Kits” is at [http://www.usaid.gov/our\\_work/global\\_health/aids/TechAreas/scms/scms.html](http://www.usaid.gov/our_work/global_health/aids/TechAreas/scms/scms.html).

## **B. Office of Acquisition and Assistance (OAA) and CO and AO Approvals.**

1. Source/origin waivers and OAA “restricted commodity” approvals under ADS 312.5.3c are not required for the test kits on the list.
2. Under contracts and agreements awarded prior to the issuance of this AAPD, COs and AOs may give advance CA/CO consent to proceed with the procurement of any Approved Test Kits under the (a) the AIDAR provision 752.225-70, "Source, Origin and Nationality Requirements", (b) source/origin or “restricted commodity” provisions of the Mandatory Standard Provisions for U.S., Nongovernmental Recipients "USAID Eligibility Rules for Goods and Services", or (c) other similar provisions. For contracts and agreements awarded after the issuance of this AAPD, COs and AOs may include language in the schedule or elsewhere that indicates that, under the authority of the source waiver, advance CO/AO approval is granted for procurement of Approved Test Kits under the above AIDAR clause or similar assistance agreement provisions. This language must state that such procurement must be made in accordance with terms of this AAPD and cite the number assigned to this AAPD.
3. COs may give advance consent to subcontracts for procurement of Approved Test Kits in amounts in excess of the simplified acquisition threshold under FAR clause 52.244-2, Subcontracts.
4. Once a contractor requests CO consent of a subcontract for the procurement of Approved Test Kits in excess of the simplified acquisition threshold, the CO may consent to the current and any future subcontracts that are solely for the procurement of any of the Approved Test Kits.

## **D. Technical Requirements and Considerations.**

AA/M no longer approves test kits; that is now done by GH/OHA. GH/OHA establishes the technical requirements and issues technical guidance for test kits. The technical requirements, technical guidance and points of contact are at [http://www.usaid.gov/our\\_work/global\\_health/aids/TechAreas/scms/scms.html](http://www.usaid.gov/our_work/global_health/aids/TechAreas/scms/scms.html).

**POINT OF CONTACT:** Please direct questions about this AAPD to Carl Hawkins, GH/OHA/SCMS, [chawkins@usaid.gov](mailto:chawkins@usaid.gov), 202-712-4539.

### **Attachments:**

Sample Letter to Contractors  
Sample Letter to Recipients

Sample Letter to Contractors

From: Contracting Officer

Subject: Procurement of USAID-Approved HIV/AIDS Test Kits

The purpose of this letter is to provide USAID approval for “USAID-Approved HIV/AIDS Test Kits”. The HIV/AIDS test Kits that have been approved by USAID are on the “USAID List of Approved HIV/AIDS Test Kits” which can be found at [http://www.usaid.gov/our\\_work/global\\_health/aids/TechAreas/treatment/scms.html](http://www.usaid.gov/our_work/global_health/aids/TechAreas/treatment/scms.html).

Advance approval is hereby given under the AIDAR provision 752.225-70, "Source, Origin and Nationality Requirements" in your contract. Office of Acquisition and Assistance “restricted commodity” approval of pharmaceuticals under ADS 312.5.3c or source, origin, and nationality waivers are not required for Approved HIV/AIDS Test Kits.

Advance consent [is hereby given] [is still required] for subcontracts for approved test kits in amounts in excess of the simplified acquisition threshold, under FAR clause 52.244-2, Subcontracts.

The above approval is given with the understanding that: (1) sufficient funding exists in the contract to cover the expenditures; (2) the approval does not increase the total estimated amount of the contract; and (3) additional funding will not be required. All other conditions of the contract remain unchanged.

Please contact your CTO for technical questions on HIV/AIDS Test Kits.

Sample Letter to Recipients of Grants and Cooperative Agreements

From: Agreement Officer

Subject: Procurement of USAID-Approved HIV/AIDS Test Kits

The purpose of this letter is to provide USAID approval for “Approved HIV/AIDS Test Kits” on the “USAID List of Approved HIV/AIDS Test Kits”. The "USAID List of Approved HIV/AIDS Test Kits" can be found at [http://www.usaid.gov/our\\_work/global\\_health/aids/TechAreas/treatment/scms.html](http://www.usaid.gov/our_work/global_health/aids/TechAreas/treatment/scms.html),

Advance approval is hereby given under the Mandatory Standard Provisions for U.S. and Non-U.S. Nongovernmental Recipients "USAID Eligibility Rules for Goods and Services" [*or other similar assistance agreement provision*] in your agreement. Office of Acquisition and Assistance “restricted commodity” approval of pharmaceuticals under ADS 312.5.3c or source, origin, and nationality waivers are not required for Approved HIV/AIDS Test Kits.

The above approval is given with the understanding that: (1) sufficient funding exists in the agreement to cover the expenditures; (2) the approval does not increase the total estimated amount of the agreement; and (3) additional funding will not be required. All other conditions of the agreement remain unchanged.

Please contact your CTO for technical questions on HIV/AIDS Test Kits.