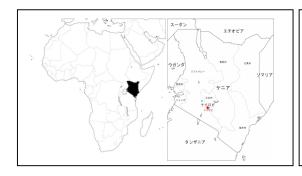
## Republic of Kenya

Ex-Post Evaluation of Japanese Grant Aid Project

"The Project for Improvement of Facilities for Control of Infectious and Parasitic Diseases at Kenya Medical Research Institute in the Republic of Kenya"

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## 1. Project Description





#### 1.1 Background

The Kenya Medical Research Institute (KEMRI), the organization implementing the Project, is a state corporation established through the Science and Technology (Amendment) Act of 1979, as the national body responsible for carrying out health research in Kenya. In 1979 the first Japan's technical cooperation, "the Communicable Diseases Research and Control Project", started, and in 1985 Japan's Grant Aid project built the facilities of the KEMRI headquarters (including the laboratory, administration, animal experimentation, etc.). Technical cooperation had continued in five phases in total for the purpose of strengthening the research capacity of KEMRI for infectious diseases (viruses, bacteria, parasites, diarrhea, HIV/AIDS, acute respiratory disease, etc.), utilizing the facilities.

As for viral hepatitis, technical cooperation had been implemented since 1985 and the test kit for Hepatitis B in blood was developed in Phase 3 and Phase 4. In addition, in Phase 4, the P3 laboratory (high-level bio-safety laboratory) was constructed through Japan's Grant Aid (1999) and test kits for HIV in blood were also developed in the laboratory through the applied research activities. After this progress, manufacturing and establishing of stable supplies of these test kits were planned in order to reduce the prevalence of Hepatitis B and HIV. As for parasitic diseases that had been cooperated since Phase 1, the activities led to the creation of a regional hub center of human resource development and of communication networks of researchers in Phase 5. Then, the project was recognized as one of component of Japan's Global Parasite Control Initiatives.

As Phase 5 of technical cooperation, "the Infectious and Parasitic Disease Control Project" (which was split into "the Research and Control of Infectious Diseases Project" and "the International Parasite Control Project") had implemented the following cooperation.

· Blood safety related to HIV/AIDS and viral hepatitis

- Applied development of treatment measures and traditional medicine for opportunistic infections associated with HIV/AIDS
- · Human resource development and networking of researchers for parasitic disease control

In order to efficiently implement the cooperation mentioned above, the Government of Kenya planned the construction of facilities (a production unit for the test kit and a training unit) and the procurement of equipment. However, because of the lack of financial resources, the Government of Kenya requested Grant Aid from the Government of Japan.

The basic design studies were implemented twice, and this ex-post evaluation was based on the second basic design study. After the first basic design study (2002), the Government of Kenya changed the policy for production of the testing kit reflecting the recommendation on the use of HIV test kits by the World Health Organization (WHO). Accordingly, re-study of the demand of test kits production was required. A preparatory study was again implemented in May 2003, and the second basic design study was implemented in August 2003.

## 1.2 Project Outline

The objective of the Project is to establish the manufacturing system of blood test kits and to improve the training functions by developing and expanding the manufacturing facility of blood test kits and the facilities for infectious and parasitic diseases in the premises of KEMRI and in addition, to strengthen the measures to parasitic and infectious diseases in Kenya and surrounding countries, linked with technical cooperation project.

Table 1. Project outline

Grant Limit/ Actual Grant Amount	1072 million yen / 955 million yen
Exchange of Notes Date	February, 2004 (for detailed design study)
Exchange of Notes Date	August, 2004 (for construction)
Implementing Agency	Ministry of Health (MoH) (currently the Ministry of Public
Implementing Agency	Health and Sanitation)
Project Completion Date	November, 2005
Main Contractor	Sumitomo Mitsui Construction Co., Ltd. (Construction)
Walli Collifactor	Mitsubishi Corporation (Equipment)
Main Consultant	Nihon Sekkei Co. Ltd.
	"Basic design study on the project for improvement of
	facilities for control of infectious and parasitic diseases at
Basic Design	Kenya Medical Research Institute in the Republic of
	Kenya" Japan International Cooperation Agency (JICA)
	and Nihon Sekkei Co. Ltd., August – September 2003
Detailed Design	February, 2004 - July, 2004
	[Japanese Technical Cooperation] Japan International
	Cooperation Agency (JICA) "Communicable Diseases
	Research and Control Project" (1979-84), JICA "Project of
Relevant Project	the Kenya Medical Research Institute" (1985-90), JICA
Relevant i roject	"Project on Research and Control of Infectious Diseases"
	(1990-96), JICA "Research and Control of Infectious
	Diseases Project II" (1996-2001), JICA "Third Country
	Training Programme on Blood Safety" (1998-2001, 2003-

2007), JICA "Research and Control of Infectious Diseases Project" (2001-2006), JICA "International Parasite Control Project" (2001-2006)
[Japanese Grant Aid] MoH "Project for the Construction of the Kenya Medical Research Institute" (1982-83), MoH "Project for Improvement of the Kenya Medical Research Institute" (1999), MoH "Project for Improvement of Facilities for Control of Infectious and Parasitic Diseases at the Kenya Medical Research Institute" (2005)

## 2. Outline of the Evaluation Study

#### 2.1 External Evaluator

Hirofumi Tsuruta, Consultant, Binko International Ltd.

#### 2.2 Duration of Evaluation Study

Duration of the Study: December, 2009 – November, 2010

Duration of the Field Study: March 15, 2010 - March 27, 2010

May 23, 2010 - May 29, 2010

## 2.3 Constraints during the Evaluation Study

Some of the core stakeholders in the Project were unavailable during the survey because of their retirement, personnel changes or illness. This may have caused in limitation of information on the Project, particularly of the information of management decisions. However, this was made up for by the full cooperation of KEMRI and reviews of various documents.

## 3. Results of the Evaluation (Overall Rating: C)

This evaluation equally weighted the production unit and the training unit because the construction and equipment cost for each was almost equal (production unit: 51.6%, training unit: 48.4%) as shown in Table 2.

Table 2 Cost of the amount of each unit at the time of the basic design study
(Thousand Japanese yen)

Facility	Construction and Equipment Cost	Proportion (%)
Production Unit	385,000	43.5
Animal Unit	72,000	8.1
Training Unit	429,000	48.4
Total	886,000	100.0

Source: JICA, Basic Design Study Report on the Project for Improvement of Facilities for Control of Infectious and Parasitic Diseases at Kenya Medical Research Institute in the Republic of Kenya (2003)

#### 3.1 Relevance (Rating: b)

#### 3.1.1 Relevance with the Development Policy of Kenya

At the time of the basic design study and the ex-post evaluation, the relevance of the Project purpose with the development policy of Kenya was/is high in regard to the diseases and area targeted as follows.

In the basic design study, health issues comprised one of the social development agenda items in the Economic Recovery Strategy for Wealth and Employment Creation 2003-2007. In addition, even in the National Health Sector Strategic Plan 1999-2004 (NHSSP I) there was a shift from curative to preventive and to primary health care services, which was consistent with the Project purpose focusing on preventative approaches including blood safety and parasitic disease control.

As diseases targeted by the Project, HIV/AIDS and hepatitis were regarded as the ones requiring blood screening in the National Blood Safety Policy 2002. In addition, the blood safety itself was one of the prevention components in the Kenya National HIV/AIDS Strategic Plan 2000-2005 (KNASP I). On the other hand, as for parasitic diseases, it was the targets of the NHSSP I that the prevalence and mortality rate of parasitic disease of children under five years old would be reduced from 70% to 40%, and malaria prevalence and mortality rate would be reduced by 30%.

Even at the time of ex-post evaluation, health issues are placed as a social pillar in the first Medium-term Plan of Kenya Vision 2030, and it aims at restructuring its health system in order to shift its emphasis mentioned above, from curative to promotive and preventive health care. This concept is similarly noted even in the National Health Sector Strategic Plan 2005-2010 (NHSSP II).

In addition, HIV/AIDS and Hepatitis B are still targets of blood screening in the National Blood Safety Policy 2002, and the statement on blood safety in the Kenya National HIV/AIDS Strategic Plan 2009-2012 (KNSAP III) has not been changed. As for parasitic diseases, although they were not emphasized in the NHSSP II, there are policy concerns regarding treatment of parasitic diseases for children under twelve years old and a school health program that included de-worming activities.

#### 3.1.2 Relevance with the Development Needs of Kenya

Table 3 shows the health situation at the time of the basic design study and of the ex-post evaluation. It shows that there were/are the crucial needs of intervention to the health problems of Kenya in the planning period. Even at present, it is significant although some have been improved in these five years.

As shown in Table 3, at the time of the basic design study, because the screening rate of blood for transfusion had not achieved 100%, and because epidemics of HIV/AIDS and hepatitis were reported, countermeasures were urgent needs. Even regarding parasitic diseases, because coverage of preventative activities was low, Kenya government had to increase them.

Five years after, at the time of ex-post evaluation, there are still needs. The screening rates of blood have achieved 100%, but it must be sustained even in the future. Epidemics of HIV/AIDS and hepatitis have improved but the situation is still serious. Similarly, the coverage of preventive measures has been partly improved but there is still risk of transmission.

Table 3 Health situation at the time of the basic design study and the ex-post evaluation

	Basic Design Study	Ex-post Evaluation		
Blood Safety		Screening rate of blood for transfusion: 100%*2 (2009)		
HIV/AIDS	Adult prevalence: 6.1%*3 (2004) Prevalence in blood for transfusion: 5-7%*5 (2001) Mother-to-child transmission: 35%*3 (2005)	(2009)		
Hepatitis B	Prevalence: more than 8% *6 (2001) Prevalence in blood for transfusion: 2-4%*5 (2001)	Prevalence: more than 8% *7 (2008) Prevalence in blood for transfusion: more than 34% *2 (2009)		
Parasitic Disease				
Malaria	Population receiving indoor residual spraying: 300,000*8 (2004) Prevalence among outpatients: 1/3 *1	Population receiving indoor residual spraying: 3,061,966*8 (2008) Prevalence among outpatients: 1/3*9		
helminthes	Population of school-aged children (5 to 15 years old) requiring preventive chemotherapy: 4.31%**10 (2003)	Population of school-aged children (5 to 15 years old) requiring preventive chemotherapy: 6.32*10 (2008)		
Schistosomiasis	Prevalence among 5 to 12-year-old schoolchildren in Nyanza Province: 31.6%*12 (2001)	Population requiring preventive chemotherapy: 30,839,766*10 (2008)		
Fillariasis		Population requiring preventive chemotherapy: 36.0%*10 (2008)		

Sources: 1 JICA, Basic Design Study Report on the Project for Improvement of Facilities for Control of Infectious and Parasitic Diseases at Kenya Medical Research Institute in the Republic of Kenya (2003)

- 2. Information submitted by KEMRI for the ex-post evaluation
- 3. The Government of Kenya, Country Report for UN General Assembly Special Session on HIV/AIDS 2006
- 4. The Government of Kenya, Country Report for UN General Assembly Special Session on HIV/AIDS 2010
- 5. Family Health International, Implementation of the New Blood Safety Policy Proceedings of a Consultative Technical Meeting April 29-30, 2002 Nairobi, Kenya (2002)
- 6. WHO, Introduction of Hepatitis B Vaccine into Child Immunization Services (2001)
- 7. WHO/CDC, Map of Hepatitis B, Countries or areas at risk (2008)
- 8. WHO World Malaria Report 2009 (2009)
- 9. Republic of Kenya, Annual Health Sector Statistics Report 2008 (2009)
- 10. WHO, PCT (Preventive Chemotherapy and Transmission Control) Databank
- http://www.who.int/neglected\_diseases/preventive\_chemotherapy/sth/en/
- 11. T. Handezel et al., Geographic Distribution of Schistosomiasis and Soil-transmitted Helminths in Western Kenya: Implications for Anthelmintic Mass Treatment, Am. J. Trop. Med. Hyg. 69(3) pp. 318-323
- 12. F. W Thiong'o et al., Intestinal Helminths and Schistosomiasis among School Children in Rural District in Kenya, East African Medical Journal 78(6), pp.279-282

## 3.1.3 Relevance with Japan's ODA Policy

The relevance of the Project with Japanese ODA policy was high, because the Project was designed to contribute to blood safety and parasitic disease control that are targeted by the Okinawa Infectious Disease Initiatives and Country Assistance Plan for Kenya.

In 2000, Japan launched the Okinawa Infectious Disease Control Initiative and represented the importance of efforts against infectious diseases. In this initiative, HIV/AIDS, tuberculosis, malarial/parasitic diseases, and polio were targeted as the primary diseases, and particularly in the HIV/AIDS area, the contribution of blood safety was included.

In addition, in the Country Assistance Plan for Kenya (2000), health issues were one of the important areas. In particular, HIV/AIDS was described as follows: "With treatments yet to be established for HIV/AIDS, it will be vital to support research toward treatment development, as well as education and informing of the public of HIV/AIDS prevention measures, supply of contraceptive devices, and establishment of testing for early detection." On the other hand, parasitic diseases control was regarded as the target of follow-up of south-to-south and regional cooperation.

These targets were confirmed in the policy discussion implemented between the Kenyan Government and Japanese ODA taskforces in Kenya in August 2004 after the Project started. Considering the outcomes of cooperation with KEMRI, promotion of infectious disease control including blood safety, and promotion of parasitic disease control as a regional center in eastern and southern Africa based on the initiatives were confirmed.

#### 3.1.4 Adequacy of Measures

The construction of the production and training facility was planned as a measure for stable supply and procurement of the test kits and creation of opportunity of training. However, as mentioned below, the construction of the production facility might have been partially in adequate in comparison to alternative measures.

## (Production Facilities)

Domestic manufacturing as aimed in the Project was lack of certainty as a measure of stable supply and procurement, and it is unclear whether the construction of a production facility was the most appropriate for that purposes. The brand of the test kits used in Kenya could be changed by policy decision, and any brand had the risk of losing opportunities and routes for use and/or sale.

Another measure to supply and procure test kits was the import of products of foreign manufacturers, besides domestic production. Even at the time of the basic design study, distribution of foreign-brand test kits had already started in Kenya and these foreign-brand test kits were competitors of the KEMRI test kits. In addition, because there were various uncertainties such as technical innovation, the influence of other development partners, and entry into the market with which KEMRI had little experience, it seems to have been difficult to make a definite promise that the test kits would be used. Even though the KEMRI test kits were superior to the other foreign brands at the basic design study, there was the risk to make the situation worse.

Even though, construction of production facilities lacked certainty as a measure for stable supply of test kits, it had a potentially bigger impact because of the possibility of establishing

sustainable domestic production and utilization if all conditions were favorable. Thus, it seems that the Project takes high-risk/high-return approach.

## (Training Facility)

The construction of a training facility was almost adequate as a measure for efficient management of training. According to the basic design study, the training facility would be a center to conduct training for parasitologists, clinical technologists and medical students of Kenya and neighboring countries. This will contribute greatly to human resource development in this region, and hence reduction of infection rates of parasitic diseases.

If we focus only on the creation of training opportunities, the Project might lack adequacy because other existing facilities of other educational and/or training organizations in Nairobi could be options as training places. They existed even at the time of the basic design study.

However, borrowing the facilities of other organizations means that KEMRI could be influenced by the decisions, etc. from the other organizations. Reflecting the responsibility of KEMRI as a regional center of Eastern and Southern Africa, it may have been necessary to increase the efficiency of training management. This is why it was considered fairly appropriate for KEMRI to construct its own training facility.

As mentioned in 3.1.1-3.14, the Project was partly irrelevant with the adequacy of measures, although it was relevant to development policy and health needs of Kenya, and Japan's ODA policy, therefore its relevance is fair.

## 3.2 Efficiency (Rating: a)

## 3.2.1 Project Outputs

Table 4. Outputs

Actual Implementation*2
n and improvement of the
unit for test kits, animal unit, and
t for infectious and parasitic disease
procurement of equipment
n facility (new construction):
on and manufacturing room
PCELL), office, mechanical room,
ply facility, etc.
cility (improvement): Rabbit room,
g room, inoculation room, etc.
unit (new construction): Parasitic
, infectious disease laboratory,
cture room, office, etc.
t: Lyophilizer, refrigerator,
ed centrifuge, refrigerator, safety
tc. (total: 91 items, 555 devices)

Sources 1. JICA, Basic Design Study Report on the Project for Improvement of Facilities for Control of Infectious and Parasitic Diseases at Kenya Medical Research Institute in the Republic of Kenya (November 2003)

2. Documents at completion of the Project (2005)

As shown in Table 3, there was no big gap between planning and implementation. There was only minor change from the basic design study, which was displacement of the mechanical room (moved 11.7 m west from the plan) in order to secure a sufficient loading area due to the construction of a research facility by the U.S. Center for Infectious Disease Control (CDC), which was not related to the outputs of this Project.

# 3.2.2 Project Inputs

## 3.2.2.1 Project Period

As shown in Table 5, the implementation period of the Project was exceeded by about three months in comparison to the 18 months in the plan. It seems that this was due to unexpected issues such as political instability in Kenya and/or needs to secure safety (e.g., pirates in Somalia). In practice, the Project was completed without any extension of contract or E/N, and there were no reports of additional costs or problems due to the delay, and no problems with the implementation period were found. Thus, the Project period was mostly adequate as planned.

Table 5. Comparison of period between plan and implementation

	Plan	Implementation
Detailed Design	4 months	5 months (E/N (detailed design study) 2004.2.20 – end of contract 2004.7.22)
Tender	3 months	4 months (E/N (construction) 2004.8.4 - contract with contractor 2004.12.6)
Construction	11 months	11.5 months (contract with contractor 2004.12.6 - handing over 2004.11.24)
Total	18 months	20.5 months

Source: Documents at completion of the Project (2005)

#### 3.2.2.2 Project Cost

As shown in Table 6, the overall implemented Project cost was 95.9% of the overall Project cost estimate in the basic design study, and there was no excess. In addition, all of the supervision cost, construction cost and equipment cost were also below the cost estimates in the basic design study. This was seemingly due to 1) cooperative efforts of consultants, constructors, and suppliers and 2) currency exchange rate. Thus, the Project cost was lower than planned.

Table 6. Comparison between planned and actual cost

(Thousand yen)

	Planned Cost*1	Actual Cost*2	Ratio (%)
Supervision	196,000	194,132 <sup>*3</sup>	99.1
Construction	699,000	659,500	94.3
Equipment	187,000	183,732	98.3
Total	1,082,000	1,037,364	95.9

Sources: 1. JICA, Basic Design Study Report on the Project for Improvement of Facilities for Control of Infectious and Parasitic Diseases at Kenya Medical Research Institute in the Republic of Kenya (2003)

In summary, as mentioned 3.1 and 3.2, both project period and project cost were mostly as planned. Therefore efficiency of the project is high.

<sup>2.</sup> Documents at completion of the Project (2005)

<sup>3.</sup> Total amount of E/N (82 million Japanese yen) and amount of supervision cost of construction and equipment

## 3.3 Effectiveness (Rating: b)

#### 3.3.1 Quantitative Effects

## 3.3.1.1 Results from Operation Indicators

(Production Facility)

As shown in Table 7, because the production of HIV test kits had been decreased since 2006 and terminated in 2008, and the production of the Hepatitis B test kits was also terminated after 2006, the goal set by the basic design study was not achieved. In addition, although the completion of the Project was the end of November 2005, and production of test kits by the facilities constructed by the Project was started in 2006, the number of test kits' product did not increase very much before and after the Project. According to the observation and interviews in the field survey for this evaluation, the facilities for the production have not been much operated at present.

There is a reason that the expected utilization route of test kits could not be established. As mentioned above in 3.1 Relevance, there was competition with other test kits produced by foreign manufacturer, which have been used widely in Kenya unlike the KEMRI HIV test kits.

Table 7. Number of test kits produced

Те	est Kits for	Target (2010)	2002	2003	2004	2005	2006	2007	2008	2009
	HIV*	1,200	60	100	100	100	75	36	0	0
Н	Iepatitis B	2,000	600	1120	1450	320	1500	0	0	0

Source: Information submitted by KEMRI for the ex-post evaluation

As for HIV test kits, the expected number of kits that could be self-chosen by KEMRI for its use was only 15.8% of the total projection, including use for "the Third Country Training Programme" (JICA's program for blood safety, implemented by KEMRI) and use for "quality control and research in KEMRI". Other uses in the public sector in Kenya including "training for laboratory technicians in Kenya" and "provision and training for public hospitals" were depended on Kenyan policy. That is, the most demand for the KEMRI test kits could not be generated without governmental determination on the brand to use for the diagnosis in public facilities, although the basic design study report mentioned that the expected use was changed from the diagnosis to research. Therefore, in the situation where there was also competition with other brands of test kit, the projected demand was not ensured.

As for the test kits of hepatitis B, it was promised that the test kits would be purchased by MoH as mentioned in the Minutes of the Discussion at the basic design study. However, in practice, 2006 was the last year for the purchase. After that, other test kits manufactured by foreign manufactures came to be used widely in Kenya, and accordingly, the test kits planned in the study has not been produced in the facility.

<sup>\*</sup>The number includes both the test kit that can detect only the HIV-1 subtype and the test kit that can detect both the HIV-1 and HIV-2 subtype, developed by technical cooperation with the Infectious Disease Research and Control Project.

Table 8. Use of HIV test kits in the basic design

Use	Number of Kits (Number of test*) (Percentage of total)
Third Country Training Programme	20 (4,000) (9.3%)
Training for laboratory technicians in Kenya	79 (15,800) (36.7%)
Provision and training for public hospitals	102 (20,400) (47.4%)
Quality control and research in KEMRI	14 (2,800) (6.5%)
Total	215 (43,000) (100%)

Source: JICA, Basic Design Study Report on the Project for Improvement of Facilities for Control of Infectious and Parasitic Diseases at Kenya Medical Research Institute in the Republic of Kenya (2003)

As for the marketing of these KEMRI test kits, KEMRI made self-efforts such as employment of a marketing manager experienced in a private company in December 2005, after completion of the Project, as well as seeking utilization and sale routes in neighboring countries. However, it has not been successful yet. If succeeded, the constructed facility and procured equipment could be utilized more.

At present, although KEMRI has not continued to look for ways to produce or sell these test kits planned in the basic design study, KEMRI has proceeded with the development of new products with diversification of its own products, and has a business plan to improve the operation rate of facilities.

For example, as for the test kits, the rapid test kit for HIV, Hepatitis B, and Hepatitis C was developed and stated to sell. These test kits were manufactured with the coating membrane imported from a foreign country. KEMRI purchased a coating machine with its own budget and expects to coat antigen on the membrane by itself in the future. In addition, KEMRI has started to produce the panel sera first ordered by WHO Somalia, disinfection for tuberculosis, and Taq polymerase for PCR. In addition, KEMRI has started to collaborate with the U.S. Center for Infectious Disease Control (CDC) and international NGOs. Thus, compared to the situation at the time of the basic design study, the KEMRI production unit has significantly expanded its scope of business.

#### (Training Facility)

As shown in Table 9, the training facility has been highly utilized from completion to the present with achievements of the target indicator. As reasons, there has been implementation of not only the Third Country Training Programme (on blood safety, school health, parasitic disease control, etc.) for sub-Saharan African countries, but also collaborative training with international NGOs. This implies that there were potential needs for training and utilization of the facility.

However, if we look at the trend of the overall number of days and participants of training, they have been decreasing year by year. The reason is not clear, but the presidential election in 2007 or the split of the Ministry might have resulted in a confusing situation.

<sup>\*200</sup> tests / kit

Table 9. Utilization of the training facility

	Target (2010)	2006	2007	2008	2009
Total days of training (days)	N.A.	149	106	83	72
Total domestic participants (person)	300	1402	1036	1161	897
Total international participants (person)	100	1402	1030	1101	097

Source: Information submitted by KEMRI for the ex-post evaluation

## 3.3.1.2 Utilization of Facilities and Equipment

The operation rate of production facilities is low because the test kits planned in the basic design study have not been manufactured. However, the maintenance condition of the facilities and equipment is good as mentioned below in 3.5.2 with, for example, the implementation of periodical cleaning and checking. This is why comprehensive rating in Table 10, based on the two aspects of operation rate and maintenance condition of procured equipment by the exevaluator, is relatively high.

As for the training facility, the operation rate is high. However, focusing only on the equipment, some of them are not used very much. Although equipment for educational purposes was procured through the Project, the high-price experimental equipment was allocated to the experimental room, which is not always used in the training conducted in the facility because some training can be conducted in the lesson room.

Table 10. Utilization and maintenance of equipment

Facility	Equipment procured costing more than one million Japanese yen	Equipment with rating >3 by the ex-evaluator
Total	41	51.3%
Production Unit	25	44.0%
Training Unit	16	64.3%

Source: Results of observation by the ex-evaluator at the ex-post evaluation

- 4: 1) Used as planned 2) partly maintained, or 1) used periodically but not as planned 2) well maintained
- 3: 1) Used periodically but not as planned 2) partly maintained, or 1) sometimes used 2) well maintained
- 2: 1) Sometimes used 2) not maintained
- 1: 1) Not used 2) not maintained

Summarizing from the results in 3.3.1.1 and 3.3.1.2, utilization of the production facilities is poor because the test kits expected in the plan were not produced. On the other hand, the utilization of the training facility is good because operation has exceeded the target since completion, although it should be noted that the number of participants has decreased recently.

## 3.3.2 Qualitative Effects

## 3.3.2.1 Synergy with Technical Cooperation

Although there was the relationship between the Project and two technical cooperation; the "Research and Control of Infectious Diseases Project" (April 2003 – April 2006) and the "International Parasite Control Project" (April 2003 – April 2006), the synergies were limited.

<sup>\*</sup>Rating (judged from 1) utilization and 2) maintenance condition)

<sup>5: 1)</sup> Used as planned 2) well maintained

In the design stage of the Project, the basic design study had discussion and ideas to gain synergistic effects between the Grant Aid project and technical cooperation. For example, the chief of the National Cooperation Committee for the Research and Control of Infectious Diseases Project participated in the basic design study as a leader of study team. The basic design made the plan that the test kits developed through the Research and Control of Infectious Disease Project were manufactured by the facility constructed by the Grant Aid project. As for the training facility, the Grant Aid project played the role of providing a facility for utilization of the training function established by the International Parasite Control Project.

However, in practice, completion of facilities and procurement of equipment took place in November 2005 and completion of technical cooperation took place in April 2006. Thus, there were only four months between them.

Regarding the production facilities, although the report of the basic design study mentioned that "technology transfer by technical cooperation projects is greatly desired" for management of test kit production, process, quality control, etc., there was an insufficient time for technical cooperation to do so. In addition, because routes of utilization and/or sale could not been established even after the end of the Project, and because the operation status of the facility is not good, there has had no environment where synergy was generated.

On the other hand, according to the terminal evaluation report on the International Parasite Control Project, it was recognized that the effects of technical transfer of management and training implementation to counterparts of the Eastern and Southern Africa Center of International Parasite Control (ESACIPAC) were limited. Thus, the handing over of the facility and equipment of the Project seemed to be implemented in a situation where capability and experience for facility management was not sufficiently strong and where activities to raise synergy were limited.

In summary, as mentioned in 3.3.1 and 3.3.2, the production facility is partially not operated and overall synergy with technical cooperation is not sufficient. However, the operation of the training facility exceeds the target indicator and the training facility is well utilized. Therefore, the Project has somewhat achieved its objectives, therefore its effectiveness is fair.

## 3.4 Impact

- 3.4.1 Intended Effects
- 3.4.1.1 Screening rate of blood for transfusion

In the basic design study, the screening rates of blood for transfusion were set as an indicator because the stable supply of test kits would become possible with expansion of the amount of the stock. As shown in Table 11, the screening rate was improved. However, it was not related to the Project because test kits planned to be manufactured by the facility constructed by the Project were not used in Kenya after completion of the Project.

Table 11. Screening rate of blood for transfusion in Kenya

	Baseline (2002)	Target (2010)	Achievement (2009)
Screening rate*1	75.5% <sup>*2</sup>	95%	100%*3

<sup>\*1</sup> Number of tests/ units of blood for transfusion x100

Source: 2. JICA, Basic Design Study Report on the Project for Improvement of Facilities for Control of Infectious and Parasitic Diseases at the Kenya Medical Research Institute in the Republic of Kenya (2003)

# 3.4.1.2 Mother-to-Child Transmission of HIV and Prevalence of Parasitic Diseases (Mother-to-Child Transmission)

As well as the blood-screening rate, the mother-to-child transmission was an indicator to measure the decline in the incidence due to an increase in testing through the stable supply of test kits. This was defined by the basic design study. As for this indicator, although a decline can be observed, it is not due to the production facility constructed by the Project.

However, because training related to HIV transmission (blood safety (JICA Third Country Training Programme, domestic training), HIV awareness seminars (Kenya Commercial Bank), and other HIV-related programs (CDC)) were conducted in the training facility, there might be a somewhat contribution to reduction in mother-to-child transmission.

## (Prevalence of Parasitic Disease Infections)

Prevalence of parasitic disease infections was an indicator to measure effects of training conducted in the training facilities. However, there are/were no comparable national data of Kenya before and after the Project. The coverage of preventive measures is indicated in Table 2. Some improvement could be observed. Thus, it is possible that there are contributions of the Project as side support for the improvement because the training facility has became the center of training for parasitic disease control used by various partners and trainees.

## 3.4.1.3 Research Outcomes by Use of the Test Kits

Research papers using the KEMRI test kits have been reported as mentioned in Table 12. Thus, it seemed that the test kits produced by the production facility made a scientific contribution. However, because the development and the production of small numbers of test kits had already been achieved in the technical cooperation project before the Grant Aid Project, these research outcomes could be realized even without the production facility. Thus, it might not be clear there is a causal relationship between the Project and research outcomes.

## Table 12. Examples of researches using the test kits

- M. K. Kiptoo, Z. W. Ng'ang'a, S. S. Mpoke, S. Osman, A. Mwangi, E. M. Songkok, "Indirect Immunofluorescence Assay, Particle Agglutination and ELISA for the Detection of HIV Type 1" (2009), International Journal of Integrative Biology vol. 5. no. 1.9
- R. Yamada, T. Sasagawa, L. W. Kirumbi, A. Kingoro, D. K. Karanja, M. Kiptoo, G. W. Nakitare, H. Ichimura, M. Inoue, "Human Papillomavirus Infection and Cervical Abnormalities in Nairobi, Kenya, an Area with a High Prevalence of Human Immunodeficiency Virus Infection (2008), Journal of Medical Virology vol. 80:847-755

<sup>3.</sup> Information submitted by KEMRI for the ex-post evaluation

## 3.4.2 Other Impacts

#### (Impact on Natural Environment)

The impact of the Project on nature is small. There have been no reports of air pollution, inadequate sewage management or waste pollution. However, the Project procured equipment using hydrofluorocarbon (HFC) gas as a refrigerant that is regarded as problematic for global warming. While it might be said that there is a potential negative impact for the future, it might be a low negative impact if we look at the efforts of KEMRI to preserve the natural environment and the fact that there have been no reports of gas leakage.

Generally speaking, KEMRI is a proactive organization for the natural environment. In 1998, KEMRI opened the first Waste Disposal Advisory Committee (later becoming the Bio-safety Advisory Committee, and then the Health Safety Environment Advisory Committee) and has had a health, safety and environment policy as an organizational policy, to make clear the requirements for risk management in order to protect the environment, persons, and the community from hazardous materials, which include microorganisms and/or recombinant DNA technologies, chemicals (radioactive or non radioactive), and animal or plant materials.

#### (Land Acquisition and Resettlement)

Because the Project was implemented on KEMRI's land, there was no need to displace the inhabitants to other places. According to a Project document and interview with KEMRI staff, there have been no complaints from neighboring inhabitants during the Project period or now. Thus, there is no negative impact by displacement or land acquisition for the Project.

In summary, as mentioned in 3.4.1 and 3.4.2, the training facility made a possible contribution to alleviating the epidemic, while the production facility had no positive impact due to low operation rates at the present. In addition, overall, no negative impact of the Project was observed.

#### 3.5 Sustainability (Rating: b)

#### 3.5.1 Structural Aspects of Operation and Maintenance

There is no problem regarding structural sustainability because the management structure of KEMRI is institutionalized.

Currently, KEMRI is one of two independent administrative cooperates under the Ministry of Public Health and Sanitation (MoPHS), which appoints the director of KEMRI. The KEMRI secretariat is under three deputy directors (research and development, research and training, and administration and finance). KEMRI is governed by a Board of Management, which consists of a chairman, six appointed members, and representatives from various government ministries, departments, and agencies. In addition, besides the Board of Management, there are three standing committees of the Board; the Scientific Programmes Committee, Staff and Finance Committee, and Audit Committee. In this organizational structure, there have been no big changes since the basic design study, although there have been some personnel changes.

## 3.5.2 Technical Aspects of Operation and Maintenance

The techniques of operation and maintenance for the facilities and equipment are well organized. Currently, the maintenance unit is responsible for maintenance of the facility and equipment with corrective maintenance and preventive maintenance.

As for corrective maintenance, there are sufficient technical staffs as shown in Table 13. However, in the case that new equipment is procured and/or introduced, staff training will be necessary. According to the interview, when the staff cannot manage problems, they contact the supplier or manufacturer agency.

As for preventive maintenance, the staffs implement it once a quarter. In addition, the attitude of researchers and technicians to "use clean" also can be observed. Although the researchers and technicians in laboratories do not have enough knowledge of preventive maintenance, they seem to have awareness of contamination prevention, etc. However, according to the interview, the staff aimed at WHO standard<sup>13</sup> and considered that it is ideal to implement maintenance once a month. If KEMRI can ensure or increase the budget for maintenance, this might be feasible.

Table 13. Staff of maintenance unit

Technical Background of Staff	
Staff who have a degree in medical equipment or technology	4
Staff who have no degree in medical equipment or technology, but a degree in	10
electricity, engineering, etc.	
Staff who have no degree but experience	8
Other (secretary, messenger, etc.)	2
Total	24

Source: Information submitted by KEMRI for the ex-post evaluation

#### 3.5.3 Financial Aspects of Operation and Maintenance

There are fewer problems on financial sustainability of KEMRI because the overall budget of KEMRI and the one of the Ministry of Public Health, the supervising ministry (data not shown), has been increased. As for the international aid, the troubles such as sudden cancellation have not been happened in the last 10 years.

Table 14. KEMRI's budget and international aid

(million KSh)

	2005	2006	2007	2008
Budget from GoK*	879.4	926.5	926.4	1,028.3
International Aid	1,852.1	2,095.3	2,238.4	2,848.0
KEMRI Total Budget	2,731.5	3,021.8	3,164.8	3,876.3

\*GoK: Government of Kenya

Source: Information submitted by KEMRI for the ex-post evaluation

<sup>&</sup>lt;sup>13</sup> There are WHO standards for maintenance of facilities and equipment such as Medical Device Regulations – Global Overview and Guiding Principles (2003)

However, it should be noted that KEMRI has faced the situation of high-dependency on international aid where the amount of budget from international organizations (85% is from the U.S.) was 2.8 times KEMRI's own budget (in 2008). In these days the stagnancy of the overall international aid has started to be argued and the international aid flow to the health sector of Kenya has not been increased as shown in Table 15. If the international aid to KEMRI would be declined in the future, its impact might be big. Thus, KEMRI has certain financial vulnerability to the change of the trend international aid. As for this dependency on international aid, the Director of KEMRI has also similar concerns, and has recognized the importance of efforts to increase the ratio of owner's equity.

Table 15. International aid to health sector of Kenya

(million USD)

	2005	2006	2007	2008
International Aid	70.11	59.11	70.69	51.43

Source: OECD International Development Statistics (Access in September 2010)

In addition, both of production facility and training facility has the aspects of debts that continuously make negative cash flow such as maintenance cost, etc. Thus, in the case if the facility has not produced expected outputs, such facility might oppress the finance or reduce the financial sustainability.

#### 3.5.4 Current Status of Operation and Maintenance

The current situation of maintenance of facility and equipment is good, according to the observation and interview in the field survey. Not only is the organizational structure of KEMRI institutionalized as mentioned above, but KEMRI has also made plans to acquire ISO certification, which make KEMRI have high awareness of appropriate maintenance.

However, some inhibitors in improving the situation of maintenance have been recognized. For example, it is difficult to dispose of damaged equipment because there are complex procedures. In addition, it is difficult to procure the equipment consumables and accessories due to cost and/or difficulties.

In summary, as mentioned in 3.5.1-3.5.4, some problems have been observed in terms of financial vulnerability and current status (dependency on international aid, and disposal of equipment and procurement of consumables, etc.), therefore sustainability of the Project is fair.

## 4. Conclusion, Lessons Learned and Recommendations

## 4.1 Conclusion

In KEMRI, the production facility and training facilities were constructed by this project. It was implemented efficiently, but the relevance was partly insufficient from the viewpoint of adequacy of measures aiming at the stable supply of test kits, the effectiveness is also limited because the facility is partly not operated, and sustainability is concern on finance because of the high dependency on international aid, etc. However, the training facility has been utilized more than expected in the basic design study and KEMRI have continued to make further efforts for production facilities to improve the current situation. In addition, maintenance of the facilities is also good. In light of the above, the Project is evaluated to be fairly satisfactory.

#### 4.2 Recommendations

- 1. KEMRI should recognize the need to re-confirm its own value and role as a public-sector entity and should continuously conduct analysis of organization and marketing at its own production and training facility, in order to increase the sustainability of production and training facilities by distinguishing from other organizations and institutions. In this process, collaboration with governmental organizations such as the Ministry of Public Health and Sanitation and the Ministry of Medical Services is particularly important to increase the uniqueness of KEMRI as public institution.
- 2. KEMRI has high dependency on international aid, which makes its finance vulnerable. In order to overcome the vulnerability, KEMRI for example should strengthen the collaboration with ministries, enhance its organizational capacity, and increase the portion of self-budge in its total expenses.

#### 4.3 Lessons Learned

- 1. The implementation period of the Grant Aid project and technical cooperation need to be examined and coordinated carefully and comprehensively, considering synergy among the projects as well as burdens of implementing organization.
- 2. As for measures for procurement of health commodities such as HIV test kits in developing countries, the adequacy of measures needs to be examined with considering the risk of change in the policies of other development partners and of the recipient country for procurement.