

# **HIV home testing,**

*the key to reaching high risk groups.*

## Introduction

In 1999 MiraTes Europe BV introduced the first HIV home test on the market in the Netherlands. Since then the MiraTes HIV HomeTest has been sold for six years in many pharmacies in the Netherlands and through the internet. As of December 7, 2005 the new European Directive in vitro diagnostics (98/97EG) has become effective. This directive requires that all in vitro diagnostic home tests are CE registered. Obtaining CE is a time consuming process. Nevertheless, theoretically it should be feasible within several years. MiraTes encountered the fact that in practice it is made practically impossible to obtain CE certification for an HIV home test. The regulation concerning this topic can be and is being interpreted in many different ways by different competent authorities and notified bodies throughout Europe. The Goal of this report is to provide contribution to the discussion about the benefits of HIV self-testing and a call for clarity in the concerning EU regulations.

The data presented in this report was initially intended to give insight into the user population for the HIV home test. This would be part of the data to be used for the CE certification and based upon this data further lay-user studies would be developed. After an ongoing discussion between the Dutch Health Care Inspectorate (IGZ) and MiraTes about the interpretation of the EU directive, MiraTes was repeatedly subjected to negative publicity in the beginning of 2007. MiraTes lost its leading position in the field of medical diagnostic test for home use. In February 2008 MiraTes Europe announced it would stop with all its activities in Europe.

To prevent the useful data from being lost it is made public though this report. It will give insight in the group of people who prefer to test themselves with a home test above going to regular test facilities. What are their reasons for testing? What is their motive to choose for a home test? And how did they experience performing an HIV home test? To some extent these questions will be answered in this report. Hopefully, it will contribute to the idea that medical professionals are not necessarily required for HIV testing and lay-users are very well capable of testing themselves for HIV. On scientific, medical, political and ... grounds it may not be the first choice, HIV home testing however is the preferred - and sometimes the only - option for a group of people. This study also demonstrates that HIV self testing contributes to larger awareness amongst people about their HIV status.

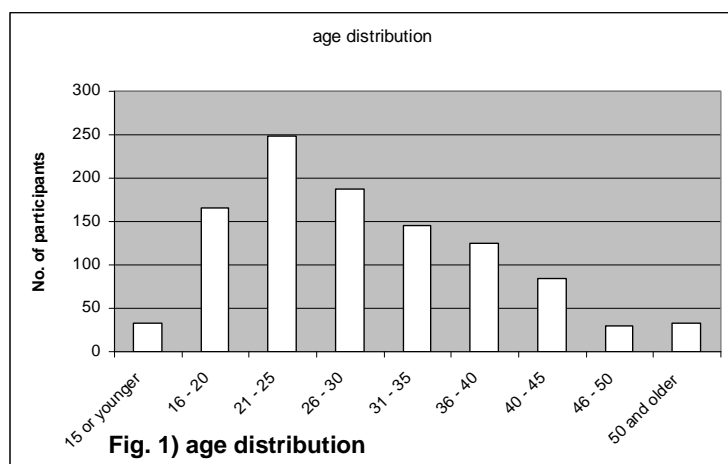
## HIV home test user study

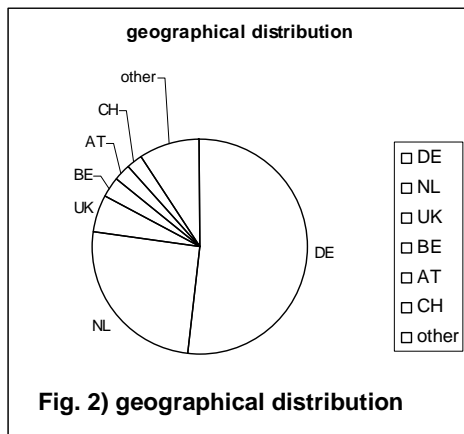
Two online questionnaires were available on the websites of MiraTes. Both can be found in the appendices. They were offered in English on [www.mirates.com](http://www.mirates.com) and [www.mirates.co.uk](http://www.mirates.co.uk), in German on [www.mirates.de](http://www.mirates.de) and in Dutch on [www.mirates.nl](http://www.mirates.nl). Questionnaire A has the same questions as questionnaire B. Besides questionnaire A has extra questions regarding the usability of the test, the test result and what the implications of the test were for the user.

On several locations on the website which contained information about HIV and the HIV home test people were asked to join the study and to fill in questionnaire B. Later on an invitation to join the study with a specific internet address for questionnaire A was added to the HIV test. This offered the opportunity to gain insight in the experience of people who had performed the HIV test.

## Test group

In 2006 and 2007 1113 questionnaires were filled in. 393 times questionnaire A was filled in and 720 times questionnaire B. Of the 393 people who have performed the questionnaire A, 5 indicated they have had a positive test result and 388 respondents indicated they have had a negative test result. Due to a high probability of a responder bias for this question, it is difficult to draw any conclusions from this number.





**Fig. 2) geographical distribution**

The age of the respondents ranges from 13 to 76 years old with a peak around 21-25 (fig. 1). Over half of the questionnaires (Both A and B) were filled in by people living in Germany (52%), little more than a quarter by people living in the Netherlands (26%) and the rest by people from countries like the United Kingdom, Austria, Switzerland, and Belgium (fig. 2). Should there be a significant differences between responses to certain questions of the Questionnaires of the different nationalities this will be reported.

442 women (40%) have participated and 680 men (58%) did. Of this last group 237 (36%) is MSM (Men who have sexual contact with men). The high rate of MSM men who have participated probably is caused by the fact that the HIV

incidence of MSM is higher than of heterosexual men and women. In the Netherlands the incidence of HIV of MSM is 1-2%. Probably MSM are aware of the increased risk they are in compared to not-MSM and will therefore have themselves tested more regularly. Even though still 20-40% of HIV positive MSM still do not know their HIV status. This group was responsible for 90% of the new HIV infections in the Netherlands in 2007 [HIV monitor 2007].

83 respondents (7%) have a medical profession.

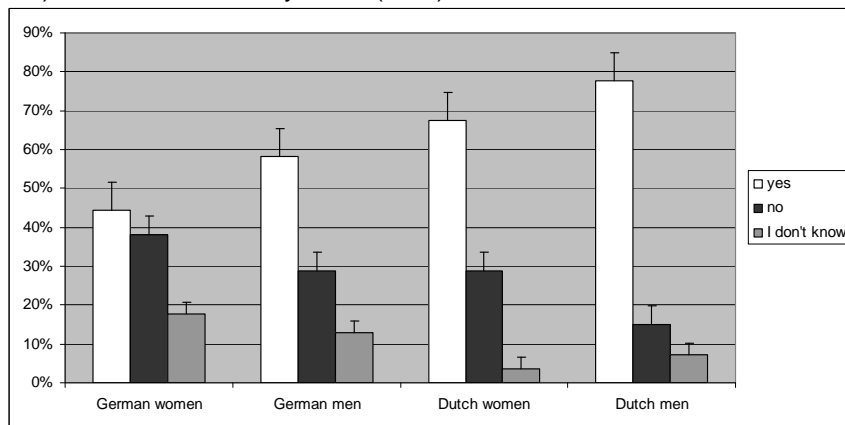
### Testing for HIV

Since the respondents were somehow looking for an HIV test, they were asked whether they were familiar with the regular test facilities.

#### *Are you aware of the various test locations that exist where you can have yourself tested on HIV?*

Over all 60% of the respondents answered yes to this question. The remaining 40% is not aware of what the regular test possibilities are (27%), or are not sure they know (13%). Remarkable is the

difference between men and women and between the nationality of the Netherlands and Germany. In figure 3 the percentages for each of the three possible answers is depicted for German women, German men, Dutch women and Dutch men. Over all men are, or think they are, more aware of all the regular possibilities to have themselves tested than women. Furthermore, respondents from the Netherlands are better informed about the testing possibilities than the German respondents. Still many Dutch, and particularly men, choose to test themselves for HIV.



**Fig. 3) Do you know the regular facilities for HIV testing?**

#### *Why do you want to test yourself on HIV?*

For this question the respondents had the choice of the answers below. It was possible to choose more than one answer. There were no significant differences between respondents from different sex, sexual orientation, or nationality. Neither were there differences between people who have filled in Questionnaire A or B.

I have had unsafe sex	50%
I just want to know if I am infected	47%
I don't want to be worried about it anymore	36%
I have a new partner and want to have sex without a condom	21%
I cheated on my partner and want to avoid the risk that s/he might be infected	7%
another reason	5%
I have been in contact with (potentially) infected blood	3%

For the question below the respondents had the possibility to choose both practical answers (gray background) and answers more driven by emotion. More than one answer was possible. The practical advantages of HIV home testing are important for a large part of the respondents. However the most important factor for choosing for a home test is the possibility to test fully anonymously. Quite often people feel ashamed and don't want to be confronted with someone.

***Why do/did you choose for the HIV HomeTest?***

It is anonymous	53%
I am feeling ashamed and don't want to be confronted with it by anyone	19%
I am afraid to go to the doctor/hospital	17%
I want to avoid being told off by a doctor, I know what I have done wrong	15%
I don't want my partner/parents to find out	11%
I cheated and don't want anyone to find out	5%
It is accessible	46%
A home test can be done anywhere and anytime	36%
A home test is quicker	31%
another reason	4%

***If a home test did not exist, would you have yourself tested elsewhere?***

Surprisingly only 67% of the respondents answered "yes" to this question. One third of the people who perform an HIV home test answered "no" or they were not sure about it.

***If your test result is/were positive, would you go to a doctor?***

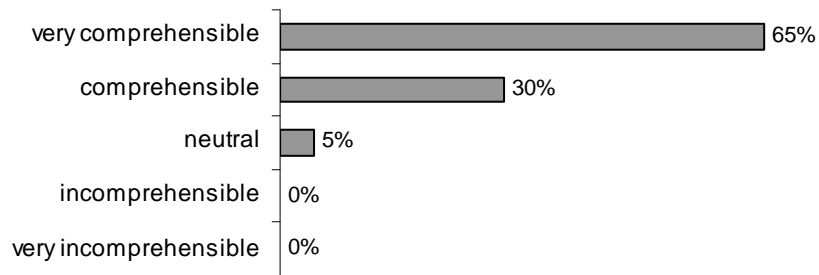
To this question 98% of the respondents of Questionnaire A answered "yes".

***Have you performed the test alone or together with someone else present?***

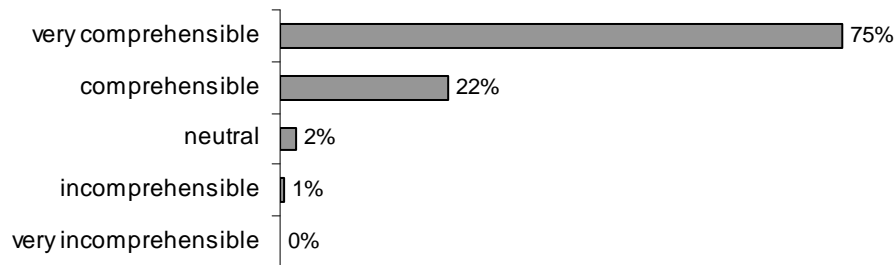
77% of the respondents who had performed the test indicated that they did so alone. 23% performed the test with someone else as advised in the IfU of the MiraTes HIV HomeTest.

**Usability of the MiraTes HIV HomeTest**

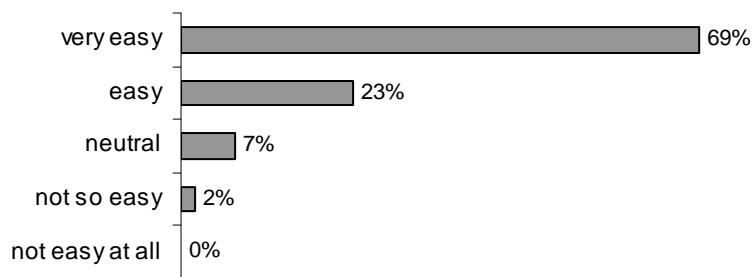
In Questionnaire A several questions were asked about the comprehensibility of the instructions for use, the usability of the test and the interpretation of the test result. The results are shown below in figure 4a to 4h.



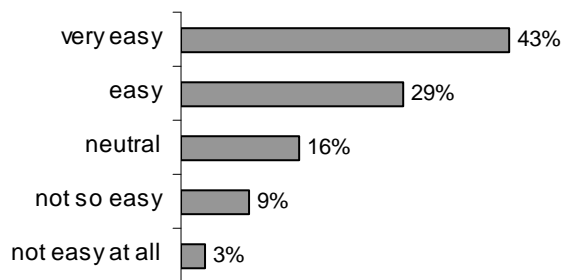
**fig. 4a) Comprehensibility of the information on HIV in IfU**



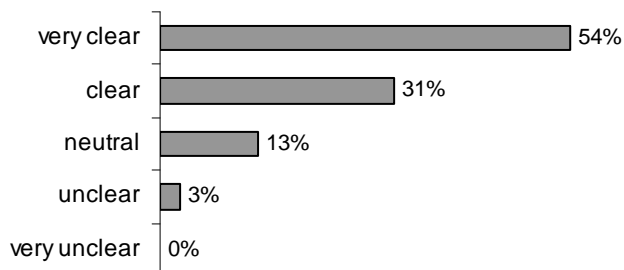
**fig. 4b) Comprehensibility of the instructions for performing the test**



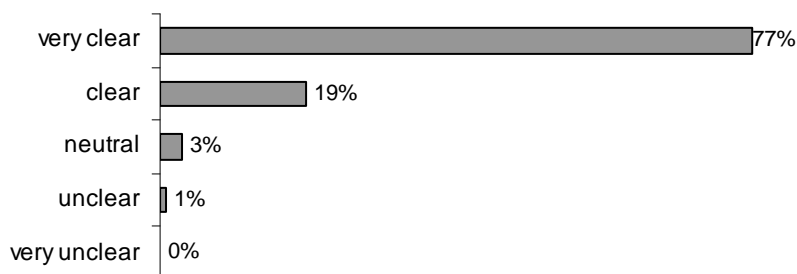
**fig. 4c) Is the test easy to use?**



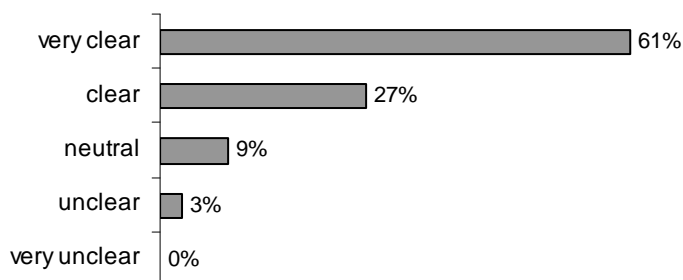
**fig. 4d) Is it easy to obtain the right amount of blood?**



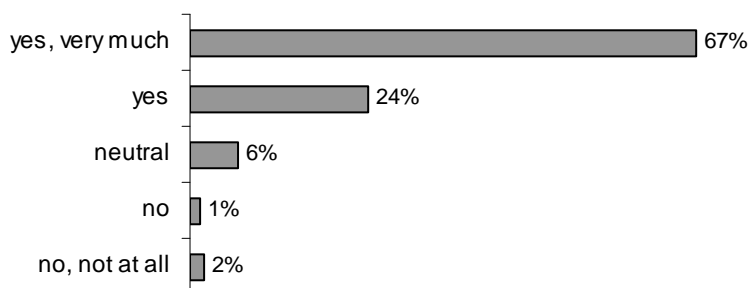
**fig. 4e) Is it clear where to turn to with questions about the use of the test?**



**fig. 4f) Is the IfU clear about how to interpret the test result?**



**fig. 4g) Is it clear where to turn to with questions about the test result?**



**fig. 4h) Did the test set your mind at peace?**

The effect of doing an HIV home test respondents of this study clearly shows from the result of the question: **Will doing the HIV home test affect your behaviour with respect to HIV?**

Yes, I will avoid risk as much as possible	62%
No, I always was careful and will stay careful	37%
No, I won't avoid risk	1%

## Discussion

From the first moment the HIV home test was brought to the market it has been a controversial subject. The critics talked about the risk of people jumping from roofs after they had discovered they tested positive. (In almost 10 years of HIV home testing there hasn't been a single report.) More reasonable arguments were that there are more sexual transmitted diseases than HIV. A doctor could inform about the risks and the possibility to test for the other diseases. A medical professional also can support a person who just has been told he or she is infected with HIV. In general the most preferable way of testing for HIV still is visiting your doctor or one of the regular test facilities.

It is striking though that in The Netherlands still 20-40% of MSM infected with HIV is not aware of their HIV status. For some reason these people (and more) do not want to make use of the regular test possibilities. These might be the preferred way of testing, but if such a large group is missed by the regular test method, should we not look further to the next best thing?

It becomes clear from this study that people who choose for an HIV home test belong to a high risk population. 50% of the respondents indicated they have had unprotected sex. Besides a large portion of the respondents were MSM. An HIV home test makes HIV testing more convenient resulting in a higher diagnosis rate of HIV infected people. Should the HIV home test not exist, 33% of the people who choose for an HIV home test doubt they would have themselves tested or will not test at all. Should the test result be positive, practically all respondents would go to the doctor after all. Clearly, an HIV home test can contribute in reaching a high risk population, which now is very difficult to reach and responsible for a large part of new HIV infections.

Part of the people who choose for an HIV test do this for practical reasons like, accessibility, it can be done anywhere and at any moment and it is fast. Another part chose for home testing because they want to stay anonymous (53%). Probably, with anonymous they not only mean 'not registered', but they also do not want to face anybody while testing, or receiving the result. 19% say this is one of the reasons they want to test at home.

The MiraTes HIV test is rated very well by its users. Both the instructions for use and the usability of the test is rated positively. The HIV home test definitely can be improved. Despite the test requires a very small amount of blood, obtaining blood is still rated as the most difficult procedural step. However, there are new tests being developed which require a fraction of the blood which is used for current tests. New sampling methods could contribute to a home test which can be practically as easy as a pregnancy test.

Without the stigma, HIV home testing could be well accepted and developed. It could truly offer a contribution to the fight against the spread of HIV. It would be less controlled than with the regular test methods, but as second best option it will increase awareness.

# HIV Research - after the test

1. What is your age?:

2. What is your nationality?:

3. What is your sex?

Male

Female

4. What is your sexual preference?

Heterosexual

Homosexual

Bisexual

5. Do you have a medical profession or education?

Yes

No

*The home test*

6. Have you performed a home test before?

Yes

No

7. Why did you take the HIV home test?

I had unsafe sex

I got in contact with (potential) contaminated blood

I have a new partner with whom I would like to have sex without a condom

I just want to know if I have it or not

I cheated and want to avoid the risk that my partner is infected through me

I want to get rid of the stress

Other, please specify:

8. Are you aware of the various test locations that exist where you can have yourself tested on HIV?

Yes



- Don't know
- No

**9. Why did you choose for the HIV HomeTest?**

- It is accessible
- It is anonymous
- I am feeling ashamed and don't want to be confronted with it by anyone
- I cheated and don't want anyone to find out
- I don't want my partner/parents to find out
- I am afraid to go to the doctor/hospital
- I want to avoid being told off by a doctor, I know what I have done wrong
- A home test is quicker
- A home test can be done anywhere and anytime

Other, please specify:

**10. If a home test did not exist, would you have yourself tested elsewhere?**

- Yes
- Don't know
- No

**11. If your test result is/were positive, would you go to a doctor?**

- Yes
- No

*Performing the test*

**12. Have you performed the test alone or together with someone else present?**

- Alone
- Together with someone else

**13. In terms of comprehensibility, how do you consider the background information about HIV and Aids in the instructions for use?**

- Very comprehensible
- Comprehensible
- Neutral
- Incomprehensible

Very incomprehensible

**14. In terms of comprehensibility, how do you consider the instructions on how to perform the test?**

Very comprehensible

Comprehensible

Neutral

Incomprehensible

Very incomprehensible

**15. Do you find the test easy to perform?**

Very easy

Easy

Neutral

Not so easy

Not easy at all

**16. Do you find it easy to obtain the right amount of blood?**

Very easy

Easy

Neutral

Not so easy

Not easy at all

**17. Do you find it clear who to turn to in case of questions?**

Very clear

Clear

Neutral

Not clear

Very unclear

*The test result*

**18. What was your test result?**

Positive

Negative

**19. Do you find the instructions for use clear in how the result should be**

**interpreted?**

- Very clear
- Clear
- Neutral
- Not clear
- Very unclear

**20. Do you find the instructions for use clear in where you should turn to in case of questions?**

- Very clear
- Clear
- Neutral
- Not clear
- Very unclear

**21. Did doing the test put you mind at peace?**

- Yes, very much
- Yes
- Neutral
- No
- No, not at all

**22. Will doing the HIV home test affect your behaviour with respect to HIV?**

- Yes, I will avoid risk as much as possible
- No, I always was careful and will stay careful
- No, I won't avoid risk
- If you have any remarks or suggestions, please leave them here.

*Many thanks for your feedback*

# The MiraTes HIV Study

1. In which country do you live?:

2. How old are you?:

3. What is your sex?

- Male  
 Female

4. What is your sexual preference?

- Heterosexual  
 Homosexual  
 Bisexual

5. Why do you want to test yourself on HIV?

- I have had unsafe sex  
 I have been in contact with (potentially) infected blood  
 I have a new partner and want to have sex without a condom  
 I just want to know if I am infected  
 I cheated on my partner and want to avoid the risk that s/he might be infected  
 I don't want to be worried about it anymore

Other:

6. Are you aware of all possibilities that exist to test for HIV?

- Yes  
 Don't know  
 No

7. It is possible to test yourself for HIV at home with a home test device. Would you choose to use such a test?

- Yes  
 No, *please go to question 10*

8. Why do you choose to use a home test device?

- It is easily accessible  
 It is anonymous

- I am embarrassed about it and don't want to be confronted with it by anyone
- I have cheated on my partner and don't want anyone to find out
- I don't want my parents/ partner to find out
- I am reluctant to go to a doctor/ test facility
- I want to avoid a reprimand: I know what I have done wrong
- A home test is just as reliable as a test a doctor does
- The test can be done everywhere and anywhere

Other:

**9. Should a home test not be available, would you do a test elsewhere?**

- No
- I don't know
- Yes

*Many thanks for your cooperation!*

**10. Why don't you choose to use a home test?**

- I find it difficult to execute
- It is too expensive
- I don't believe that an HIV home test is reliable
- I want a professional consultation in advance

Other:

*Many thanks for your cooperation!*