

Alive & Well \$50,000 Fact Finder Award  
Find One Study, Save Countless Lives

Non-profit education, research and support network offers money in exchange for missing science

<http://www.AliveandWell.org>

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Alive & Well will present a cash award of \$25,000 to the first person to locate a study that provides us with the missing scientific proof that HIV tests are accurate. To celebrate this important finding, Alive and Well will donate an additional \$25,000 to Heifer International, a unique charity working to end hunger in the developing world by using a holistic approach to building sustainable communities.

The missing evidence we're looking for is a study published in a peer reviewed medical journal that shows the validation of any HIV test by the direct isolation of HIV from the fresh, uncultured fluids or tissues of positive testing persons.

Since no HIV test directly detects HIV itself, and since the tests currently used to diagnose HIV infection rely on surrogate markers such as antibodies or genetic material, a study should exist somewhere in the published medical literature which shows that at least one type of surrogate test for HIV has been validated for accuracy by the direct isolation of HIV itself from people who test antibody, RNA or DNA positive.

The \$50,000 offered through Alive & Well will be paid by two anonymous donors committed to the possibility of integrity in AIDS science and to creating a world in which no one goes hungry. Award funds will be disbursed within 30 days of presentation of the required evidence as described above.

For each month the award remains uncollected, Alive & Well founder Christine Maggiore, will make a personal donation to Heifer International (<http://www.heifer.org>) whose work resolves the most prevalent causes of disease and death in Africa: poverty and malnutrition.

The Fact Finder Award expires on April 23, 2009, the 25-year anniversary of the historic announcement by the US Department of Health and Human Services that HIV had been found and identified as "the probable cause of AIDS."

Potential participants should note that detection of other surrogate markers not specifically mentioned in this text (reverse transcriptase, p24, etc) or the presence of "retrovirus-like particles" in co-culture do not substitute for evidence of direct isolation of HIV from fresh, uncultured fluids or tissues.

**Can a study that validates HIV tests really be missing from the medical literature?**

That's what we want to find out. It's been 23 years since the discovery of HIV and the development and marketing of the HIV antibody test, yet it appears that no study ever validated HIV tests by the direct purification of HIV from persons who test positive or have a "viral load." As far as we can tell, the accuracy of the HIV antibody tests used around the world to say someone is infected with HIV has never been properly established, and there's no information in the published medical literature showing how many positive tests occur in the absence of infection with HIV.

**What would a validation study prove?**

The accuracy of an antibody or other surrogate test for a virus can only be established by verifying that positive results are found only in people who actually have the virus. This standard for determining accuracy was not met in 1984 when the first HIV antibody test was developed. To this day, positive HIV antibody screening tests (ELISAs) are verified by a second antibody test of unknown accuracy (HIV Western Blots) or by "viral load," another unvalidated test.

A validation study would prove the ethical and scientific basis for the practice of telling people who test antibody, DNA or RNA positive that they are infected with HIV. Without evidence of validation by direct purification of the virus, a diagnosis of HIV infection rests on unverified beliefs and unfounded assumptions.

**Is a validation study worth \$50,000?**

To us, \$50,000 is a small price to pay for scientific validation that HIV tests give positive results only to people who actually have the virus.

Current HIV tests signal the presence of antibodies that react with an assortment of proteins associated with HIV, however, none of these proteins are unique or specific to HIV. Without a validation study, no honest, well-informed doctor can say with any degree of certainty that someone who tests positive is indeed infected with HIV.

**Why can't "viral load" tests be used to validate HIV antibody tests?**

Like HIV antibody tests, viral load tests are not able to directly detect HIV itself. Instead, these tests detect only fragments of genetic material (DNA or RNA) associated with HIV. To date, we have not found a study showing that the DNA or RNA attributed to HIV is found only in people who are actually infected with HIV using direct isolation as a gold standard to determine true infection.

In fact, viral load tests carry disclaimers stating they are "not intended to be used as a screening test for HIV or as a diagnostic to confirm the presence of HIV infection" (Roche, Amplicor HIV-1 Monitor Test).

**Why isn't an antibody test that's verified by another antibody test good enough to say someone is infected with HIV?**

The rationale for the use of antibody tests is that the immune system has the ability to detect foreign agents or viruses and to respond by producing antibodies that react with those agents or viruses. However, this rationale does not work in reverse. That is, the observation of an antibody reaction with a particular agent or virus does not prove that the antibody was produced in response to that particular agent or virus.

The problem with using antibodies alone to indicate infection with a particular agent or virus is twofold:

1. Antibodies can only be associated with a disease after it is shown that they are consistently generated after exposure to the pure virus. We are unaware that this has ever been accomplished with HIV.

2. Antibodies engage in indiscriminate relationships with a variety of agents or viruses. One could say that antibodies are "promiscuous," that is, antibodies meant for one agent or virus may react with another agent or virus that is a perfect stranger. Or, to put it technically, there is ample evidence that antibody molecules, even the most pure (monoclonal antibodies) are not mono-specific, and that they cross-react with other, non-immunizing antigens.

#### **What does all this mean?**

What this means is that people do not necessarily have the virus that their antibodies may appear to suggest they have. Here are some examples of how misleading antibody tests can be:

1. People can have positive antibody responses to certain laboratory chemicals, but this does not mean they are infected with laboratory chemicals.
2. People vaccinated for polio may test positive for antibodies to polio even though they don't have polio.
3. People exposed to TB may test antibody positive for TB but this does not necessarily mean they are currently infected with TB.
4. The test for glandular fever measures antibody response to red blood cells of sheep and horses, but a positive test does not mean that someone is infected with sheep or horse blood, or that animal blood causes glandular fever.

From these few examples, we understand why antibody response alone cannot determine if someone is infected with a particular virus.

#### **What's the solution to the problems with HIV antibody tests?**

Since antibody reactions can come from more than one possible cause, scientists need more information before they can claim that an antibody reaction alone means a person is actually infected with a particular virus.

Long before the HIV test was introduced into routine clinical practice, scientists needed to prove that a positive test means that HIV itself is present, too. This is especially important given the profound implications of testing HIV positive. People's lives literally depend on the specificity of HIV tests.

### **What is specificity?**

In this case, the formal, mathematical definition of specificity is the number of negative tests in a large group of individuals who do not have HIV infection. If 100% of 1,000 people who do not have HIV infection also test antibody negative, the specificity of the antibody test is 100%. If one uninfected person tests antibody positive, the specificity of the test is reduced to 99.9% (999/1000) due to the single false positive result. A high specificity is desired when screening to make sure that very few false positives occur.

As far as we know, the specificity of HIV tests has not been established in this very necessary scientific manner.

### **What is sensitivity?**

The formal, mathematical definition of sensitivity is the number of positive tests in a large group of individuals who actually do have HIV infection. If 100% of 1,000 people who have HIV infection also test antibody positive, the sensitivity of the antibody test is 100%. If one infected person tests antibody negative, the sensitivity of the test is reduced to 99.9% (999/1000) due to the single false negative result. A high sensitivity is desired when you don't want any gold standard positives to slip through undetected.

### **Is specificity the same as accuracy? How is the accuracy for an HIV test determined?**

A study that establishes the sensitivity and specificity of an HIV test would provide a scientific basis for claims of accuracy.

Sensitivity + Specificity = Accuracy

### **How did AIDS experts arrive at the specificity of the HIV antibody tests used today?**

According to the medical literature on AIDS, the specificity of HIV antibody tests has been evaluated by testing healthy individuals such as blood donors. Because these individuals are healthy, it's assumed that negative antibody test results mean they don't have HIV, and because few if any of these people test positive, AIDS experts use this information to claim that the antibody tests are highly specific. This evaluation is the wrong type of experiment from which to draw such conclusions for two reasons.

First, healthy people do not have a large number or a variety of antibodies to react with the test, so there are not enough antibodies available to measure the propensity for unwanted reactions. Second, good health cannot be used as a substitute measure for the absence of HIV infection any more than good health can be used as a substitute measure for the absence of kidney stones, pregnancy, cerebral aneurysms, pathogenic bacteria or coronary artery disease.

**What is the correct solution to the problem of distinguishing who is and who is not HIV infected?**

According to Dr Valendar Turner (<http://www.thepertgroup.com>), a medical doctor who has examined the problems with HIV tests, "The solution is obvious, scientifically speaking. You have to use HIV itself to validate the tests. To do this, you must take two samples from each person in a study and divide the two blood samples from each person in two groups: One sample to test for the antibody reactions and the other to try to directly isolate HIV. To know what the HIV antibody tests tell you about HIV infection, you then compare the reactions (positive tests) with what you are trying to find or measure (actual virus). The only way to distinguish between real reactions and false reactions (cross-reactions) is to use direct isolation of HIV as an independent yardstick or gold standard."

**What would the results of such an isolation experiment show?**

The results of such an experiment would show how many of an appropriately chosen group people from whom HIV cannot be isolated have a positive antibody reaction anyway. This

would tell us how many positive antibody tests occur in the absence of HIV infection.

Without validation by direct isolation of the virus from the fresh, uncultured fluids or tissues of people who test positive, AIDS experts cannot know what positive and negative test results actually indicate.

That there appears to be no data establishing the accuracy of HIV tests is particularly concerning given that people who test positive are said to be infected with a fatal, incurable virus and treated as if this were an indisputable truth.

### **Why is it called a Fact Finder Award?**

What we want to find meets the dictionary definition of a fact\*, which is:

1. Something that can be shown to be true, to exist, or to have happened.
2. The truth or actual existence of something, as opposed to the supposition of something or a belief about something.
3. A piece of information that shows that statistics or statements are true.
4. The circumstances of an event, motion, occurrence, or state of affairs, rather than an interpretation of its significance.
5. Something that is based on or concerned with the evidence presented in a legal case.

In our search of the published medical literature, we have not found evidence showing that popular interpretations of the significance or accuracy of HIV tests are scientifically valid or correct. In exchange for this fact, we will award the finder. Hence, the "Fact Finder Award."

**If a study that validates HIV tests may not exist, what's the point of offering the award?**

We hope a monetary incentive will motivate someone to find a study we've missed or to inspire a group of AIDS researchers to conduct.

The spirit of the Fact Finder Award is win-win. Whether or not the award is ever claimed, everyone would benefit from a forthright and scientific discussion of HIV tests.

With this in mind, we invite you to join an effort that's good for one and all by passing this offer on to AIDS doctors, AIDS scientists, AIDS organizations, AIDS activists and celebrity spokespersons, journalists, teachers, medical students, or anyone who wants to help Heifer International end hunger and poverty in the developing world by building sustainable holistic communities.

\*2007 Edition Encarta Dictionary