# AFFIDAVIT OF RODNEY RICHARDS PHD

I, RODNEY RICHARDS Ph.D do hereby make the following sworn declaration. All matters contained herein are of my own personal knowledge unless stated as based upon information and belief:

1. I am an expert as defined by South Carolina law. No previous opinions rendered by me have been disqualified by any court of law. I have never been found guilty of fraud or perjury. A copy of my curriculum vitae is attached hereto as Exhibit A, which outlines my education, training and background.

2. In 1977, I received an MS in organic chemistry from the University of Denver. In 1984, I received a Ph.D. in chemistry from the University of Colorado. In 1982, I began full-time work for a small start-up biotechnology company called Applied Molecular Genetics, Inc. in Boulder, Colorado. This company eventually changed its name to Amgen, Inc., and is recognized today as the largest and most successful independent biotechnology company in the world. I worked at Amgen for over 13 years, first as a research scientist, and from 1986 on as a senior research scientist. My responsibilities at Amgen were primarily centered on the development of novel technologies to enhance therapeutic drug discovery and to improve diagnostic testing methods for the detection of infectious agents associated with human disease.

3. In 1983, a co-worker and I designed and synthesized a modified human interferon gene that ultimately resulted in the production of a recombinant protein with novel anti-viral activity. The Food and Drug Administration (FDA) approved this product (Infergen) in 1997 for use as an anti-viral drug in the treatment of Hepatitis C infections. I also supervised the development of several diagnostic technologies, which resulted in a novel diagnostic test for the detection of genetic material known as DNA/RNA, unique to the "Human Immunodeficiency Virus" (HIV). This technology proved to be equal in sensitivity and specificity to a competing technology known as the Polymerase Chain Reaction (PCR), which is used routinely for the determination of what has become known as the "HIV viral load" levels.

4. During the development of this "HIV test," I retained several consultants including Dr. Kary Mullis, who won the Nobel Prize in 1993 for his invention of PCR, and Dr. Peter Duesberg, a noted authority on retroviruses and a tenured professor at the University of California at Berkeley. These two men brought to my attention many unanswered questions regarding the development and significance of "HIV tests."

5. I have actively reviewed the scientific literature concerning HIV science and related areas, with particular focus on the problems associated with HIV diagnostic testing.

6. To date, the vast majority of diagnostic tests approved by the FDA for medical use related to HIV neither claim to, nor even attempt to, confirm the actual presence of HIV in a patient's sample. In fact, none of the 35 HIV-related diagnostic tests or devices currently listed on the FDA's Website claim to confirm the actual presence of HIV in any sample with any degree of stated accuracy.

7. In short, the standard lingo "HIV test," "testing HIV positive," or a "confirmatory test for HIV," is a complete and total misnomer because none of these tests confirm the actual presence of the virus in a patients sample. As such, all diagnoses of HIV infection in patients are presumptive based on their risk factors, immune status, and clinical condition (actual health) in combination with other indirect diagnostic evidence for either the past or current presence of HIV in a blood, urine, or saliva sample.

8. The so-called "HIV tests," that are approved by the FDA are intended for use in diagnosing the presence or absence of either antibodies to HIV in a sample, or of molecular fragments of HIV in a sample; never the actual virus. Nevertheless, based on guidelines and recommendations put forth by the CDC in 1987, virtually all diagnoses of HIV infection since that time have been, and still are, based solely on combinations of HIV antibody tests.[1]

[1] CDC. *MMWR* 1987; 36(31): 509-15.

9. Antibodies are proteins that the body's immune system produces in response to the presence of germs, such as bacteria and viruses, and do not represent the germ itself.In fact, these antibodies assist in the elimination of the germ by binding to it, thereby interfering with its ability to replicate, and marking it for digestion by other cells in the immune system. Furthermore, germ specific antibodies produced in this way remain at detectable levels in the body for several months to several years, even after the complete elimination of the infectious agent from the body. By analogy, footprints from a mountain lion in a forest do not necessarily mean there is a danger.It could mean the lion has gone away or has been captured. Similarly, antibodies to a germ do not mean the germ is present. Indeed, in the vast majority of cases (such as polio, small pox, measles, hepatitis, chicken pox), it means the germ has been neutralized and eliminated from the body.

10. The two primary classes of so-called "HIV tests" for detecting antibodies to HIV are known as the ELISA (or EIA) and the Western Blot (WB). The detection of antibodies to HIV in a sample is intended to aid a physician in their presumptive diagnosis of infection with HIV. But neither test confirms, or is intended to confirm, the actual presence or absence of virus in a sample.

11. According to current CDC guidelines and recommendations, when a blood, urine, or saliva sample from a patient is presented for testing, it is initially screened for the presence or absence of antibodies to HIV using the ELISA test. If positive, it is retested, and if positive again, the probability that antibodies to HIV are present is considered to be high. However, because "non-specific results [false positives] are found commonly when screening tests are used in low risk populations," and "[s]ince the psychosocial and medical implications of a positive antibody test may be devastating," samples repeatedly reactive on screening assays such as the ELISA should be further tested using an additional, more specific test for HIV antibodies, such as WB. (Epitope/Organon Plasma)

12. The FDA-approved WB kits are intended for use "as an additional, more specific test for HIV-1 antibodies," in persons already found to be repeatedly reactive on screening tests such as ELISA. However, paradoxically, the manufactures of such products inform us that a sample testing positive on both the EIA screening test and the WB can only be "**presumed** to be positive for **antibody** to HIV-1." (**emphasis** added. OraSure, Epitope/organon, and Bio-Rad)

13. The reason that manufacturers of these more specific tests can offer no estimate of how probable it is that such a sample has antibodies to HIV, is because there is currently "no recognized standard for establishing the presence or absence of [HIV] antibody in human blood." (Abbott ELISA) The manufactures of HIV-antibody tests also emphasize: "A person who has antibodies to [HIV] is **presumed** to be infected with the virus." (**emphasis** added. Epitope/Organon, Bio-Rad, Abbott ELISA.) The reason one can only presume this is that according to the scientific literature, "there is no 'gold standard' laboratory test that defines the true infection status."[2] Recognizing that a sample testing positive on both ELISA and WB is only presumed to be positive for antibodies, and further presumed to therefore be positive for the virus, the manufacturers of WB tests agree that the best one can conclude from such a result is that it "… **may** indicate infection with the HIV-1 virus" (**emphasis** added. OraSure, Epitope/Organon,Cambridge Summary).

14. In spite of the fact that a person testing "positive" on both ELISA and WB are only **presumed** to be positive for antibodies to HIV, and therefore further **presumed** to be infected with the virus, which means they **may** be infected with HIV; at the recommendation of the CDC, it is standard practice in the medical community to use such a combination of test results to tell patients that they have with certainty, a confirmed infection with virus itself (HIV). Furthermore, this will be the case even if the patient is without any symptoms (asymptomatic) or risks consistent with the possibility of infection.

[2] Sheppard HW, et al. *JAIDS* 1991; 4: 819-23.

15. This is particularly disturbing when one considers that with the release of the first WB approved for medical use, the FDA announced: "The significance of antibodies in an asymptomatic individual **is not known**." (**emphasis** added. Suzan Cruzan. FDA News Release. April 30, 1987; P87-11.) The manufacturers of WB tests currently on the market likewise emphasize: "The clinical implications of antibodies to HIV-1 in an asymptomatic person **are not known**." (**emphasis** added. Camgridge PI, Bio-Rad.) This is why test manufacturers warn: "Do not use this kit as the sole basis of diagnosis of HIV-1 infection;" (Epitope/Organon, OraSure, Cambridge Summary) and emphasize for all persons testing positive on both ELISA and WB: "Clinical correlation is indicated … to decide whether a diagnosis of HIV infection is accurate." (Bio-Rad, Epitope/Organon). In my opinion, it is more likely than not that the currently accepted practice of telling people that they are infected with a deadly virus that has no cure, based solely on the results of antibody tests, not actual confirmation of the virus, falls well outside of the FDA-approved use of these products and is scientifically unsound. In part, this disparity between the positions taken by the FDA and CDC can be explained by the fact that the FDA functions under a legal mandate to base product approval on reproducible scientific observations demonstrating statistically significant results. The CDC on the other hand, has no such legal restrictions and can therefore base recommendations solely on theoretical considerations, or simply expert opinion.

16. On the surface, the fact that the CDC would recommend the use of antibody tests for the purpose of telling persons that they are with certainty infected with a deadly and contagious virus – when the manufacturers of these tests warn that they cannot be used to establish with any degree of stated certainty that this is the case – may seem so incredulous that it simply cannot be true. This is particularly the case for persons who were young adults in the late 1980s and 1990s who recall reading in reputable organs of the popular press that the tests being used to diagnose infection with HIV are greater than 99.9 percent accurate.

17. In fact, the manufacturers of HIV antibody tests do report measures of accuracy known as **sensitivity** and **specificity** and, in many cases, these reported measures of accuracy are 99.9 percent, or even greater. However, if one reads the package inserts for these test kits carefully, they will discover that these measures of accuracy have nothing to do with whether or not HIV is present. In fact, the vast majority of these reported measures of accuracy refer to how well one test performs as compared to another test already on the market. In other words, these measures of accuracy refer to the concordance between two tests; namely, how often a new test says a sample is positive when one already on the market says it is positive (**sensitivity**), and how often does this same test says a sample is negative when the one already on the market says it is negative (**specificity**). Given the fact that all HIV antibody tests are based on the same molecular principles and built from the same portfolio of basic molecular building blocks, it is no wonder that there is a remarkable concordance between their outputs. However, even if two different tests demonstrate 100 percent concordance, that does not justify the use of either for purposes other than what they have been validated and approved for. By way of analogy, if two different manufactures were to construct two different timepieces using the same specifications for the gears and wheels, only to put them in different casings, it is very likely that these two clocks would perform quite similarly. However, even if there were greater than 99.9 percent concordance between these two timepieces, one cannot conclude that either clock accurately measures time.

18. Since the first ELISA and WB tests approved by the FDA had no other approved test for comparison, the manufacturers of these tests choose to validate their products according to their ability to distinguish between persons with confirmed clinical AIDS, and healthy blood donors; the former of which have experienced a plethora of infections and illnesses, and the latter of which represent the healthiest of the healthy and are pre-screened to be free of any risk factors or infections. And in fact, these two tests performed well in distinguishing between these two select populations. However, this tells us nothing about the significance of positive test results in persons in the

general population without clinical symptoms of AIDS, and who are not routine blood donors.

19. By way of analogy, a simple test of having persons walk the distance of a balance beam may perform remarkably at distinguishing between persons who are intoxicated, and say, young athletic adults who have not been drinking. However, even if a preliminary evaluation of this test revealed that 99 out of a hundred intoxicated persons fell off the beam (99% **sensitivity**), and only one out of a hundred young athletes fell off the beam (99% **specificity**), one cannot then simply apply this test to persons in the general population and conclude that 99% of all persons who fall off the beam must be drunk. While it may be the case that 99% of all intoxicated persons in the general population who are subjected to this test will fall off the beam; many others may fall off for other reasons: Perhaps they are clumsy, or had a recent ankle injury or knee surgery, or maybe they are blind. It is for this reason that we cannot say with any degree of certainty how likely it is that any given individual who falls off the beam is drunk. Nevertheless, this would still represent an example of an excellent "screening assay" in that 99% of intoxicated persons who participate in the test most likely would fall off. However, in the absence of a follow-up "confirmatory assay" — in this case measuring the actual blood alcohol content in all positives — the majority of persons who fall from the beam (i.e., positive) may actually be sober.

20. Unfortunately, as detailed above, in the case of HIV, there is no confirmatory laboratory test for either antibodies to HIV, or the virus itself. Although—at the recommendation of the CDC—the WB test is utilized as a confirmatory test for HIV, it is unequivocally not. All of the WB tests on the market are approved only as additional, more specific tests for antibodies to HIV. And even when positive, the best one can do is "presume" the sample is positive for antibodies. And even if that presumption were correct, the significance of those antibodies in persons without symptoms is "unknown." In other words, WB cannot even confirm the presence of antibodies, let alone the virus itself. It is for this reason that the manufacturers of these

tests warn that all persons testing positive for antibodies should be referred to a physician, who can, based on risks, symptoms, and other laboratory data, "decide whether a diagnosis of HIV infection is accurate." The true value of the WB test is that, since it is more specific, it can be used to rule out infection, when negative, in persons testing positive on ELISA screening tests.

21. Although CDC researchers acknowledged by 1986 that "no established standard exists for identifying [HIV] infection in asymptomatic people,"[3] they announced that same year that, "**For public health purposes**," all persons testing positive on ELISA and WB "should be **considered** both infected and infective."[4] (**Emphasis** added.) Of the three references put forth to support this conclusion, one states: "... the frequency of virus in antibody-positive persons is yet to be determined;"[5] another makes no mention of whether or not antibodies can be used to infer infection,[6] and the last one makes reference to yet another CDC publication that states, "the proportion of these seropositive [i.e., antibody-positive] donors who have been infected with [HIV] is not known."[7] Even if it were the case that only half, or even a quarter, of persons testing positive on both ELISA and WB were actually infected with the virus, if physicians were to follow the manufactures instructions and simply tell these persons you "may be infected," then those who may be truly infected and are still without symptoms might continue to engage in, for example, unprotected sexual activities thereby contributing to the further spread of the virus into the general population. As such, if we want to guarantee that none of these persons contribute to the further spread of this virus into the general population, it is necessary to ignore the manufacturers' instructions as well as the scientific facts and tell all of these persons that they are with certainty infected; even if they have no risks or symptoms to support such a conclusion.

[3] Ward JW, et al. *JAMA* 1986; 256: 357-61
[4] CDC. *MMWR* 1986; 35(20): 334-9.
[5] CDC. *MMWR* 1984; 33(27); 377-9
[6] CDC. *MMWR* 1985; 34: 477-8
[7] CDC. *MMWR* 1985; 34: 1-5

22. By way of analogy, in the interest of public health, it would be best to tell all persons who fell off the balance beam in the above example that they cannot drive. After all, this would guarantee that 99% of the intoxicated persons in the group tested would not be on the road. Many other sober persons who fell off for other reasons would likewise not be on the road. However, in the absence of a confirmatory test, this would be the sacrifice that would have to be made in order to protect the public from intoxicated drivers. Nevertheless, to turn this scenario on its head and declare all persons who fell of the beam to be unequivocally intoxicated would be absurd and without any scientific merit whatsoever.

23. Regardless, shortly after FDA approval of the first WB test just over a year later in 1987, the CDC published another report that stripped out any reference to public health, and simply declared, "The presence of antibody [to HIV] indicates current infection [with HIV];" this time without making reference to any scientific study or internal document to substantiate this statement.[8]

24. Fourteen years later (2001), the CDC published revised guidelines stating that persons testing positive for antibodies on both ELISA and WB "are considered HIV-positive and indicative of HIV infection." Although the authors of this document emphasize that "approximately 5,000 abstracts were screened and approximately 600 relevant publications were reviewed," along with "approximately 20 previously published CDC guidelines related to HIV," they do not provide any references to substantiate this statement (i.e., that antibodies equal infection). They also note that in cases where evidence to support their recommendations is lacking, "opinion of 'best practices' by specialists in the field have been used."[9] In summary, the position taken by the CDC and the medical community that all persons testing positive for antibodies to HIV are unequivocally infected with HIV is not a position based on scientific evidence; but rather, one taken in the interest of "public health" based on the "opinion" of specialists in the field.

[8] CDC *MMWR* 1987; 36: 509-15.
[9] CDC. *MMWR* 2001; 50/RR-19: 1-86.

25. In addition to the concerns detailed above, the scientific literature reveals several studies demonstrating false positive HIV-antibody reactions on ELISA and WB as the result of other conditions completely unrelated to HIV. These include conditions such as infection with other viruses and bacteria, autoimmune conditions, lymphoma, dermatologic disorders, vaccination, hepatitis, herpes, alcoholic liver disease, arthritis, multiple pregnancies.[10][11][12]

26. Another class of FDA-approved "HIV tests," which detect a molecular fragment of HIV (not the virus) are the so-called Viral Load (VL) tests. Like the antibody tests, VL tests are not intended for use in diagnosing infection with HIV; rather, they are approved for either assisting a physician in offering a prognosis of disease progression, or to assist in the clinical management of medications in persons already deemed to be HIV positive by other means. In fact, the manufacturers of these tests – i.e. COBAS® AmpliPrep and COBAS® TaqMan® HIV-1 Test – explicitly warn that their tests are "not intended for use as a screening test for the presence of HIV-1 in blood or blood products or as a diagnostic test to confirm the presence of HIV-1 infection." The manufacturer of another VL test also emphasizes "The AMPLICOR HIV-l , MONITOR Test is not intended to be used as a screening test for HIV or as a diagnostic test to confirm the presence of HIV infection." (Amplicore) The reason VL tests cannot be used to diagnose infection with HIV is because, as highlighted in the literature, "viral load tests for HIV-1 were neither developed nor evaluated for the diagnosis of HIV infection."[13] This is because, as mentioned above, there is no method to establish with certainty which samples are, or are not, truly HIV positive or negative, which could be used in order to establish how well the VL test results might compare.

27. The ultimate standard for proving the existence of a germ is to obtain it in sufficient quantities and purity so that its chemical, morphological, and biological

[10] Midthun K, et al. *J Infect Dis* 1990; 162: 1379-82.
[11] Celum CL, et al. *Arch Intern Med* 1994: 154: 1129-37.
[12] Guan M. *Clin Vaccine Immun* 2007; 14: 649-59.
[13] Rich J, et al. *Ann Int Med* 1999; 130: 37-39).

properties can be determined. Given that most germs are present in the body at insufficient levels to achieve this directly, they first have to be "grown" in the laboratory using a process known as "culture." This involves taking a sample from a patient and placing it in an appropriate laboratory environment where the germ can replicate in vitro (outside of the body) to levels where it can be purified for characterization. This purification step is necessary in order to ensure that any chemical or biological phenomena observed during characterization is indeed due to the germ, rather than something else, either alone or in combination, that might be in the mixture.

28. Following such characterization of the purified germ, it may no longer be necessary for the scientist to purify the germ from every culture; rather, they can simply look for "phenomena," which have been demonstrated to be unique to the newly characterized germ. For example, the germ may have a peculiar shape that is so unique that the scientist can simply look at some fluid from the culture or directly from the patient under the microscope in order to declare the presence or absence of the germ. Alternatively, the germ may have a unique chemical building block or unique biological activity that the scientist could use as proxy to determine if the germ is present or absent in the culture.

29. Unfortunately, some germs, such as HIV, are so fragile that they have never been obtained in purified form for direct chemical and biological characterization in the first place. As a result, all chemical and biological phenomena said to be due to HIV are necessarily inferred through indirect techniques. As such, while these phenomena are entirely consistent with the presence of HIV, in my scientific opinion, it is impossible to prove they are beyond a reasonable doubt due to HIV, or even that they are unique to HIV. Since the current consensus among virology experts is that a positive culture for HIV is synonymous with infection with HIV, it is reasonable to use HIV culture in combination with other factors to determine if a patient is infected with HIV.

30. In my opinion, it is more likely than not that at a minimum, the only valid determination on whether a patient is infected with HIV would be: 1) a positive result from ELISA; 2) a positive result from WB; 3) a positive culture of the virus; 4) risk factors consistent with the possibility of infection; and 5) clinical symptoms characteristic of AIDS that cannot be accounted for by other factors. Anything short of meeting these criteria to determine the HIV status of a patient is speculative and unreliable.

**JASON ALEXANDER YOUNG**

31. I have reviewed the documents provided in this case. The earliest indication that the Defendant, Jason Young, was tested for evidence of antibodies to HIV comes from Rio Grande Medical Group Progress Notes for July 23, 2009. Under "Assessment," the Defendant is characterized with "HIV." However, the documents provided offer no continuity of evidence or other evidence that corroborates this assessment; i.e., physician's request, laboratory report, patient consent form, follow-up physician's assessment, State report, or CDC report. As such, there is no evidence in the documents provided that can be used to reasonably conclude with any degree of scientific certainty that the Defendant was positive either for antibodies to HIV, or infected with HIV, as of July 23, 2009.

32. The next indication that the Defendant was tested for evidence of antibodies to HIV comes from a Case Management Intake Form prepared by a case manager from HopeHealth-LS on November 9, 2009. Under the heading "Date HIV Diagnosis;" this form states "7-22-03 contracted, 8-2004." A New Referral Form from HopeHealth also indicates that the Defendant was "Diagnosed 2004." However, the documents provide no evidence that could be used to corroborate this diagnosis, i.e., physician's request, laboratory report, patient consent form, follow-up physician's assessment, State report, or CDC report. As such, the documents contain no reliable evidence that can be used to reasonably conclude with any degree of scientific certainty that the

Defendant was positive either for antibodies to HIV, or infected with HIV, as of November 9, 2009.

33. The next indication that the Defendant was tested for evidence of antibodies to HIV comes from a four-page laboratory report that was printed by LabCorp on November 11, 2009. This report indicates that a sample collected from the Defendant on November 9, 2009 tested repeatedly reactive on an HIV ELISA kit, after which it was evaluated by WB. Unfortunately, Page 4 of this report is missing, which makes it impossible to know what the results were. As such, the documents contain no reliable evidence that can be used to reasonably conclude with any degree of scientific certainty that the Defendant was positive either for antibodies to HIV, or infected with HIV, as of November 9, 2009.

34. Aside from the uncertainty surrounding the testing of this November 9, 2009 sample, even if we ASSUME the sample was found to be repeatedly reactive on ELISA and positive on WB testing, this cannot be used to conclude the Defendant was infected with HIV. According to the manufacturers of FDA approved test kits, persons with this combination of test results are only "PRESUMED" to be positive for "antibodies" to HIV, which means they "may" or may not be infected with HIV.

35. The manufacturers further emphasize: "Clinical correlation is indicated … to decide whether a diagnosis of HIV infection is accurate." (Bio-Rad, Epitope/Organon). None of the documents provided in this case indicate that the Defendant ever had any clinical symptoms of HIV disease; either before or after this sample was allegedly tested. As detailed above, according to the FDA and manufacturers of FDA-approved test kits, the significance of a repeatedly reactive ELISA followed by a positive WB in persons without symptoms (e.g. asymptomatic) is completely "unknown." As such, even if we were to assume that the WB results for the testing of this sample were positive, the documents contain no reliable evidence that can be used to reasonably conclude with any degree of scientific certainty that the Defendant was positive either for antibodies to HIV, or infected with HIV, as of November 9, 2009.

36. The next indication that the Defendant was tested for evidence of antibodies to HIV comes from a Case Management Intake Form prepared by a case manager from HopeHealth Waterloo Clinic on December 1, 2010. Under the heading "Date HIV Diagnosis;" this form simply states "2009." However, Discovery provides no evidence that could be used to corroborate this diagnosis; i.e. there is no physician's request, WB laboratory report, patient consent form, follow-up physician's assessment, State report, or CDC report that could be used to substantiate this diagnosis. As such, Discovery contains no evidence that can be used to reasonably conclude with any degree of scientific certainty that the Defendant was positive either for antibodies to HIV, or infected with HIV, as of December 1, 2010.

37. Note also that the two aforementioned Intake Forms from the same clinic (assuming HopeHealth-LS represents the Lower Savannah clinic, which is on Waterloo Street) characterize the Defendant's date of HIV diagnosis on dramatically different days (i.e., one in 2003/04 and the other in 2009) – discrepancies that may be related to the fact that nothing corroborates or substantiates these diagnoses. Although these Intake Forms characterize the Defendant as having AIDS, they also indicate that the Defendant has never had symptoms characteristic of AIDS and characterize the Defendant's overall health as "Good," and "Very Good." These Intake Forms indicate that the Defendant's only risk of infection is heterosexual intercourse, that he consistently uses condoms and has never had a confirmed STD (i.e., a marker of risky sexual practices). According to recent estimates put forth by the CDC, the chance that a heterosexual male with no other risk factors will contract HIV in any given year is only about 1 in 10,000. (CDC Fact Sheet. June 2010.) False positive test results for any disease can be expected to be extremely problematic when testing such low risk populations.

38. The only reason these two Intake Forms characterized the Defendant as having "AIDS" is because he has low CD4 T-cell counts. This is as a result of a change in the definition of AIDS by the CDC in 1993 that allows for a diagnosis of AIDS in perfectly healthy persons with no symptoms of any disease solely on the basis of low

T-cell counts. Nowhere else in the developed world would such persons be considered to have AIDS.

39. Although this kind of cellular immunodeficiency is characteristic of HIV infection, it cannot be used to confirm infection, because other conditions can likewise account for chronically low T-cell counts. Many perfectly healthy persons in the general population have persistently low CD4 T-cell counts for no known reason. This condition, referred to as idiopathic CD4 lymphocytopenia, or ICL, first came to light in the late 1980's when it was discovered that many persons considered to have AIDS on the basis of risks, symptoms, and low CD4 T-cell counts, were actually HIV negative. No one knows how prevalent this condition is in the general population, because CD4 T-cell counts are not part of routine medical diagnostic testing. However based on available information scientists estimate "more than 300,000 persons in the United States alone" have chronically suppressed CD4 T-cell counts characteristic of ICL.[14]

40. Many other conditions including bacterial and viral infections, malignancies, autoimmune disorders including rheumatoid arthritis, steroids, certain congenital disorders, and malnutrition, have also been linked to acute and chronically suppressed CD4 T-cell counts.[15] This is why low CD4 T-cell counts cannot be used to strengthen a presumption of HIV infection unless all other possible explanations have been ruled out. The medical record shows that the Defendant's CD4 T-cell counts remained low despite the use of antiretroviral medications (ARVs) that are designed to target HIV. This fact is consistent with the possibility that the Defendant's low CD4 T-cell counts are due to factors unrelated to HIV.

41. The Defendant was tested on several occasions using so-called Viral Load tests, which are approved by the FDA only for use in managing therapy or offering a prognosis of disease progression. As detailed above, "viral load tests for HIV-1 were neither developed nor evaluated for the diagnosis of HIV infection." The

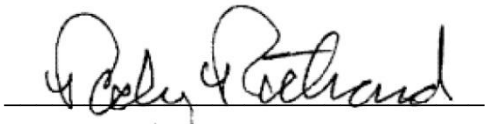
[14] Laurence *J. Ann Intern Med* 1993; 119: 55-62
[15] Walker UA and Warnatz K. *Curr Opin Rheumatol* 2006; 18: 389-95.

manufacturers of such tests explicitly warn that these tests are "not intended for use as a screening test for the presence of HIV-1 in blood or blood products or as a diagnostic test to confirm the presence of HIV-1 infection" (COBAS). As such, results from these tests provide no reliable evidence that can be used to reasonably conclude with any degree of scientific certainty that the Defendant is, or ever was, infected with HIV.

42. Based upon the aforementioned facts as well as my training and expertise, it is my expert opinion that prosecutors have provided no evidence that can be reasonably used to conclude that the Defendant is, or ever was, infected with what is known as "Human Immunodeficiency Virus" (HIV).

I, RODNEY RICHARDS, do hereby swear under penalty of perjury under the laws of the State of South Carolina that the foregoing, consisting of SIXTEEN of SIXTEEN pages is true and correct.

Executed this 14th day of AUGUST, 2011 in CARBONDALE, ILLINOIS.



RODNEY RICHARDS PH.D.