DNA Shadows and False Positives in RNA Tests

March 21, 2017 By Greg Jefferys

At least a couple of times a month I get an email from someone who has got viral load test some time after end of treatment and has been told that they have relapsed after having reached “undetected” in earlier viral load tests and at EOT. Some of these relapses are genuine relapses but a high portion are what is now being called a “False Positive”.

That is when the viral load test shows the presence of Hep C virus but there is actually no live virus in the body.

This issue of “False Positives” has become common enough for me to write about.

I should also add that I am not a medical doctor but am writing from my general knowledge about Hep C.

Below is an email thread between myself and the daughter of a man with Hep C. You may find the discussion and the results interesting. The the course of events is common with “False Positives”.

Hi Greg

Hope everything is well with you and that you’ve been having a very good start to 2017.

I am writing to you again hoping that you could provide me with some advice regarding my dad’s situation.

As you probably can remember, my dad treated his Hep C type 2 last year with a combination of Sofosbuvir and Daclatasvir and after the 3 months treatment period, we thought he had been cured - the result of his last blood test post treatment showed “virus not detected” (please see file Results_Oct2016).

As recommended by his doctor, my dad has just repeated the same test, 4 months post treatment, and unfortunately it seems like the virus is back. The latest result shows 720 UI/ml (2,86 LOG) - Please refer to file Results_Feb2017.

He is going back to see his doctor this week to discuss the next course of action but I was wondering if you have seen this same problem happen to other people? If so, do you have any knowledge on how they’ve dealt with this situation? Were they able to repeat the treatment or take a different type of medication?

Thanks again in advance for all your help.

Best regards,

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Hi ######

Firstly I do understand what anxiety that this would produce in your family..

Next I must say that it is possible that the virus has not returned and this is a faulty test.

I talk about this in my blog and this link will take you there:

https://www.hepmag.com/…/hepatitis-c-tests-test-results-ove…

The reason that I suspect a false positive is that the virus numbers are so low.

THe Hep C virus reproduces very fast so if it is present after treatment ends it returns to pretreatment

levels very quickly.
Viral load tests with these very low results 4 months after ETO are very unusual and should be combined with a Liver Function Test and then repeated after one month.
However if it turns out that your father has relapsed then there is no problem repeating treatment.
The best process would be to use an extra DAA (Direct Acting Antiviral) For example generic Epclusa (Sofosbuvir + Velpatasvir) + Daclatsvir. Extending the treatment time is also a good idea.
So so sum up everyone I know who has relapsed and re-treated has cleared the virus.
However I would suggest that there is also a chance that this is a false positive.
I hope this helps and please write to me at any time if I can assist further
best wishes to you and your family
Greg

Hi Greg,
Thank you very much for your reply. My family and I are very grateful that we are able to discuss these issues with you and get your perspective on things.
I had no idea that it was possible to receive a false positive result due to dead viruses staying in the body.
I've discussed this information with my dad and just to give you a bit more context, this is what has happened to him:
- He finished his treatment in early October and soon after that, the quantitative HCV RNA test came back as "Not detected". Also, the liver function test (ALT, ASP, ALP) were all within normal ranges.
- 13 weeks after the end of the treatment (end of January), he repeated his tests for the first time: the quantitative HCV RNA came back as 720 UI/ml (Please note that the unit of measure in Brazil seems to be UI/ml and not UI/L) and the liver function test are still all within normal ranges.
The fact that the last test was done 13 weeks after the end of treatment make us believe that the result may not be a false positive unless the "shadow" effect described in your blog can last for this long.
My dad is going to see his doctor again on the 23rd of February and I believe she is going to ask him to repeat the tests again before deciding on any further treatment.
If it is confirmed that my father has relapsed, at least we are glad to know that re-treatment is an option other people that have re-lapsed were successful in re-treating.
In case my dad does need to re-treat, do you know of any suppliers for the generic Epclusa? and is it a similar price?
Thank you again for all your help and I will keep you informed of my dad's progress.
Regards,
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Hi ######
Yes your father should definitely repeat the test. It is rare to get these false positives however I personally know about 6 people who have had them. So it seems to be 1/3000 or so.
If the liver functions are all in normal range it is a good indication that the virus has not returned.
If your father does need to be treated again then he should consider generic Epclusa + Dacltasvir. So the treatment would be Sofosbuvir 400 mg + Velpatasvir 100 mg + Daclatasvir 60 mg.
There is no problem getting this and recently prices have dropped so this combination of three drugs would be the same price as the Sof+ Dac previously cost.
best wishes
Greg

Hi Greg,

Hope you are well.

I'm writing to you to share some fantastic news about my dad - he has repeated his blood test a few more times after my last email to you and the last 2 results show that the virus is no longer detected. It seems you were right regarding the possibility of being a false positive. smile emoticon:)

This is roughly how things went for him:

- Finished treatment at the beginning of October/16 - blood test result was "not detected" at the end of the treatment
- Repeated blood test after 13 weeks (at the end of January/17) - blood test result came back as "detected" and virus count was 720 UI/mL
- Repeated blood test again one week later at a different pathology lab and again blood test result came back as "detected" and virus count was around 800 UI/mL
- Repeated blood test at the end of February/17 and the result was "not detected"
- Repeated blood test again after 1 week at a different pathology lab and again the result was "not detected"

Does this sound similar to other false positive cases that you've seen before? My dad's doctor didn't really give him an explanation for the change in results - she doesn't seem to know that false positives are possible.

We are extremely happy with these latest results and grateful to have had your help throughout this process.

Thanks again,
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So the story had a happy outcome and now this person is relaxed about no longer carrying the virus.
What causes these "false positive" results is probably particles of virus RNA that are floating around in the blood and are detected and reported as a very low level viral load.
For me the "clues" to a false positive are that the viral load is extremely low and that the liver function results are in normal ranges.
Normally if a person does relapse after treatment the viral load levels return to pre-treatment levels very fast. For example if a person had a vrial load of 2 or 3 million pre-treatment then in a genuine relapse one would expect to see those levels again within less than 12 weeks.
Also if there are no live virus in the blood the liver will not be experiencing "leaking" of liver enzymes so liver functions tests will show enzymes like ALT and GGT at normal levels.

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http://beta.docker.hepmag.com/blog/dna-shadows-false-positives-rna-tests