

Response

I am writing to respond to your request sent on the 28th November 2016. OUHFT can confirm that it holds the data that you requested which is presented below.

1. Do you currently offer a clinical testing service for HCV?

- Yes, In-house service
- Yes, Send-out to another laboratory
- No

If you have selected send-out testing above, to which laboratory do you send samples for HCV testing?

2. What type of clinical HCV testing do you offer?

- HCV Antibody testing
- HCV RNA testing
- HCV Genotyping
- HCV Drug resistance testing – sent out to Colindale
- Other. Please Specify: **HCV antigen testing is provided as part of confirmatory testing**

3. If you are offering HCV antibody testing as well as HCV RNA testing, what is the laboratory algorithm used for testing?

- RNA testing is automatically performed as a reflex test dependant on the Antibody result
- The HCV antibody result is reported to the clinician and RNA testing is only performed when specifically requested by the clinician

The presence or absence of HCV antigen (HCV confirmatory testing) has a good correlation with the presence or absence of circulating HCV RNA, thus HCV RNA analysis is performed when specifically requested.

4. HCV antibody testing details:

Is HCV antibody testing performed using a kit or laboratory developed technique? If appropriate, please specify kit details:	Architect – Closed system only Architect HCV antibody assay can be performed on this platform
What platform is used for HCV antibody testing?	Architect i2000SR
What is the laboratory turnaround time for HCV antibody testing?	1 – 3 days
How frequently is HCV antibody testing performed (on sample receipt, daily, twice a week, monthly)?	Daily

5. HCV RNA testing details:

Is HCV RNA testing performed using a kit or laboratory developed technique? If appropriate, please specify kit details:	Roche cobas - Closed system only cobas HCV RNA assay can be performed on this platform
What platform is used for HCV RNA testing?	Roche cobas AmpliPrep / TaqMan48
What is the laboratory turnaround time for HCV RNA testing?	1 – 7days

How frequently is HCV RNA testing performed (on sample receipt, daily, twice a week, monthly)?	1 to 3 times a week depending on demand
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6. HCV sample volume:

	Annual Sample Volume 1 st Nov 2015- 1 st Nov 2016	Positivity Rate 1 st Nov 2015- 1 st Nov 2016
HCV Antibody testing	1 st April '15 - 31 st March '16 16194	3.56% clinical specimens are reactive when assayed for HCV antibody. Note reactivity will include those specimens which on confirmatory analysis would indicate that the initial result may be non-specific.
HCV RNA testing	1 st April '15 - 31 st March '16 1783	43.07% clinical specimens are reactive when assayed for HCV RNA. Note is assay is only valid for the testing of patients who are known to be HCV antibody reactive. This assay has not be validated for the screening of patients for HCV infection.
HCV Genotyping (If applicable)	1 st April '15 - 31 st March '16 298	Not applicable
HCV Drug resistance testing (If applicable)	3	Not applicable

Request

To whom it may concern

This is a request, under the Freedom of Information Act, for access to information held by your organisation.

I would like to access information with regard to HCV testing offered by your institution; this testing will likely be performed in microbiology/infectious diseases/virology laboratories. The questions below are mostly multiple choice tick box questions/answers and I believe that this information will be readily available and not time consuming to complete.

If your institution does not currently offer HCV testing in-house then I would please ask that the request is still sent to the relevant laboratory as there are questions included regarding whether they send samples for this testing to be conducted in other laboratories. If your institution does not in fact have any testing laboratories, then do please let me know and accept my apologies for my error in thinking that you did.

The questions to complete are detailed below:

For convenience, most questions are multiple choice, with space for extra details where relevant.

In each case please all that apply

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- No

If you have selected send-out testing above, to which laboratory do you send samples for HCV testing?

2. What type of clinical HCV testing do you offer?

- HCV Antibody testing

- HCV RNA testing
- HCV Genotyping
- HCV Drug resistance testing
- Other. Please Specify:

3. If you are offering HCV antibody testing as well as HCV RNA testing, what is the laboratory algorithm used for testing?

- RNA testing is automatically performed as a reflex test dependant on the Antibody result
- The HCV antibody result is reported to the clinician and RNA testing is only performed when specifically requested by the clinician

4. HCV antibody testing details:

Is HCV antibody testing performed using a kit or laboratory developed technique?	
If appropriate, please specify kit details:	
What platform is used for HCV antibody testing?	
What is the laboratory turnaround time for HCV antibody testing?	
How frequently is HCV antibody testing performed (on sample receipt, daily, twice a week, monthly)?	

5. HCV RNA testing details:

Is HCV RNA testing performed using a kit or laboratory developed technique?	
If appropriate, please specify kit details:	
What platform is used for HCV RNA testing?	
What is the laboratory turnaround time for HCV RNA testing?	
How frequently is HCV RNA testing performed (on sample receipt, daily, twice a week, monthly)?	

6. HCV sample volume:

	Annual Sample Volume		Positivity Rate	
	1 st Nov 2015- 1 st Nov 2016		1 st Nov 2015- 1 st Nov 2016	
HCV				
Antibody testing				
HCV RNA testing				
HCV Genotyping (If applicable)				
HCV Drug resistance testing (If applicable)				