

# Needs Assessment Project – Year 2 Standard Operating Procedure

## A guide for ODNs and services

## Contents

TITLE PAGE.....	1
CONTENTS, VERSION HISTORY & PURPOSE.....	2
NEEDS ASSESSMENT PROJECT – YEAR 2 .....	3
INFORMATION REQUIRED - DATA.....	4
TESTING NUMBERS.....	4
SERVICE USER INFORMATION AND CONSENT .....	5
TESTING EQUIPMENT.....	5
INCENTIVES FOR CLIENTS.....	7
REIMBURSEMENTS FROM NHS ENGLAND NATIONAL TEAM .....	7
TESTING METHOD FOR THE PROJECT.....	7
SAMPLE COLLECTION, PACKAGING & PROCESSING FOR POSTING .....	9
INFORMATION SYSTEM FOR TESTS AND RESULTS.....	13
DATA COLLECTION RETENTION AND MANAGEMENT .....	17
ADDITIONAL RESOURCES.....	19

### Version History

Version	Date	Name	Sign off
1.0	12/05/2023	Prof Ashley Brown Mark Gillyon-Powell Dr Beatrice Emmanouil Sannaa Raja	AB MGP BE SR

### Purpose of Document

This document identifies a range of key information and issues necessary to ensure the successful delivery of this project on time, within budget, and to the required levels of quality. It provides a foundation for the project against which progress, and delivery can be monitored.

### General Information

Project Name	Needs Assessment Project – Retesting
Project Type	Bespoke
Project Kick Off	4 <sup>th</sup> September 2023

## Needs Assessment Project – Year 2

The purpose of this guide is to assist the management of the NHSE Needs Assessment Project – Year 2 in Addiction Services and Needle exchanges/ community pharmacy. This document is for guidance and we encourage local initiatives to achieve the same goals

### Aim of the Project

The aims of the Needs Assessment Project – Year 2 are to:

1. Accurately source and retest the same population that were tested in the initial phase of the Needs Assessment Project.
2. Determine how close we are to elimination across the country in addiction services and needle exchanges, to inform future resource allocation.

### Project Funding Participants

Covered by NHSE’s Hepatitis C elimination programme  
23 Operational Delivery Networks (ODNs), aligned drug services, and Hep C trust peers.

### Overall Accountability Operational Accountability Project Management

ODN Clinical Lead  
ODN Lead Nurse  
ODN Manager

### Project Timeline

6 months; from the week commencing the **4<sup>th</sup> of September 2023** ending the week commencing **4<sup>th</sup> March 2024** carried out simultaneously in ODNs across the country. These timelines are important to allow a sufficient window to source and retest those previously tested.

### Location

a. Addiction Services  
b. Community Needle Exchange Pharmacies/ODN  
Community Vans

### Cohorts to be tested

People who inject drugs and those who do not (in defined proportions)

### Scope

ODNs and Addiction Services will invite those tested in the initial phase of the project to be retested. Patients tested in the initial phase of the project will have been allocated a patient identification number, this same identification number will be used for the retest phase, allowing linkage between the two results.

### Delivery Method

Capillary blood test for HCV antibody and RNA testing (along with HBV and HIV screening serology)

## Information required - Data

Information for testing purposes only will be categorised into two categories.

### 1. **Group i** (*injector*):

**Defined as:** - People who have a history of injecting drugs, PWID.

- a. Current client
- b. Clients who have not been tested nor engaged with addiction services (structured treatment) in the last 12 months but who remain on the records of the service.
- c. Clients who use needle exchanges, who are not necessarily on the records of an addiction service

### 2. **Group o** (*other*):

**Defined as:** - Clients who have not openly declared that they have injected drugs, non-PWID. These clients might attend for other addiction problems (alcohol or non-opiates). They might have injected in the past, but have not declared this, and this is not the reason why they are in service or how they are known to the service. In some services they may not routinely be offered a Hep C test.

#### **Please note a change regarding barcode labels in Year 2, compared to Year 1:**

In Year 2, barcode labels will have a simple format denoting the ODN number and the patient number. Group allocation in Is (injecting) and Os (Other) was done in the first year, and, as we already have this information, it will not be required in the second year. For more updated information on how to use the barcode labels and adding them to the sample tubes, on the forms, and on NPEx in Year 2, please read the section on [Sample collection, packaging & processing for posting](#)

## Testing Numbers

**The same people who were tested in Year 1, need to be retested in Year 2.**

**We ask you to retest at least 95% of the people tested in the first year.**

**Only test people who had either a valid Hep C AB test or a Hep C RNA test. One of the two samples at least, should have not been void.**

**Please do not test new people within the remit of the Needs Assessment Project and do not send blood samples to Nottingham unless they are taken from those people that were tested in year 1.**

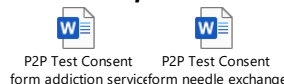
All tests for the Needs Assessment will need to be Capillary Blood tests only, in the same way they were taken last year.

Of course, testing of service users and other people at risk of Hep C outside structured services remains an overall priority for the Hepatitis C Elimination programme so please continue to test other patients, using your normal testing methods (e.g. DBST).

## Service User Information and Consent

- a. Updated Posters and patient information leaflet will be created and co-branded between the NHS and the Hepatitis C Trust. There will be an editable option to include the logo of the addiction service if preferred.
- b. These will serve as information for all users and for staff at the services. The posters and patient information leaflet will contain information about Hep C testing, this project, thanking people for the participation and support in the first year, inviting the same people to re-test and the reason for re-testing.
- c. The posters and patient information leaflet will inform clients that testing will be offered, and verbal or written consent obtained.
- d. The posters and patient information leaflet will also contain information about their data being held confidentially by NHS Trusts for the ordering of the tests and the reporting and all necessary follow-up as part of their clinical care.
- e. The posters and patient information leaflet will contain information on how people receive their results/outcome of testing and how 'detected', or 'reactive' results are followed up.
- f. **People must be informed of their right to decline to be tested even if they consented in year 1.**
- g. Consent forms to be used as a guide are embedded in this document. Formatting changes are permitted to reflect local preferences.

***N.B. It is important to inform service users that NHSE will only know anonymised information.***



## Testing equipment

- a. The required tests and testing equipment supplied by NHSE have been ordered and will be drop shipped by Nottingham laboratory to each ODN **in July 2023**.
- b. ODNs will be responsible for distributing the consumables (testing items), the paper testing forms and postage stamps to all sites (addiction services and vans), as necessary.

Shipping of testing equipment will be done via Nottingham to the ODNs main site, already specified.

Items to be sourced and drop shipped by Nottingham are:

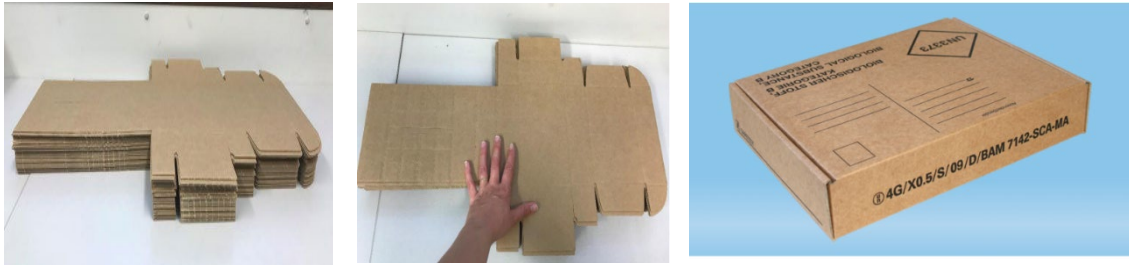
- a. BD Microtainer MAP (K2 EDTA) tubes
- b. BD Microtainer Contact activated lancets
- c. Microbiology request forms (**supply for year 2**)
- d. Barcoded sample labels with space for PII (3 per sample – 1 for the tube, 1 for the testing form and 1 for the Microbiology request form) – these are coded for the ODN and site
- e. Mailing boxes/ mailing containers (flat packed) with integral foam bag to absorb any leaks.  
[Here is a link to the item specification](#)

Please send confirmation of receipt of the equipment to Nottingham as soon as you receive it for procurement purposes.

## Mailing boxes

Flat pack boxes (the same specification as in Year 1) will be sent to allow sending of 1 sample per box. If testing is slow, a box per sample could be used, but on busier days, flat pack boxes are able to fit 4-5 samples if required. **It is important to send the sample and to enter the form on NPEX on the day that it is taken in order to ensure that the sample is analysed as early as possible upon receipt.**

Please do not delay sending samples in order to fit more into a box or to send multiple samples together, we have provided enough sample boxes so that this will not be necessary.



**ODN managers :** When items are delivered to your ODN please send a copy of the delivery note to [sharon-anne.foster@nuh.nhs.uk](mailto:sharon-anne.foster@nuh.nhs.uk); this is to enable the NUH team to receipt goods /items for payment



**Lancets – in boxes of 200** (e.g. 5x boxes for 500 samples as two lancets are provided per collection in case a second puncture is required)

**Sample collection tubes – in packs of 50** (e.g. 10x packs for 500 samples)

**\*N.B. Items might arrive separately from Nottingham**

### Ordering testing equipment – ODN responsibilities

ODNs will need to obtain:

- Alcohol wipes (any 70% suitable for skin cleansing); cotton balls and plasters
- Postage costs (Royal Mail Special Delivery).
- ODNs are responsible for printing and distributing the testing form to testing sites as appropriate. A copy of the testing form template is embedded under testing form section

It is up to the ODN to arrange postage. A suggestion is to purchase sheets of stamps which could be added to each box in the correct combination to cover the postage costs. These can be purchased in bulk from the Royal Mail website. Boxes would then be dropped in a priority post box or at a PO for delivery. It may also be worth ODNs checking with their Trusts on any arrangements they might have with sending samples to other laboratories (either via courier or postage). Some Addiction Services and people facilitating the vans may not be able to procure the postage, so ODNs will need to procure the postage in advance.

## Incentives for Clients

Both in addiction services and in pharmacies, people who participate in the project will be given a voucher. For the follow up test in autumn 2023, they will receive £10.

The type of voucher offered to clients will be at the discretion of each ODN and the cost of these can be reimbursed by NHSE. For information, during the pilot, the Barts team used Sainsburys vouchers. Please note regarding **people tested outside the needs assessment at the same time as people who were tested in the first year as part of the need assessment:**

- Please do not turn anyone away if they want to get tested for Hep C.
- As mentioned before, please do not use the capillary blood tubes allocated specifically for the project, and only send samples to Nottingham if the person tested was also tested as part of the needs assessment in year 1.
- If a person gets tested at the same time as someone who took part in year 1 of the needs assessment and asks for the £10 voucher – it should be offered to them.
  - Whilst we will not pay £10 for everyone tested for Hep C for the duration of this project (6 months), we encourage discretion so that people do not feel excluded.
  - As a guide, we will allow up to 10% extra £10 vouchers to be given to people outside of the needs assessment project for the duration of the Year 2 phase.

## Reimbursements from NHS England national team

There will be allowances for reasonable additional expenses incurred by ODNs for the needs assessment project. Each ODN will be able to submit a request for reimbursement for these costs. Embedded below is a needs assessment reimbursement form that needs to be completed.



Needs assessment  
reimbursement form |

Reasonable costs that might be requested are:

- Consumables such as alcohol cleansing wipes
- Incentives for clients
- Postage costs
- Additional bank or agency staff required for data entry, for example.

Costings that would not be appropriate include: any tests or laboratory costs, as these are already covered by the Nottingham Laboratory, or incentives for addiction services staff and volunteers. If you would like to check the acceptability of any claims for reimbursement before committing expenditure, please submit a draft of the proposed reimbursement form in advance of spending.

Requests for reimbursement will need to be submitted to the national team at the end of the Needs Assessment Year 2 project within your end of year financial return to [england.hepc-enquiries@nhs.net](mailto:england.hepc-enquiries@nhs.net).

The national team cannot guarantee that all requests for reimbursement will be covered.

## Testing Method for the project

Capillary Blood Testing (CBT) will be used to test for Hepatitis C, B and HIV for this project. The Hepatitis C test will include Hepatitis C antibody and PCR (regardless of the antibody status). This is different to previous practices and unique to this needs assessment. Acute infections will be captured this way and have a more accurate idea of the current burden of infection.

NB. Capillary testing is the method used in many on-line sexual health screening programs where people are sent a lancet and testing bottle along with instructions. We know that the general public are able to perform the test at home, so we are confident that clinical staff can also perform them.

## Capillary Blood Testing

Capillary blood testing (CBT) is a simple test that can be carried out through pricking the finger with a lancet. The blood is then collected in a small vial which is then sealed and sent via post for analysis.

Rationale as why Capillary blood testing was selected for this project as opposed to DBST

### Why capillary tests according to a leading clinical scientist in virology:

Here are some general positives for CBT vs DBST, including some positives that extend beyond this project as to why CBT would make a good alternative to DBST in the future.

- From the pilot sites that have been worked with, there is anecdotal evidence that the healthcare workers and patients preferred CBT samples over DBST as they were easier to collect. The tube has a collection lip that can be held against the finger to aid blood collection, so you do not have to wait for free-flowing blood drops to form as per a DBST card.
- The samples do not have to sit and air dry like DBST cards, so can be capped and packaged immediately after collection.
- Samples can still be posted to the laboratory.
- CBT samples are much quicker to process than DBST in the laboratory so the turnaround time to results is much faster.
- Serology and molecular investigations can be performed on one CBT sample; some sites need 2x five spot DBST cards to perform both types of assays.
- Although not used in this project, one could ALSO receive a quantifiable HCV viral load and an HCV genotyping result from the same CBT sample.
  - You cannot obtain a quantifiable viral load result from a DBST as one cannot quantify the volume of blood eluted.
  - The patient would not need to have venous blood collected/another DBST card collected at a later date for HCV genotyping.
  - This reduces patient appointments and reduces the risk of loss to follow-up as all information to diagnose active HCV infection and aid treatment selection can be collected from one sample. This process is more efficient than DBST with reduced cost.
- CBT tubes were found to be cheaper than DBST cards to purchase.

### Training for capillary testing

1. New or refresher training needs to be coordinated by each ODN and their services according to their needs.
2. Please ensure that a training assessment has been carried out for all those that will be involved in the project especially for those that will be doing the testing. ODNs and service providers need to make a learning needs assessment and plan accordingly.



Video of\_ Capillary  
Blood Testing Traini

3. Embedded here is a video of how to carry out capillary blood testing.
4. More information and resources on capillary testing, which can be given to staff, can be found [here](#).



## Sample collection, packaging & processing for posting

As part of the procurement, each ODN will receive sample stickers (labels), pre-printed, in sets of 3 per test. Stick additional labels to both the testing form and the Microbiology form and **check it is the same as the one on the sample**. See step by step layout of the procedure of processing samples in the table below.

## Capillary Blood Sample Collection for Needs Assessment

This protocol is a guide for good practice collection of capillary blood samples.

### Before you begin collection

1. Make sure you have the following ready:

- 1x Purple top BD EDTA MAP sample tube
- 1x NUH Microbiology request card (specimen bag attached)
- 2x Fingerstick lancets
- 1x Alcohol wipe

2. Complete the Microbiology request form

- All boxes on the form should be completed. **Please PRINT clearly in capital letters.**

3. Label the MAP sample tube after sample collection

- Ensure to include the patient's name, DOB and the date/time the sample was collected.
- These data are needed to confirm the correct sample/request cards are received and to match results to the correct samples.

4. Prepare the site for collection

- Ensure the patient's hands have been washed prior to sampling.
- Clean the finger with the alcohol wipe provided and allow to dry.

### Collect the sample

5. Select finger

- The ring or middle finger on the non-dominant hand is ideal as these are usually less calloused and less sensitive to pain.
- The fingertip may be massaged prior to (or after) puncture to stimulate blood flow.
- Uncap the MAP sample tube ready for sample collection.

6. Puncture the finger with the lancet – light pressure at the moment of puncture ensures adequate penetration.

- Puncture off centre from the central, fleshy part of the fingertip, but not on the very side of the finger.



- Following fingerprick, apply gentle pressure to the finger and allow a large drop of free-flowing blood to collect at the puncture site.
- Collect this drop into the MAP sample tube - the raised lip on the tube edge can be placed against the skin to aid sample collection.
- Continue until ~500µl has been collected.
- Use the spare lancet if necessary to draw more blood from a different finger.
- Ensure the sample is inverted adequately to allow mixing of the blood sample in the tube.

## 7. Packaging sample

- Recap the MAP sample tube, check it is labelled correctly and place in the specimen request bag.
- Double check all boxes on the Microbiology request form have been completed.
- Ensure the sample has been registered on NPEx before it is posted to the laboratory.
- Store samples at 4°C prior to transporting to the laboratory the same day.

Nottingham lab: All testing will be performed by Nottingham University Hospitals NHS Trust department of Clinical Microbiology using accredited assays. Results will be reported to the ODNs who will inform the client of the result in the usual manner.

- Once collected, the capillary blood samples are sent to the Nottingham laboratory for analysis
- Every testing day, all tests need to be sent on the same day as collection.
- It is recommended to have a collection cut-off time around **3pm** to allow time for collected samples to be posted.
- Samples must be sent **Monday to Thursday** ideally as analysis cannot be carried out on the weekend. **If Friday is the best testing day for the ODN due to footfall in some services, then ODNs may collect samples on Fridays, but must ensure all are posted the same day to allow delivery to Nottingham within 5 days to maintain viability of the sample.**

## Sample Kit Packaging for Needs Assessment

**This is the final check and process prior to posting samples.**

### Make sure you have:

1. Sample test bottle (filled and labelled)
2. NUH Microbiology sample bag
3. Completed NUH Microbiology request form
4. Flat pack box.
5. Protective foam bag for box.



Once you have taken a sample, check that the 3 barcode stickers (that are matching) are attached to:

1. The testing Form
2. The Microbiology request form\*
3. The sample bottle

Check that the information you have is matching what you have uploaded onto the NPEX Database and Spreadsheet.

**\*The form will look different to the blue form shown here as project specific testing request forms are provided.**

To reduce the risk of mixing samples up and ensure clinical governance criteria at the laboratory are met, **a patient identifier (DOB, for example) should be added to the sample tube with the barcode sticker. These details MUST match those provided on the Microbiology request form or the sample will be rejected.**

A Microbiology request form and coloured sample bags will be provided. Complete the Microbiology request form at the time of sample collection, with at least **two patient identifiers** e.g. (name or pseudo identifier and DOB).

The paper testing forms to be given to ODN the same day as testing to complete the electronic order on the [NPEX portal](#) to Nottingham lab for sample analysis. [More details about this in the testing form section](#)

Operational Delivery Network: BARTS  
ODN Number: 10DN  
Site and postcode: Reset Tower Hamlets, E1 1DN  
Site Number: S1

Please use BLOCK LETTERS and complete all sections.

NHS Number: [ ] - [ ] - [ ] Lab Number: [ ]  
Date of Birth: 01/01/1980

Forename: DAISSY Surname: DUCK

NOTTINGHAM UNIVERSITY HOSPITALS NHS TRUST  
**MICROBIOLOGY** LAB No. [ ]

Use BLOCK LETTERS or Identity Label

Hospital No. [ ] NHS No. [ ]  
Surname: Daisy Forename: Duck  
Date of Birth: 07/07/1980  
Male  Female

Date Taken: 08/08 Time: 12:00  
Doctor/Practitioner: [ ]  
Signature: [ ] Lab codes only: [ ]

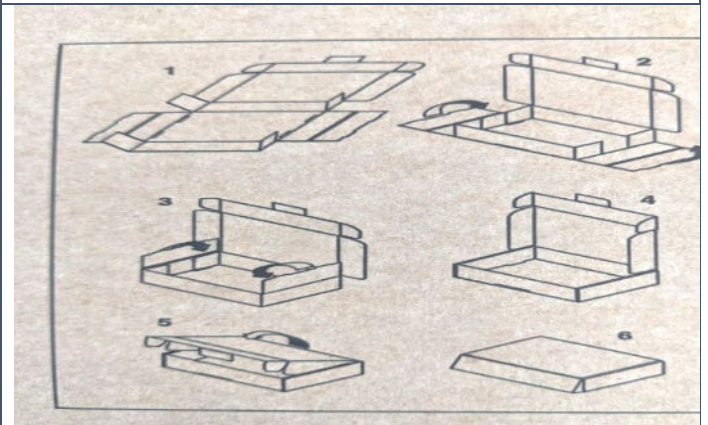
WARD [ ] Consultant [ ]  
OMC  CITY

Specimen [ ] Request [ ]  
Date of Birth: 01/01/1980  
Date of Birth: 01/01/1980

Comments  
1. Date tested previously for Hep C, if ever? 01/01/2020  
Collect below 2 questions in Needle Exchanges only:  
2. Are you engaged with structured treatment? Yes  No   
3. Have they been tested before as part of this project? Yes  No

Please enter answers to comments in the comments field on NPEX separated by a semi colon (;)  
e.g. Answer 1; Answer 2; Answer 3;  
Internal Use Only

Assemble the flat pack box as instructed, if not already.  
Do not seal the box until sample is included.



Once box has been assembled and you have added matching barcode stickers to

1. The testing Form
2. The Microbiology request form
3. The sample bottle

Place the sample bottle inside the coloured sample bag attached to the Microbiology request form. Place sample(s) in foam protective wallet, place in the box and seal.

**We will provide enough boxes to be able to send 1 sample per box.** However, on a busy day, 4-5 samples can be transported per box.

**Samples must be sent the same day as collection to ensure they do not haemolyse in transit.**

*This is important to keep tabs on, especially if testing is done by staff outside the ODN; if the testing rate is very slow, it is important to check that people don't forget to send the sample or let the ODN have the form to order the sample to be analysed on NPEX.*



**Add the laboratory address to the box:**

**Microbiology Main Reception  
A Floor, West Block  
Queens Medical Centre  
Derby Road  
Nottingham  
Nottinghamshire  
NG7 2UH**

Stick the postage stamps or 'Tracked 24', postage label onto the box.

This is now ready for posting.

**The boxes can be sent through any priority red post box similarly to COVID-19 tests.**



It is understood that in your considerable experience, it might be OK if the sample is delayed. However, in this project, due to the large volume of samples that will be arriving in Nottingham every day from all over England, it is essential that the samples are as fresh as possible and that any potential risks that may cause delays are mitigated to avoid wastage of samples.

**\*Please, therefore, send the samples on the same day, always\***

# Information System for Tests and Results

Proper management of data from this project is vital to protect patients and maintain trust.

**Remember that these are NOT NHS patients who have provided ‘presumed consent’ by attending for health care – they are addiction service clients who have attended for confidential management of their addiction problems. Data must be managed accordingly.**

The results of the test **MUST NOT BE ADDED TO ANY NHS HEALTH RECORD** without additional approval from the patient (i.e., if he or she requires NHS treatment for a BBV infection).

NHS is acting as the data conduit, requesting tests, and delivering results. As with last year, we recommend that patient data is stored on a secure NHS computer that is separate from the patient records and can only be accessed by NHS staff involved in the program.

1. **National Pathology Exchange (NPEX)** - NPEX portal is both a lab booking portal and a results tool.
2. The portal for the National Pathology Exchange is only accessible through NHS Trusts firewall (not NHSE for instance) due to the high security it has.
3. Only people who can use an ODN Trust computer will be able to access it.
4. Some ODNs will not be able to access it straight away and their computer location (IP address) will need to be added to the permitted list by Labgnostics.
5. During the on-boarding session for NPEX, training is offered as well.
6. Attached is the NPEX user’s guide (how-to document).



NSHEI HEPC ODN  
Year 2 User Guide.pdf

## Testing form:

Operational Delivery Network: Site and postcode: I confirm that the patient has had access to the patient information material and has given verbal /written consent (delete as appropriate) Sign and date here:		<b>NHS</b>
Please use <b>BLOCK LETTERS</b> and complete all sections. NHS Number <input type="text"/> - <input type="text"/> - <input type="text"/> - <input type="text"/> - <input type="text"/> - <input type="text"/> Lab Number <input type="text"/>		 AFFIX BARCODE HERE
Forename <input type="text"/> Surname <input type="text"/> Date of Birth <input type="text"/> / <input type="text"/> / <input type="text"/> Gender Male <input type="checkbox"/> Female <input type="checkbox"/>		
Reason attending service (as recorded for client by service): Injector/Other please specify: <input type="text"/> Patient identifier group from Lab Number Label last letter (above) "I" for history of injecting or "O" for all others: <input type="text"/>		
Address Line 1 <input type="text"/> Address Line 2 <input type="text"/> City/Town <input type="text"/> Post Code <input type="text"/> Phone Number <input type="text"/>		
NHSE BBV requesting -BBVN Collection Date <input type="text"/> / <input type="text"/> / <input type="text"/>		Collection Time <input type="text"/> - <input type="text"/>
<b>Comments</b> 1. Please enter Year 1 label code here: <input type="text"/> 2. Date tested previously for Hep C. <input type="text"/> / <input type="text"/> / <input type="text"/> 3. Is patient aware whether they currently have or have ever had a Hep C infection? <i>circle appropriate answer below</i> [A. current/B. cured/C. never/D. never tested/E. awaiting result] 3. Are they engaged with structured treatment (in the last 12 months)? Y <input type="checkbox"/> N <input type="checkbox"/> <b>Collect below additional question in Needle Exchanges only:</b> 4. Have they been tested before as part of this project in Y2? Y <input type="checkbox"/> N <input type="checkbox"/>		
Please enter answers to comments above in the comments field on NPEX separated by a semi colon (;) e.g. IODN1P10; 10/11/22; A; Y; N Internal Use Only		

- a. Data will be initially collected on a paper testing form.

- b. Attached testing form to be used to collect information from Clients /participant at point of testing.
- c. **ODNs to print and distribute testing form to the respective testing sites.**
- d. The testing form will then go to the ODN (on the same day) to be used to order the lab tests on NPEX. **This MUST be completed before MIDDAY the day following sample collection to ensure all NPEX orders are inputted prior to the laboratory receiving the samples.**



NAP Testing Form  
Y2.pdf

Please note: Service users will be tested according to how they are known to the service. Service users will not be surveyed according to their habits or if they (for instance) have ever injected. The person collecting the blood sample will note on the testing form how the service user is known to the service. **Getting this information correctly recorded is essential for the success of this project** for this will determine the risk of Hep C in all the groups and will help inform future service delivery.

### Recording Results

- a. The results of each test will be available on NPEX.
- b. Once the result is available this result should be added to the addiction service clinical notes system just as results would normally be inputted (for addiction services).

c. **For year 2: Please copy the Year 1 label code (ctrl +C from the spreadsheet) and paste it in the 'Patient Number' field not the Lab number field. This will enable matching of the new sample label (which will be scanned into the Lab Number field) to the old sample number label from the previous year. This is essential as this is a follow-up project and we need correct patient matching to be able to understand the incidence level.**

### Giving results

- a. Staff must ensure that service users are given their results in line with their own organisational policies.
- b. All clients tested must be informed of their result – even if negative or sample not tested (for example due to leakage or insufficient volume).
- c. PDFs of all results will be provided on a weekly basis to the ODN by Nottingham Pathology. These will need to be circulated to the addiction services within two working days if the patient is their client. This is to ensure clinical governance standards regarding notification of results in addiction services are adhered to.
- d. **Regarding HIV and HBV results only, if a patient has already been informed as a part of last year's needs assessment that they have had a confirmed positive result for either of these two viruses, they should not be informed of this again. If they query the HIV / HBV positive result that they were previously given (and the HIV diagnosis was confirmed with confirmatory testing), they should be told that those results would not have changed from last year.**

### Needs Assessment – Results interpretation table:

## Hepatitis C

HCV Antibody	HCV RNA	Comment
Any result  (reactive, non-reactive or not-tested)	Detected	Indicates active infection with HCV. Please refer to an appropriate specialist for further management.
Reactive	Not detected	No evidence of active HCV infection. Reactivity observed in the hepatitis C antibody assay may be due to past infection or non-specific reactivity.  If there has been a recent or ongoing exposure risk, consider repeat testing.
Non-reactive	Not detected	No evidence of HCV infection at any time.  However, if there has been a recent or ongoing exposure risk, consider repeat testing.
Insufficient/not tested	Not detected	No evidence of active HCV infection.  However, if there has been a recent or ongoing exposure risk, consider repeat testing.
Non-reactive	Insufficient/not tested	No evidence of HCV infection. However, if there has been a recent or ongoing exposure risk, consider repeat testing.  Please send a repeat sample for HCV RNA testing.
Reactive	Insufficient/not tested	Reactivity observed in the hepatitis C antibody assay, which could be due to current or past infection.  Please send a repeat sample for HCV RNA testing.

## Hepatitis B

HBsAg	Comment
Reactive	Reactivity detected in Hepatitis B surface antigen screening test, which may be non-specific and requires further testing.  We are not able to perform confirmatory testing on capillary blood samples due to the small sample volume. Please send a venous blood sample to your own laboratory for confirmatory testing.
Non-reactive	No evidence of active HBV infection.

	However, if there has been a recent or ongoing exposure risk, consider repeat testing.
--	--

#### HIV

Result	Comment
Reactive	<p>Reactivity detected in the HIV screening test, which may be non-specific and requires further testing.</p> <p>We are not able to perform confirmatory testing on capillary blood samples due to the small sample volume. Please send a venous blood sample to your own laboratory for confirmatory testing.</p>
Non-reactive	<p>No evidence of HIV infection.</p> <p>However, if there has been a recent or ongoing exposure risk, consider repeat testing.</p>



## Process flowchart and testing pathway

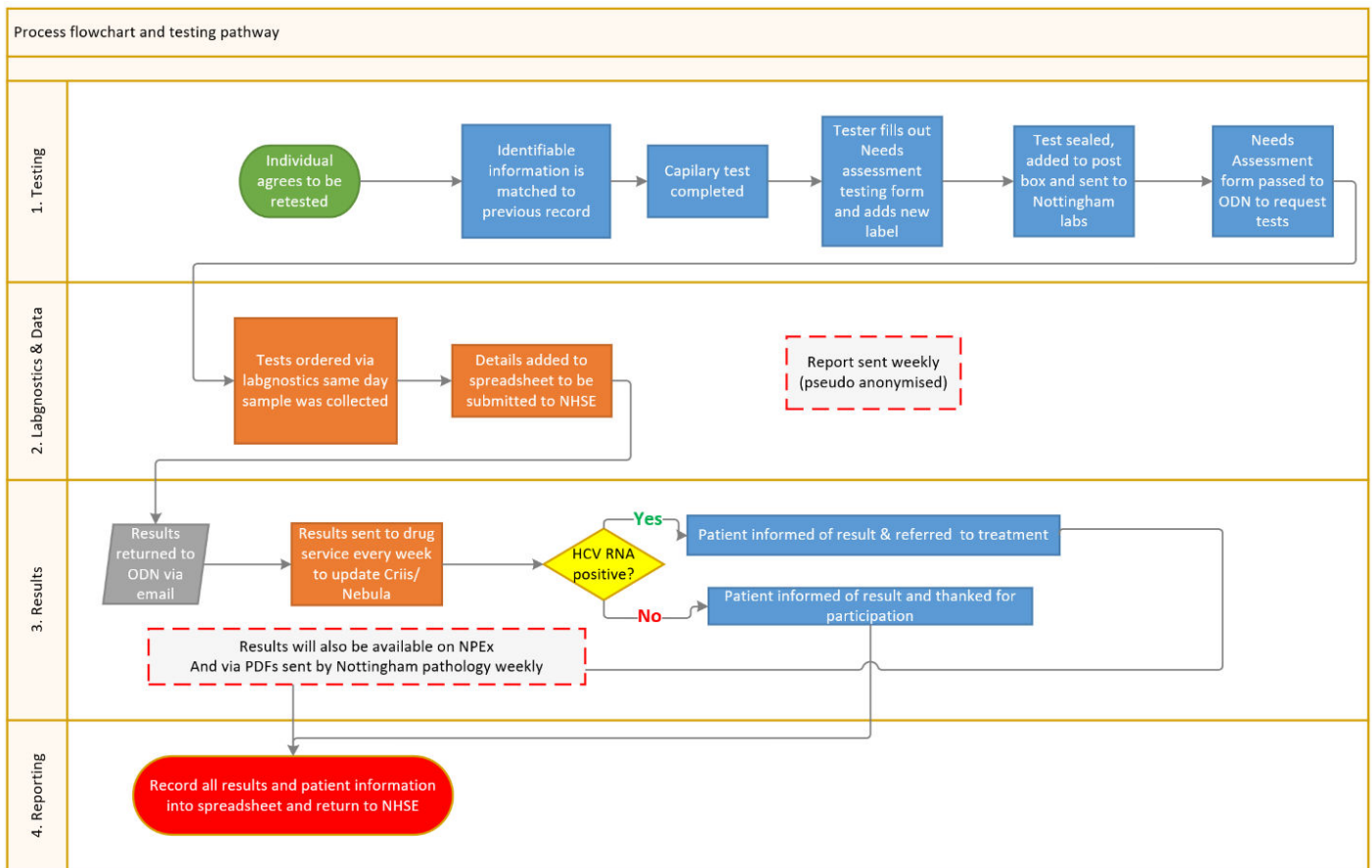


Figure 1: testing pathway

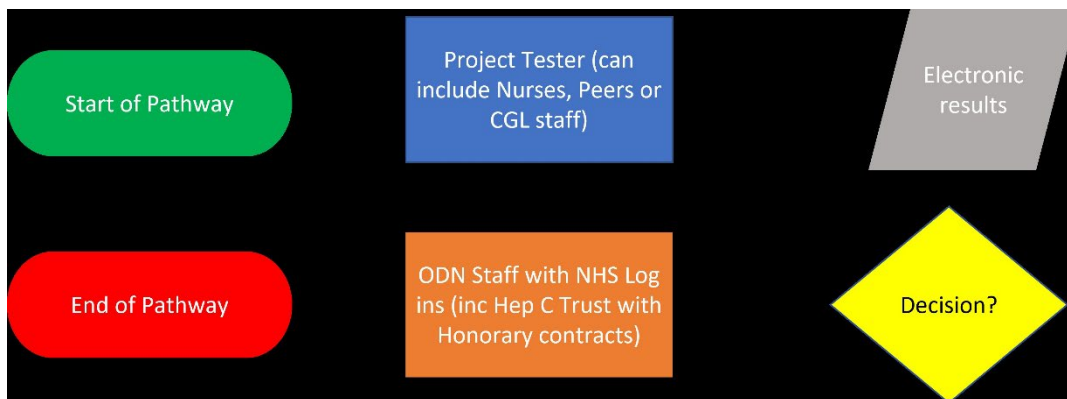


Figure 2: testing pathway key

### Data Collection Retention and Management Collection

- Testing will be confidential with only those providing clinical care accessing patient identifiable data.
- It is mandatory to complete the testing form and to record the data on the spreadsheet provided. Some of the data on the testing form will not be recorded anywhere else (e.g. NPEx) and it is vital to record everything correctly.
- For those tested in addiction services, the result will be recorded in the clinical record, in line with standard practice, and general practitioners will be informed, with the client's consent.

- d. For those tested by community vans, the relevant health care professional will record client details.
- e. This information will be shared with other health care professionals only with the client's approval.
- f. Anonymised data will be provided to NHSE to allow information to be analysed.

**Management**

a. **ODNs:**

- A record of who has been tested needs to be sent back to the addiction service (if the testing is being done there) to update their records.
- Please do that every day if possible, or, weekly at minimum.
- It is very important to share this information with the addiction services as soon as possible so they may update their clients' records.
- Addiction services and ODNs must retain a spreadsheet of who has been tested and their contact details to allow for clinical follow-up. Attached is the spreadsheet (there is a dummy patient on it as an example).



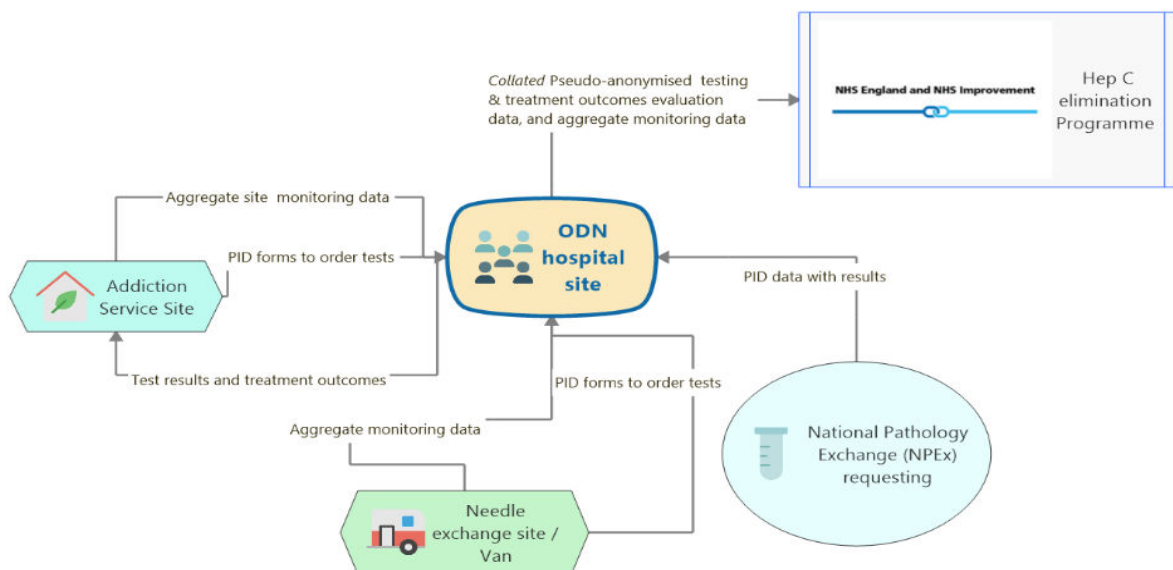
Data collection template y2 v0.2.xlsx

b. **For addiction services:**

- It is also good practice to add an entry to the service user's notes if they have participated in the testing.

All results need to be reported back to addiction services within 2 working days of receipt if this is where the testing took place. This is a collaborative project and we need to ensure timely flow of information.

Data flow:



## Daily data entry during the project

1	<b>Testing form</b>	To be completed always, every time
2	<b>Spreadsheet tab Site data</b>	To be completed always, every day from testing form (additional mandatory fields to NPEx)
3	<b>NPEx</b>	To be completed always, every day from testing form
4	<b>Consent form</b>	To be completed, if agreed that written consent is necessary

## Additional Resources

There is dedicated website with a lot of useful information, which includes a webinar for the needs assessment and an electronic copy of the SOP.

<https://befreeofhepc.co.uk/providers>

*Be Free Of Hep C has been developed and funded by Gilead Sciences Ltd, as part of an initiative with industry partners to support the NHSE England Hepatitis C Elimination Programme. The information in this guidance document, including those linked to, were solely developed by NHS England and provided to Gilead Sciences Ltd to upload to the Be Free Of Hep C website.*