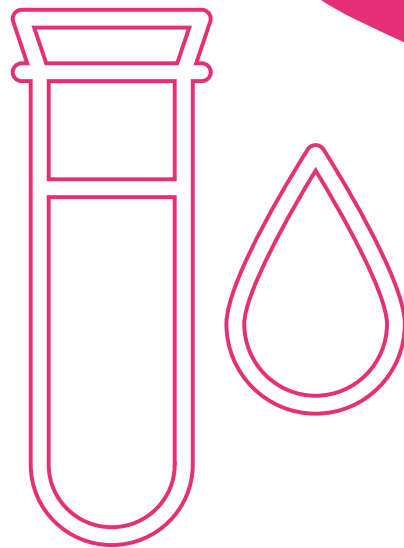


HEP C
U Later

**Internal Cepheid (*Genexpert*)
Machine Implementation and
Management SOP**



Introduction:

This document is an Internal Standard Operating Procedure that will set out the process for the loan of Cepheid GeneXpert machines between Hep C U Later and the Addictions Provider Alliance services who we have a working agreement with.

The purpose of this document is to support the management of the complex loan process of a Cepheid GeneXpert machine. The SOP will cover responsibilities and accountability from an internal perspective and, once the machines are delivered to the service, their responsibilities. It will also ensure transparency and assurance for Hep C U Later's partners at MSD and Cepheid.

It will inform who the points of contact are for the loan of the machine and the process of requesting to loan one. The loan documents and service operating procedures (for provider use) will be embedded within this document.

What is a Cepheid GeneXpert Machine?

Hep C U Later currently manage two machines that are loan to us from MSD and Cepheid, these machines can be utilised by drug and alcohol services across the addiction provider alliance network.


As part of the loan agreement MSD fund the consumables (Cepheid cartridges and minivettes) that Hep C U Later will provide to the services that have machines on loan.

Each machine has an individual name allocated to them all beginning with "C", they are called:

- Candy
- Christine

What is a Cepheid GeneXpert Machine?

Cepheid GeneXpert machines are a quick effective way of determining if a person is RNA positive, by taking a blood sample via a finger prick test. A sample is extracted with a minivette kit and transferred into a special cartridge, the cartridge is then placed in the GeneXpert machine that will run a test taking 60 minutes. Each machine has 4 ports and can run 4 tests simultaneously. This will give a test result of RNA detected or not detected and also a viral load result if the person has an RNA positive result. There will be a certificate produced by the system which can be saved and uploaded to person's case notes.





It will not give you a hepatitis C antibody test result, therefore it is essential that you have a method of testing for antibody only before running a Cepheid test (this for cost efficiency purposes).

A Cepheid GeneXpert machine is portable and can be used anywhere where there is access to two electricity sockets. It can be used in a clinical room setting, transported in a clinical van or taken to outreach settings that have appropriate places for the running of the test.

The Cepheid GeneXpert is available for use with any person who has put themselves at risk of contracting the hepatitis C virus. It is more appropriate to use after an antibody test has been completed or if a person has had an antibody positive result in the past, this may be if a person has spontaneously cleared the virus in the past or has completed treatment episode previously. It can be used as a way of determining

if a person has been reinfected after clearing. SVR (sustained viral response) tests can be completed using Cepheid as a way of determining if a person's virus has remained un-detectable following treatment and should be completed at 12 months and 24 months post completion of treatment.

Loan process and agreement:

The Cepheid GenXpert machines are available for loan to services within the NHS Addiction Provider Alliance who have a working agreement with Hep C U Later. The process for loaning one of the machines managed by Hep C U Later is as follows.

A request to be made through the Intensive Engagement Coordinator, Tony Mullaney, who can be contacted at Tony.Mullaney@mpft.nhs.uk or by calling 07977 397820.

Alternately a request can be made through regional elimination coordinators:

- Louise Hansford (London and South) Louise.hansford@mpft.nhs.uk and 07966 899327
- Laura Hughes (Midlands and North) Laura.Hughes@mpft.nhs.uk and 07811 023878



Enquiries can also be made at through the Hep C U Later email HepC.Ulater@mpft.nhs.uk.

Once an enquiry has been made, a meeting can be arranged to discuss the loan agreement and then loan agreement documents can then be exchanged. These documents will outline the responsibility of the service and the support that can be expected from Hep C U Later and our partners at Cepheid and MSD. Once a date for the loan of the machine has been agreed, Hep C U Later can arrange for the delivery of the equipment to the service. Once delivered the Hep C U Later training coordinator will plan to be at your service the day after delivery, to deliver a training session on the set-up and operation of the equipment.

The service that has loaned the Cepheid machine will have a designated lead person or persons responsible for the operation of the machine while on loan. The

nominated people will be responsible for the day-to-day operation of the machine, this will include:

- The installation of the machine.
- The setting up process.
- The running of tests, the saving of results certificates.
- The cleaning of the machine.
- The safe storage of the machine when not in use.
- The recording and sending of data each month (or if loaning for less than a month at the end of the agreed period).

The loan period will be negotiated prior to the delivery of the Cepheid machine. It is normal for a service to request the use of the machine for a period of 1 month but this can be reviewed depending on the need of your service in regards to your outstanding testing numbers.

Hep C U Later's point of contact for Cepheid machines that Hep C U Later have on loan are:

- Deborah.Cook@Cepheid.com

The Hep C U Later loan information check list and information sheets can be accessed below.

[Requirements for loan](#)

[HCUL Customer Implementation Checklist](#)

Responsibilities:

Hep C U Later hold responsibility for the quality of the Cepheid machine's that they have on loan from MSD and Cepheid who are the owners of the equipment.

Once the machine is loaned to a member of the APA, they then have a responsibility for the safe keeping and management of the machine in line with the loan agreement and the shared SOP.



Hep C U Later will be responsible for the ordering and delivery of the cartridges and Minivettes from MSD, the rest of the equipment needed to complete a RNA test will need to be ordered by the service through their usual supply route.

- Antibody testing kits
- Lancets
- Gloves
- Aprons
- Disposable card trays
- Alcohol wipes
- Cotton swabs
- Plasters
- Bleach (household)
- Clinell anti-bacterial wipes

The service that has the machine on loan has a responsibility to keep track of the number of cartridges they have, to ensure they have enough to run tests.

Ordering should be made through the Intensive Engagement Coordinator, Tony Mullaney, who will request a delivery from MSD to the service. It is the services responsibility to provide a monthly audit of cartridges they have in stock and inform Hep C U Later via email.

The cartridge order form can be found on the button below.

[Order form](#)

Setting up and running the GeneXpert machine:

Before the Cepheid machine is delivered to the service, all the relevant documentation must have been sent to the receiving service and the loan agreement must be returned to HCUL. Once the Cepheid machine is delivered to the service, all of the relevant documents must have been read by the receiving service and a training session completed by the Hep C U Later Intensive Engagement Coordinator.

Please see the documents listed below.

- [Hep C U Later loan checklist](#)
- [Cepheid Working Guide](#)
- [Pre-Installation checklist](#)
- [Cepheid top tips](#)
- [Cepheid SOP](#)

Escalating issues:

There are several ways of escalating issues that a service may encounter when using the cepheid GeneXpert.



The first port of call would be to communicate the issue to the Hep C U Later mailbox, we will then attempt to trouble shoot the issue. If the issue cannot be resolved by the team at Hep C U Later it can be escalated to the Cepheid team via the emails provided below:

- Tony.Mullaney@mpft.nhs.uk, Hep C U Later
- Deborah.Cook@Cepheid.com, Cepheid

Technical support:

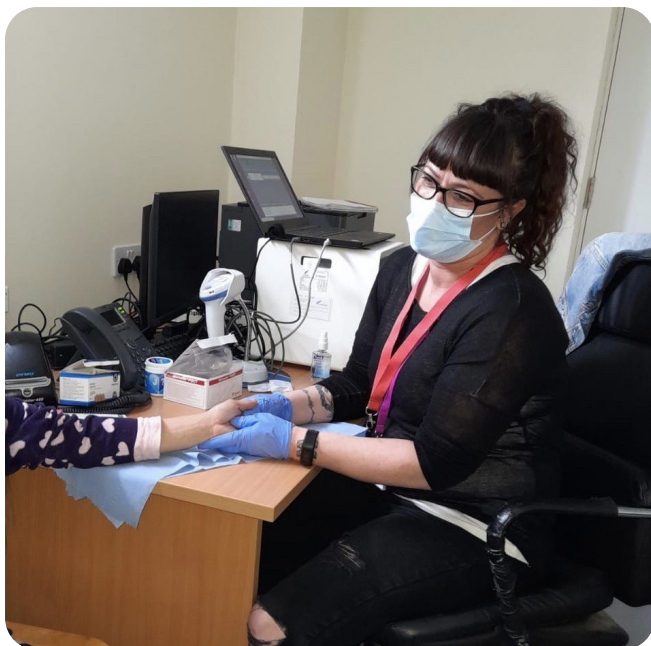
Cepheid (GeneXpert) are also available for any technical support via 0330 222 2533.

When contacting them, be sure to quote the machine serial number. This is normally found on the sticker on the back of the machine.

Sharing the data from loaned cepheid machines:

In line with the Hep C U Later loan agreement, the loaning service must supply Hep C U Later with all data relating to RNA testing that is completed within the agreed timeframe. This must be provided to Hep C U Later monthly as a minimum. If the Cepheid is on loan for a shorter period than one month, then all data must be provided at the end of the agreed loan period. This data will then be anonymised by the Hep C U Later team and the data will then be provided to MSD on a monthly basis.

Hep C U Later will provide data to our partner in week 1 of each month. This means we require data to be provided by the loaning service by the first of each month. When recording data for each person you must record; name, DOB, NHS no, reason for test eg post anti-body test, past spontaneous clear, past treatment completion, reinfection risk or SVR12, SVR24 etc.



If the person has been treated on a previous occasion, please record where and when the treatment was started (use the comments section on spreadsheet for this information). Once the loan period has come to an end, the Cepheid must be purged in order to clear any persons identifiable data before moving to the next service who are going to use the machine in-line with Information governance.

Follow the link below for guidance on purging data:

[5.1.3.4.3 How to Purge Tests.pdf \(cepheid.com\)](#)

Once tests have been purged from the Cepheid GeneXpert files it is important to go into the reports folder and delete any saved certificates. Once the reports folder is empty it is important to go to the GeneXpert recycle bin and delete any remaining items in this folder.

Liability:**MSD policy relating to liability****1. LIMITATION OF LIABILITY**

1. Nothing in this Loan shall limit or exclude any liability for death or personal injury resulting from negligence; fraud or fraudulent misrepresentation; or any other liability that cannot be excluded or limited by law.
2. You shall not be responsible and shall have no liability for any incidental damage or loss to the Equipment.
3. You agree not to use the Equipment for any commercial, business or resale purposes, and we have no liability to you for any loss of profit, loss of business, business interruption, or loss of business opportunity.
4. The Equipment is intended only as a support tool and the data collected and submitted by the Equipment are not a substitute for a professional's diligence and responsibility in monitoring a condition and seeking or referring to appropriate medical advice.
5. The Equipment is provided "as is" and no representation is made or warranty given, either expressly or by implication, in relation to the reliability, availability, completeness, correctness or functional capability of the Equipment or that the Equipment will be uninterrupted or error-free or that its use will not infringe any third party rights. You confirm that you will use the Equipment at your own risk. MSD and Cepheid disclaim all warranties to fullest extent permitted by law.
6. Save as provided above, MSD and Cepheid shall not be responsible and shall have no liability for any adverse effects, or consequences or other damage, injury, loss or expense resulting from the use of or inability to use the Equipment, including as a result of failure or damage to: (a) hardware or (b) public or private telecommunications networks. We are not responsible and shall have no liability for any error, omission or data in the Equipment.
7. We are not obliged to make the Equipment permanently available and reserve the right to withdraw the Equipment or stop the service at any time.

Cleaning the machine:

There is a process to cleaning the Cepheid GeneXpert machine to ensure the efficacy of testing.

The machine should be cleaned:

- Daily
- Weekly
- Monthly
- And at the end of loan agreement before a machine is shipped to the next service

Follow the link for the instructions below:

[Maintenance of GeneXpert \(fondazione.sanraffaele.it\)](http://fondazione.sanraffaele.it)

Cepheid cartridge stock and stock rotation:

The Intensive Engagement Coordinator will have mid-month contact with all the providers who have the machines on loan to co-ordinate the ordering of stock, including testing cartridges and minivettes.

This contact will give an opportunity to manage the remaining stock of cartridges at each service, ensuring that cartridges are used before the end of the expiry date. If the service has a number of cartridges and they feel they will not have the capacity to use the cartridges before they expire, a plan will be implemented to have some of their excess stock couriered to another service.

After each mid-month contact, the number of cartridges (and expiry date) at each service will be recorded on the Cepheid contact planning sheet, on the cartridge audit page. Regular emails will be sent to the services who have Cepheid machines on loan to encourage the use of their cartridge stock in an effort to reduce waste.



Cepheid machine implementation/management process:

