

## Cepheid (Genexpert) SOP

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**This Cepheid (GeneXpert) SOP is for use by other drug and alcohol providers, the Hep C Trust and Operational Delivery Networks (ODNs). This SOP can be used as a template for the organisation using it to amend in line with their own Trust policies and governance arrangements if they so wish. As such the content and use of the SOP, if changed, subsequently falls under the responsibility of that organisation and not Hep C U Later.**

## ***Version control:***

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**Changes made by:** Deanne Burch

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**Changes made by:** Laura Hughes

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**Signed off:** September 2022

## ***Introduction:***

**This Standard Operating Procedure (SOP) is to be used in conjunction with the following policies:**

- Blood Borne Virus SOP
- Infection Prevention and Control Policies
- Sharps Injury Policies
- Data, Information, Record Keeping and Governance Policies
- Moving and Handling Policies

# Purpose of the Cepheid (GeneXpert) machine

## *What is it?*

A Cepheid (GeneXpert) machine is a portable testing unit that can test for hepatitis C RNA in 60 minutes. A finger prick of blood is added to a cartridge that is inserted inside the machine. It gives you a detected (including viral load) or not detected result and produces a certificate that can be shared or uploaded to patient notes.

It will not give you a hepatitis C antibody test result therefore it is vital that you have a method of doing this prior to using the Cepheid (GeneXpert).

## *Where it is used?*

A Cepheid (GeneXpert) machine can be used anywhere where there is access to two electricity sockets. It can be used in a clinic or transported in a clinical van.

## *Who is it for?*

Cepheid (GeneXpert) machines test for hepatitis C RNA and are therefore best used for anyone who is at risk of contracting the hepatitis C virus.

They have been successfully utilised within services, on clinical vans and at testing events.

### **TOP TIP:**

Learning from other drug and alcohol services: Although it is possible to test anyone using the Cepheid (GeneXpert) machine it has been found to be very successful when testing for hepatitis C re-infection. For example, if a person has had a previous hepatitis C infection and either spontaneously cleared the virus or has cleared it through treatment they will always have a hepatitis C antibody present in their blood. Therefore, solely using the Cepheid (GeneXpert) machine to test them would enable a quick diagnosis without wastage of other types and forms of testing.

**If you are planning to use one of the Hep C U Later Cepheid (GeneXpert) machines it is recommended that you pull a report of who needs re-testing (of those who have had hepatitis C previously) and who needs a SVR after having treatment.**

## *Cepheid (GeneXpert) machine training*

Training must be in place for all staff using the machine. In some circumstances train the trainer can be arranged and training can be adapted to suit the needs of the person using the machine. For example, one member of staff supporting a clinic may only need to know how to do the test and the responsibility for cleaning may be with another staff member.

If you are a provider who is borrowing a Cepheid (GeneXpert) machine from Hep C U Later, it is essential that a meeting is held with the Hep C U Later Coordinator to ensure the appropriate planning and governance paperwork is in place for training prior to holding any events where the machine will be used.



# Using the Cepheid (GeneXpert) machine

The Cepheid (GeneXpert) is available in 2, 4, 16, 48 or 80 module configuration. The manufacturer's guidance for the specific machine you are using should be followed at all times.

*Youtube video link (please click the link below to watch the video):*

Xpert HCV VL Fingerstick - YouTube

Section 3 demonstrates how the blood sample is taken with the minivette and section 5 demonstrates how to put the sample into the cartridge.

*Sample technique:*

It is essential to take a good sample when using the Cepheid (GeneXpert) machine. If the sample is insufficient then the test will not be able to give any results and the service user will have to be called back in for a test. We recommend following the below process to maximise success.

*Prepare the environment:*

- Take machine, laptop and cables out of the case – make a note of how they're stored, as this is how they will be put back when you're done.
- Ensure that there is a consistent source of power to plug the Cepheid into – if the power drops out then any tests running on the Cepheid will fail.
- Connect all the wires – laptop charger, barcode scanner into laptop USB, power cable into Cepheid, Ethernet cable from Cepheid into the laptop (ensuring a firm connection – plug should 'click' in).
- Turn on Cepheid via switch at the back – ensure that the little blue light flashes on at the front of the Cepheid machine (below cartridge modules).
- Turn on the laptop via power button.
- Log in to Cepheid-Admin user with the correct password for relevant machine
- All the apps you need will open when the laptop is logged in (if this does not happen, after 2 minutes of the laptop being switched on, double click the GeneXpert DX app on the desktop).

*You will need to ensure you have 2 plug sockets available - one for the laptop and one for the machine.*

# Using the Cepheid (GeneXpert) machine

## *Prepare the environment continued:*

- Take machine, laptop and cables out of the case – make a note of how they're stored, as this is how they will be put back when you're done.
- Ensure that there is a consistent source of power to plug the Cepheid into – if the power drops out then any tests running on the Cepheid will fail.
- Connect all the wires – laptop charger, barcode scanner into laptop USB, power cable into Cepheid, Ethernet cable from Cepheid into the laptop (ensuring a firm connection – plug should 'click' in).
- Turn on Cepheid via switch at the back – ensure that the little blue light flashes on at the front of the Cepheid machine (below cartridge modules).
- Turn on the laptop via power button.
- Log in to Cepheid-Admin user with the correct password for relevant machine
- All the apps you need will open when the laptop is logged in (if this does not happen, after 2 minutes of the laptop being switched on, double click the GeneXpert DX app on the desktop).
- Complete GeneXpert log in. Username and password varies based on location and machine being used. You will have been given these details when you have taken delivery of the machine. If unsure of any log in details, contact Tony Mullaney via Hep C U Later [HepC.ULater@mpft.nhs.uk](mailto:HepC.ULater@mpft.nhs.uk) and [Tony.Mullaney@mpft.nhs.uk](mailto:Tony.Mullaney@mpft.nhs.uk) or telephone 07977 397820.
- Once logged in, the pop up 'Do you want to perform database management tasks?' may appear. Select NO.
- DO NOT under any circumstance do any updates as Hep C U Later are responsible for these with Technical Support (these can corrupt the software).
- The machine will make some weird noises (don't worry), and lights above the modules should flash blue and switch off. Definitely ensure there are no red lights above the cartridge modules.
- If any modules are red, please contact Tony Mullaney or Hep C U Later for assistance before using the Cepheid further.
- If all is well, the Cepheid machine is now ready to use.

# Using the Cepheid (GeneXpert) machine

## *Prepare the environment continued:*

- Ensure the area is clean, there is a sharps box within reach, all equipment is laid out and appropriate PPE is being worn.

## *Prepare the service user:*

- Talk them through the purpose of the test, how the test is taken, the result takes an hour and what the steps are following the results.
- It is important to let them know tests sometimes throw an error and there is a slight risk they will need to complete the sampling again.
- Ensure the contact details for the service user are up to date and gain verbal consent for the test.

## *Take the sample:*

- Ask the service user to stand up whilst the sample is collected if possible, with their arms hanging down by their sides as this may help blood flow.
- Wipe the finger with an alcohol swab and allow to air dry.
- Lancet the finger causing blood to flow.
- Wipe away the first show of blood with gauze.
- Hold the minivette (blood collection device pictured in the image below) horizontally without covering the end. Insert image of how to hold the minivette horizontally



Fig 1: Recommended required area for GeneXpert system

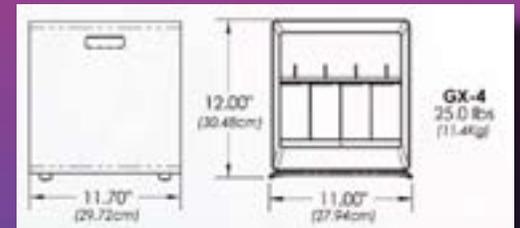


Fig 2: GeneXpert 4-4 footprints

# Using the Cepheid (GenExpert) machine

## *Take the sample continued:*

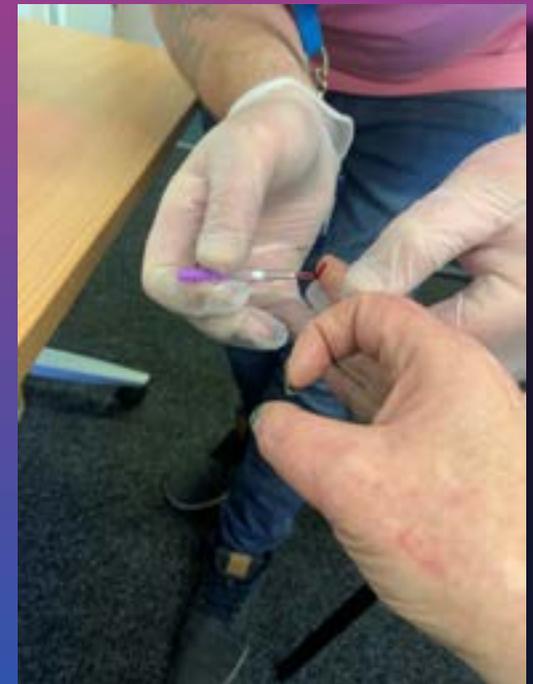
- Wait until there is a good drop of blood on the finger and let the minivette touch the blood, avoiding the skin. The minivette will suck up the blood because it works like a vacuum.
- To ensure the minivette fills to the line keep milking the finger to get drops of blood into the minivette.

## *Put the sample in the cartridge:*

- Open the new sealed cartridge (you should hear a slight click as it opens)
- Slot the minivette into the cartridge and push the purple end down slowly without tipping the cartridge.
- Remove the minivette and close the cartridge lid securely.
- The cartridge must be kept flat at all times.

### **TOP TIP:**

If you are testing multiple services users it is recommended that you deal with one test at a time and also add their details on to the front of the cartridge to limit the potential of mixed samples. Remember to keep the cartridge flat - do not shake it or tip it.



# Using the Cepheid (GeneXpert) machine

## *Data Management:*

If you are borrowing a Cepheid (GeneXpert) machine from Hep C U Later you will be given a unique username and a password. You must keep this secure at all times.

It is important that you follow the manufacturer's guide when running the test due to the variety in set-up of machines.

It is possible for the Cepheid (GeneXpert) machine to encrypt any service user details that are added at a later stage, therefore, NHS number, name and DOB can be used. When 'creating a test' on the screen anything which is inputted is added to the results certificate.

When running the test use the notes section of the screen to add in additional details that would be useful to see on the results certificate - these will have to be entered on one line. We recommend these are:

1. Name of the collector
2. Name of the person running the test
3. Reason for the test (ie. SVR or new antibody positive swab result)

The Cepheid (GeneXpert) laptop can be linked to the internet for the purpose of sending results via NHS.Net email, however - **additional apps or software should not be added due to the risk of it corrupting the machine. DO NOT under any circumstance do any updates as Hep C U Later are responsible for these with Technical Support (these can corrupt the software).**

## *Purging and Cloaking:*

The following is the process for ensuring good information governance and must be followed if borrowing a Cepheid (GeneXpert) machine from Hep C U Later (across different providers) or if the machine is travelling across different sites within the same organisation. Purging and cloaking is a process undertaken with the data (on the laptop provided with the Cepheid (GeneXpert) machine) that can prevent a breach of service user data.

*If you need support regarding an issue with the machine contact the tech support number on the side of the machine*

***Purging and Cloaking:***

Before purging or cloaking it is essential that all results certificates are emailed to the appropriate NHS.Net email address prior to the purge taking place. If they have not been sent and the purging and cloaking takes place then the information will be lost and cannot be retrieved.

Only once all of the results certificates are sent on should the following process take place to ensure that service user data is safe and there are no data breaches. If the provider is borrowing a Cepheid (GeneXpert) machine from Hep C U Later then this process will be supported by the Hep C U Later coordinators either in person or via being talked through the process online.

1. Delete the certificates from the machine
2. Cloak the data
3. Purge the data

***Cleaning Schedules:***

The manufacturer's guidance should be followed when using synthetic samples (varying types of viral load) to test the machine's validity. It must only be carried out by staff who know this process. If a provider is borrowing a Cepheid (GeneXpert) machine from Hep C U Later this process should be completed by Hep C U Later team, who will update the maintenance log to give assurance that the machine is in working order.

If the machine is being used regularly the filters should be washed and dried monthly.

Clinell wipes can be used to carefully clean the cartridge holders (modules) and plunger rods once they have been lowered. It is recommended that this cleaning process takes place after roughly 20 tests.

The use of synthetic samples, cleaning of filters, cartridge holders and plunger rods should be recorded. If a Cepheid (GeneXpert) machine is being borrowed from Hep C U Later they will advise on the cleaning schedules.

Providers must ensure that at the end of each day the modules of the Cepheid (GeneXpert) machine do not have any cartridges inside.

The used cartridges must be disposed of within clinical waste.

## Using the Cepheid (GeneXpert) machine

### Results:

Results certificates must be emailed via NHS.Net and not saved on the Cepheid (GeneXpert) laptop. Due to the purging and cloaking of data to maintain good information governance, results certificates cannot be saved on the machine long term and should be emailed securely after each clinic.

If secure email cannot be used then alternatively an encrypted memory stick can be used with the Cepheid (GeneXpert) laptop if the organisation allows it.



*Multiple providers using the Cepheid (GeneXpert) machine:*

Cepheid (GeneXpert) machines are often used at intensive testing events where there are likely to be multiple organisations working together to meet service users' needs across the hepatitis C pathway.

It is important to ensure that each organisation and practitioner knows what their responsibility is when working with the machine. Training and agreements are central to ensuring that no incidents (such as sample mix-ups) occur when these agencies are working together. To further minimise the risk of incidents occurring there should be an agreement in place around which individual has the responsibility for using the machine throughout the event, for inputting data, for cleaning the machine and for ensuring its safety.



## *Handling & transporting the Cepheid (GeneXpert) machine:*

The Cepheid (GeneXpert) machine, laptop and all other wires should be transported in its transport box with the padding to support it. It weighs approximately 26.5 kg. Transporting the machine should be the responsibility of one agreed individual. All efforts should be made to keep this vital and expensive equipment secure and undamaged.

If a provider is borrowing a machine from Hep C U Later then a pre-meeting will be arranged with the provider to look at transporting the machine to their premises as well as looking at the other preparation that must be in place.



# *Process for borrowing a Cepheid (GeneXpert) machine from HCU:*

## **STEP ONE**

Requests to borrow the Cepheid (GeneXpert) need to be made via email contact with HepC.ULater@mpft.nhs.uk titled 'Cepheid (GeneXpert)' or via Hep C U Later Coordinators.

Once a request is made the 'Cepheid (GeneXpert) Loan Checklist' (with embedded documents) will be sent out to the provider, this needs to be completed and returned to Hep C U Later before booking will be confirmed.

## **STEP TWO**

Before borrowing a Cepheid (GeneXpert) machine from Hep C U Later a meeting must be arranged between Hep C U Later and the provider. The purpose of this meeting will be to look at:

1. How data on the use of the machine is collected and sent
2. Transporting the machine
3. Storage of the machine (ensuring 2 plug sockets for machine and laptop)
4. Training for staff using the machine
5. Dates and timeframes
6. Support available for using the machine
7. Passwords and username set up
8. Cost of antibody tests (sometimes these can be provided for free by the ODN or Hepatitis C Trust)
9. How to get the most from the machine
10. How to utilise your Hep C Trust Peer Support Leads and mentors to increase engagement and support with anyone who needs treatment
11. Confirmation of the preparation checklist

# *Process for borrowing a Cepheid (GeneXpert) machine from HCU:*

## **STEP THREE**

Equipment the provider must ensure they have prior to receiving the Cepheid (GeneXpert):

- Sharps bin needed for cartridge/lancets, clinical waste for the rest
- Lancets
- Disposable cardboard trays
- Gloves and aprons
- Clinell wipes
- Skin disinfecting wipes
- Sterile gauze and plasters
- Thick paper towel/gauze for table
- Alcohol gel/wipes if no sink in room

Optional extra equipment can be:

- Instant result hepatitis C antibody swabs (using these prior to the Cepheid (GeneXpert) for people who have never tested positive for hepatitis c can lower the overall costs)
- Incentives vouchers (The PHE UAM Anonymous Unlinked Survey can be used alongside to enable service users to receive

## **STEP FOUR**

Collecting data on the use of the Cepheid (GeneXpert) machine:

- To continue to provide evidence on the value of the Cepheid (GeneXpert) machine Hep C U Later will ask for simple and unidentifiable data from the provider to be sent weekly to [HepC.ULater@mpft.nhs.uk](mailto:HepC.ULater@mpft.nhs.uk) This completely anonymised data is sent securely to MSD. Failure to provide this data will not only jeopardise Hep C U Later's supply of cartridges but also the ongoing loan of the Cepheid (GeneXpert) machines to the NHS APA.

*Process for borrowing a Cepheid (GeneXpert) machine from HCU:*

**STEP FIVE**

Purging and cloaking before returning the Cepheid (GeneXpert) machine:

- Hep C U Later will arrange with the provider to ensure any personal identifiable data is wiped from the machine. They will either arrange to do this in person when the machine is collected or will talk the provider through how to do this step by step.



**Support using the Cepheid (GeneXpert) machine:**

Tony Mullaney will be available for support on the use of the machine and can be contacted via HepC. ULater@mpft.nhs.uk, tony.mullaney@mpft.nhs.uk or 07977397820.

Alternatively Cepheid (GeneXpert) are also available for any Technical Support 0330 222 2533 and quote the machine serial number normally found on a sticker on the side or back of machine.

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 [www.hepculater.com](http://www.hepculater.com)

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