

Background

Central TB division has now provided the function in Nikshay to directly upload CBNAAT results to Nikshay. The results need to be exported in bulk from the CBNAAT machine and uploaded to Nikshay **on a daily basis**.

Once uploaded, the test details and the performance of the site are visible through a calendar based report with the details on number of tests performed, MTB detected/not detected and Rif sensitive/resistant patients.

Who should upload CBNAAT Test?

PHIs with CBNAAT facilities will be provided with the ability to upload CBNAAT test details to Nikshay. The Lab technician responsible for reporting results of CBNAAT tests will be responsible for uploading CBNAAT results on to Nikshay.

What are the requirement prior to uploading the test results?

The CBNAAT facility needs to be mapped in the respective PHI in Nikshay. If not already done, the same may be done through User Management Module or raising a request for the same in Nikshay. Broadband Internet connection in the Desktop linked to the CBNAAT machine would be mandatory. The user may also use the option of uploading through Tablet or transferring the file to another Desktop with a working broadband connection in the above order of preference.

What should be uploaded?

The machine generated export of results from the CBNAAT machine, which is available in CSV (Comma Separated Values) file format is to be uploaded against the PHI in which the CBNAAT laboratory is situated. The export should include all tests done irrespective of final result (including error, invalid and indeterminate results).

What is the frequency at which tests should be uploaded?

CBNAAT test details should be uploaded at least once every day, either at the beginning or end of business, regularly. If upload was missed on any day, it should be ensured that all tests done after the previous upload should be included in the next upload.

What will be the details uploaded be used for?

The Test details uploaded will be used to assess the CBNAAT lab performance in terms of tests done, Cartridge consumption; CBNAAT Machine and module utilisation including monitoring of non-functional machines, invalid tests and ambiguous tests; and epidemiological analyses of Drug Resistance etc. Hence, to ensure accurate reporting, it important that all test performed on the machine irrespective of results are uploaded to Nikshay.

Please follow the SOP provided below to upload CBNAAT Tests to Nikshay.

Note:

1. All tests done after 01st of December 2018 are to be uploaded.
2. Tests are to be uploaded daily to Nikshay. Preferably after the last test has been done for the day.

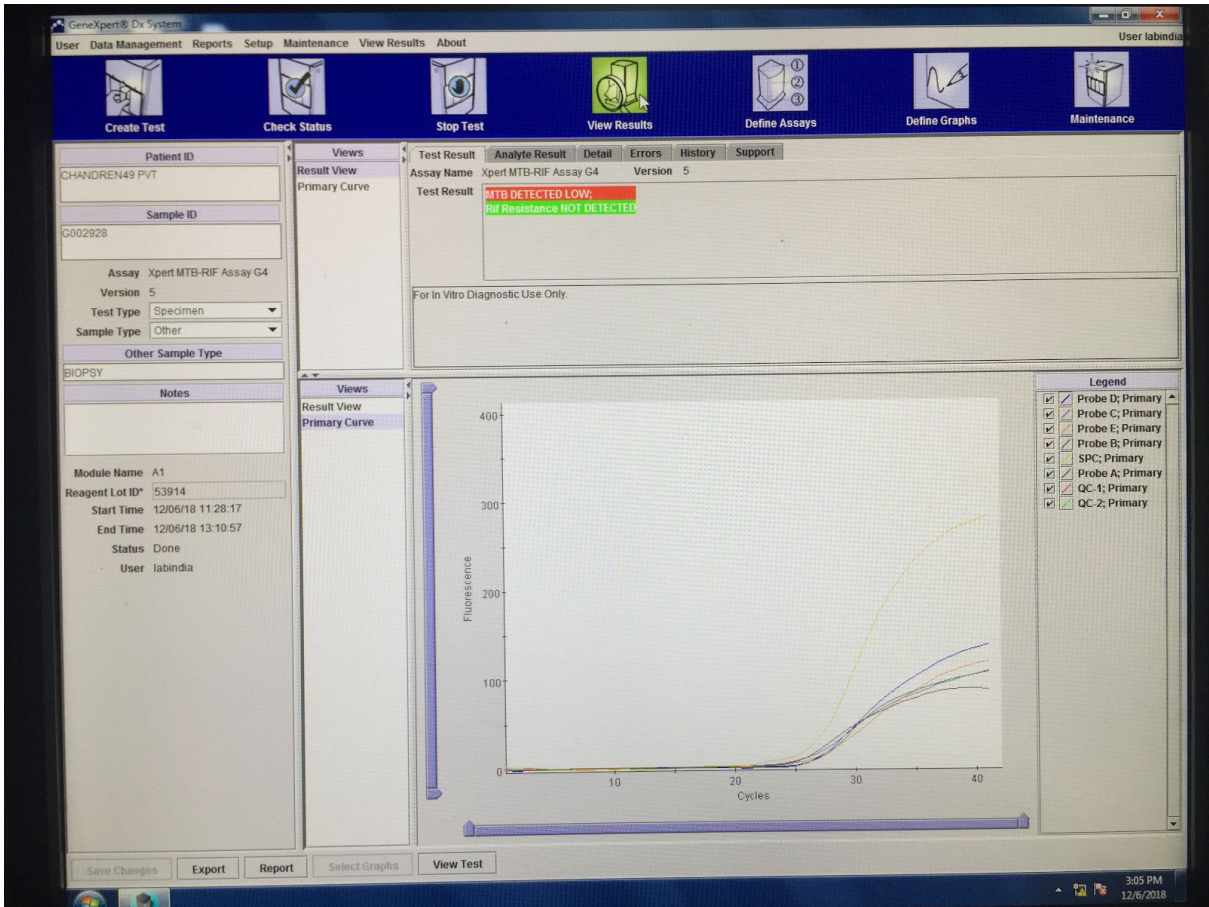
SOP for uploading the CSV File exported from GeneXpert to Nikshay

The SOP has two parts, one in which the data file need to be exported from the GeneXpert Machine and the second step in which this file is uploaded to Nikshay.

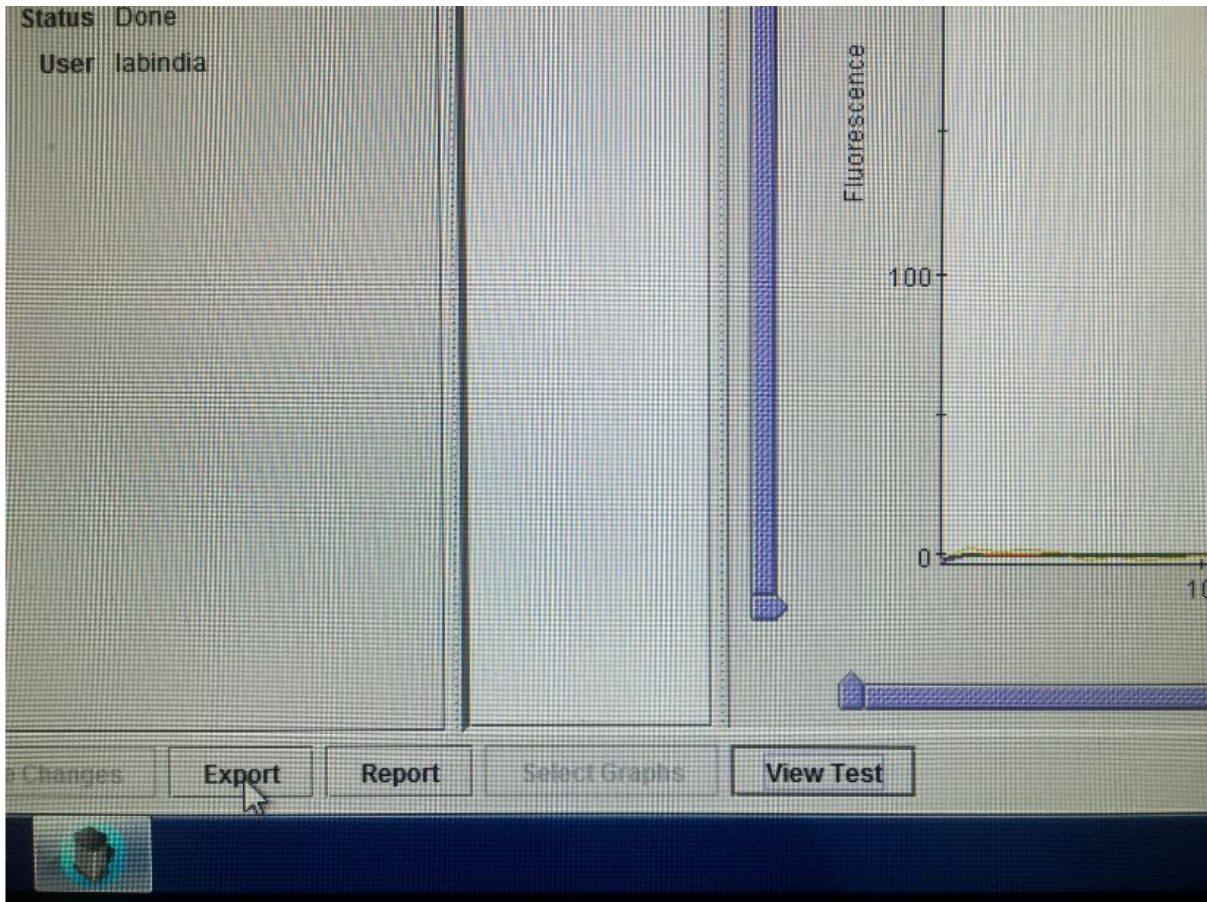
Part 1: Exporting the data from the GeneXpert Software (5 Steps)

1. Open the GeneXpert application and login





2. Go to **Export** (Bottom left of the screen)

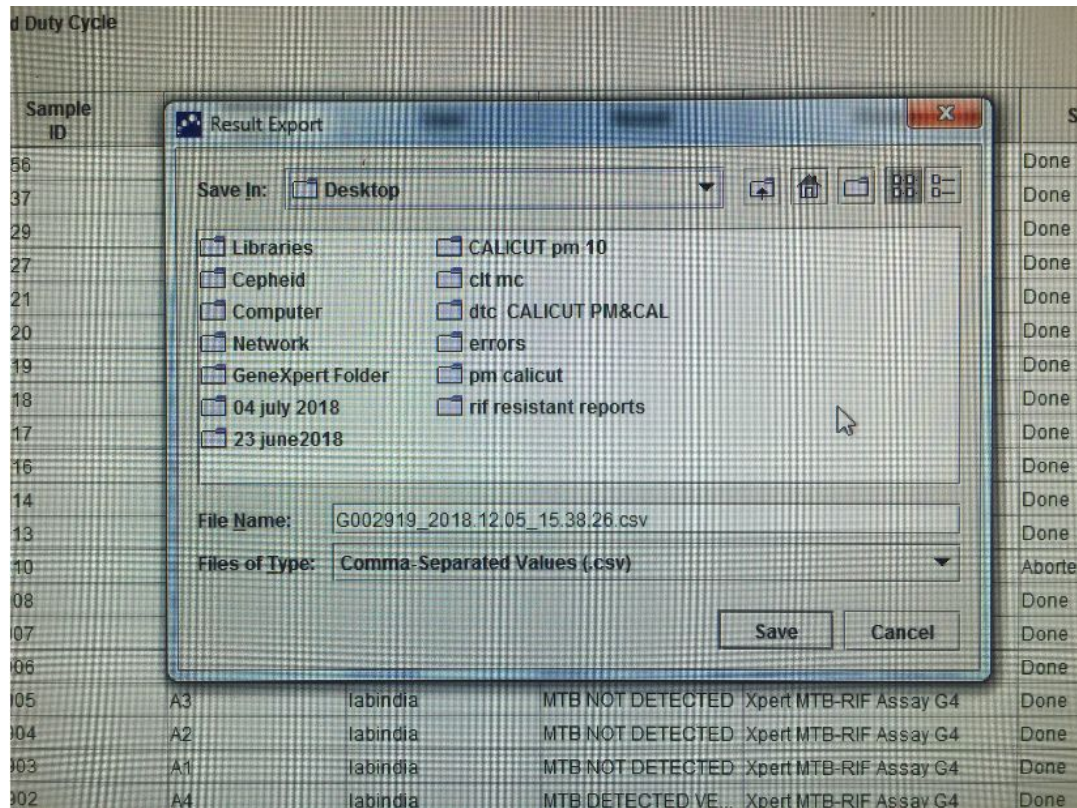


3. Select (tick mark on the extreme left of each test in the view results screen) all the tests that need to be exported and click on the export button (top right on the view results screen).

Melt Data
 Pressure
 Ultrasonic Horn Amplitude, Frequency and Duty Cycle
 Heater Temperature

	Patient ID	Sample ID	Module Name	User	Result	Assay	Stat
<input checked="" type="checkbox"/>	NASAR 49ID	G002956	A3	labindia	MTB NOT DETECTED	Xpert MTB-RIF Assay G4	Done
<input type="checkbox"/>	MUHAMMEDIASABITH9	G002937	A2	labindia	MTB NOT DETECTED	Xpert MTB-RIF Assay G4	Done
<input type="checkbox"/>	BINDU K 40 MCH	G002929	A1	labindia	MTB NOT DETECTED	Xpert MTB-RIF Assay G4	Done
<input type="checkbox"/>	MUKUNDA N49RNTCP	G002927	A4	labindia	MTB NOT DETECTED	Xpert MTB-RIF Assay G4	Done
<input type="checkbox"/>	JASHEER30 MOH	G002921	A3	labindia	MTB NOT DETECTED	Xpert MTB-RIF Assay G4	Done
<input type="checkbox"/>	NAMBI50M4	G002920	A2	labindia	MTB NOT DETECTED	Xpert MTB-RIF Assay G4	Done
<input checked="" type="checkbox"/>	KUNJIRAMAN 67 M6	G002919	A1	labindia	MTB NOT DETECTED	Xpert MTB-RIF Assay G4	Done
<input type="checkbox"/>	CHAND23M6	G002918	A4	labindia	MTB NOT DETECTED	Xpert MTB-RIF Assay G4	Done
<input type="checkbox"/>	BASHHEER45	G002917	A3	labindia	MTB DETECTED ME	Xpert MTB-RIF Assay G4	Done
<input type="checkbox"/>	VIJAYAN55M6	G002916	A2	labindia	MTB NOT DETECTED	Xpert MTB-RIF Assay G4	Done
<input type="checkbox"/>	BILU3P1	G002914	A1	labindia	MTB NOT DETECTED	Xpert MTB-RIF Assay G4	Done
<input type="checkbox"/>	HASSANKUTTY60M4	G002913	A4	labindia	MTB NOT DETECTED	Xpert MTB-RIF Assay G4	Done
<input type="checkbox"/>	NAZAR49ID	G002910	A3	labindia	ERROR	Xpert MTB-RIF Assay G4	Aborted
<input type="checkbox"/>	KUTTOSE 65 M6	G002908	A2	labindia	MTB NOT DETECTED	Xpert MTB-RIF Assay G4	Done
<input type="checkbox"/>	THEERATHA 15 M4	G002907	A1	labindia	MTB NOT DETECTED	Xpert MTB-RIF Assay G4	Done
<input type="checkbox"/>	DEVASSIA 58 CD1	G002906	A4	labindia	MTB NOT DETECTED	Xpert MTB-RIF Assay G4	Done
<input type="checkbox"/>	RAFA 15 M4	G002905	A3	labindia	MTB NOT DETECTED	Xpert MTB-RIF Assay G4	Done
<input type="checkbox"/>	PENNUTTY 63 M6	G002904	A2	labindia	MTB NOT DETECTED	Xpert MTB-RIF Assay G4	Done
<input type="checkbox"/>	VIJAYAKUMARI 52 M3	G002903	A1	labindia	MTB NOT DETECTED	Xpert MTB-RIF Assay G4	Done
<input type="checkbox"/>	CHANDRAN 58 CD3	G002902	A4	labindia	MTB DETECTED VE	Xpert MTB-RIF Assay G4	Done
<input type="checkbox"/>	AMBIKA 57 M3	G002901	A3	labindia	MTB NOT DETECTED	Xpert MTB-RIF Assay G4	Done
<input type="checkbox"/>	FATHIMA 4 P1	G002915	A2	labindia	MTB NOT DETECTED	Xpert MTB-RIF Assay G4	Done
<input type="checkbox"/>	AMRAN 63 M4	G002912	A4	labindia	MTB NOT DETECTED	Xpert MTB-RIF Assay G4	Done

- In the save in box, select Desktop



- In the file name box name the file using the naming format <CBNAATLabName>DDMMYYYY.csv (For example DTCKollam18072018.csv for a file exported from the PHI DTCKollam on the 18th July 2018). No space to be entered when naming the file.

Part 2: Uploading the data into Nikshay (8 Steps)

1. Go to the Nikshay website (www.nikshay.gov.in)
2. Log in to Nikshay using the login ID and password provided (TU/ PHI level).
3. Click on **CBNAAT** on the left-hand menu.
4. Select your PHI (The PHI in which the CBNAAT lab is present).
5. Click **Choose File** and browse and find the CSV file saved earlier.

6. Click > **Upload the GeneXpert CSV file.**
7. Wait for the file to upload and the **upload successful** message to appear. The tests uploaded will appear in the table below.

Sample ID	Patient ID	Assay	Assay Version	Assay Type	Test Type	Sample Type	Notes	Test Result MTB	Test Result Rif R	Test Disclaimer	Cartridge Index	Module Name	Module SN	Cartridge SN	Instrument SN	SW Version	Real
		Xpert MTB-RIF Assay G4	5	In Vitro Diagnostic	Specimen			MTB DETECTED HIGH	Rif Resistance DETECTED	For In Vitro Diagnostic Use Only.	1	A1	661327	608150913	801668	4.8	39
		Xpert MTB-RIF Assay G4	5	In Vitro Diagnostic	Specimen			MTB NOT DETECTED		For In Vitro Diagnostic Use Only.	1	A2	658783	608150950	801668	4.8	39
		Xpert MTB-RIF	5	In Vitro Diagnostic	Specimen			MTB NOT DETECTED		For In Vitro Diagnostic	1	B3	658981	608151037	807035	4.8	39

8. Facilities having more than one machine need to upload files exported from the all machines separately. They can upload the second file by repeating the above instructions.

Reporting modules as not functional

If no tests are done, because modules are not functional, then this detail need to be updated in Nikshay. A functionality for the same is provided as in the screenshot below.

The screenshot displays the Nikshay web application interface. The browser address bar shows the URL: <https://localhost:44371/Genxpert/GenxpertoNikshay>. The application header includes the Nikshay logo, a search bar, and a user profile dropdown for 'tbu-MHBCL01'. The left sidebar contains a navigation menu with items: Overview, New Enrollment, Add Tests, Patient Management, DBT, Task Lists, Unvalidated (99DOTS), Admin, Reports, Others, CBNAAT, and Active Case Finding. The main content area shows the 'Dashboard / Genxpert Upload to Nikshay' page with three tabs: 'Genxpert Upload to Nikshay', 'Report Module As Non Functional', and 'GenXpert Calander Report'. The 'Report Module As Non Functional' tab is active, displaying a form with the following fields: PHI (JJ HOSPITAL), Inst. SN (801668), Module SN (658783), From Date (03-12-2018), To Date (05-12-2018), Status (radio buttons for Functional, Non Functional, Under Maintenance, Replaced), and Remark (Text Data). A blue 'SUBMIT' button is located at the bottom of the form.

In case a module is not functional it may be reported using the **Report Module as Non-Functional Button**

On clicking a new box will open up asking further details.

- a. Select the PHI and the instrument and the module serial number.
- b. Select the from and to date for the status
- c. the status of the module.
- d. Click on Save

Linking up Patient records in Nikshay and the test records of CBNAAT

In order for Nikshay to identify each CBNAAT test against a person and the test request made, it is necessary that the export from the CBNAAT machine contains the patient and test request information in the exported CSV File. Two fields in the CBNAAT Dx Application; Patient ID and Sample ID will allow us to record this information while performing the test. The following instructions provide details on what should be entered into these two fields while performing the test.

Task by PHIs requesting a test

To ensure the smooth operation of this process it is imperative that all PHIs requiring a CBNAAT test to be done has to perform the following at the time a sample/ Patient is being sent to the CBNAAT lab for testing

1. Enrols the patient, requests a test to obtain the **Patient ID** and the **Test ID** (from Nikshay)
2. Ensure that any documentation (Laboratory form, Falcon Tube label) contains the two IDs along with Patient Name, Age and Sex

On Treatment / [Redacted]

Add Case 1 » Add Test 2 » Initiate Treatment 3 » Close Case 4

Patient ID: [Redacted]
Old Nikshay ID: [Redacted]
Sector: **Public**
Status : **On Treatment (Notified)**
Adherence Technology: **NONE** Refill Monitoring: **Unknown**

Adherence Enrollment Tests Treatment Details DBT Close Case Notes Comorbidity Contact Tracing Others ▾

Show Columns Search **Test ID** + Add Test

ID	Reason for Testing	Type of Test	Results Pending/Available	Result: Positive/Negative	
3030486	Diagnosis of DRTB	CBNAAT	Results Available	Positive	View/Edit
5103452	Diagnosis of DSTB	CBNAAT	Results Pending	Invalid	View/Edit

Task by Labs performing/ Reporting test results

Obtain the Patient ID and Test ID of the test to be performed from Nikshay or from the PHI requesting the test.

When creating a test on the GeneXpert Dx application, there are two fields provided.

1. Patient ID - In this field enter the Name; Age; and Sex and any other variable you would like to maintain each separated by a semicolon (;).
2. TestID - This field is to be reserved for the Nikshay GeneXpert interaction. You need fill in the Nikshay patient ID and test ID which has been provided by the test requesting facility in the format **<Patient ID>,<Space><TestID>**. For

example if the patient id is 12343567 and the test ID is 98907, the you need to fill in 1234567, 98907.

Viewing reports based on the data uploaded

Once the tests are uploaded, the following report is available for viewing.

1. Calendar View: All the tests uploaded can be viewed on a calendar based on the date of test. Each day a summary based on the type of result is provided.

The screenshot shows the 'GenXpert Calander Report' interface. At the top, there are filters for Year (2018), Months (May), PHI (J J HOSPITAL), and Inst. SN (801668). A 'GET DATA' button is present. The main area is a calendar for May 2018. Each day cell contains a circular icon with a number and a horizontal bar chart. The bar chart is divided into four segments: MTB Detected (green), MTB Not Detected (orange), Error/Invalid (red), and Total (blue). A 'Data Recived' notification is visible at the bottom left.

May 2018							MTB Detected	MTB Not Detected	Error/Invalid	Total
Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday				
		01	02	03	04	05				
06	07	08	09	10	11	12				
13	14	15	16	17	18	19	4	0	0	5
20	21	22	23	24	25	26	3	1	0	4
27	28	29	30	31			3	0	0	3

FAQs

1. When should I upload the tests done on CBNAAT to Nikshay?

The results should be exported and uploaded to Nikshay regularly every day.

2. What tests should I export?

The export should contain all the tests that were done on that day.

3. Can I upload all pending tests at one time?

It is to be ensured that all tests (irrespective of reason for testing, and test result) done after 01/12/2018 should be uploaded to Nikshay. All pending tests may be uploaded at one go. However, depending on internet connectivity, larger files will take longer to get uploaded; and smaller files containing less than 30 tests are preferred.

4. Can I upload the results from a Tablet?

Yes. If the results are being uploaded from a Tablet, the CSV file needs to be transferred to the tablet by connecting it through USB and copying the CSV file into the Tablet's storage disk.

5. When are the results visible in the patient management module?

Once uploaded, the test details and the performance of the site are visible in GeneXpert Calendar Report. By 1st January 2019 we expect the entire country to be trained in this functionality and the patient and test fields contain the correct information in the correct format. Once this upload process has been completed, direct linkage between patients and GeneXpert Tests will begin; tentatively from 1st January 2019.