REPORT

INTERNSHIP AT MOLBIO DIAGNOSTICS Pvt Ltd

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Contents

INTRODUCTION

Molecular Diagnostics is the state of the art in the diagnosis of infectious diseases. It works on the principle of DNA amplification, hence providing the ability to diagnose the disease early in infection because of its excellent sensitivity and specificity. This technique has thus far, been limited to centralized laboratories due to dependency on complex and expensive infrastructure, highly skilled manpower, special storage conditions, and the need for batch testing. This results in high turn round time and poses major logistics challenges such as sample degradation, contamination, delays, etc.

For long Molecular Diagnostics has been the domain of large central laboratories requiring patients and samples to travel long distances for a test to be conducted. These pose several logistic and technical challenges leading to increased costs and delayed results. The veracity of such results and the impact of such intervention on treatment outcomes have always been questionable. This has led to poor uptake of such reliable and cutting-edge technologies that have the potential to save millions of lives, mitigate sufferings and reduce disease burden and anti-microbial resistance. The lack of timely access to good diagnostics has been the bane of healthcare needs, particularly of the Low- and Middle- Income countries. Therefore, The **Truelab Real-Time quantitative micro-PCR system** which is a compact battery-operated system has a single testing capability and provides a sample result within 1 hour. Hence, it enables same-day reporting and initiation of evidence-based treatment for the patient. It also has real-time data transfer capability (through SMS/E-mail/data push) for immediate reporting of results in emergency cases.

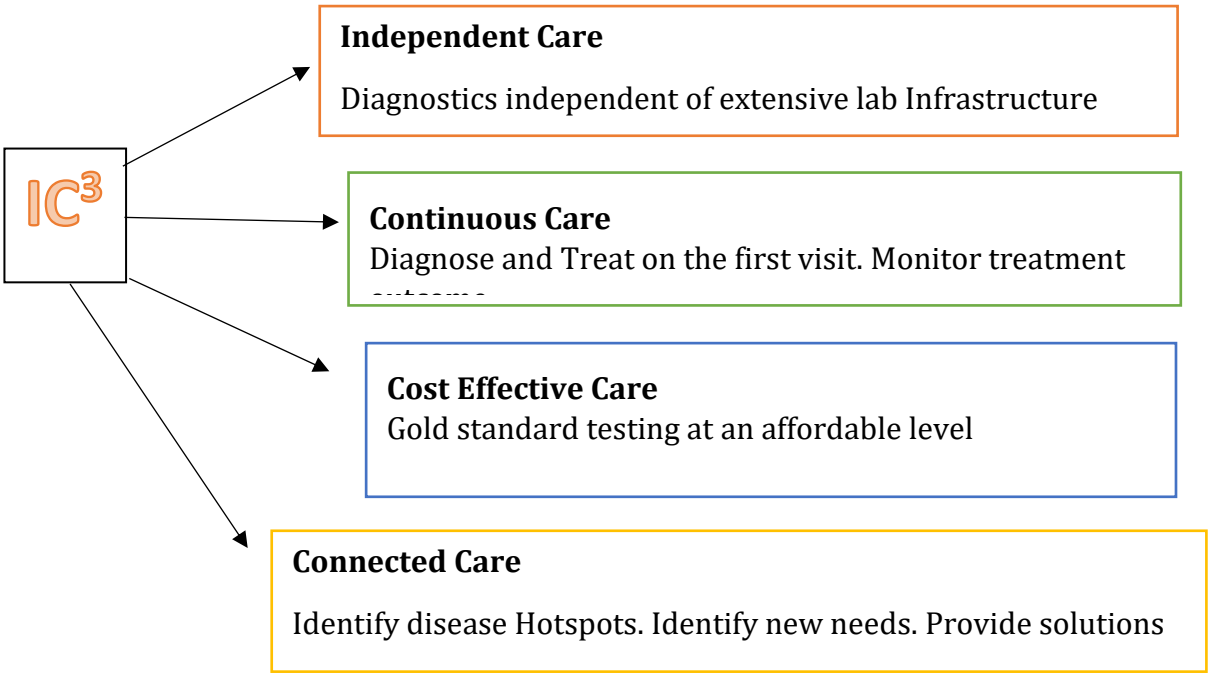
MISSION

- To enable better medicine through precise, faster, cost-effective diagnosis at the Point of Care (POC)
- To reduce patient suffering, fatalities, and resultant economic loss due to inadequate diagnosis
- To provide every patient access to the best health care through cutting-edge technologies
- To stay connected to the needs of the patient through constant engagement with all stakeholders.

VISION

- To transform healthcare practices by providing near-care diagnostic solutions using robust portable platforms
- To enable decentralization and democratization of diagnostics through a high ended point of care technologies
- To be a leading global player in the point-of-care diagnostics segment.
- To continue to innovate and bring new technologies for social betterment.

MOTTO



Molbio Diagnostics Pvt Ltd

https://www.molbiodiagnostics.com/about-us.php

1. PRODUCTS

Truelab®	**Truenat®**	**Trueprep®**	**Truemix™**	**STABILYSE®**
Equipment that allows testing to occur (RT-PCR)	Consists of all the products involved in nucleic acid testing	Involves all the products required for nucleic acid extraction.	Involves the preparation of micro mix	Products that do not require the prep device for nucleic acid extraction

2. PRODUCTION

In general, there are 4 main sections in Molbio: Truelab, Truenat, Trueprep, and Truemix section. Molbio site V consisted of all except the Truelab section

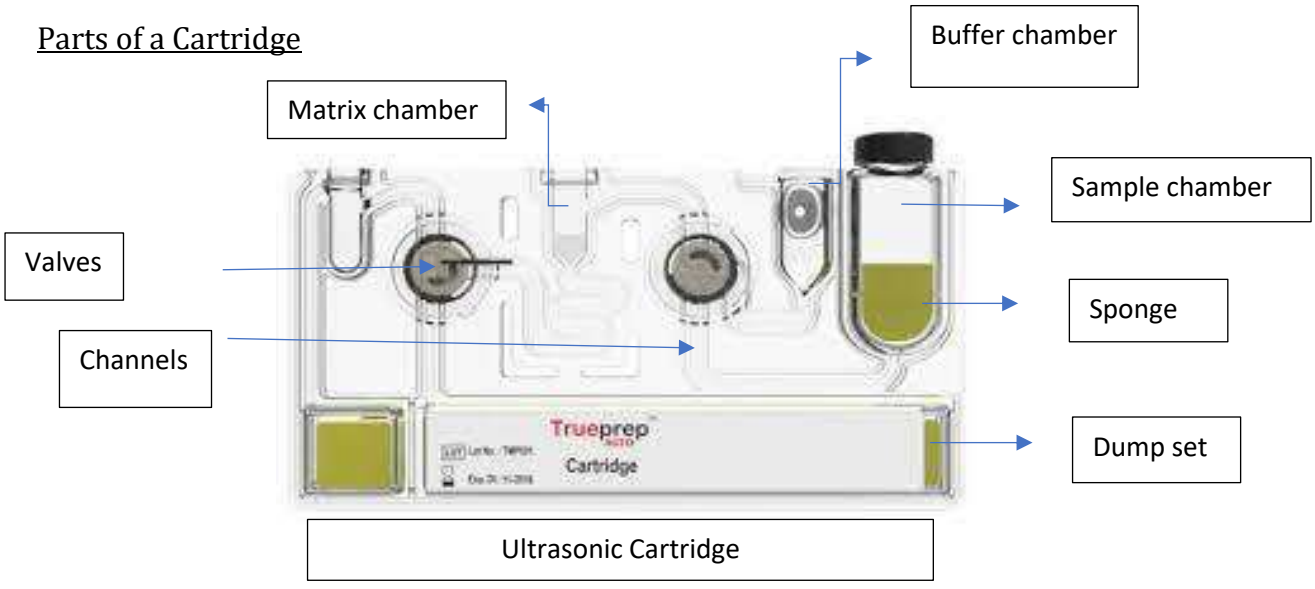
2.1. Trueprep section

The Trueprep section involves all the products that are required for extracting nucleic acids.

1. **<u>Cartridge section</u>**

The cartridge plays a vital role in separating the nucleic acids. There are two types of cartridges obtained from the vendors: Laser cartridges and ultrasonic cartridges. Once they are purchased, a few of them are taken for testing to check their performance.

<u>Parts of a Cartridge</u>



Types of cartridges:

- Ultrasonic Cartridges: These are transparent cartridges wherein the channels are made by ultrasonic welding, hence its name. This type of welding may cause issues or errors leading to leakage of the samples. Hence, they are sealed with DCM coating.
- Laser Cartridges: These are black in colour and the channels are made by laser welding hence reducing the errors.

Cartridge coating section

Around 90 cartridges obtained are arranged in each tray. After the procurement and arrangement, the following steps are carried out:

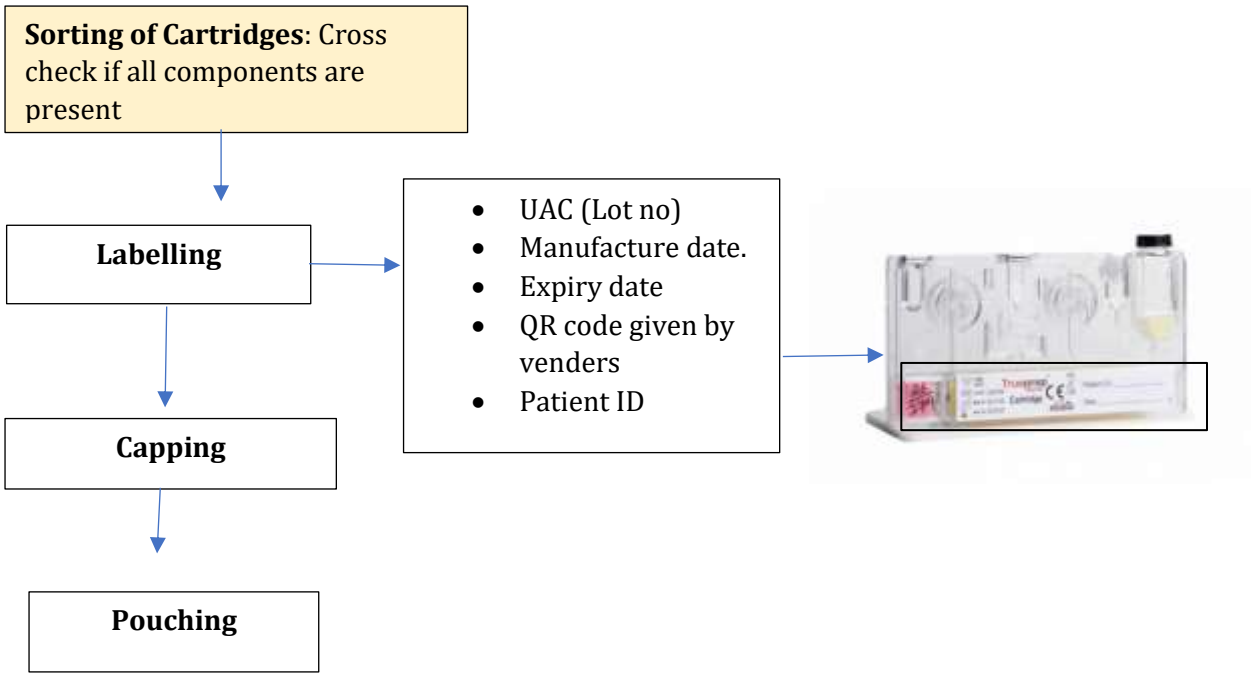
- Buffer chamber cap insertion
- Dispension of 30ul IC (internal control)
- Drying of IC for about 22±2 hrs
- Testing of batches to QC (Quality control)
- Pouching

IC Filling

IC or Internal control is dispensed into the sample chamber of the cartridge to validate the entire process, from extraction to amplification of the nucleic acids. Dispensing of the IC is carried out manually using stapper pipettes (Thermo scientific or ependorff) having a capacity to dispense 10ul to 5ml while another one called multi-pipettes have the capacity to dispense from 1ul to 10ml. The cartridges are stored at 2-40^{o}C .

Pouching

Once the cartridges are dispensed, they are sent to the pouching section where the following steps are carried out:



Each of the cartridge pouch consists of:

- Cartridge
- Elute collection tube
- Dropper (stored in UV cabinet)
- Label for elute collection tube.

Packaging

Once the cartridges are pouched, they are packed into cartons:

- The cartons are issued from the store.
- Overprinting
- Folding of boxes
- Final kit can be for 50, 25 or 5 tests containing:

i) 50, 25 or 5 Cartridges

ii) 1 reagent box

iii) Package inserts

iv) Disposable pipette

Trueprep® AUTO v2 Universal Cartridge-Based Sample Prep Device

This is the device in which the cartridges are inserted for nucleic acid extraction. They are of two types: **AUTO and AUTOV2**

The kit consists of:

Trueprep® AUTO Universal Cartridge-Based Sample Prep Kit

Dropper

cartridge

Carton

Reagent pack

Wash buffer A

Wash buffer B

Elution buffer

Priming waste

2. Buffer and reagent preparation section

The buffers are required for the extraction and purification of the nucleic acids. There are 4 main products produced:

- USPT (Universal lysis buffer)
- MSPT (MTB lysis buffer)
- ATM (transport medium)
- Stabylize

There are 2 types of **lysis buffers: MSPT and USPT**. MSPT is used for MTB (tuberculosis) sputum samples only while USPT is used for all the other samples except sputum. Only the MSPT buffers are provided with a **glass bead** and a separate **liquefaction buffer** which helps in thinning the thick sputum sample so that they can be easily pipetted. The liquefaction buffer also helps in dissociating the bacterial colonies in case of MTB.

The **ATM is the transport medium** required for **swab samples**. Once swab samples are collected, they are dipped into USPT lysis buffer.

The **stabylize prep free** consists of the **collection and lysis medium**. This was used for COVID-19 testings which did not require the need of the Trueprep device for extraction, therefore, helping to give the results quicker.

Preparation of buffers

Overhead stirrers are used to mix the buffers stored in large tanks (500 liters). Here the pH is constantly maintained. A small amount of the prepared buffers is given for QC testing. Once approved, the buffers are filled in bottles. For buffer preparation, ultra-pure water is used.

Filling of buffers

From the vendors, the bottles are first washed using UP (ultra-pure) water and kept at 80^0 C to remove contamination. QA (Quality Assurance) approval is required for starting the filling process.

- For the lysis buffer, 2.5ml of USPT, as well as MSPT, are filled in each bottle. The filling is done using an automatic 3-piece machine. The placement of the beads in MSPT as well as bungs are done manually.
- For the liquefaction buffer, the quantity depends on the number of tests i.e., 50, 20, or 25 test kits. The filling is achieved using a Liquefaction Buffer dispensing machine.

Kits	Quantity of liquefaction buffer
50 test kits	9ml
20 test kits	4ml
25 test kits	5ml

- About 1.5ml of Transport medium is filled in each bottle per test while about 0.5 ml of collection and lysis medium is filled for stabilyze prep free

Trueprep® AUTO Transport Medium for Swab Specimen Pack

Packing

There are 4 main pack size that are produced: 5, 20, 25 and 50 Pack size. Therefore, the 5 test will have 5 buffers provided, the 20 test will 20 buffers and so on. The packaging of lysis buffers consists of:

- 1 carton
- One 5, 20,25 or 50 buffer fitment
- Pipettes (eg. For 25 test- 25 pipettes)
- Package insert (manual)

The buffers are shrinked wrapped in the buffer fitment to prevent them from falling. The carton consists of a certified and external label which consists of their branch details. Any problems regarding the product that has been encountered can be discussed with the branch via the label. For QC testing, for 5 kits, 3 kits are given while for other kits only 1 is given.

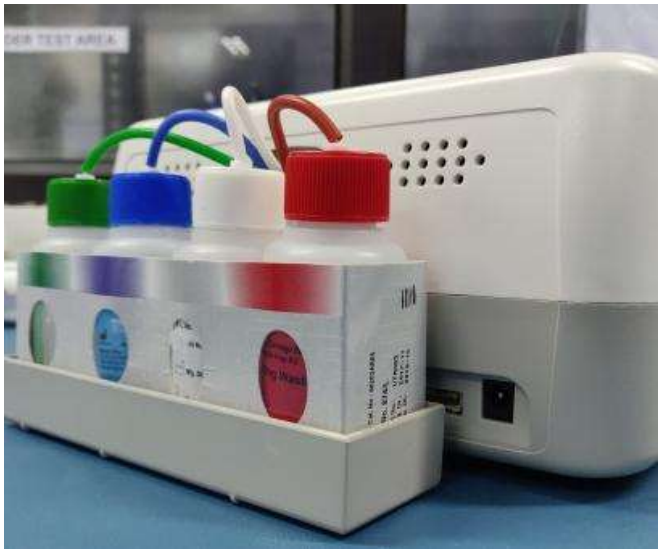
ATM are also manufactured with 4 pack size while stabilyze prep-free only has 50 test kits produced. Stabilyze kit is also provided with throat and nose swab.

Reagent preparation section

Since there are 2 types of devices AUTO and AUTO V2 used for sample extraction, they are provided with reagents prepared separately with the latter packaged in large transparent pouches while the former is provided with reagents filled in bottles.

- **Universal test AUTO reagents:** Consists of:
    - Wash A (green cap)
    - Wash B (blue cap)
    - Elution buffer (white cap)
    - Priming waste (should be empty)

These reagents are filled in the laminar air flow using a semi-automatic **Peristaltic pump.**



Universal AUTO reagents

- **Universal AUTO V2 reagents**

Also consists of: Wash A, B, elution buffer and priming waste. The reagents are filled in transparent pouches using a **reagent filling machine**. The volume of the buffer to

be filled in each of the packets is set directly by the machines. The entire process involves 4 steps:

i. **Vacuuming** (30 seconds): Sucks the air out of the pouches.
ii. **Priming** (15 seconds): involves collection of the buffer in the machine
iii. **Dispensing** (90 seconds): filling of the pouches
iv. **Air filling** (30 seconds): all the remaining remnants are filled in the pouches.

Priming waste bottle is given a **pinhole.** The pinhole is required to pump out the air that enters the priming waste bottle along with the other waste. After completing the filling process, the pouches are weighed to check for any errors and to know if the dispensing was proper.

Packing

All the 3 reagents along with the empty priming waste is packaged into one carton. The box also consists of a switch that is used to plug the reagent box to the AUTO V2 device. The packaging involves:

- Seal label
- Packaging label
- QR code
- Switch sealed with parafilm

The entire box is then sealed with an outer plastic covering consisting of a reagent card. Every day, 4 kits are sent to QC for approval and lot printing. Once Lot details are approved from QC, the labelling of the buffers is carried out using **Automatic Self-Adhesive Vertical Stickers.** In case of ATM, **Automatic self-rotary stickers** Labelling machine is used. For the reagent pouches, label printing is done by vendors.

Trueprep® AUTO v2 Universal Cartridge-Based Sample Prep Kit

2.2 Truemix section

Mastermix preparation and filling

Master mix contents

- Taq polymerase
- Code UNG (Uracil N-glycosylase)
- RNAse inhibitors
- Buffers (5 types): K40, K50, K80
- dUTPs, dCTPs, dATPs, dGTPs
- Primers
- Probes
- 40% trehalose
- Double distilled water

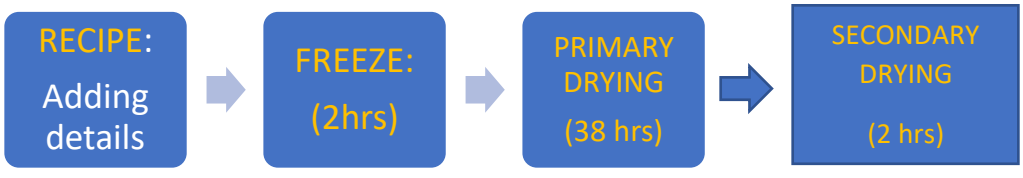
After the preparation of the master mix, the vials are wrapped in the aluminium foil to avoid any contact with light since the probes are light sensitive. Once QC approved, the

master mix is dispensed and the bungs are placed. This is then carried to the lyophilization room.

Lyophilization room

- First the lyophilization machines are allowed to cool down at -46^0 C.
- Master mix preparation is started.
- 8-10 block trays are cooled in the lyophilizer for 2 hours.
- Cooled trays are taken to the master mix preparation room and filled.
- Bungs are loosely placed on the master mix tubes and the trays are kept back into the lyophilizer.
- There are 4 temperature probes present in the machine: 1,2,3,4. The shelves in the lyophilizer contains silicon oil which should be at a temperature of -46^0 C.
- In order to exactly know the temperature inside, probe 1 is placed in the master mix, probe 2 is placed on the tray blocks, 3 and 4 are placed on the shelf.
- They lyophilizer is closed and kept at -46^0 C for 42 hours. This helps to completely remove the moisture from the master mix thereby solidifying it.
- Bungs of the master mix tubes are tightened by the vial stoppering present in the machine itself

Operation of the lyophilizer consists of the following steps:



2.3. Truenat section

The chips procured from the vendors are first sent for QC testing. Once the chip meets the given acceptance criteria it is approved and a desired amount of chips is issued from the stores.

- **Washing, Drying and UV treatment of chips**

About 240 chips are arranged on a blank tray either manually or an automatic chip pick and place machine. The washing of the chips is carried out by the **PCB Air dry system conveyer.**

- First the chips are washed using **ultra-pure water** which is then reused. Later, the chips are dried using air pressure affixed to the machine itself.
- Furthermore, chips are also washed with **electronically deionized water** followed by air pressure for drying.

The chips are dried in the hot air oven at 80^0 C for 20 minutes after which they are checked for any dirt and sorted manually. These chips undergo UV treatment in the UV chamber for 20 minutes after which they are cleaned and transferred to coat dispenser.

- **MG filling room**

The chips are coated with BSA coat and the hydrophilic coat via the Biodot Reagent dispensing machine. The dispensing procedure is as follows:

A. 10ul of BSA is dispensed in each chip via Biodot reagent dispensing machine.
B. 40 trays are used to coat the chips.
C. Chips are dried using the vacuum dryer for 1 hour
D. QA clearance required

E. Second coat of 10ul BSA and 6ul hydrophilic coat applied and dried in the vacuum cabinet.

Polymer filling room

Here, paraffin wax is dispensed in each chip via the biodot wax dispensing machine. The wax is later dried using the dryer to get a concave shape.

Chip sorting

The LTCC wells on the chips are checked if they have wax that is too low or high or have any bubbles or particles present. Such chips are rejected.

Sample inversion

This is done to check the quality of the chips. Here, the chips are placed in an inversion device. Then, 6ul of the solution is added to the ceramic well of the chip. Once the chip is fixed into the inversion device, click on start button. As the temperature in the device increases, it causes the wax to melt pushing the sample inside while the wax will come to the top forming a dome. This prevents the sample from evaporating.

Flash writing room

Here, the memory card of the chip is provided with the expiry date, disease-specificity etc.

- After sorting the chips about 240 chips are loaded in the loading station
- Fill in all the required details in the set-up.
- Whatever is included in the set-up (expiry date, etc) will be fed onto the memory card of the chip by pogo pins.

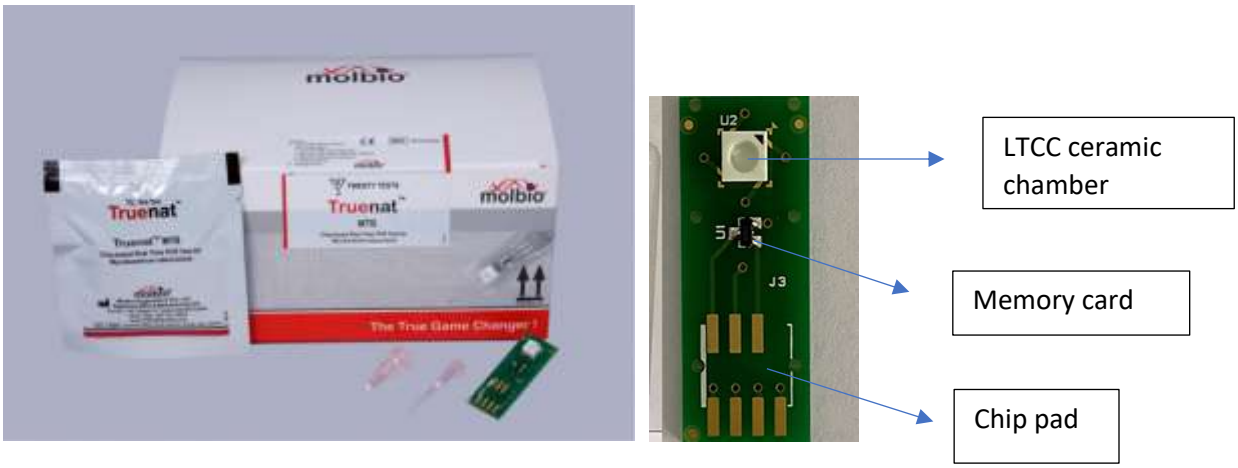
Pouching

After flash writing and QA verification, the chips are pouched. The pouch consists of a :

- Master mix tube
- 1 chip (which is disease-specific)
- A micropipette tip
- Silica

The package is sealed at 250± 5 ^{0}C. The pouch consists of the chip ID, disease specificity, IVD (in-vitro diagnosis), temperature etc on the front side while at the back, lot number, expiry date, manufacture date, chip number etc are printed.

After pouching and QA clearance, the pouches are sent to be packaged in cartons. Details such as date, generic name, brand, quantity etc are printed on the cartons. They can be of different pack sizes i.e., 5 test, 20 test, 25 test or 50 test. The cartons also have MRP and SET number printed on them and not on the pouches. The ones exported outside do not have MRP mentioned on the carton while the ones sold in India itself have the MRP mentioned. The finished product is then sent to QC for approval which is then verified by QA and If approved, it is dispatched.



Truenat® kit

3. QUALITY CONTROL

Any product or service defines and speaks for the company or brand that creates it. This is exactly why there is a need for perfection for a product, from the manufacturing phase to the outcome phase. In order to achieve that perfect quality, every organization should adopt a quality control plan and strategy. This is crucial and requires continuous reviewing and efforts. After all, the quality of the product ultimately decides its place in the market, in the long run.

What is Quality control?

Quality control is the process by which products/services are tested and measured to ensure they meet a standard. Through this process, a business can evaluate, maintain, and improve product quality. Ultimately, there are two crucial goals of quality control:

- To ensure that products are as uniform as possible
- To minimize errors and inconsistencies within them.

How is it done?

Quality testing is a part of every stage of a manufacturing or business process. Here, samples are frequently collected and tested from the production line, finished products, and raw materials. Testing during various production phases can help identify the cause of a production problem and the necessary corrective actions to prevent it from happening again.

What is the benefit?

Quality control measures can help to protect the reputation of a company and prevent its products from being unreliable, thereby increasing trust on the side of consumers. Moreover, quality control is necessary because it ensures that a company will look at evidence-based data and research and not just anecdotal observations to ensure that products are living up to their standard. One important aspect of quality control is that the entire process does not just occur once but it involves a routine evaluation to ensure that the product is meeting up to the company's standards.

Each stage of the QC testing involves:

- STP (standard testing procedures): these are specific to a particular product
- SOP (standard operating procedures): These are general procedures
- Acceptance criteria: this is set up for any raw materials obtained from the vendors. These materials are checked whether they meet up with the company's own acceptance criteria, if not, the raw materials are rejected.
- Checking the product specifications, which are unique to each product.

3.1. Incoming materials

The quality of the incoming raw materials needs to be tested and checked if they meet up to the company's set '**acceptance criteria'**. The purpose is to identify any defects prior

to placing the material in the inventory or moving it to the production flow. Every packaging and raw materials have to be tested by QC before producing in bulk.

Testing incoming packaging materials and raw materials

- The materials that come from the vendors to the stores are initially dedusted, the amount is verified, weight is checked and they are then kept in the quarantine room.

- The incoming materials are pouches, reagent and buffer bottles, bungs, cartons etc. An intimation form is then filled by the store as well as QC and a batch of the incoming material is sent to QC for testing

- Then a sampling advice is given from the store to QC wherein all the details in the sampling advice such as material, material no., name of manufacturer, invoice no., date, GRN No, quantity received, batch no., Mfg date, Exp. Date etc needs to be cross checked.

- These materials undergoing QC testing are labelled using **'Under testing label'**. These labels are printed by the QC and put by the store.

- The incoming materials such as labels or cartons are checked for various parameters like proper measurements, artwork, printing, overprinting etc. Here the sales and marketing make the artwork of the labels which is then sent to the store. The store initiates a purchase order to the vendors who print the labels according to the provided details and alignment. The artwork is again sent to QC for testing. Once approved, a hard copy is sent to QC.

- Materials like bottles and cartons are tested for cometic defects, dimensions, printed defects, leak test and check if their bungs and caps meet the acceptance criteria set up by the company.

- After testing the raw materials an **analytical report (AR)** is made of all the specifications of the raw materials tested. If they don't fall under the acceptance criteria, materials are rejected by labelling them as **'out of specification'**. If the materials are approved, then affix '**APPROVED**' and they are moved to the AMD warehouse while if they are rejected, then affix '**REJECTED**' label and they are moved to the NMD warehouse.

Primers and Probes

All the raw materials i.e., probes and primers must be tested for their physical performance and also for other components such as MgCl2, BSA etc. Three main probes are produced: FAM, ATTO647 and ATTO0565.

Probes are Primers are tested by:

- UV-Visible spectrophotometer: check concentration
- PAGE
- Probe check
- Performance

The **concentration** is tested using 1:100 dilutions using TE buffer. In this test:

- 10ul of probe + 900 ul of TE buffer is taken

- This is done in triplets
- Later an average is taken and the concentration is calculated. The range of accepted probe concentration should be above 70%.

PAGE is used to check if the probes/primers are proper or not. In this procedure:

- 2ul of primer/Probe + 8ul of formamide loading dye is added
- Heated for 2mins at 95^0 C
- Cooled for 1 min
- Load 10 ul in the Gel
- After the run, electrophoresis is done for 45 mins and staining is done using methylene blue. A single crisp band should be obtained in the results.

Probe check is done using a Truelab® Uno DX-Probe checking device and it **involves** the following procedure:

- 6ul of probe + 8ul of mineral oil
- Run the test
- Plot
- Check the run (if the signal is between 5-5.8 V, its approved)

Performance test: here the amplification is tested using the master mix.

3.2. Testing of in-process materials

This involves routine checks that are performed during production. The tests are performed to check if the established product meets the company's standards.

Leak test Apparatus

As mentioned above, the incoming bottles and pouches have to be tested if they have any defects which leads to leakage. This is carried out by the **leak test apparatus**.

The leak test apparatus consists of a **separator.** Below the separator is filled with **methylene blue** in which pouches are dipped to check for any leaks. A maximum of 20 truenat and 5 cartridge pouches can be tested at a time. The leak test of bottles are carried out in the following manner:

- Initially a blotting paper is placed on top of the separator.
- The bottles are tested by placing them above the separator.
- Make sure that the valve near the desiccator has the arrow facing the desiccator.
- Connect the apparatus and switch on the MAINS. A vacuum will be created inside
- When the pressure reaches -15 Hg the vacuum valve must be tightened to maintain the pressure at that value.
- Run the test for 20 mins.
- Once test completed, release both the valves.

Microprocessor leak test apparatus

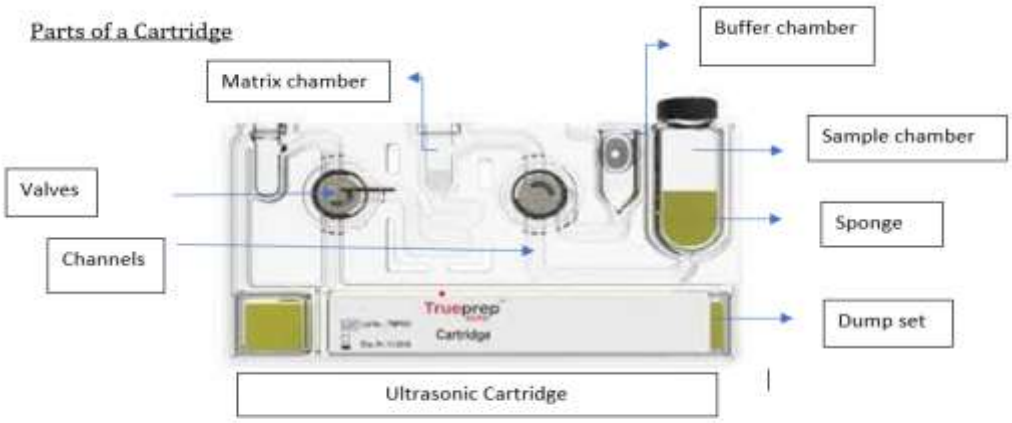
Unlike the usual leak test apparatus, this is automatic and does not need to frequently set up the time or pressure. There is no vacuum valve present.

Testing of Chips

The chips from the vendors are segregated into batches of 350 chips. These chips are analyzed for:

- Physical parameters: Like if the placement of LTCC, flash writing memory, and chip pad are placed properly and even if the edges are smooth or not.
- Fitting test: it is carried out to check if the chip fits in the device
- Chip resistance: the chip resistance is cross-checked by a multimeter and the reading should not exceed more than 14.9
- A vernier caliber is used to measure the length and breadth.
- Amaranth dye is also added to the LTCC to check if it absorbs the dye. LTCC is used as it cools and heats quickly.

Rapid testing room: Testing of Trueprep® Products



Working of cartridge

- About 0.5ml of sample along with the 2.5ml of lysis buffer is added into the **sample chamber**. The chambers consist of a filter i.e., is a sponge.
- There are 2 **valves** present that rotate depending which part of the cartridge is functioning. These valves consist of a red colour component called as **smiley.**
- From the sample chamber, the sample moves towards the **buffer chamber**. Here the sample is washed off using wash buffer A and B to remove any PCR inhibitors.
- From here, the sample moves into the **matrix chamber** which consists of a matrix made of **cellulose**. The pore size of the matrix enables the viral and bacterial particles to get trapped.
- This is then further eluted into the **elution chamber** wherein, 1.5ml of elute is collected.
- There is aluminum foil placed to cover the elute and matrix chambers. All the waste moves into the **dump set.**

WORK DONE: The various tests carried out for cartridges:

- Physical defects
- Fitting test
- QR Code
- Jig-test
- Leak test
- Performance test

QR code and jig test

The QR code on the cartridge is printed by the vendors and it talks about all the different specifications such as vendor code, serial number, line number, etc. This QR code is then recorded on the excel sheet using QR Code Jig Machine.

- Place the cartridge in the jig machine
- The machine reads QR Code
- Checks if the valves rotate
- Pressure will be passed through to check if there is any leakage.
- Detects any kind of leakage in the elution chamber or in channels
- Failed and passed cartridges QR code details will be recorded.

Any **physical defects** will be detected manually. The rejected cartridges will undergo further leak tests to find the errors by using buffers.

Fitting test

Cartridges should be properly fitted into the cartridge tray of the Trueprep® AUTO/ AUTO V2 device.

Leak and performance tests

The cartridges are divided into batches. From each batch, about 10 cartridges are sent for leak and performance tests. The extraction of the nucleic acids is carried out in the **extraction room** using the following procedure

- 0.5ml of sample is added to either universal or MTB lysis buffer using a disposable pipette.
- This is properly mixed and added to the sample chamber.
- Close the chamber with a cap and discard the empty bottles and used pipette.

- Place the cartridges onto the cartridge tray of the AUTO/ AUTO V2 device.
- Prior to starting the device, check if the reagent pack is filled and the priming waste is empty.
- Start the device. The AUTO device takes 40 mins while the AUTO V2 device takes 45 mins to complete as it initially also reads the QR code.
- Once the elute is extracted, the cartridge tray will be ejected.
- Remove the cartridge and set the micropipette to 1.5 ml to collect the elute (1.5 ml is the amount of elute collected in the elute chamber). The elute is collected in the elute collection tube and labeled.

In the case of the performance and leak test of cartridges, once elute is collected, adjust the micropipette to remove the bubbles and reduce the errors. The elute collected is then recorded in the book. The accepted range is 1.2-1.5ml. Methylene blue is then added to the empty elute chamber and kept for 1 minute to check for any leakage. Also, during the extraction process, if the cartridge shows any errors, they are also recorded in the book.

Adding the cartridge to the cartridge tray

PCR room: loading of samples

Once the elute is extracted, it is loaded in the PCR room. The general procedure is as follows:

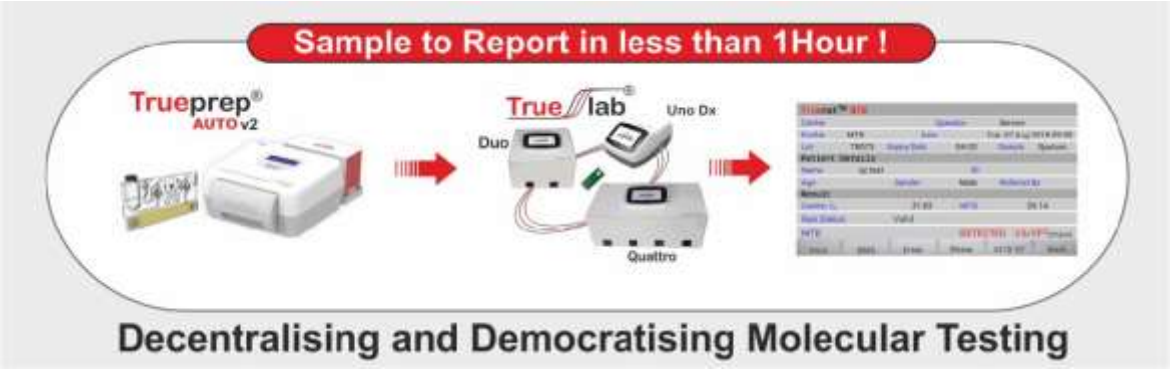
- The chip is placed in either Truelab® UNO Dx, Duo, QUATTRO, or 4X4 Real Time Quantitative micro–PCR Analyzer.
- Place the chip in the chip tray, and add the details such as the disease type, patient ID, patient name, etc.
- Simultaneously add 6ul of elute into the master mix tube and wait for it to dissolve.
- Add 6ul of the elute into the LTCC chamber, close the tray and run the test.
- Depending on whether the target sequence is RNA or DNA, the test will take 45 and 40 mins respectively. The extra time for RNA is due to the reverse transcription to form cDNA.

Once the run is completed, check for the results. If the test is successful, the report will show VALID; if there were any errors, it will show INVALID. If the samples added were negative, the Ct value of the control was recorded while in the case of positive samples, Ct values of both the control and sample are recorded.

Only during the extraction of swap samples eg. Of COVID 19

- First, a throat/nose swab is used to collect the sample
- This swab sample is added into the transport medium first
- 0.5 ml of this is then added to the USPT buffer.

The remaining procedure is the same as mentioned above.



WORK DONE

- **Checking of old and modified reagent buffer**

The modified elution buffer performance was checked using approved wash buffers A and B. Here samples were loaded in the cartridges and extracted. The elutes were then amplified using Real-time PCR.

- **Validation of IC (Internal control)**

The IC is the internal control that undergoes all the processes the specimen undergoes from extraction to amplification to result thereby validifying the results. The IC can be of two types: endogenous and exogenous. Here, the IC volume is validified to check which volume gives the best results.

Stability room

Stability testing provides evidence for the claim on how the quality of the product varies with time under the influence of environmental factors such as temperature, humidity, light, etc. Stability testing helps to establish a shelf life as well as recommended storage conditions for the products. Here, the products are placed in different temperatures such as 45^0 C, 40^0C, 2-8^0 C, room temperature, or 30^0 C to check if the performance of the product is altered. Secondly, the products are also subjected to either pressure or shocks that could be experienced during shipping after which their performance is tested.

WORK DONE

The stability of the lysis buffer was checked by observing for any precipitate present on the lysis bottles subjected to different temperatures.

CONCLUSION

Molbio offers a 'global first' platform that can perform Molecular Diagnostics for infectious diseases at the point of care using the ‘Truelab Real Time Quantitative micro–PCR System”. This is a compact battery-operated system that is much more affordable and portable. It has a single testing capability and provides a sample result within 1 hour making the system even more valuable by helping and preventing the spread of diseases by ensuring immediate reporting of results in emergency cases. This company looks forward to transforming healthcare practices for betterment by providing near-care diagnostics solutions using robust portable platforms.