INTERNSHIP REPORT

MolBio Diagnostics Pvt. Ltd.

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Department of Zoology

School of Biological Sciences and Biotechnology

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INTRODUCTION

The Internship course under Laboratory Course on Life Processes was carried out at MolBio Diagnostics Pvt. Ltd, Verna Goa for a period of 1 month starting from 1st December through to 31st December. MolBio Diagnostics is a medical equipments and diagnostic tools manufacturing company located in Verna, Goa, India with its Research and Development branch being in Bangalore, India. Mr. Sriram Natarajan, a technocrat, is founder Director and Chief Executive Officer of Molbio Diagnostics Pvt. Ltd. He holds M.Sc, M.Phil. degrees, has four years of academic research experience and 34 years of experience in developing, manufacturing and marketing of Diagnostic devices and kits, catering to worldwide markets in both the private and the public sector.

Image 1: MolBio Diagnostics Pvt. Ltd. Verna, Goa, India

Bigtec Labs is a Bangalore (India) based, technocrat-entrepreneur driven, Patent & IP focused Product innovation Company in the private sectors which provides the Research and Development for MolBio Diagnostics. Mr. Chandrasekhar Nair heads Bigtec labs and is Chief Technical Officer of Molbio Diagnostics. He has extensive experience in bioprocess modeling, scale up and commercial implementation of bio and chemical processes. Bigtec Labs use innovative techniques to create and bring together various academic disciplines under a common umbrella to develop game-changing/unique products in the area of diagnostics and resource limited settings worldwide. Bigtec has a proven track record of developing & commercializing novel medical devices. Bigtec has developed a portable and battery-operated micro-PCR system under the aegis of CSIR (NMITLI) that has since been

extensively validated (under DBT & ICMR). Bigtec has also developed various tests and nucleic acid preparation devices to facilitate "sample to result" molecular diagnostics in resource limited settings.

Image 2: Bigtec Labs, Bengaluru, India

MolBio Diagnostics is driven by their missions of:

- 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 best health care through cutting edge technologies
- To stay connected to the needs of the patient through constant engagement with all stake holders

Their vision is to:

- To transform healthcare practices by providing near-care diagnostic solutions using robust portable platforms
- To enable decentralisation and democratisation of diagnostics through 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

The company works on values like:

- Collaborative Innovation
- Driven by Passion and Compassion
- Designing for Global Use
- Delivering Excellence
- Remaining Socially Conscious
- Being Transparent and Truthful
- Building Relationships on Trust
- Engaging with Courage and Conviction as well as customer satisfaction

MolBio Diagnostics has an ic^3 motto which involves:

- Independent Care: Diagnostics independent of extensive lab Infrastructure
- Continuous Care: Diagnose and Treat on the first visit and monitor treatment outcome
- Cost Effective Care: Gold standard testing at affordable level
- Connected Care: Identify disease Hotspots, new needs and providing solutions.

PRODUCTS OF MOLBIO DIAGNOSTICS

1. Truelab® Uno Dx Real Time Quantitative micro PCR Analyzer

Fully automatic Real time Quantitative micro PCR analyzer, three wavelength system, performs 10-12 tests in 8 hours. It is based on patented real time micro PCR. Its key features include: -Battery Operated

- Portable
- Runs on any Truenat Chip
- Completely Randomized Operation
- Performs 10-12 Tests in 8 Hours
- Three Wavelength System
- Fully Automatic

2. Truelab® Duo Real Time Quantitative micro PCR Analyzer

Fully automatic Real time Quantitative micro PCR analyzer, two channel-three wavelength system, performs 20-24 tests in 8 hours. Its key features include:-Fully Automatic

-Three Wavelength System
- Performs 20-24 Tests in 8 Hours
-Completely Randomized Operation
-Runs on any Truenat Chip
-Portable
-Battery Operated

3. Truelab® Quattro Real Time Quantitative micro PCR Analyzer

Fully automatic Real time Quantitative micro PCR analyzer, Four channel-three wavelength system, performs 40-48 tests in 8 hours. Its key features include: - Fully Automatic

- Three Wavelength System
- Performs 40-48 Tests in 8 Hours
- Completely Randomized Operation
- Runs on any Truenat Chip
- Portable
- Battery Operated

4. Trueprep® AUTO v2 Universal Cartridge Based Sample Prep Device

Fully automatic sample prep device works in tandem with Trueprep AUTO cartridge and Trueprep AUTO v2 Reagent Kits for extraction and purification of nucleic acids from clinical specimen. Its key features include: - Fully Automatic

- Cartridge Based
- Works with Multiple Sample Types
- DNA/RNA Extraction in ~20 Minutes
- Proprietary Matrix Based Extraction
- High Purity and Efficiency
- Point-of-Care
- Portable
- Battery Operated

5. Truelab® micro PCR Printer

Bluetooth Printer, prints wirelessly the results of the PCR tests performed by Truelab Uno Dx/Duo/Quattro Real Time Quantitative micro PCR Analyzer. Its key features include:

- Easy paper loading
- Dust tolerant
- Vibration resistant
- Compact & Rugged
- Mains/Rechargeable Battery operated
- Bluetooth and USB compatible for connecting to the Truelab Analyzer
- Portable

6. Trueprep® AUTO Universal Cartridge Based Sample Prep Kit

It is a sample preparation kit for nucleic acid extraction on Trueprep AUTO. Trueprep AUTO Universal Cartridge Based Sample Prep Kit works with Trueprep AUTO Universal Cartridge Based Sample Prep Device and is used for extraction and purification of nucleic acids from a wide range of biological specimens. It enables extraction of nucleic acids in 20 minutes and has storage stability of two years when stored at 2^{o} to 40^{o} C. its key features include:

- Cartridge based
- Composite and complete reagent pack
- Cartridge with pre-loaded Internal Positive Control (IPC) that validating the analysis from sample to result

It comes in 5 tests and 25 tests boxes.

7. Truenat®

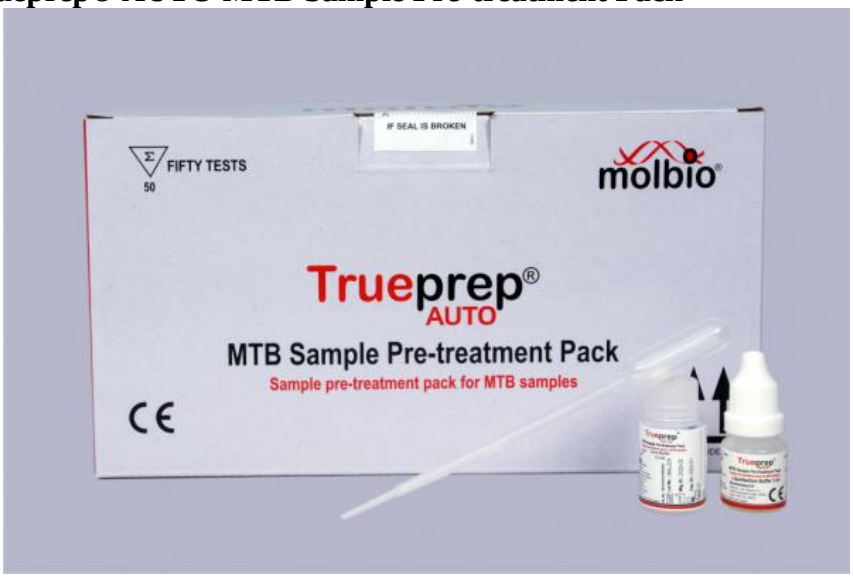
These are disease specific Real Time micro PCR Tests. The micro PCR Chips are pre-loaded, ready-to-use and disposable. They are disease-specific and can be run on the Truelab® Uno Dx/Duo/Quattro to get a quantitative real-time PCR results. These Truenat chips are enable PCR to be carried out within 35-45 minutes on a chip based PCR device. These are available for the following diseases:

- MTB
- Dengue
- Chikungunya
- H1N1
- HIV
- Salmonella
- Influenza A
- Covid 19
- NG
- CT
- Rabies
- Nipah
- LTS
- Shigella
- HCV
- HIV 1

- GBS
- Malaria
- HAV
- HEV and many others

These have a stability of two years when stored at temperature of 20^{o} to 30^{o} C. These come in 5 tests, 20 tests, 25 tests and 50 tests boxes.

8. Trueprep® AUTO MTB Sample Pre-treatment Pack

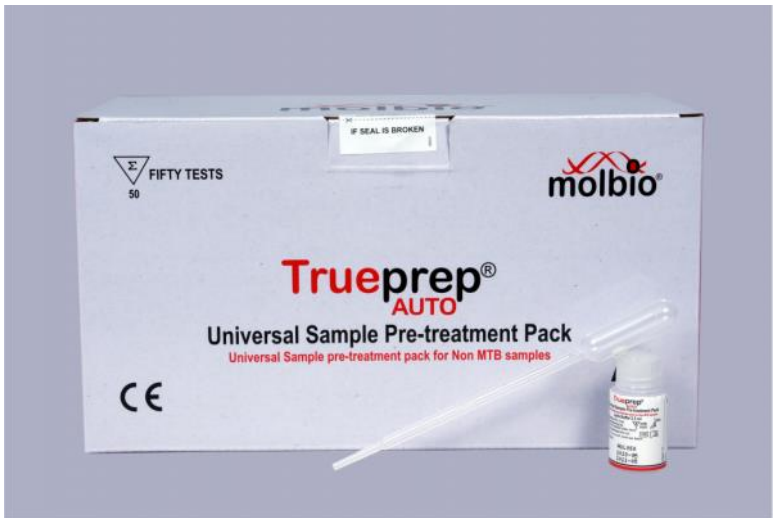


It is a sample pre-treatment pack for MTB samples. It is used to liquefy and pretreat the pulmonary and EPTB specimen before proceeding for extraction and purification of nucleic acids using Trueprep AUTO Universal Cartridge Based Sample Prep Kit and Trueprep AUTO Universal Cartridge Based Sample Prep Device. Its key features are:

- Composite and complete reagent pack
- Compact kit size

It has a storage and usage stability of two years when stored at temperatures between 2^{o} to 40^{o} C. it comes in 5 tests and 20 tests boxes.

9. Trueprep® AUTO Universal Sample Pre-treatment Pack



It is Universal Sample pre-treatment pack for Non MTB samples like plasma. It is used to pre-treat the samples such as whole blood/ serum/ plasma/ urine/stool/swab specimen before proceeding for extraction and purification of nucleic acids using Trueprep AUTO Universal Cartridge Based Sample Prep Kit and Trueprep AUTO Universal Cartridge Based Sample Prep Device. Sample Pre-treatment decontaminates the specimen and makes it ready for storage/ transportation/ extraction. Its key features are: - Composite and complete reagent pack

- Compact kit size.

It is available in 5 tests and 20 tests packs and has a storage stability of two years when stored at 2^{o} to 40^{o}C.

10. Truemix™ COVID -19

It is a Real Time Duplex PCR Test for COVID -19. It is a lyophilized, ready-to-use, open format, duplex Real Time Reverse Transcription Polymerase Chain Reaction (RT PCR) test for the qualitative detection of SARS CoV-2 RNA in human oropharyngeal and nasopharyngeal swabs and aids in the diagnosis of COVID-19. The test detects the E and Orf1a genes of the virus. Truemix COVID-19 runs on standard Real Time PCR analyzers. It enables testing for Covid 19 to take place in less than an hour. Its key features include:

· Assay based on Taqman chemistry

· lyophilized, ready-to-use, open format

· Simple, one step procedure. Built in process control

· Proprietary formulated RT-PCR components.

· Dried down, ready to use positive control included in the kit

· Packed as 8 tube strips, highly flexible for sample load. No wastage of reagents

· Built in amplicon cleavage mechanism. Minimal risk of amplicon contamination

It is commercially available in 8 tests, 24 tests, 48 tests and 96 tests packs and has a storage stability of two years when stored at 2^{o} to 30^{o} C.

11. Trueprep® AUTO Transport Medium for Swab Specimen Pack

It is a medium for Collection, Decontamination and Transport of Swab Specimen. It is intended for use with clinician-collected endocervical, vaginal, anorectal, nasal and throat swab specimens. The transport media is used as a medium for collection, decontamination and transport of various types of swabs specimens before proceeding for pre-treatment using Lysis buffer, extraction and purification of nucleic acids using Trueprep Universal Cartridge

Based Sample Prep Kit and Trueprep Universal Cartridge Based Sample Prep Device. The transport medium will keep the nucleic acids of the respective organism intact thus maintaining the integrity of the nucleic acids. The medium does not maintain the viability of the microorganism. The collection and transport medium ensures for the safe collection and transport of the microorganisms which includes bacteria and viruses from the site of collection to the testing centre. Its key features are:

- Composite and complete reagent pack
- Compact kit size.

It comes in 5 tests and 20 tests packs and has a storage and usage stability of two years when stored at 2^{o} to 40^{o} C.

12. STABILYSE® Prep Free

It is a sample Collection and Lysis Medium for Prep Free Swab Specimen.
It is used fors ample collection and has a lysis medium for oropharyngeal and nasopharyngeal swab specimens. Its key features include: -Prep-free protocol

-Simple workflow

-Rapid turnaround

-Minimal biosafety and biosecurity requirement

-Flexibility with throughput

-Ready to use room temperature stable reagents

-Single testing capability

-Small footprint

-Minimal training

It is commercially available in 5 tests, 25 tests and 50 tests packs. It has a storage and usage stability of two years when stored at temperatures between 2^{o} to 40^{o} C.

DEPARTMENTS AND PRODUCTION

A brief description of some the major departments present at MolBio Diagnostics and their role and functions is as follows:

1. **Quality Control**:

Quality control (QC) is a procedure or set of procedures intended to ensure that a manufactured product or performed service adheres to a defined set of quality criteria or meets the requirements of the client or customer. The main objective of quality control in the Pharmaceutical Industry is to test the drugs and diagnostic kits and tools in their various stages of production, verifying that they are able to proceed to the next stage and release the manufacturing process in accordance with the regulations and specifications required for their usage and consumption.

In order to implement an effective QC program, an enterprise or the company must first decide which specific standards the product or service must meet like the ISO standards. Then the extent of QC actions must be determined -- for example, the percentage of units to be tested from each lot. Next, real-world data must be collected -- such as the percentage of units that fail -- and the results reported to management personnel. After this, corrective action must be decided upon and undertaken.

For example, defective units must be repaired or rejected, and poor service repeated at no charge until the customer is satisfied. If too many unit failures or instances of poor service occur, a plan must be devised to improve the production or service process; then that plan must be put into action followed by which the QC process must be ongoing to ensure that remedial efforts, if required, have produced satisfactory results and to immediately detect recurrences or new instances of trouble.

2. Quality Assurance/Assessment:

Quality Assurance or Quality Assessment (QA) is any systematic process of determining whether a product or service meets specified requirements. The Quality Assurance department then establishes and maintains set requirements for developing or manufacturing reliable products. A quality assurance system is meant to increase customer confidence and a company's credibility, while also improving work processes and efficiency, as it enables a company to better compete with others.

The ISO (International Organization for Standardization) is a driving force behind QA practices and mapping the processes used to implement QA. Many companies use ISO recommended standards to ensure that their quality assurance system is in place and effective. The concept of QA as a formalized practice started in the manufacturing industry, and it has since spread to most industries, including software development.

Quality assurance helps a company create products and services that meet the needs, expectations and requirements of customers. It yields high-quality product offerings that build trust and loyalty with customers. The standards and procedures defined by a quality assurance program help prevent product defects before they arise.

3. Validation:

Validation is the procedure which authorizing documentary evidences that prove, the following process/ method or activity will consistently produce the product which leads to the expected result or the predetermined requirements. The validation department in pharmaceutical industries involves looking into and monitoring various components which are related to processing, cleaning, facilities, equipment, or instrumentation. The Validation department comes up with and designs process validation which might include stages of process design, identification of process variables, control strategy, process qualification, process monitoring and process improvement.

4. Sales and Marketing:

This department is responsible for managing the sales of the various products that the company produces and looks after the marketing of these products. They devise plans and strategies to advertise their products as well as keep track of how many products have been sold in a fiscal year, based on which they can then make modifications to their marketing strategies. Representatives from this department are employed by pharmaceutical manufacturers and distributors to inform and educate doctors, physicians, surgeons, pathologists, etc about their products in the rapidly advancing pharmaceutical industry. These representatives rely on their interpersonal skills and knowledge of the products to sell to providers and influence them to prescribe the drugs to their patients.

PRODUCTION:

The production facility of MolBio Diagnostics has 2 keys sections- **Truenat** and **Trueprep**

Truenat:

Truenat section involves production of the disease specific chips and their packaging. The Truenat consists of a disease specific chip, a mastermix vial, a pipette tip and a silica pouch to avoid moisture.

The process of Truenat production involves:

● Mastermix preparation and documentation- this involves preparation of the mastermix that comes along with the Truenat pouches. It consists of all the materials like primers, probes, etc that help in the PCR process. Various types of buffers are also prepared and tested. Performance testing of new products along with pre batch testing of the mastermix is carried out. Line checking and Quality assurance is done at this step. The buffers are stored at low temperatures in cool chains while master mix heads on to next step of production.
●Lyophillization- this step essentially means to take out all the water or moisture from a substance by applying low temperature and high pressure. The mastermix is lyophillized in a lyophillizer which takes out all the moisture from the mastermix. The lyophillizer can lyophillize roughly 26,880 tubes in 42 hours. The entire process of lyophillization is fully automated using lyometer software with various cycles set up for cooling, drying, pressure application, etc. The entire process is constantly monitored with hourly inspection and documentation of activity. The tubes are also fit tightly with the stoppers or bungs by pressure at this stage.
●Chip Assembly and Washing- this step involves obtaining chips from vendors, line clearance and QC approval followed by chip assembly on large trays. The chip arrangement is automated after which the chips undergo thorough washing using Ultrapure Electron Deionized water. The chips are then dried in hot air oven and sterilized using UV treatment. The water is not wasted but is recycled. The chip conductivity is also tested at this stage and manual checking takes place to ensure no dust or unwanted fine particles.

●Coat dispensing- There are 2 major types of chip coats like hydrophilic coat which are dispensed by Biodot reagent dispensers followed by vacuum drying of the chips and finally clearance from QA.

●Polymer filling- in this room wax polymer is put on to the chips by automated wax dispensers. Polymer weight is determined before and after Polymer filling as a precaution. Once wax is dispensed the chips are subjected to pressurized air to smoothen it and to remove any bubbles.

●Chip sorting- the chips are manually checked at this stage for their density, Polymer filling, dust, etc. Each and every chip undergoes such painstaking manual checking to ensure quality is maintained.

●Flashwriting- The chips till this stage are common for all but the flash writing step gives it disease specificity. Computers with specialized software are set up along with loading and testing stations. These softwares are used to setup chip memory and information which is the flash written on to the chip pad. The chip trays are put on to the loading station after which flash writing of the information is carried out. There is also automated testing and chips which have not been flash written or are not functioning properly are automatically send to the rejection station. This step also involves manual verification of the entire process.

●Assembly- In this room the QA verifies the quality and quantity of the chips. Here the chips are packaged into pouches. Each Truenat pouch consists of 1 tube with 6 µl master mix, one disease specific chip, one filter tip or micropipette tip and a silica pouch which are neatly packed in sleeves before putting in the pouch case. The tips are sterilized and the silica gel pouches are activated before packing. The pouches are sealed, leak test is done, QC testing is performed and it then goes for packing into boxes.

● Printing and packing- The pouches for previous step of production need to be printed with information like disease, company name, specifications, storage, lot number, batch number, company contact details, price etc. Similar information is also printed on the boxes and cartons in house. The sealed and tested Truenat pouches and then packaged into boxes of different sizes which are based on number of tests like 5 tests, 20 tests, 25 tests and 50 tests. Once packaged, they are tested by QC and QA that eventually put approved label on approved lots which are then dispatched.

Trueprep:

The Trueprep section of the production facility involves:

●Reagent preparation- Various Reagents are required for the extraction and purification process of the nucleic acids. In an extraction kit there are Wash buffer A, Wash buffer B and elution buffer. These buffets are first prepared in small batches and their pH is checked followed by which they are send for QC approval. QC conducts its own tests on the buffer to check ph and working and then gives approval. Once approved, the buffer is then made on a large scale in big containers with overhead stirrers that help to mix the contents of the buffer evenly. Once the large batch is made, it is tested for ph again. Ultra Pure water is used to make these buffers.

●Reagent filling- here the various buffets are filled into bottles or pouches based on requirements and specifications. A three piece machine automates the entire filling process of the buffers into pouches and bottles. The filling process is streamlined via set timings for various cycles of filling, vacuuming, priming, air filling, etc. It takes the machine approximately 3 minutes to complete filling of one entire set of buffets as filling of buffer takes place simultaneously. The lysis and liquefaction buffets are filled into respective bottles via a peristaltic pump and involves manual filling.

●Packing and labelling- A wrapping machine puts printed labels on to bottles and pouches. Some labels are printed within the company facility itself while some are brought through vendors. QC approval is a key part of this step. Once the pouches and bottles are labeled, each pouch and bottle is manually checked to ensure all the details are printed correctly and in correct position and order.

●Pre packaging- There is a step of pre packing verification that is done before the pouches and bottles are packed in cartons. It involves in process QA sampling of the buffers and other reagents, their print etc. Once tested by QA and approved the pouches and bottles are filled into printed boxes or cartons. The test packs are put together which consist of buffers with fitment, droppers, pack insert, etc. Along with this the printing on the cartons or boxes is manually checked for price, lot number, etc. The reagents are filled according to number of tests like 5 test or 20 tests.

●Cartridge coating- There are 2 types of cartridges sold by MolBio Diagnostics which include Ultrasonic cartridges and Laser cartridges with the only difference being that laser

cartridges have laser welding. Both are however, equally efficient in the nucleic acid extraction procedure. In the cartridge coating section, cartridges that come from various vendors are placed neatly on trays. Some cartridges are then sent to QC for testing of physical defects and testing for working and leaks. Once a lot of cartridges gets approved, IC or internal control is manually dispensed in the sample chambers of the cartridges. This IC helps to validate the entire extraction procedure. The cartridges are then left for drying for about 24 hours.

- Cartridge sorting- All cartridges are checked manually once again for any holes, dusts, defects, whether the IC has been properly dispensed, etc. Along with this QR codes are also printed and stuck on the cartridges to help in identification of their lot number, batch number, etc.
- Cartridge pouching and labelling- In this section the cartridge pouches are printed with requisite information followed by which each cartridge is individually packed into the cartridge pouches. Each pouch is manually checked for any tears as well as printing information. Once checked and sealed, the pouches are packed into cartons or boxes which are printed and verified for specified details and information. In a box, along with specified number of cartridges, droppers and pack inserts are also put. There is QA approval which is taken again followed by which the final products are sent to dispatch.

WORK DONE IN QUALITY CONTROL (QC)

I was placed in the Quality Control (QC) department of MolBio Diagnostics. The QC is an integral department in the functioning of the company. This department is responsible for testing and verifying quality and functioning of raw materials as well as products in various stages of the production process. The QC further has different subsections which involve:

a) Incoming raw material testing- the new materials which come in from different vendors first need to pass testing by this section of the QC department to ensure quality is maintained. The entire QC department follows standardized SOPs (Standard Operating Procedures) and STPs (Standard Testing Procedures) for testing of all the raw materials right from bottles, bottle caps, pouches to printed cartons, bungs of bottles, weight and other physical parameters. N-sampling method is used to check the raw materials from a given lot. Dye leak tests are conducted on pouches and bottles to check for any leaks. Printed labels are checked for printed information, pattern, order, etc. any new material that has modifications need to be approved by QC before the company places order for its mass production. Lot printing is also job of the Incoming materials section. Once testing of a lot of materials is done, this section prepares an Analytical Report or AR and finally puts approved or rejected labels on the product cartons.

b) Instrumentation- This is where the chemical testing aspect of the raw materials as well as finished products is handled. All raw materials, chemicals, buffers, reagents, etc are tested here via techniques like PAGE, Leak test apparatus, spectrophotometry, pH meter, etc.

c) Rapid testing- this section is responsible for mainly checking the cartridges. Here the cartridges are put through manual as well as jig tests which enable to find any defects that might be present in the cartridges like any holes, leaks, proper working of the valves in the cartridge, presence of matrix, proper passage of reagents through it, etc.

d) Extraction and documentation- this section involves testing of cartridges for proper elution by subjecting the cartridges to the extraction process in the Auto and Auto V2 machines. Also, before PCR nucleic acid extractions are also performed in this section of the QC.

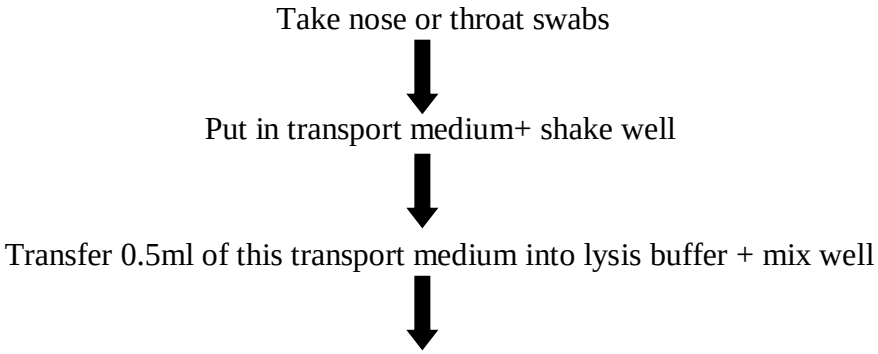
e) PCR- PCR stands for Polymerase Chain Reaction. It is a process for amplifying a given amount of nucleic acids. RT PCR involves component of Reverse transcription to amplify RNA in particular. MolBio Diagnostics produces machines and kits for

Real Time RT-PCR and PCR which enables not only amplification of RNA and DNA but also simultaneous quantification of these nucleic acids. Their Uno, Duo and Quattro machines via Truenat chips enable amplification and quantification of nucleic acids. In the PCR section checking of the functioning of Truenat chips or testing of biological samples, etc is done.

f) Sample storage- this essentially involves cold rooms dedicated to storing of various kinds of biological samples, elutes, etc.
g) Stability testing- before sending any product to the market, its stability has to be tested. Here, stability essentially means how long a product can be deemed fit for use without the product spoiling physically and chemically, what conditions are apt for proper functioning of the products, at what temperatures they can be stored, what is their expiry date, tolerable humidity levels, etc all such things are determined.
h) Control room- this room is a storage for all tested materials so that the company can continue monitoring their products even after they have gone to the market to ensure quality and safety standards are maintained.

In our first few days in the QC department we were allowed to read all the SOPs and STPs that the company and the QC department follow. We were shown around all the sections of QC as well as the Truenat and Trueprep production facilities where the designated Officers explained to us about each step of production and importance and functioning of each section of the facility. While in QC, we were made to follow the standard sanitation measures like wearing designated lab coats in production and QC departments, wearing head cap, separate footwear in production and QC, etc to ensure clean working conditions and to avoid any contamination.

We were shown the process of extraction and PCR and were allowed to do it for ourselves by taking a Swab based test for Covid-19. The procedure for the Swab test is as follows:



Transfer entire 3ml content of the lysis buffer + transport medium into sample chamber of a cartridge

Put cartridge for extraction in Auto or Auto V2 devices for extraction of nucleic acids.

Collect all of the elute

Put 6 µl of this elute into mastermix tube accompanying the Truenat chip for Covid 19 and mix

Load 6 µl of this mastermix solution on to the well in the Truenat chip

Load into Truelab PCR unit like Uno or Duo, fill in profile and patient details and start run.

The extraction process takes 20 minutes while the PCR process takes about 40 to 45 minutes. The results can then be viewed. The optical graph of PCR progression is also obtained.

Some of the work we were allowed to do as interns is as follows:

- Validation of IC using only buffers involving extraction.
- Any cartridge based extraction involving blanks and negative plasma samples.
- QR code scanning of the incoming cartridges in the QC before they go for physical tests.
- Working at the jig machine and manually checking for any defects in individual cartridges (physical test).
- Leak test to check for any leaks in the physical test approved cartridges and checking for elute quantity.
- Marking the level of reagents in buffer bottles and labeling them for dye leak test.
- PCR of blank samples or of negative plasma samples as part of IC Validation and modified buffer Validation.

● Stability testing involving checking of modified buffers at different temperatures like 2 to 8 degrees, 40 and 45 degrees. We had to check for any kind of precipitation or cloudiness of the product.

● Data entry of Validation results and some PCR related data entry.

CONCLUSION

The internship programme under Laboratory Course on Life Processes was carried out in MolBio Diagnostics Pvt. Ltd. Verna, Goa, India from 1st December 2022 to 31st December 2022. MolBio Diagnostics is a diagnostic tools and kits manufacturing company located in Verna Goa with its Research and Development branch in Bangalore, India. They produce kits for diagnosis of various disorders like MTB, Covid 19, HIV, HBV, Influenza A, Chikungunya, Malaria, etc. The company was started with the aim of easing accessibility of disease diagnosis to every part of the country. Their goal is to make disease diagnosis cost effective, rapid and easily accessible. Some of the major products of MolBio Diagnostics include Trueprep, Truenat chips for over 50 different diseases, Truelab Devices like Auto, Auto V2, Uno, Duo, Quattro, Transport medium for swab specimens, Stabilyse prep free kits, etc. Some of the major departments operating in the company are QC, QA, Validation, Sales and marketing, etc. The production facility has two key sections- Trueprep and Truenat production sections.

I was placed in the QC department. The QC department is involved in verifying quality, quantity and functioning of the different products manufactured by the company in different stages of production. They conduct tests at every stage of production, right from testing of raw materials to testing finished goods that will be dispatched. QC has further subsections like incoming material testing, stability testing, extraction, rapid testing, PCR, etc. In the QC department, as interns, some of the work that we were assigned include helping in IC validation process, preparing bottles for dye leak test, QR scanning for logging of incoming cartridges into QC, physical testing of cartridges, leak testing of cartridges, PCR of negative and blank samples, stability testing of buffers with modified composition and data entry.

This internship was truly a great learning experience as it was most informative and we got to learn about the functioning of a major pharmaceutical company. We were also shown how the production process goes about and our doubts were readily solved by Officers in charge. We were also allowed hands on training for some important techniques like PCR. I would sincerely like to thank MolBio Diagnostics as well as our teachers Dr. Shanti N. Dessai and Dr. Shamshad Sheikh for providing us with this wonderful opportunity to learn new techniques and information through practical experience in a major pharmaceutical company.