



Dated: 31/12/2022

TO WHOM IT MAY CONCERN

This is to certify that Ms. Aditi Tripathi a student of the School of Biological Sciences and Biotechnology, pursuing M.Sc. Biotechnology (Part II), have successfully completed internship programme at Molbio Diagnostics Private Limited Verna, Goa from 01st December 2022 to 31st December 2022.

During the period of her internship programme with us she was found hardworking, punctual and inquisitive.

Yours sincerely,
For Molbio Diagnostics Private Limited

Dushyant Bhawar
Head- HR & Administration

Molbio Diagnostics Private Limited

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DEPARTMENT OF BIOTECHNOLOGY

M.Sc MARINE BIOTECHNOLOGY

2021-2023

INTERNSHIP REPORT

Submitted by:

Aditi Tripathi

21P050003

ABOUT THE COMPANY:

MolBio Diagnostics Private Limited is a non-government Company, founded on 20th October 2000. It is majorly in manufacturing (machinery and equipment) business from local 23 years and currently Company operations are active.

Board members and Directors are Chandrashekhar Bhaskaran Nair, Sampath Sudarshan and Sriram Natranjan. Company is registered in Goa with address:



MolBio Diagnostics Private Limited, plot no.
246 Phase II D, Verna Industrial Estate,
Verna

Goa 403722- Site I

MolBio Diagnostics Private Limited, Plot no.
242 Phase II B, Verna Industrial Estate,
Verna,

Goa 403722- Site V

Products:

- Truenat Chips:

Disease specific ready to use and disposable micro-PCR chips that run on Truelab uno, Dx/Duo/Quattro/4X4 to get quantitative real time PCR result.

- Trueprep auto cartridge:

Disposable plastic cartridge for automated extraction of nucleic acid from clinical specimen.

- Trueprep Auto V₂ reagent kit:

Reagent kit for use with Trueprep Auto V₂ cartridge for automated processing of clinical specimens.

- Trueprep Auto V₂ universal cartridge-based sample prep device:

The fully automatic sample prep device works in tandem with Trueprep auto cartridge and Trueprep Auto V₂ reagent

kit for extraction and purification of nucleic acid from clinical specimens.

- Truelab uno or Real time

- Quantitative micro-PCR analyser:

- Fully automatic Real time Quantitative micro-PCR analyser, three wavelength system, performs between 10-12 test in 8 hours. Controls amplification, detection and reporting of result.

- Truelab Duo real time quantitative micro-PCR analyser:

- Fully automated real time quantitative micro-PCR analyser, sixteen channel three wavelength system.

Major Departments of the Company and their Roles:

- Human Resources:

HR Department is a group of people responsible for managing the employee's life cycle like recruiting, hiring, onboarding, training, and firing employee and administering employees benefits.

- Information Technology:

A department which is responsible for hardware, software, and networking of Computers in the Company.

They ensure full access of employee to computer system.

- Validation:

They Validate process, products and machine.

They ensure that the products meet the standard.

- Quality Assurance:

This department is responsible for ensuring the products and the service meet the established standard set by the Company and regulatory bodies.

- **Quality Control:**

Analysing and measuring, conducting test, monitoring the production phase and checking the quality of all raw materials and products at every stage of production.

- **Manufacturing:**

Deals with manufacturing of the products.

Washing > coat dispensing> wax dispensing> flash writing> pouching> packaging> dispatch.

- **Marketing and Sales:**

It has responsibility for deciding where the Company should sell and what its prices should be and includes choosing wholesale distributors or retailers.

QUALITY ASSUARANCE:

QA has three departments under it-

1. IPQA- In Process Quality Assurance
2. QMS- Quality Management System
3. RA- Regulatory Authority

QMS deals with documentation part and RA deals with licensing and regulatory works.

QUALITY ASSURANCE DUTIES:

>Batch Compilation:

QA complies and verifies the documents of each lot of products manufactured. This include MSPT, USPT, VUCPK, ATM, USPK etc.

- MSPT: Trueprep Auto MTB Sample Pre-treatment pack.
MSPT is used for MTB samples wherein sputum sample is collected which is very thick and hence viscosity has to be reduced using liquefaction buffer.
- USPT is used for samples other than sputum

e.g., blood, swab etc.

- ATM: Auto transport medium for Swab Specimen pack.

Transport medium is used as medium for collection, decontamination and transport of various types of swab specimens before proceeding for pre-treatment using lysis buffer extraction purification of nucleic acid using trueprep kit. Collection and transport of microorganisms which include bacteria and virus from site of collection.

>Log Book verification:

IPQA verifies logbook maintained by each department twice a month (beginning and middle of month \pm 4 day) i.e.; every 15 days.

We were taken for log book verification of extraction and PCR of QC department, where we verified logbook details, cross checked with checklist provided and verified the entries made.

>Stability report verification:

IPQA verifies stability reports of sample tested at various temperatures at various time intervals by QC department.

- i) Real Time Stability: It is performed at 2-8 degree Celsius and 30 degree Celsius with 3 months interval.
- ii) Accelerated Stability: It is performed at 45 degree Celsius and 40 degree Celsius with interval of 2 weeks and 1 month respectively. IPQA verifies details, cross checks calculations and result of device result page.

>Document Verification of Incoming Materials:

IPQA verifies incoming material details, vendor details, and cross checks nucleotide sequence of primers and probes.

>Instrumentation verification:

IPQA checks functioning of machinery (Trueprep and truelab) devices, physical parameters and accessories. They cross check the result and software details.

Instrumentation of Trueprep devices and packaging has to be done in the presence of QA officer. Where they have to ensure that the details in the provided form are corrected, serial number has to be verified, bays have to be checked manually and they should be free from dust and moisture. Trueprep devices adaptors, cables, reagent bottles, covers, manual has to be packed.

Instrumentation of Truelab Quattro device was performed where we had to verify all the details like serial numbers, approving labels, ensure all connectors and their slots, bays should be free from dust and moisture, software details, physical parameters, etc.

Details should be filled in given form and one have to pass/fail each criterion.

Once all criteria are passed it is approved by QA along with approval of device accessories.

Apart from this IPQA plays role in:

- Line clearance
- On-line rejection
- Destruction
- Out of specification
- Controlled copy distribution
- Daily meetings
- Change in protocol

CONCLUSION:

At MolBio Diagnostics Pvt. Ltd. we got hands-on industrial experience of how these molecular biology kits are produced on a large scale.

The role of a Quality Assurance officer in handling the whole production and testing of the product, making sure all the parameters are perfectly in coordination with the protocol.

This company targets:

- 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 stakeholders

Acknowledgement:

I would like to thank Department of Biotechnology for providing us this internship opportunity.

I would like to thank Goa University and our dean Prof. Savita Kerkar for providing us the opportunity to intern at such prestigious organisations.

I would like to thank MolBio Diagnostics Pvt. Ltd. for providing such amazing exposure to industrial experience in the field of Biotechnology.

I would like to thank my Professor Samantha Fernandes D'Mello for arranging this internship for us.

I would also like to thank Dr. Sivakumar, Ms. Rutuja Desai and Ms. Mansi for helping us during the complete internship and being so patient with us and helping us gain such a good industrial experience.

Thank you.

