REGULATORY AFFAIRS

By Regulatory Affairs Team

molbio®
INNOVATE • IMPACT • INSPIRE

CONTENTS

Product Licensing

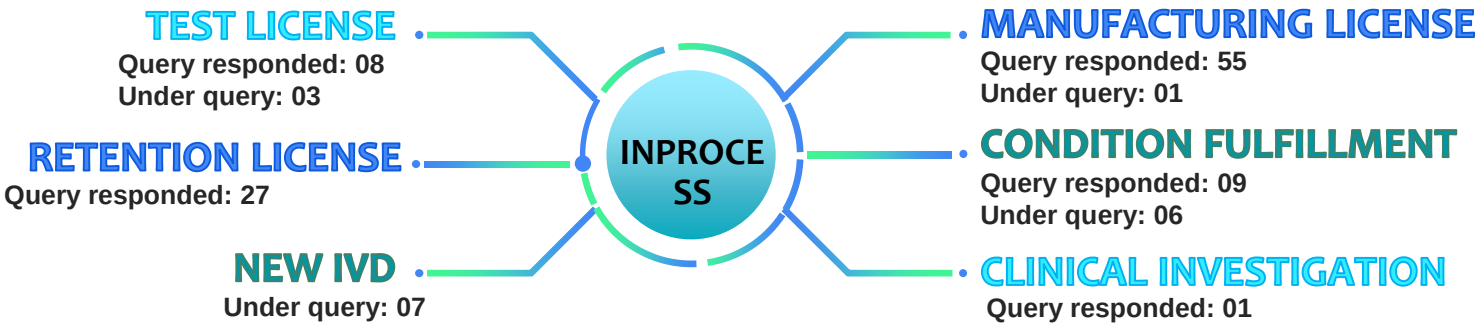
Central and State Licensing Authority

July 2025 - December 2025

1. Approvals, Submission & Inprocess (July 2025 - December 2025)

	Approved	Submitted	Inprocess
Test license	Site I - 04 products Site V - 02 products	Site I - 04 products Site V - 02 products	Site V - 02 products
Manufacturing license	Site I - 21 products Site V - 04 products	Site I - 53 products Site V - 14 products	Site I - 32 products Site V - 10 products
Condition fulfillment	Site I -04 products	NA	NA
Total	**Site I - 29 products** **Site V - 06 products**	**Site I - 57 products** **Site V - 16 products**	**Site I - 32 products** **Site V - 12 products**

2. Inprocess Applications (Overall)



Sr. No.	Type of license	Product Name	Site	Status
01	Test license	Truenat® Dengue/Zika (Reapplication)	I	Awaiting CDSCO approved testing lab
02		Truenat® CHPV	I & V	No CDSCO approved predicate device
03	Manufacturing license	Truenat® KFDV	I	Approval of Form MD-29
04	New IVD	Truenat® KFDV	I	Clinical evaluation data on specimen collected from feild and statistically powered sample size
		Truenat® Inf A,B/COVID-19, Truena[t®] Nipah, Truenat® COVID-19, Truenat® SARS CoV-2, Truenat® Beta CoV & Truemix™ COVID-19	I	Recent Clinical evaluation data (last 1 year)
05	Condition Fulfillment	Truenat® MTB, Truenat® MTB Plus, Truenat® MTB RIF Dx, Truenat® HCV, Truenat® CT & Truenat® COVID-19	V	Stability study and PER for EPTB Sample as claimed in IFU

3. Products in Pipeline

01

Truecyte

AI based digital pathology

(Awaiting product details)

05

Trueprep Mag V2

(Awaiting product details)

Trueamp Mini

Real Time Multiplex qPCR Analyzer

(Awaiting approved user manual)

02

Trueprep Mag V3

(Awaiting product details)

06

03

Trueamp HPV-HR Genotyping

Real Time PCR Test for Human Papillomavirus High Risk Types 16/18/33/35, 31/39/45, 51/52/56/58, 59/66/68

(Awaiting finalised product details)

07

Trueamp CureDx-TB

Real-time reverse transcription polymerase chain reaction (RT-PCR) assay for the qualitative assessment of host-response mRNA biomarkers associated with Mycobacterium tuberculosis infection

(Awaiting finalised product details)

Truepoc

Integrated point-of-care NAAT platform

(Awaiting product details)

04

Truenat Ebola-Marburg

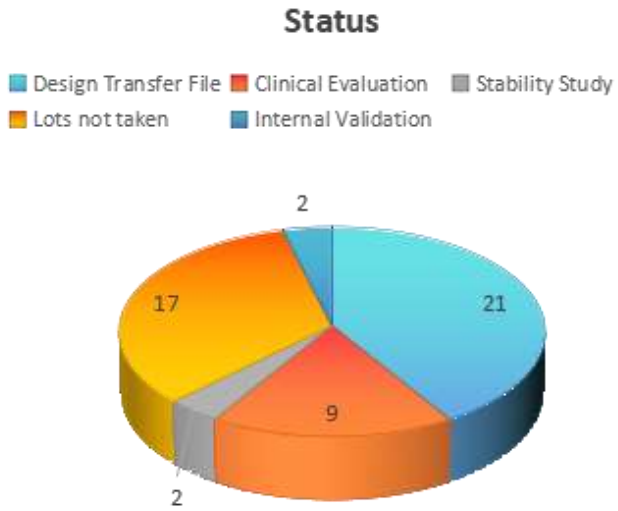
Chip-based Real Time PCR Test for Ebola and Marburg virus

(No provision for International Testing Sites)

08

4. Manufacturing License Status (to be applied)

LOTS (03) NOT TAKEN
Truenat® Staph/ MRSA
Truenat® Rota V (Reapplication)
Truenat® Mucormycosis (Reapplication)
Truenat® Rubella / Measles
Truenat® Mumps
Truenat® Positive Control Kit - Panel VI
Truenat® Positive Control Kit - Panel VII
Truenat® Positive Control Kit - Panel VIII
Truenat® Toxo
Truemix™ HCV (Reapplication)
Truemix™ HBV (Reapplication)
Truemix™ HIV-1/HIV-2 (Reapplication)
Truemix™ HPV-HR Plus
Truemix™ MPX
Truenat® HMPV
Truenat® JEV (Reapplication)
Truenat® SCD (Reapplication)
Truenat® RSV (Reapplication)



Internal Validation
Truetell™/Promilless™ 0.02%
Truetell™/Promilless™ 0.05%

STABILITY
Truenat® MPX (more 2 lots)
Truetell™/Promilless™ 0.0%

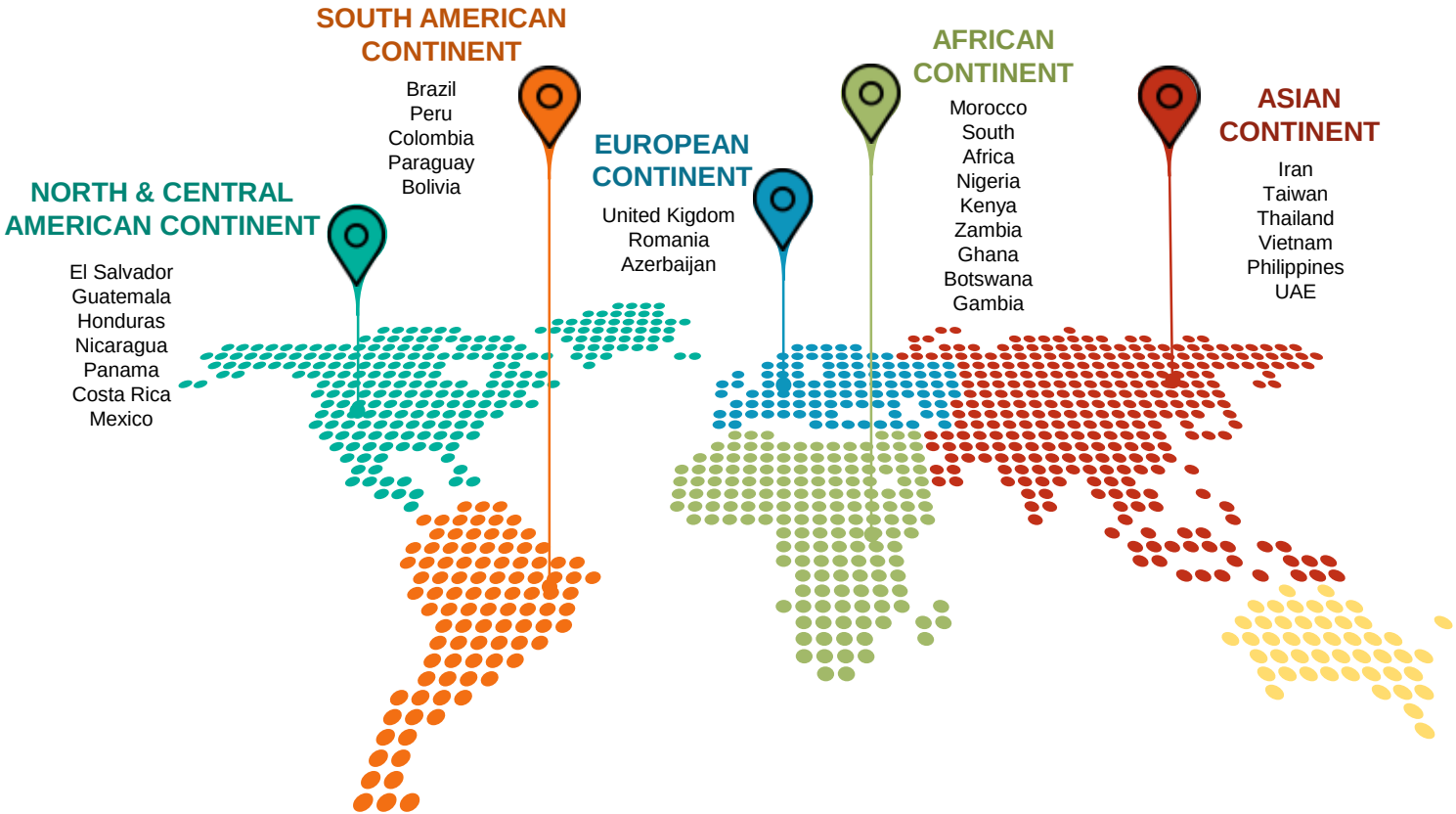
CLINICAL EVALUATION
Truenat® MTB Ultima
Truenat® HPV-HR 16/18
Truenat® Zika
Truenat® Brucella
Truenat® RSV
Truenat® Malaria Pv/Pf Hi-Sens
Truenat® Salmonella-FQ
Truemix™ HPV-HR Plus
Truelyse™ Buffer

DESIGN FILE
Truemix™ HPV-HR 16/18
Truemix™ Zika / Dengue / Chikungunya
Truemix™ Beta CoV
Truemix™ SARS CoV-2
Truemix™ Carb-R
Trueamp™ MDR-TB Plus
Truemix™ BCR-ABL
Truemix™ MTB Plus
Truemix™ MTB-INH
Truemix™ MTB Ultima
Truemix™ Sepsis Panel
Truemix™ Respiratory Panel
Truebact™ MTB DST
Truemix™ MTB Rif Dx
Truenat® HMPV / COVID-19,Influenza
Truenat® HMPV and M. pneumonia
Truenat® H5N1
Trueamp™ Respiratory Panel
Sickelcert™
Truedetect™
Truetell™/Promilless™ 0.03%
Truenat® Syphilis

GLOBAL REGISTRATIONS

July 2025 - December 2025

4. Global Registrations (July 2025 - December 2025)



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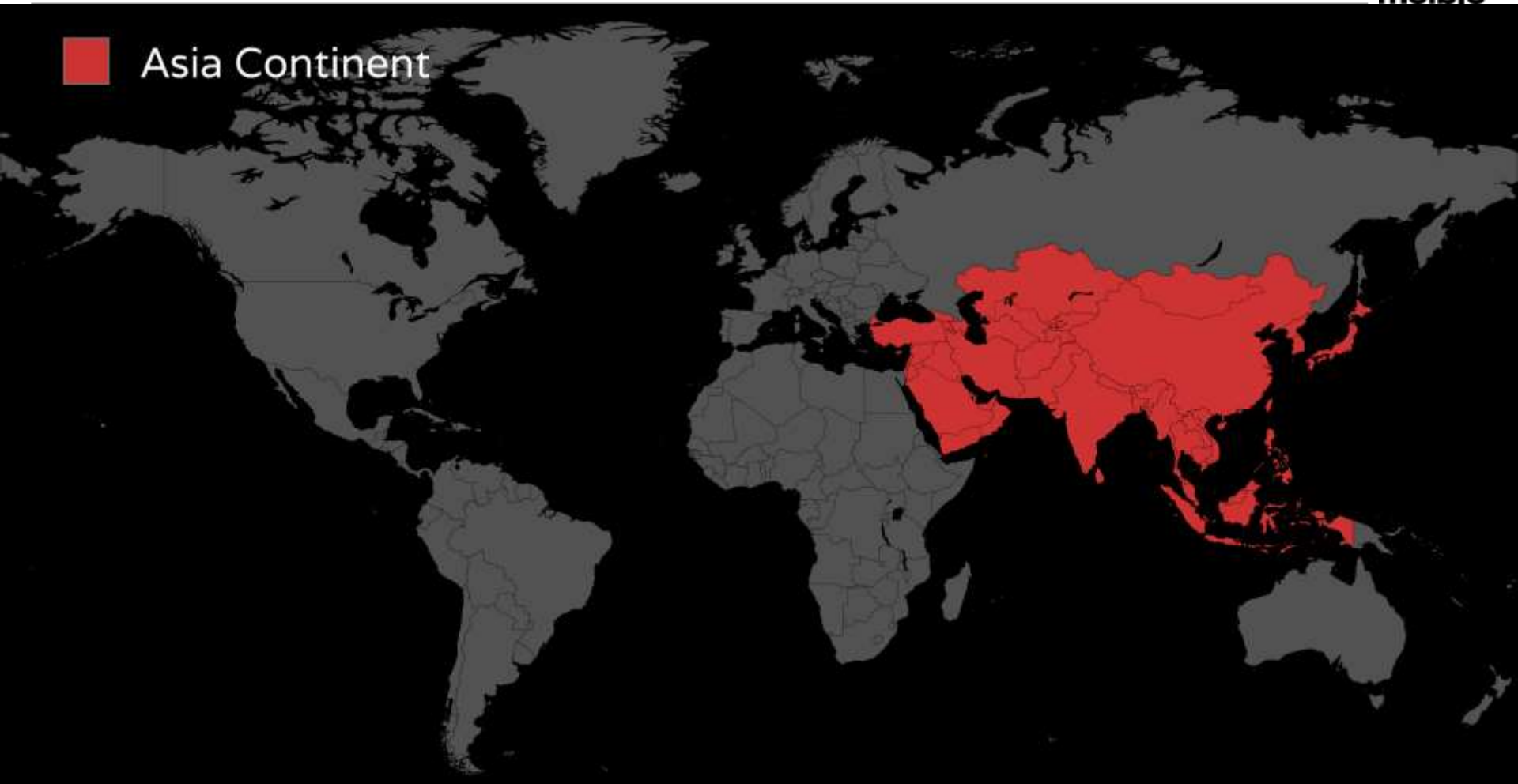

4. Global Registrations (July 2025 - December 2025)

Country	Regulator	No. of products registered	No. of products (Registration Ongoing)
Iran	Iranian Food and Drug Administration	NA	41
Taiwan	The Taiwan Food and Drug Administration (TFDA)	NA	15
Thailand	Thai Food and drug Administration	NA	21
Vietnam	Ministry of Health	NA	06
Philippines	Center for Device Regulation, Radiation Health, and Research (CDRRHR)	01	01
UAE	Ministry of Health and Prevention (MOHAP)	05	NA

4. Global Registrations (July 2025 - December 2025)

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Country	Regulator	No. of products registered	No. of products (Registration Ongoing)
Morocco	Directorate of Medicines and Pharmacy	NA	39
South Africa	South African Health Products Regulatory Authority (SAHPRA)	NA	08
Nigeria	National Agency for Food and Drug Administration and Control (NAFDAC)	NA	02
Kenya	Pharmacy and Poisons Board (PPB)	NA	02
Zambia	Zambia Medicines Regulatory Authority (ZAMRA)	NA	01
Ghana	Food and Drugs Authority (FDA)	NA	20
Botswana	Botswana Medicines Regulatory Authority (BoMRA)	NA	09
Gambia	Medicines Control Agency (MCA)	NA	10

4. Global Registrations (July 2025 - December 2025)

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Country	Regulator	No. of products registered	No. of products (Registration Ongoing)
El Salvador	National Directorate of Medicines	11	03
Guatemala	Departamento de Regulacion y Control de Productos Farmacéuticos y Afines (DRCPFA)	35	04
Honduras	Health Regulation Agency (ARSA)	06	11
Nicaragua	National Health Regulatory Authority	NA	01
Panama	Ministry of Health (MINSA)	NA	10
Costa Rica	Ministry of Health (MOH)	NA	18
Mexico	Comision Federal para la Proteccion contra Riesgos Sanitarios (COFEPRIS)	NA	07

4. Global Registrations (July 2025 - December 2025)

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Country	Regulator	No. of products registered	No. of products (Registration Ongoing)
Brazil	Agencia Nacional de Vigilancia Sanitaria (ANVISA)	03	04
Peru	Direccion General de Medicamentos, Insumos y Drogas (DIGEMID)	01	07
Colombia	National Food and Drug Surveillance Institute (INVIMA)	NA	11
Paraguay	National Directorate of Health Surveillance (DINAVISA)	NA	07
Bolivia	La Agencia Estatal de Medicamentos y Tecnologías en Salud (AGEMED)	09	01

4. Global Registrations (July 2025 - December 2025)

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Country	Regulator	No. of products registered	No. of products (Registration Ongoing)
United Kingdom	Medicines and Health care products Regulatory Agency (MHRA)	NA	42
Romania	National Agency for Medicines and Medical Devices (NAMMD)	NA	03
Azerbaijan	Analytical Expertise Center (AEC)	NA	06

WHO Technical dossier

Section-Wise Schedule for Technical dossier(TD) and Related documents

Month-wise progress for Truenat® MTB Plus WHO PreQ TD Submission

Completed

Inprocess

July to October

- Coordination with cross-functional teams for data as per GAP assessment prepared
- Verification and finalization of analytical performance study data
- Artwork review and verification for compliance.
- Preparation of sections for Technical Dossier (TD)
- Compilation of TD with supporting documents
- Review of TD sections stakeholders
- Preparation of the pre-submission form

October to November

- Finalization and submission of pre-submission form
- Allotment of PreQ number (07/10/2025)
- Pre-submission call with WHO
- Signing of Letter of Agreement
- Fees payment (26/11/2025)
- Updating and compilation of TD with all review comments
- Submision of TD to WHO (27/11/2025)

December

- 1st Dossier Screening of WHO recieved (5/12/2025)
- Coordinating for data as per screening review

Preparation & Review Progress Track for Truenat® MTB-RIF Dx WHO PreQ Submission

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Completed

Inprocess

5/12/2025-6/12/2025

- Coordination with cross-functional teams for data to be included in the dossier.
- Preparaton of Pre-submission form and shared the same for review
- Initiation of TD preparation
- Review of Artwork recieved(Kit Label)

1/12/2025-2/12/2025

- Preparation and sharing of EP checklists
- Reviewing of documents
- Sharing of Analytical study summary for review
- Incorpation of reviewed content and sharing for second review

3/12/2025-4/12/2025

- Sharing of Section 6.0 and Stability summary data for review
- Incorporating review commnets and sharing the same for second reviewreview
- Sharing section 1.0 for review

5/12/2025-6/12/2025

- Incorporating all recieved comments and resharing section 1 and 2 for second review
- Sharing Section 4.0 (Clinical evidence) for review
- Sharing of Analytical summary for third review
- Review of Artwork(Pouch) recieved
- Finalization and submission of pre-submission form
- Pre-submission call with WHO
- Allotment of PreQ number (05/12/2025)
- Signing of Letter of Agreement

8/12/2025-Till date

- Review of Pack insert (Intended Use)
- Preparation of Risk documents
- Compilation of annexures

QUALITY OBJECTIVES

Quality Objective- Year 2025

Quality Objective 1 : To register Truenat® CT/NG, Truenat® MTB-INH, Truenat® HCV Under IVD Regulation (EU) 2017/746 of European Parliament and of the Council.

Quality Indicator 1: Truenat® CT/NG under IVDR, 2017

Task	Quality Indicator	Task % allotted	Status	Task % completed
T1	Certification by NB	70	Ongoing	75
T2	EU DOC	15	Ongoing	0
T3	Updation of Annex IV	15	Ongoing	0
TASK % (TOTAL)		100%	NA	75%

Quality Objective- Year 2025

Quality Objective 1: To register Truenat® CT/NG, Truenat® MTB-INH, Truenat® HCV Under IVD Regulation (EU) 2017/746 of European Parliament and of the Council.

Quality Indicator 2: Truenat® MTB-INH under IVDR, 2017

Task	Quality Indicator	Task % allotted	Status	Task % completed
T1	Technical Dossier preparation	70	Ongoing	40
T2	Technical Dossier review by all stake holders	15	Ongoing	0
T3	Technical Dossier Submission to Notified body	15	Ongoing	0
TASK % (TOTAL)		100%	NA	40%

Quality Objective- Year 2025

Quality Objective 1 : To register Truenat® CT/NG, Truenat® MTB-INH, Truenat® HCV Under IVD Regulation (EU) 2017/746 of European Parliament and of the Council.

Quality Indicator 3: Truenat® HCV under IVDR, 2017

Task	Quality Indicator	Task % allotted	Status	Task % completed
T1	Technical Dossier preparation	70	Ongoing	75
T2	Technical Dossier review by all stake holders	15	Ongoing	0
T3	Technical Dossier Submission to Notified body	15	Ongoing	0
TASK % (TOTAL)		100%	NA	75%

Quality Objective- Year 2025

Quality Objective 2 : To plan and implement EN ISO 14001:2015 [Environnental management systems Requirements with guidance for use] at Molbio Diagnostics Limited.

Quality Indicator 1: Gap Assessment

Task	Quality Indicator	Task % allotted	Status	Task % completed
T1	Gap Analysis	50	Completed	100
T2	Inter - Department Meeting	50	Ongoing	30
TASK % (TOTAL)		100%	NA	65%

Quality Indicator 2: Implementation

Task 1: Procedures developed in accordance with the guidelines - 30% Completed

Quality Objective- Year 2025

Quality Objective 3 : To plan and implement IEC 62366-1 : 2015 [Medical devices Part 1: Application of usability engineering to medical devices]

Quality Indicator 1: Gap Assessment

Task	Quality Indicator	Task % allotted	Status	Task % completed
T1	Gap Analysis	50	Completed	100
T2	Inter - Department Meeting	25	Completed	100
T3	Feedback Assessment and Conclusion	25	Completed	100
TASK % (TOTAL)		100%	NA	100%

Quality Indicator 2: Implementation

Task 1: Procedures developed in accordance with the guidelines - 30% Completed

IMPLEMENTATION

July 2025 - December 2025

Stage 1

- Launch of IVDR Project
- Gap Assessment

Status: COMPLETED

Stage 2

- Appointment of AR and NB
- Registration of Economic Operator in Actor Module of EUDAMED

Status: COMPLETED

Stage 3

- Appointment of PRRC
- Classification of Products

Status: COMPLETED

Stage 4

- Implementation of IVDR Compliant Procedures
- Registration of Class A devices*

Status: COMPLETED

Stage 5

- IVDR Audit
- IVDR Certification

Status: COMPLETED

COMPLETED

- IVDR QMS Certificate Received
- Truenat® CT-NG registered

Implementation of IVDR and Registration Products under IVDR

***Truelab and Trueprep® Devices, Trueprep® and STABILYSE® reagents are registered**
****Truenat® CTNG is registered. Truenat® HCV, HPV-HR Plus, MTB-INH and MTB Ultima are in process**

Launched Regulatory Update Forum

Designed to track and communicate applicable regulatory updates and amendments on a monthly basis

Targeted Communication

Updates and amendments issued by various regulatory bodies will be shared with all impacted departments

Release Summary

delivers a clear and concise summary of updates and amendments issued by various regulatory authorities

Goal

Stay updated with current regulatory requirements to ensure timely compliance, minimize regulatory risks and maintain audit readiness

What's New?

QMS CERTIFICATES

July 2025 - December 2025

CERTIFICATIONS

Successfully achieved QMS certificates:

01 MDSAP

MEDICAL DEVICE SINGLE AUDIT PROGRAM

MDSAP Certificate
Valid from: 11/07/2025
Valid until: 25/07/2026

02 EU-IVDR

EU IVDR Certificate
Valid from: 26/08/2025
Valid until: 25/08/2030

03 ISO 13485 CERTIFIED

ISO Certificate
Valid from: 09/07/2025
Valid until: 26/04/2026

THANK YOU