



MOLBIO DIAGNOSTICS PRIVATE LIMITED

ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

Mfg. Lic. No.: MFG/IVD/2019/000018

Date: 22/10/2020

BRAND NAME	Truenat™ Malaria Pf
GENERIC NAME	Chip-based Real Time PCR Test for <i>Plasmodium falciparum</i>
LOT No.	PF015
MFG. DATE	2020-10
EXP. DATE	2022-09
PACK SIZE	5T, 20T
STORAGE	2°C to 30°C
A.R. No. : B-PF-015	

PRECAUTION: Refer Safety Data Sheet and Instructions for Use.

Sr. No.	Components in each kit	Specification	Observation
1	Pouch contains 1 chip, 1 micro tube, 1 desiccant pouch and 1 filter barrier tip	5 no, 20 no.	Pass
2	Colour of desiccant pouch	Blue	Pass
3	Package insert	01 no.	Pass

PERFORMANCE		
CONTROLS	(Ct Values)	
Specificity Tests	FAL	Control
Negative Control	ND	28.6
Positive Control	27	29.25
	26.8	29
	25.6	29.5
	26.6	30.2
Standard deviation	± 0.62	± 0.51

*ND- Not detected, Ct- Cycle threshold, FAL- *Plasmodium falciparum*

*A deviation of ≤ 1.5 is acceptable for Ct values

MANUFACTURING RECORDS ARE VERIFIED, CHECKED AND PRODUCT IS MANUFACTURED AS PER THE MASTER FORMULA, SAMPLES TESTED AND LOT IS QC APPROVED FOR SALE

QUALITY CONTROL
Name: Dr. Praveen Kumar
Designation: QC Head

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Molbio Diagnostics Private Limited

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