



MOLBIO DIAGNOSTICS PVT. LTD.

An ISO 9001 & ISO 13485 certified company

CERTIFICATE OF ANALYSIS

Mfg. Lic. No. : 874/L

Date: 29/06/2018

PRODUCT : Truenat™ Malaria Pf
LOT. NO. : PF009
MFG. DATE : 2018- 06
EXP. DATE : 2020- 05
PACK SIZE : 5T, 20T
STORAGE : 2°C to 30°C

A.R. NO. : B-PF-009

PRECAUTION: The product is offered without warranty for any other specific use than that specified in the 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 nos, 20 nos.	Pass
2	Colour of desiccant pouch	Blue	Pass
3	Package insert	01no.	Pass

Performance		
CONTROLS	Test Lot (Ct Values)	
	PF	IC
Specificity Tests		
Negative Control	ND	26.75
Positive Control	28.13	26.67
	29.11	27.33
	29.29	27.14
	28.67	27.33
Standard deviation	± 0.51	± 0.31

*ND- Not detected

*A deviation of ± 1 is acceptable for Ct values

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



QUALITY CONTROL

Name: Dr. Praveen Kumar

Designation: QC Head

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Molbio Diagnostics Pvt. Ltd.

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