



MOLBIO DIAGNOSTICS PVT. LTD.

An ISO 9001 & ISO 13485 certified company

### CERTIFICATE OF ANALYSIS

Mfg. Lic. No. : 874/L

Date: 10/05/2018

PRODUCT : Truenat™ Malaria Pf  
LOT. NO. : PF008  
MFG. DATE : 2018- 03  
EXP. DATE : 2020- 02  
PACK SIZE : 5T, 20T  
STORAGE : 2°C to 30°C

A.R. NO. : B-PF-008

**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 contain 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			
Sr. No.	CONTROLS	Test Lot (Ct Values)	
Specificity Tests		PF	IC
Negative Control		ND	30.67
Positive Control		31.13	29
		31.1	28.09
		31	27.2
		32.5	27.5
Standard deviation		± 0.71	± 0.79

\*ND- Not detected

\*A deviation of  $\pm 1$  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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