



**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. : PF007**  
**MFG. DATE : 2018- 03**  
**EXP. DATE : 2020- 02**  
**PACK SIZE : 5T, 20T**  
**STORAGE : 2°C to 30°C**

**A.R. NO. : B-PF-007**

**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)	
<b>Specificity Tests</b>		<b>PF</b>	<b>IC</b>
<b>Negative Control</b>		ND	24.6
<b>Positive Control</b>		32	28.67
		32.14	28.33
		30.75	27.2
		30.57	28
<b>Standard deviation</b>		$\pm 0.81$	$\pm 0.62$

\*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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**Molbio Diagnostics Pvt. Ltd.**

**Regd. Office:** H. No. 13, Sagar Society, Dona Paula, Panaji, N. Goa 403 004. INDIA  
**Works:** Plot Nos. M 46-47, Phase III - B, Verna Industrial Estate, Verna - Goa 403 722. INDIA  
**Tel:** 91 832 2783267/6624783 **E mail:** admin@molbiodiagnostics.com  
**Office:** No. UGO-7, Ground Floor, Ambrosia Residency, Cabesa, Alto Santacruz, Goa - 403 005. INDIA  
**Tel:** 91 832 2458111/2458112 **Email:** sales@molbiodiagnostics.com  
**Website:** www.molbiodiagnostics.com **CIN:** U33125GA2000PTC002909