



MOLBIO DIAGNOSTICS PVT. LTD.

An ISO 9001 & ISO 13485 certified company

CERTIFICATE OF ANALYSIS

Mfg. Lic. No. : 874/L

Date 20/08/2018

PRODUCT :Truenat™ GBS

LOT. NO. : GB001

MFG. DATE : 2018- 07

EXP. DATE : 2020- 08

PACK SIZE : 5T, 20T

STORAGE : 2°C to 30°C

A.R. NO. : B-GB-001

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	01 no.	Pass

Sr. No.	Performance CONTROLS	Test Lot (Ct Values)	
		GBS	IC
Specificity Tests			
Negative Control		ND	27.17
Positive Control		29.8	27.22
		30.33	29.4
		29	26.5
		28.8	26.6
Standard deviation		± 0.71	± 1.35

*ND- Not detected

*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 RELEASED FOR SALE


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

Page 1 of 1

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 6624783/6682000 Fax: 91 832 2783139 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