



MOLBIO DIAGNOSTICS PRIVATE LIMITED

ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date: 29/10/2021  
Doc ID: COA/TN/GB009

BRAND NAME	Truenat <sup>®</sup> GBS
GENERIC NAME	Chip-based Real Time PCR Test for Group B Streptococcus
LOT No.	GB009
MFG. DATE	2021-10
EXP. DATE	2023-09
PACK SIZE	5T, 20T, 50T
STORAGE	2°C to 30°C
A.R. No. : B-GB-009	

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, 50 no.	Pass
2	Colour of desiccant pouch	Orange	Pass
3	Package insert	01 no.	Pass

PERFORMANCE		
CONTROLS	(Ct Values)	
Specificity Tests	GBS	Control
Negative Control	ND	28.4
Positive Control	28.6	25.8
	28.33	25.8
	28.43	26.17
	29	26.33
Standard deviation	± 0.30	± 0.27

\*ND- Not detected, Ct- Cycle threshold, GBS- Group B Streptococcus

\*A deviation of  $\leq 1.5$  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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