

Government of India  
Central Drugs Standard Control Organisation  
Directorate General of Health Services  
Ministry of Health & Family Welfare  
(Diagnostics Division)  
FDA Bhawan, Kotla Road, New Delhi-110002

File No. IVD/BG Sera/ NSQ/ 001/2017-DC

Dated,

15 SEP 2017

**PUBLIC NOTICE**

Subject: Report of test / analysis of **COMBIPACK ABD, Anti-A, B & D (B. No. 116160303)**, from the Govt. Analyst, NIB (NOIDA) declaring Not of Standard Quality / Spurious; -regarding.

This office has received Certificate of test / analysis (in Form 13) from the Government analyst at Blood Reagents laboratory, National Institute of Biological (NOIDA), under Section 25(1) of The Drugs and Cosmetics Act, 1940 and rule 46 of Drugs and Cosmetics Rules, 1945 for the below mentioned products manufactured by M/s Bhat Biotech India (P) Ltd. 11-A, 4<sup>th</sup> Cross Road, Veerasandra Industrial Area, Electronic City, Bangalore -560100. The samples of the said product was drawn by the Drugs Inspector, Bijnor (U.P.) and forwarded to NIB, Noida for Testing. The govt. analyst at NIB (NOIDA) has now declared the said products as Not of Standard Quality (NSQ) & Spurious under the provisions of Drugs & Cosmetics Act 1940. The details are given below:

Sl. No	Name of Product / Batch / Lot No./ Mfg. date	Analytical report	Remark
1	COMBIPACK ABD, Anti-A, B & D <b>Anti-A (IgM) monoclonal, 10 ml;</b> B. No. 116160303; Mfg. dt. 03/2016, Exp. Date : 02/2018	N/GA-04/2017-18/BRL/31 Dated 11-09-2017	Sample declared as <b>Not of Standard Quality &amp; spurious</b>
2	COMBIPACK ABD, Anti-A, B & D <b>Anti-B (IgM) monoclonal, 10 ml.</b> B. No. 116160303; Mfg. dt. 03/2016 Exp. Date : 02/2018	N/GA-05/2017-18/BRL/32 Dated 11-09-2017	Sample declared as <b>Not of Standard Quality &amp; spurious</b>
3	COMBIPACK ABD, Anti-A, B & D <b>Anti-D (IgM) monoclonal, 10 ml</b> B. No. 116160303; Mfg. dt. 03/2016 Exp. Date : 02/2018	N/GA-06/2017-18/BRL/33 Dated 11-09-2017	Sample declared as <b>Not of Standard Quality</b>

The general public is hereby notified that above mentioned product, COMBIPACK ABD, Anti-A, B & D of the said batches should not be used in any form



(Dr. S. Eswara Reddy)  
Joint Drugs Controller (India)

Copy to,

1. All State Drugs Controllers
2. All Zonal and Sub Zonal Offices of CDSCO.
3. Director, NIB, NOIDA, UP
4. CDSCO Web site.