

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/ 002/2017-DC

Date:

15 SEP 2017

DIAGNOSTIC KIT ALERT

PRODUCT: Mediclone D (Blood Grouping Sera Anti-D) Batch/Lot No: 88BG022

BACKGROUND: Monoclonal blood grouping reagents are intended for in vitro recognition of the blood group antigens A,B, and D(Rh) on human red blood cells (RBCs). Agglutination of red blood cells with Anti A, Anti B and Anti D is a positive test reaction and indicates the presence of corresponding antigens on the RBCs. Absence of agglutination of red blood cells with Anti A,Anti B and Anti D is a negative test result and it indicates the absence of the corresponding antigens on the RBCs.

PROBLEM: National Institute of Biologicals, Noida reported that the product Sample is **Not of Standard Quality** under Drugs and cosmetics Act 1940 and rules thereof in respect to the test for Specificity, Avidity/Intensity, Reactivity and Titre.

ACTION BY:

- Medical directors/Healthcare Professionals
- Staff Involved in the management of patients
- Diagnostics Labs

ACTION:

- Do not use the Combipack ABD, Anti-A, B & D Batch/Lot No: 116160303
- Return all unused product to the manufacturer.

ADVERSER EFFECTS: Mediclone D (Blood Grouping Sera Anti-D) Batch/Lot No: 88BG022 may give incorrect result on recognition of the blood group antigens D(Rh) on human red blood cells (RBCs).

CONTACTS:

1. M/s. Mediclone Biotech Pvt .Ltd. 29 Biopavilion, Velichai, Chennai-600048
2. Central Drugs Standard Control Organisation, Directorate General of Health Services Ministry of Health & Family Welfare, Food & Drugs Administration Bhawan, Kotla Road, New Delhi-110002
Tel:91-11-23236975/23236971 Fax: 91-11-23236973, E-mail: dci@nb.nic.in.
3. Drugs Controller Tamil Nadu, Sivasankaran Rd, Chokkalingam Nagar, Teynampet, Chennai -86



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DIAGNOSTIC KIT ALERT

PRODUCT: ----- COMBIPACK ABD, Anti-A, B & D Batch/Lot No: 116160303

- i. Anti-A (IgM) Monoclonal
- ii. Anti-B (IgM) Monoclonal
- iii. Anti-D (IgM) Monoclonal

BACKGROUND: Monoclonal blood grouping reagents are intended for in vitro recognition of the blood group antigens A,B, and D(Rh) on human red blood cells (RBCs). Agglutination of red blood cells with Anti A, Anti B and Anti D is a positive test reaction and indicates the presence of corresponding antigens on the RBCs. Absence of agglutination of red blood cells with Anti A, Anti B and Anti D is a negative test result and it indicates the absence of the corresponding antigens on the RBCs.

PROBLEM: National Institute of Biological, Noida reported that the product Sample is **Spurious and Not of Standard Quality** under Drugs and Cosmetics Act 1940 and Rules thereof in respect to the test for identification (Anti-A (Ig M) Monoclonal & Anti-B (Ig M) Monoclonal) , Prozone and Titre for (Anti-D (Ig M) Monoclonal).

ACTION BY:

- Medical directors/Healthcare Professionals
- Staff Involved in the management of patients
- Diagnostics Labs

ACTION:

- Do not use the Combipack ABD, Anti-A, B & D Batch/Lot No: 116160303
- Return all unused product to the manufacturer.

ADVERSE EFFECTS: Combipack ABD, Anti-A, B & D Batch/Lot No: 116160303 may give incorrect result on recognition of the blood group antigens A, B, and D(Rh) on human red blood cells (RBCs).

CONTACTS:

1. M/s Bhat Bio-tec India (P) Ltd.11-A, 4th Cross Road ,Veerasandra Industrial Area,Electronic City, Bangalore -560100, Karnataka.
2. Central Drugs Standard Control Organisation, Directorate General of Health Services Ministry of Health & Family Welfare,Food & Drugs Administration Bhawan,Kotla Road, New Delhi-110002, Tel:91-11-23236975/23236971 Fax: 91-11-23236973, E-mail:dci@nb.nic.in
3. Drugs Controller, (Karnataka), MS Building, Palace Road, Bangalore-560006