



Fortress Diagnostics Limited

Unit 2C
Antrim Technology Park,
BT41 1QS
United Kingdom

Telephone +44 28 94487676
Facsimile +44 28 94469933

Email info@fortressdiagnostics.com
website www.fortressdiagnostics.com

Certificate of Analysis

Product : Immunoglobulin M (IgM)
Catalogue Number : BXC0731A
Batch Number : 161667
Manufactured Date: 2016/07
Expiry : 2018/06

This product has been tested by Quality Control and has met all final QC specifications. This product is released for packing and is suitable for use until the stated expiry date.

This product was produced according to ISO 13485 & ISO 9001 guidelines.

The following results were obtained:

Control Description	Lot Number	Target (mg/dl)	Range (mg/dl)	Result (mg/dl)
Protein Control L1	PR 001	87.1	74.0 – 100.2	88.6
Protein Control L2	PR 002	174	148 - 200	172.9

QC PASS/FAIL: **PASS**

Products containing Human Source Material have been tested at the donor level for HbsAg and antibodies to HIV1, HIV2 and HCV and found to be non-reactive.

Signed : *Catherine Caskey*

Date : 2016/07



ISO 13485:2003
Cert. No. GB04 / 63491



ISO 9001:2000
Cert. No. GB04 / 63490