



**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**

**Cat No:** BXC0646A  
**Product:** Specific Protein Calibrator Set  
**Batch no.** 161716  
**Manufacture Date:** 2016/07  
**Expiry:** 2017/12

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

PARAMETER	QUALITY ASSURANCE
Appearance Lyophilised	N/A
Appearance Liquid Stable	Clear solution
Appearance after 6 hours of manufacturing @ 25°C – open tube	No flocculation – maintains clarity
Bio-burden	<2 CFU/bottle

HOMOGENEITY	QUALITY ASSURANCE
IgA	1.21 %
IgG	1.09 %
IgM	1.01 %

TEST COMPONENTS	Results	Unit	LEVEL 2	LEVEL 4	LEVEL 6
IgA	Expected	mg/dl	72.5	290	580
	Obtained	mg/dl	72.3	291	575
IgG	Expected	mg/dl	369.88	1479.5	2959
	Obtained	mg/dl	371	1477	2965
IgM	Expected	mg/dl	40	160	320
	Obtained	mg/dl	40	161	319

QC PASS/FAIL: **PASS**

Signed: *Catherine Caskey*

Date: 2016/07



ISO 13485:2003  
 Cert. No. GB04 / 63491



ISO 9001:2000  
 Cert. No. GB04 / 63490