

PRODUCT INFORMATION

Cat. No. PS2684

688LPC

Please note Rheumatoid Factor is present in the control material however no claims are made for its concentration or stability. If you have any queries, please contact Technical Services at technical.services@randox.com.

CCS INC1655

LIQUID ASSAYED SPECIFIC PROTEIN CONTROL - LEVEL 3 (SP CONTROL 3)

CAT. NO. PS2684 **LOT NO.** 688LPC
SIZE 3 x 1 ml **EXPIRY:** 2025-12-28
GTIN: 05055273204919

INTENDED USE

This product is intended for *in vitro* diagnostic use, in the quality control of serum on clinical chemistry and immunoassay systems. The Assayed Liquid Protein Controls are for the control of accuracy.

DEVICE DESCRIPTION

The Liquid Protein Controls are supplied at 3 levels, level 1, 2 and 3. Target values and ranges are supplied for the analytes listed in the values table.

SAFETY PRECAUTIONS AND WARNINGS

For *in vitro* diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handling laboratory reagents.

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Pictogram



Warning

Hazard statement(s)

H317 May cause an allergic skin reaction.

Precautionary statement(s)

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
P272 Contaminated work clothing should not be allowed out of the workplace.
P280 Wear protective gloves/protective clothing/eye protection/face protection.
P302+P352 If on skin: Wash with plenty of water.
P321 Specific treatment (see on this label).
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
P501 Dispose of contents/container according to local and national guidelines.

Human source material, from which this product has been derived, has been tested at donor level for the Human Immunodeficiency Virus (HIV 1, HIV 2) antibody, Hepatitis B Surface Antigen (HbsAg), and Hepatitis C Virus (HCV) antibody and found to be NON-REACTIVE. FDA approved methods have been used to conduct these tests.

However, since no method can offer complete assurance as to the absence of infectious agents, this material and all patient samples should be handled as though capable of transmitting infectious diseases and disposed of accordingly.

Health and Safety Data Sheets are available on request.

STORAGE AND STABILITY

OPENED: Store refrigerated (+2°C to +8°C). Protein control material is stable for 30 days at +2°C to +8°C, if kept capped in original container and free from contamination. Only the required amount of product should be removed. After use, any residual product should NOT BE RETURNED to the original vial.

UNOPENED: Store refrigerated (+2°C to +8°C). Stable to expiration date printed on individual vials.

Note: Free Kappa Light Chains and Free Lambda Light Chains are present in the Liquid Assayed Specific Protein Control material, but no claims are made for their expected values or stability.

PREPARATION

The Liquid Protein Controls are supplied ready for use. Allow the control to come to room temperature before analysis.

MATERIALS PROVIDED

Liquid Protein Control - Level 3 3 x 1 ml

MATERIALS REQUIRED BUT NOT PROVIDED

Not applicable.

LIMITATIONS

RF: Please note that the dilution of multi-controls on certain systems can result in the over recovery of RF compared to the undiluted control. This is due to complex Immunoglobulin interactions.

Rheumatoid Factor Values may gradually decrease during the product's shelf life.

ASSIGNED VALUES

Each batch of Protein Control is submitted to approximately 100 laboratories and values are assigned from a consensus of results obtained by these laboratories. With each batch, a control range is provided for individual parameters and each parameter method.

Due to the variation caused by test equipment, test reagents and laboratory technique, the quoted ranges are provided for guidance. It is recommended that these ranges are used until each laboratory has established its own ranges, based on individual laboratory requirements.

If a method is unavailable, contact Randox Laboratories - Technical Services, Northern Ireland, tel: +44 (0) 28 9445 1070 or email Technical.Services@randox.com.

Free Lambda Light Chains excluded.

EC	REP
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Randox Teoranta, Meenmore,
Dungloe, Donegal,
F94 TV06, Ireland

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Method		Liquid Assayed Specific Protein Control - Level 3					
Lot. No: 688LPC Cat. No: PS2684 Expiry: 2025-12-28							
Size: 3 x 1 ml		Range					
Analyte	Unit	Target	Low	High	1SD	2SD	Method
Albumin	g/dl	5.90	5.02	6.78	0.440	0.880	Abbott Alinity Albumin BCG 2
	g/l	59.0	50.2	67.8	4.40	8.80	
	g/dl	5.78	4.91	6.65	0.435	0.870	Abbott Architect Albumin BCG 2
	g/l	57.8	49.1	66.5	4.35	8.70	
	g/dl	5.67	4.82	6.52	0.425	0.850	Bromocresol Green (IFCC Cal.)
	g/l	56.7	48.2	65.2	4.25	8.50	
	g/dl	5.75	4.89	6.61	0.430	0.860	Bromocresol Green (Non IFCC Cal.)
	g/l	57.5	48.9	66.1	4.30	8.60	
	g/dl	5.56	4.73	6.39	0.415	0.830	Bromocresol Purple (IFCC Cal.)
	g/l	55.6	47.3	63.9	4.15	8.30	
	g/dl	5.36	4.56	6.16	0.400	0.800	Bromocresol Purple (Non IFCC Cal.)
	g/l	53.6	45.6	61.6	4.00	8.00	
	g/dl	5.66	4.81	6.51	0.425	0.850	Nephelometric (IFCC Cal.)
	g/l	56.6	48.1	65.1	4.25	8.50	
g/dl	5.67	4.82	6.52	0.425	0.850	Turbidimetric Assays (IFCC Cal.)	
g/l	56.7	48.2	65.2	4.25	8.50		
Alpha-1-Acid Glycoprotein	g/l	1.72	1.38	2.06	0.170	0.340	Nephelometric (IFCC Cal.)
	mg/dl	172	138	206	17.0	34.0	
	g/l	1.64	1.31	1.97	0.165	0.330	Turbidimetric (Non IFCC Cal.)
	mg/dl	164	131	197	16.5	33.0	
Alpha-1-Antitrypsin	g/l	1.62	1.30	1.94	0.160	0.320	Turbidimetric (IFCC Cal.)
	mg/dl	162	130	194	16.0	32.0	
	g/l	1.57	1.26	1.88	0.155	0.310	Agappe - Nephelometry
	mg/dl	157	126	188	15.5	31.0	
Alpha-1-Antitrypsin	g/l	2.03	1.62	2.44	0.205	0.410	Nephelometric (IFCC Cal.)
	mg/dl	203	162	244	20.5	41.0	
	g/l	1.71	1.37	2.05	0.170	0.340	Turbidimetric (IFCC Cal.)
	mg/dl	171	137	205	17.0	34.0	
Alpha-1-Antitrypsin	g/l	1.70	1.36	2.04	0.170	0.340	Turbidimetric (Non IFCC Cal.)
	mg/dl	170	136	204	17.0	34.0	
	g/l	3.39	2.71	4.07	0.340	0.680	Agappe - Nephelometry
	mg/dl	339	271	407	34.0	68.0	
Alpha-2-Macroglobulin	g/l	3.79	3.03	4.55	0.380	0.760	Nephelometric (IFCC Cal.)
	mg/dl	379	303	455	38.0	76.0	
Alpha-fetoprotein	ng/ml	52.5	42.0	63.0	5.25	10.5	Chemiluminescence (IFCC Cal.)
	KIU/l = IU/ml	43.4	34.7	52.1	4.35	8.70	

Method		Liquid Assayed Specific Protein Control - Level 3					
Lot. No: 688LPC Cat. No: PS2684 Expiry: 2025-12-28							
Size: 3 x 1 ml		Range					
Analyte	Unit	Target	Low	High	1SD	2SD	Method
Alpha-fetoprotein	ng/ml	51.1	40.9	61.3	5.10	10.2	Chemiluminescence (Non IFCC Cal.)
	KIU/l = IU/ml	42.2	33.8	50.6	4.20	8.40	
Anti Streptolysin O	IU/ml	250	200	300	25.0	50.0	Agappe - Nephelometry
	IU/ml	180	144	216	18.0	36.0	Neph., Beckman (IFCC Cal.)
	IU/ml	187	150	224	18.5	37.0	Neph., Beckman (non-IFCC Cal.)
	IU/ml	265	212	318	26.5	53.0	Nephelometric, others (IFCC Cal.)
	IU/ml	259	207	311	26.0	52.0	Nephelometric, others (Non IFCC Cal.)
	IU/ml	273	218	328	27.5	55.0	Turbidimetric (IFCC Cal.)
	IU/ml	281	225	337	28.0	56.0	Turbidimetric (Non IFCC Cal.)
Beta-2-Microglobulin	µg/ml = mg/l	3.53	2.82	4.24	0.355	0.710	Turbidimetric (Non IFCC Cal.)
C-Reactive Protein	mg/dl	6.53	5.22	7.84	0.655	1.31	Agappe - Nephelometry
	mg/l	65.3	52.2	78.4	6.55	13.1	
	mg/dl	6.52	5.22	7.82	0.650	1.30	Beckman Turb Latex HS (IFCC)
	mg/l	65.2	52.2	78.2	6.50	13.0	
	mg/dl	6.94	5.55	8.33	0.695	1.39	Beckman Turb. Latex (IFCC cal)
	mg/l	69.4	55.5	83.3	6.95	13.9	
	mg/dl	6.27	5.02	7.52	0.625	1.25	Nephelometric (IFCC Cal.)
	mg/l	62.7	50.2	75.2	6.25	12.5	
	mg/dl	6.32	5.06	7.58	0.630	1.26	Nephelometric (Non IFCC Cal.)
	mg/l	63.2	50.6	75.8	6.30	12.6	
	mg/dl	5.96	4.77	7.15	0.595	1.19	Other Dry Chemistry (IFCC)
	mg/l	59.6	47.7	71.5	5.95	11.9	
	mg/dl	6.65	5.32	7.98	0.665	1.33	Roche Turbidimetric CRP4 (IFCC Cal.)
	mg/l	66.5	53.2	79.8	6.65	13.3	
	mg/dl	6.62	5.30	7.94	0.660	1.32	Roche Turbidimetric Gen 3 (IFCC Cal.)
	mg/l	66.2	53.0	79.4	6.60	13.2	
	mg/dl	6.54	5.23	7.85	0.655	1.31	Roche Turbidimetric Gen 3 (Non IFCC Cal.)
	mg/l	65.4	52.3	78.5	6.55	13.1	
	mg/dl	6.58	5.26	7.90	0.660	1.32	Roche Turbidimetric Latex (IFCC Cal.)
	mg/l	65.8	52.6	79.0	6.60	13.2	
mg/dl	6.65	5.32	7.98	0.665	1.33	Roche Turbidimetric Latex (Non IFCC Cal.)	
mg/l	66.5	53.2	79.8	6.65	13.3		
mg/dl	6.57	5.26	7.88	0.655	1.31	Turbidimetric (IFCC Cal.)	
mg/l	65.7	52.6	78.8	6.55	13.1		
mg/dl	6.58	5.26	7.90	0.660	1.32	Turbidimetric (Non IFCC Cal.)	
mg/l	65.8	52.6	79.0	6.60	13.2		

Method		Liquid Assayed Specific Protein Control - Level 3					
Lot. No: 688LPC Cat. No: PS2684 Expiry: 2025-12-28							
Size: 3 x 1 ml		Range					
Analyte	Unit	Target	Low	High	1SD	2SD	Method
C-Reactive Protein	mg/dl	4.81	3.85	5.77	0.480	0.960	Vitros (IFCC Cal.)
	mg/l	48.1	38.5	57.7	4.80	9.60	
	mg/dl	4.96	3.97	5.95	0.495	0.990	Vitros (Non IFCC Cal.)
	mg/l	49.6	39.7	59.5	4.95	9.90	
Caeruloplasmin	g/l	0.699	0.524	0.874	0.088	0.175	Nephelometric (IFCC Cal.)
	mg/dl	69.9	52.4	87.4	8.75	17.5	
	g/l	0.634	0.476	0.792	0.079	0.158	Nephelometric (Non IFCC Cal.)
	mg/dl	63.4	47.6	79.2	7.90	15.8	
	g/l	0.581	0.436	0.726	0.073	0.145	Turbidimetric (IFCC Cal.)
	mg/dl	58.1	43.6	72.6	7.25	14.5	
	g/l	0.503	0.377	0.629	0.063	0.126	Turbidimetric (Non IFCC Cal.)
	mg/dl	50.3	37.7	62.9	6.30	12.6	
Complement C3	g/l	0.649	0.487	0.811	0.081	0.162	Turbidimetric Sentinel Reagent
	mg/dl	64.9	48.7	81.1	8.10	16.2	
	g/l	2.83	2.26	3.40	0.285	0.570	Nephelometric (IFCC Cal.)
	mg/dl	283	226	340	28.5	57.0	
	g/l	2.82	2.26	3.38	0.280	0.560	Nephelometric (Non IFCC Cal.)
	mg/dl	282	226	338	28.0	56.0	
	g/l	2.79	2.23	3.35	0.280	0.560	Ortho Vitros Microtip
	mg/dl	279	223	335	28.0	56.0	
Complement C4	g/l	2.89	2.31	3.47	0.290	0.580	Turbidimetric (IFCC Cal.)
	mg/dl	289	231	347	29.0	58.0	
	g/l	3.00	2.40	3.60	0.300	0.600	Turbidimetric (Non IFCC Cal.)
	mg/dl	300	240	360	30.0	60.0	
	g/l	0.498	0.398	0.598	0.050	0.100	Agappe - Nephelometry
	mg/dl	49.8	39.8	59.8	5.00	10.0	
	g/l	0.572	0.458	0.686	0.057	0.114	Nephelometric (IFCC Cal.)
	mg/dl	57.2	45.8	68.6	5.70	11.4	
Complement C4	g/l	0.556	0.445	0.667	0.056	0.111	Nephelometric (Non IFCC Cal.)
	mg/dl	55.6	44.5	66.7	5.55	11.1	
	g/l	0.555	0.444	0.666	0.056	0.111	Ortho Vitros Microtip
	mg/dl	55.5	44.4	66.6	5.55	11.1	
	g/l	0.550	0.440	0.660	0.055	0.110	Turbidimetric (IFCC Cal.)
	mg/dl	55.0	44.0	66.0	5.50	11.0	
	g/l	0.536	0.429	0.643	0.054	0.107	Turbidimetric (Non IFCC Cal.)
	mg/dl	53.6	42.9	64.3	5.35	10.7	
Ferritin	ng/ml = µg/l	223	178	268	22.5	45.0	Agappe - Nephelometry

Method		Liquid Assayed Specific Protein Control - Level 3					
Lot. No: 688LPC Cat. No: PS2684 Expiry: 2025-12-28							
Size: 3 x 1 ml		Range					
Analyte	Unit	Target	Low	High	1SD	2SD	Method
Ferritin	ng/ml = µg/l	244	195	293	24.5	49.0	Chemiluminescence (IFCC Cal.)
	ng/ml = µg/l	242	194	290	24.0	48.0	Chemiluminescence (Non IFCC Cal.)
	ng/ml = µg/l	199	159	239	20.0	40.0	Nephelometric (IFCC Cal.)
	ng/ml = µg/l	239	191	287	24.0	48.0	Turbidimetric (IFCC Cal.)
	ng/ml = µg/l	237	190	284	23.5	47.0	Turbidimetric (Non IFCC Cal.)
Haptoglobin	g/l	1.77	1.42	2.12	0.175	0.350	Agappe - Nephelometry
	mg/dl	177	142	212	17.5	35.0	
	g/l	1.85	1.48	2.22	0.185	0.370	Nephelometric (IFCC Cal.)
	mg/dl	185	148	222	18.5	37.0	
	g/l	1.83	1.46	2.20	0.185	0.370	Turbidimetric (IFCC Cal.)
	mg/dl	183	146	220	18.5	37.0	
Immunoglobulin A	g/l	5.17	3.88	6.46	0.645	1.29	Agappe - Nephelometry
	mg/dl	517	388	646	64.5	129	
	g/l	5.16	3.87	6.45	0.645	1.29	Chemiluminescence (IFCC Cal.)
	mg/dl	516	387	645	64.5	129	
	g/l	5.43	4.07	6.79	0.680	1.36	Nephelometric (IFCC Cal.)
	mg/dl	543	407	679	68.0	136	
	g/l	5.40	4.05	6.75	0.675	1.35	Nephelometric (Non IFCC Cal.)
	mg/dl	540	405	675	67.5	135	
	g/l	5.04	3.78	6.30	0.630	1.26	Ortho Vitros Microtip
	mg/dl	504	378	630	63.0	126	
Immunoglobulin E	g/l	4.93	3.70	6.16	0.615	1.23	Turbidimetric (IFCC Cal.)
	mg/dl	493	370	616	61.5	123	
	g/l	5.04	3.78	6.30	0.630	1.26	Turbidimetric (Non IFCC Cal.)
	mg/dl	504	378	630	63.0	126	
Immunoglobulin E	KIU/l = IU/ml	228	182	274	23.0	46.0	Agappe - Nephelometry
	KIU/l = IU/ml	222	178	266	22.0	44.0	Chemiluminescence (Non IFCC Cal.)

Method		Liquid Assayed Specific Protein Control - Level 3					
Lot. No: 688LPC Cat. No: PS2684 Expiry: 2025-12-28							
Size: 3 x 1 ml		Range					
Analyte	Unit	Target	Low	High	1SD	2SD	Method
Immunoglobulin E	KIU/l = IU/ml	227	182	272	22.5	45.0	Enzyme Immunoassay (Non IFCC Cal.)
	KIU/l = IU/ml	211	169	253	21.0	42.0	Nephelometric (Non IFCC Cal.)
	KIU/l = IU/ml	206	165	247	20.5	41.0	Turbidimetric (Non IFCC Cal.)
Immunoglobulin G	g/l	21.6	17.7	25.5	1.95	3.90	Agappe - Nephelometry
	mg/dl	2160	1771	2549	195	389	
	g/l	25.4	20.8	30.0	2.30	4.60	Nephelometer Assays
	mg/dl	2540	2083	2997	229	457	
	g/l	25.0	20.5	29.5	2.25	4.50	Nephelometric (Non IFCC Cal.)
	mg/dl	2500	2050	2950	225	450	
	g/l	26.5	21.7	31.3	2.40	4.80	Ortho Vitros Microtip
	mg/dl	2650	2173	3127	239	477	
g/l	25.7	21.1	30.3	2.30	4.60	Turbidimetric (Non IFCC Cal.)	
mg/dl	2570	2107	3033	232	463		
Immunoglobulin M	g/l	1.69	1.35	2.03	0.170	0.340	Agappe - Nephelometry
	mg/dl	169	135	203	17.0	34.0	
	g/l	2.22	1.78	2.66	0.220	0.440	Nephelometric (IFCC Cal.)
	mg/dl	222	178	266	22.0	44.0	
	g/l	2.20	1.76	2.64	0.220	0.440	Nephelometric (Non IFCC Cal.)
	mg/dl	220	176	264	22.0	44.0	
	g/l	2.12	1.70	2.54	0.210	0.420	Ortho Vitros Microtip
	mg/dl	212	170	254	21.0	42.0	
g/l	2.08	1.66	2.50	0.210	0.420	Turbidimetric (IFCC Cal.)	
mg/dl	208	166	250	21.0	42.0		
Kappa Light Chain	g/l	2.12	1.70	2.54	0.210	0.420	Turbidimetric (Non IFCC Cal.)
	mg/dl	212	170	254	21.0	42.0	
	g/l	5.26	4.21	6.31	0.525	1.05	Agappe - Nephelometry
	mg/dl	526	421	631	52.5	105	
	g/l	5.72	4.58	6.86	0.570	1.14	Nephelometric - Siemens
	mg/dl	572	458	686	57.0	114	
g/l	6.37	5.10	7.64	0.635	1.27	Turbidimetric	
mg/dl	637	510	764	63.5	127		

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Lot. No: 688LPC Cat. No: PS2684 Expiry: 2025-12-28							
Size: 3 x 1 ml		Range					
Analyte	Unit	Target	Low	High	1SD	2SD	Method
Lambda Light Chain	g/l	3.60	2.88	4.32	0.360	0.720	Agappe - Nephelometry
	mg/dl	360	288	432	36.0	72.0	
	g/l	3.23	2.58	3.88	0.325	0.650	Nephelometric - Siemens
	mg/dl	323	258	388	32.5	65.0	
	g/l	3.52	2.82	4.22	0.350	0.700	Turbidimetric
	mg/dl	352	282	422	35.0	70.0	
Prealbumin	g/l	0.255	0.204	0.306	0.026	0.051	Agappe - Nephelometry
	mg/dl	25.5	20.4	30.6	2.55	5.10	
	g/l	0.362	0.290	0.434	0.036	0.072	Nephelometric (IFCC Cal.)
	mg/dl	36.2	29.0	43.4	3.60	7.20	
	g/l	0.322	0.258	0.386	0.032	0.064	Turbidimetric (IFCC Cal.)
	mg/dl	32.2	25.8	38.6	3.20	6.40	
	g/l	0.321	0.257	0.385	0.032	0.064	Turbidimetric (Non IFCC Cal.)
	mg/dl	32.1	25.7	38.5	3.20	6.40	
Retinol Binding Protein	mg/l	70.0	56.0	84.0	7.00	14.0	Nephelometric (IFCC Cal.)
Transferrin	g/l	4.31	3.45	5.17	0.430	0.860	Nephelometric (IFCC Cal.)
	mg/dl	431	345	517	43.0	86.0	
	g/l	4.40	3.52	5.28	0.440	0.880	Ortho Vitros Microtip
	mg/dl	440	352	528	44.0	88.0	
	g/l	4.42	3.54	5.30	0.440	0.880	Turbidimetric (IFCC Cal.)
	mg/dl	442	354	530	44.0	88.0	
	g/l	4.49	3.59	5.39	0.450	0.900	Turbidimetric (Non IFCC Cal.)
	mg/dl	449	359	539	45.0	90.0	