

PRODUCT INFORMATION

Cat. No. PS2684

748LPC

Please note in Liquid Protein Control - Level 2 PS2684 the concentration of Antithrombin III & Complement C4 are lower compared to previous lots. For any queries in relation to this notice, please contact

technical.services@randox.com

qCCS 2351

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

CAT. NO. PS2684 **LOT NO.** 748LPC
SIZE: 3 x 1 ml **EXPIRY:** 2028-01-28
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)

Avoid breathing dust/fume/gas/mist/vapours/spray.
Contaminated work clothing should not be allowed out of the workplace.
Wear protective gloves/protective clothing/eye protection/face protection.
IF ON SKIN: Wash with plenty of water.
If skin irritation or rash occurs: Get medical advice/attention
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.

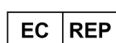
ASSIGNED VALUES

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.



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

16 Apr 26 bm

Table of Content

Method

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Method		Liquid Assayed Specific Protein Control - Level 3					
Lot. No: 748LPC Cat. No: PS2684 Expiry: 2028/01/28							
Size: 3 x 1 ml		Range					
Analyte	Unit	Target	Low	High	1SD	2SD	Method
Albumin	g/dl	5.60	4.76	6.44	0.420	0.840	Bromocresol Green (IFCC Cal.)
	g/l	56.0	47.6	64.4	4.20	8.40	
	g/dl	5.70	4.85	6.55	0.425	0.850	Bromocresol Green (Non IFCC Cal.)
	g/l	57.0	48.5	65.5	4.25	8.50	
	g/dl	5.59	4.75	6.43	0.420	0.840	Bromocresol Purple (IFCC Cal.)
	g/l	55.9	47.5	64.3	4.20	8.40	
	g/dl	5.93	5.04	6.82	0.445	0.890	Nephelometric (IFCC Cal.)
	g/l	59.3	50.4	68.2	4.45	8.90	
Alpha-1-Acid Glycoprotein	g/dl	5.61	4.77	6.45	0.420	0.840	Turbidimetric Assays (IFCC Cal.)
	g/l	56.1	47.7	64.5	4.20	8.40	
	g/l	1.72	1.38	2.06	0.170	0.340	Agappe - Nephelometry
	mg/dl	172	138	206	17.0	34.0	
Alpha-1-Antitrypsin	g/l	1.72	1.38	2.06	0.170	0.340	Turbidimetric (IFCC Cal.)
	mg/dl	172	138	206	17.0	34.0	
	g/l	1.91	1.53	2.29	0.190	0.380	Agappe - Nephelometry
	mg/dl	191	153	229	19.0	38.0	
	g/l	2.00	1.60	2.40	0.200	0.400	Nephelometric (IFCC Cal.)
	mg/dl	200	160	240	20.0	40.0	
	g/l	1.86	1.49	2.23	0.185	0.370	Turbidimetric (IFCC Cal.)
	mg/dl	186	149	223	18.5	37.0	
Alpha-2-Macroglobulin	g/l	1.91	1.53	2.29	0.190	0.380	Turbidimetric (Non IFCC Cal.)
	mg/dl	191	153	229	19.0	38.0	
	g/l	3.00	2.40	3.60	0.300	0.600	Agappe - Nephelometry
	mg/dl	300	240	360	30.0	60.0	
Alpha-fetoprotein	g/l	3.18	2.54	3.82	0.320	0.640	Nephelometric (IFCC Cal.)
	mg/dl	318	254	382	32.0	64.0	
	ng/ml	43.8	35.0	52.6	4.40	8.80	Chemiluminescence (IFCC Cal.)
	KIU/l = IU/ml	36.2	29.0	43.4	3.60	7.20	
Anti Streptolysin O	ng/ml	48.2	38.6	57.8	4.80	9.60	Chemiluminescence (Non IFCC Cal.)
	KIU/l = IU/ml	39.8	31.8	47.8	4.00	8.00	
	IU/ml	248	198	298	25.0	50.0	Agappe - Nephelometry
	IU/ml	252	202	302	25.0	50.0	Nephelometric, others (Non IFCC Cal.)
Anti Streptolysin O	IU/ml	265	212	318	26.5	53.0	Turbidimetric (IFCC Cal.)
	IU/ml	275	220	330	27.5	55.0	Turbidimetric (Non IFCC Cal.)

Method		Liquid Assayed Specific Protein Control - Level 3						
Lot. No: 748LPC Cat. No: PS2684 Expiry: 2028/01/28								
Size: 3 x 1 ml		Range						
Analyte	Unit	Target	Low	High	1SD	2SD	Method	
Beta-2-Microglobulin	µg/ml = mg/l	4.66	3.73	5.59	0.465	0.930	Nephelometric (IFCC Cal.)	
	µg/ml = mg/l	4.96	3.97	5.95	0.495	0.990	Turbidimetric (IFCC Cal.)	
	µg/ml = mg/l	4.79	3.83	5.75	0.480	0.960	Turbidimetric (Non IFCC Cal.)	
C-Reactive Protein	mg/dl	7.26	5.81	8.71	0.725	1.45	Agappe - Nephelometry	
	mg/l	72.6	58.1	87.1	7.25	14.5		
	mg/dl	7.35	5.88	8.82	0.735	1.47	Beckman Turb. Latex (IFCC cal)	
	mg/l	73.5	58.8	88.2	7.35	14.7		
	mg/dl	7.06	5.65	8.47	0.705	1.41	Roche Turbidimetric CRP4 (IFCC Cal.)	
	mg/l	70.6	56.5	84.7	7.05	14.1		
	mg/dl	6.90	5.52	8.28	0.690	1.38	Roche Turbidimetric Gen 3 (Non IFCC Cal.	
	mg/l	69.0	55.2	82.8	6.90	13.8		
	mg/dl	7.06	5.65	8.47	0.705	1.41	Roche Turbidimetric Latex (IFCC Cal.)	
	mg/l	70.6	56.5	84.7	7.05	14.1		
	mg/dl	7.15	5.72	8.58	0.715	1.43	Roche Turbidimetric Latex (Non IFCC Cal.	
	mg/l	71.5	57.2	85.8	7.15	14.3		
Caeruloplasmin	mg/dl	6.52	5.22	7.82	0.650	1.30	Turbidimetric (IFCC Cal.)	
	mg/l	65.2	52.2	78.2	6.50	13.0		
	mg/dl	6.70	5.36	8.04	0.670	1.34	Turbidimetric (Non IFCC Cal.)	
	mg/l	67.0	53.6	80.4	6.70	13.4		
	mg/dl	4.16	3.33	4.99	0.415	0.830	Vitros (IFCC Cal.)	
	mg/l	41.6	33.3	49.9	4.15	8.30		
	Complement C3	g/l	0.509	0.382	0.636	0.064	0.127	Agappe - Nephelometry
		mg/dl	50.9	38.2	63.6	6.35	12.7	
		g/l	0.594	0.446	0.742	0.074	0.148	Nephelometric (IFCC Cal.)
		mg/dl	59.4	44.6	74.2	7.40	14.8	
		g/l	0.407	0.326	0.488	0.041	0.081	Roche Turbidimetric (IFCC Cal.)
		mg/dl	40.7	32.6	48.8	4.05	8.10	
g/l		0.416	0.333	0.499	0.042	0.083	Roche Turbidimetric (Non IFCC Cal.)	
mg/dl	41.6	33.3	49.9	4.15	8.30			
Complement C3	g/l	0.501	0.376	0.626	0.063	0.125	Turbidimetric (IFCC Cal.)	
	mg/dl	50.1	37.6	62.6	6.25	12.5		
	g/l	0.502	0.377	0.627	0.063	0.125	Turbidimetric Sentinel Reagent	
	mg/dl	50.2	37.7	62.7	6.25	12.5		
	Complement C3	g/l	2.55	2.04	3.06	0.255	0.510	Agappe - Nephelometry
		mg/dl	255	204	306	25.5	51.0	

Method		Liquid Assayed Specific Protein Control - Level 3					
Lot. No: 748LPC Cat. No: PS2684 Expiry: 2028/01/28							
Size: 3 x 1 ml		Range					
Analyte	Unit	Target	Low	High	1SD	2SD	Method
Complement C3	g/l	2.44	1.95	2.93	0.245	0.490	Nephelometric (IFCC Cal.)
	mg/dl	244	195	293	24.5	49.0	
	g/l	2.49	1.99	2.99	0.250	0.500	Turbidimetric (IFCC Cal.)
	mg/dl	249	199	299	25.0	50.0	
	g/l	2.57	2.06	3.08	0.255	0.510	Turbidimetric (Non IFCC Cal.)
	mg/dl	257	206	308	25.5	51.0	
Complement C4	g/l	0.458	0.366	0.550	0.046	0.092	Agappe - Nephelometry
	mg/dl	45.8	36.6	55.0	4.60	9.20	
	g/l	0.485	0.388	0.582	0.049	0.097	Nephelometric (IFCC Cal.)
	mg/dl	48.5	38.8	58.2	4.85	9.70	
	g/l	0.450	0.360	0.540	0.045	0.090	Turbidimetric (IFCC Cal.)
	mg/dl	45.0	36.0	54.0	4.50	9.00	
Ferritin	g/l	0.414	0.331	0.497	0.042	0.083	Turbidimetric (Non IFCC Cal.)
	mg/dl	41.4	33.1	49.7	4.15	8.30	
	ng/ml = µg/l	237	190	284	23.5	47.0	Agappe - Nephelometry
	ng/ml = µg/l	258	206	310	26.0	52.0	Chemiluminescence (IFCC Cal.)
	ng/ml = µg/l	256	205	307	25.5	51.0	Chemiluminescence (Non IFCC Cal.)
Haptoglobin	ng/ml = µg/l	238	190	286	24.0	48.0	Roche Turbidimetric (Non IFCC Cal.)
	ng/ml = µg/l	222	178	266	22.0	44.0	Turbidimetric (IFCC Cal.)
	ng/ml = µg/l	193	154	232	19.5	39.0	Turbidimetric (Non IFCC Cal.)
	g/l	1.83	1.46	2.20	0.185	0.370	Agappe - Nephelometry
	mg/dl	183	146	220	18.5	37.0	
Immunoglobulin A	g/l	1.81	1.45	2.17	0.180	0.360	Nephelometric (IFCC Cal.)
	mg/dl	181	145	217	18.0	36.0	
	g/l	1.73	1.38	2.08	0.175	0.350	Turbidimetric (IFCC Cal.)
	mg/dl	173	138	208	17.5	35.0	
	g/l	1.73	1.38	2.08	0.175	0.350	Turbidimetric (Non IFCC Cal.)
	mg/dl	173	138	208	17.5	35.0	
Immunoglobulin A	g/l	4.57	3.43	5.71	0.570	1.14	Agappe - Nephelometry
	mg/dl	457	343	571	57.0	114	
	g/l	4.84	3.63	6.05	0.605	1.21	Nephelometric (IFCC Cal.)
	mg/dl	484	363	605	60.5	121	

Method		Liquid Assayed Specific Protein Control - Level 3					
Lot. No: 748LPC Cat. No: PS2684 Expiry: 2028/01/28							
Size: 3 x 1 ml		Range					
Analyte	Unit	Target	Low	High	1SD	2SD	Method
Immunoglobulin A	g/l	4.55	3.41	5.69	0.570	1.14	Turbidimetric (IFCC Cal.)
	mg/dl	455	341	569	57.0	114	
	g/l	4.63	3.47	5.79	0.580	1.16	Turbidimetric (Non IFCC Cal.)
	mg/dl	463	347	579	58.0	116	
Immunoglobulin E	KIU/l = IU/ml	245	196	294	24.5	49.0	Agappe - Nephelometry
	KIU/l = IU/ml	263	210	316	26.5	53.0	Chemiluminescence (Non IFCC Cal.)
	KIU/l = IU/ml	241	193	289	24.0	48.0	Nephelometric (Non IFCC Cal.)
	KIU/l = IU/ml	215	172	258	21.5	43.0	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	21.6	17.7	25.5	1.95	3.90	Nephelometric (IFCC Cal.)
	mg/dl	2160	1771	2549	195	389	
	g/l	21.9	18.0	25.8	1.95	3.90	Turbidimetric (IFCC Cal.)
	mg/dl	2190	1796	2584	197	394	
	g/l	22.3	18.3	26.3	2.00	4.00	Turbidimetric (Non IFCC Cal.)
	mg/dl	2230	1829	2631	201	401	
Immunoglobulin M	g/l	1.84	1.47	2.21	0.185	0.370	Agappe - Nephelometry
	mg/dl	184	147	221	18.5	37.0	
	g/l	1.84	1.47	2.21	0.185	0.370	Nephelometric (IFCC Cal.)
	mg/dl	184	147	221	18.5	37.0	
	g/l	1.75	1.40	2.10	0.175	0.350	Turbidimetric (IFCC Cal.)
	mg/dl	175	140	210	17.5	35.0	
	g/l	1.75	1.40	2.10	0.175	0.350	Turbidimetric (Non IFCC Cal.)
	mg/dl	175	140	210	17.5	35.0	
Kappa Light Chain Total	g/l	5.37	4.30	6.44	0.535	1.07	Agappe - Nephelometry
	mg/dl	537	430	644	53.5	107	
	g/l	5.13	4.10	6.16	0.515	1.03	Nephelometric - Siemens
Lambda Light Chains Total	mg/dl	513	410	616	51.5	103	
	g/l	2.76	2.21	3.31	0.275	0.550	Agappe - Nephelometry
	mg/dl	276	221	331	27.5	55.0	

Method		Liquid Assayed Specific Protein Control - Level 3					
Lot. No: 748LPC Cat. No: PS2684 Expiry: 2028/01/28							
Size: 3 x 1 ml		Range					
Analyte	Unit	Target	Low	High	1SD	2SD	Method
Lambda Light Chains Total	g/l	2.81	2.25	3.37	0.280	0.560	Nephelometric - Siemens
	mg/dl	281	225	337	28.0	56.0	
	g/l	2.92	2.34	3.50	0.290	0.580	Turbidimetric
	mg/dl	292	234	350	29.0	58.0	
Prealbumin	g/l	0.337	0.270	0.404	0.034	0.067	Agappe - Nephelometry
	mg/dl	33.7	27.0	40.4	3.35	6.70	
	g/l	0.339	0.271	0.407	0.034	0.068	Nephelometric (IFCC Cal.)
	mg/dl	33.9	27.1	40.7	3.40	6.80	
	g/l	0.329	0.263	0.395	0.033	0.066	Turbidimetric (IFCC Cal.)
	mg/dl	32.9	26.3	39.5	3.30	6.60	
	g/l	0.337	0.270	0.404	0.034	0.067	Turbidimetric (Non IFCC Cal.)
	mg/dl	33.7	27.0	40.4	3.35	6.70	
Rheumatoid Factor	U/ml	48.0	38.4	57.6	4.80	9.60	Agappe - Nephelometry
	U/ml	47.4	37.9	56.9	4.75	9.50	Latex (Non IFCC Cal.)
	U/ml	41.8	33.4	50.2	4.20	8.40	Ortho Vitros Microtip
	U/ml	63.4	50.7	76.1	6.35	12.7	Turbidimetric (Abbott Cal 6K44)
	U/ml	50.5	40.4	60.6	5.05	10.1	Turbidimetric (Non IFCC Cal.)
Transferrin	g/l	4.60	3.68	5.52	0.460	0.920	Nephelometric (IFCC Cal.)
	mg/dl	460	368	552	46.0	92.0	
	g/l	5.16	4.13	6.19	0.515	1.03	Ortho Vitros Microtip
	mg/dl	516	413	619	51.5	103	
	g/l	4.72	3.78	5.66	0.470	0.940	Turbidimetric (IFCC Cal.)
	mg/dl	472	378	566	47.0	94.0	
	g/l	4.83	3.86	5.80	0.485	0.970	Turbidimetric (Non IFCC Cal.)
	mg/dl	483	386	580	48.5	97.0	