RANDOX

PRODUCT INFORMATION

Cat. No. PS2683

747LPC

Please note in Liquid Protein Control - Level 2 PS2683 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

FORM NO. 8373-GP
REVISION (2)
2 Aug 2019

LIQUID ASSAYED SPECIFIC PROTEIN CONTROL - LEVEL 2 (SP CONTROL 2)

CAT. NO.	PS2683	**LOT NO.**	747LPC
SIZE:	3 x 1ml	**EXPIRY:**	2028-01-28
GTIN:	05055273204902		

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 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 2 3 x 1 ml

MATERIALS REQUIRED BUT NOT PROVIDED
N/A

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

16 Apr 26 bm

Table of Content

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All enzyme values are quoted to a temperature of 37°C, unless otherwise stated

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Method							Liquid Assayed Specific Protein Control - Level 2
Lot. No: 747LPC Cat. No: PS2683 Expiry: 2028/01/28							
Size: 3 x 1 ml			Range				
Analyte	Unit	Target	Low	High	1SD	2SD	Method
Albumin	g/dl	3.98	3.38	4.58	0.300	0.600	Bromocresol Green (IFCC Cal.)
	g/l	39.8	33.8	45.8	3.00	6.00	
	g/dl	4.09	3.48	4.70	0.305	0.610	Bromocresol Green (Non IFCC Cal.)
	g/l	40.9	34.8	47.0	3.05	6.10	
	g/dl	3.84	3.26	4.42	0.290	0.580	Bromocresol Purple (IFCC Cal.)
	g/l	38.4	32.6	44.2	2.90	5.80	
	g/dl	3.99	3.39	4.59	0.300	0.600	Nephelometric (IFCC Cal.)
	g/l	39.9	33.9	45.9	3.00	6.00	
	g/dl	3.81	3.24	4.38	0.285	0.570	Turbidimetric Assays (IFCC Cal.)
	g/l	38.1	32.4	43.8	2.85	5.70	
Alpha-1-Acid Glycoprotein	g/l	1.16	0.928	1.39	0.115	0.230	Turbidimetric (IFCC Cal.)
	mg/dl	116	92.8	139	11.5	23.0	
Alpha-1-Antitrypsin	g/l	1.35	1.08	1.62	0.135	0.270	Nephelometric (IFCC Cal.)
	mg/dl	135	108	162	13.5	27.0	
	g/l	1.29	1.03	1.55	0.130	0.260	Turbidimetric (IFCC Cal.)
	mg/dl	129	103	155	13.0	26.0	
	g/l	1.30	1.04	1.56	0.130	0.260	Turbidimetric (Non IFCC Cal.)
	mg/dl	130	104	156	13.0	26.0	
Alpha-2-Macroglobulin	g/l	2.07	1.66	2.48	0.205	0.410	Nephelometric (IFCC Cal.)
	mg/dl	207	166	248	20.5	41.0	
Alpha-fetoprotein	ng/ml	30.0	24.0	36.0	3.00	6.00	Chemiluminescence (IFCC Cal.)
	KIU/l = IU/ml	24.8	19.8	29.8	2.50	5.00	
	ng/ml	34.0	27.2	40.8	3.40	6.80	Chemiluminescence (Non IFCC Cal.)
	KIU/l = IU/ml	28.1	22.5	33.7	2.80	5.60	
Anti Streptolysin O	IU/ml	178	142	214	18.0	36.0	Nephelometric, others (Non IFCC Cal.)
	IU/ml	181	145	217	18.0	36.0	Turbidimetric (IFCC Cal.)
	IU/ml	184	147	221	18.5	37.0	Turbidimetric (Non IFCC Cal.)
Beta-2-Microglobulin	µg/ml = mg/l	3.19	2.55	3.83	0.320	0.640	Nephelometric (IFCC Cal.)
	µg/ml = mg/l	3.34	2.67	4.01	0.335	0.670	Turbidimetric (IFCC Cal.)
	µg/ml = mg/l	3.41	2.73	4.09	0.340	0.680	Turbidimetric (Non IFCC Cal.)
C-Reactive Protein	mg/dl	4.89	3.91	5.87	0.490	0.980	Beckman Turb. Latex (IFCC cal)
	mg/l	48.9	39.1	58.7	4.90	9.80	

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Method

Liquid Assayed Specific Protein Control - Level 2

Lot. No: 747LPC Cat. No: PS2683 Expiry: 2028/01/28

Size: 3 x 1 ml

			Range				
Analyte	**Unit**	**Target**	**Low**	**High**	**1SD**	**2SD**	**Method**
C-Reactive Protein	mg/dl	4.74	3.79	5.69	0.475	0.950	Roche Turbidimetric CRP4 (IFCC Cal.)
	mg/l	47.4	37.9	56.9	4.75	9.50	
	mg/dl	4.58	3.66	5.50	0.460	0.920	Roche Turbidimetric Gen 3 (Non IFCC Cal.
	mg/l	45.8	36.6	55.0	4.60	9.20	
	mg/dl	4.81	3.85	5.77	0.480	0.960	Roche Turbidimetric Latex (IFCC Cal.)
	mg/l	48.1	38.5	57.7	4.80	9.60	
	mg/dl	4.74	3.79	5.69	0.475	0.950	Roche Turbidimetric Latex (Non IFCC Cal.
	mg/l	47.4	37.9	56.9	4.75	9.50	
	mg/dl	4.40	3.52	5.28	0.440	0.880	Turbidimetric (IFCC Cal.)
	mg/l	44.0	35.2	52.8	4.40	8.80	
	mg/dl	4.50	3.60	5.40	0.450	0.900	Turbidimetric (Non IFCC Cal.)
	mg/l	45.0	36.0	54.0	4.50	9.00	
	mg/dl	3.56	2.85	4.27	0.355	0.710	Vitros (IFCC Cal.)
	mg/l	35.6	28.5	42.7	3.55	7.10	
Caeruloplasmin	g/l	0.396	0.297	0.495	0.050	0.099	Nephelometric (IFCC Cal.)
	mg/dl	39.6	29.7	49.5	4.95	9.90	
	g/l	0.281	0.225	0.337	0.028	0.056	Roche Turbidimetric (IFCC Cal.)
	mg/dl	28.1	22.5	33.7	2.80	5.60	
	g/l	0.275	0.220	0.330	0.028	0.055	Roche Turbidimetric (Non IFCC Cal.)
	mg/dl	27.5	22.0	33.0	2.75	5.50	
	g/l	0.344	0.258	0.430	0.043	0.086	Turbidimetric (IFCC Cal.)
	mg/dl	34.4	25.8	43.0	4.30	8.60	
	g/l	0.442	0.332	0.552	0.055	0.110	Turbidimetric (Non IFCC Cal.)
	mg/dl	44.2	33.2	55.2	5.50	11.0	
	g/l	0.367	0.275	0.459	0.046	0.092	Turbidimetric Sentinel Reagent
	mg/dl	36.7	27.5	45.9	4.60	9.20	
Complement C3	g/l	1.67	1.34	2.00	0.165	0.330	Nephelometric (IFCC Cal.)
	mg/dl	167	134	200	16.5	33.0	
	g/l	1.69	1.35	2.03	0.170	0.340	Turbidimetric (IFCC Cal.)
	mg/dl	169	135	203	17.0	34.0	
	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	
Complement C4	g/l	0.335	0.268	0.402	0.034	0.067	Nephelometric (IFCC Cal.)
	mg/dl	33.5	26.8	40.2	3.35	6.70	
	g/l	0.311	0.249	0.373	0.031	0.062	Turbidimetric (IFCC Cal.)
	mg/dl	31.1	24.9	37.3	3.10	6.20	
	g/l	0.283	0.226	0.340	0.029	0.057	Turbidimetric (Non IFCC Cal.)
	mg/dl	28.3	22.6	34.0	2.85	5.70	

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Method							Liquid Assayed Specific Protein Control - Level 2
Lot. No: 747LPC Cat. No: PS2683 Expiry: 2028/01/28							
Size: 3 x 1 ml			Range				
Analyte	Unit	Target	Low	High	1SD	2SD	Method
Ferritin	ng/ml = µg/l	173	138	208	17.5	35.0	Chemiluminescence (IFCC Cal.)
	ng/ml = µg/l	177	142	212	17.5	35.0	Chemiluminescence (Non IFCC Cal.)
	ng/ml = µg/l	161	129	193	16.0	32.0	Roche Turbidimetric (Non IFCC Cal.)
	ng/ml = µg/l	153	122	184	15.5	31.0	Turbidimetric (IFCC Cal.)
	ng/ml = µg/l	127	102	152	12.5	25.0	Turbidimetric (Non IFCC Cal.)
Haptoglobin	g/l	1.17	0.936	1.40	0.115	0.230	Nephelometric (IFCC Cal.)
	mg/dl	117	93.6	140	11.5	23.0	
	g/l	1.18	0.944	1.42	0.120	0.240	Turbidimetric (IFCC Cal.)
	mg/dl	118	94.4	142	12.0	24.0	
	g/l	1.18	0.944	1.42	0.120	0.240	Turbidimetric (Non IFCC Cal.)
	mg/dl	118	94.4	142	12.0	24.0	
Immunoglobulin A	g/l	3.28	2.46	4.10	0.410	0.820	Nephelometric (IFCC Cal.)
	mg/dl	328	246	410	41.0	82.0	
	g/l	3.08	2.31	3.85	0.385	0.770	Turbidimetric (IFCC Cal.)
	mg/dl	308	231	385	38.5	77.0	
	g/l	3.14	2.36	3.92	0.390	0.780	Turbidimetric (Non IFCC Cal.)
	mg/dl	314	236	392	39.0	78.0	
Immunoglobulin E	KIU/l = IU/ml	180	144	216	18.0	36.0	Chemiluminescence (Non IFCC Cal.)
	KIU/l = IU/ml	157	126	188	15.5	31.0	Nephelometric (Non IFCC Cal.)
	KIU/l = IU/ml	143	114	172	14.5	29.0	Turbidimetric (Non IFCC Cal.)
Immunoglobulin G	g/l	14.9	12.2	17.6	1.35	2.70	Nephelometric (IFCC Cal.)
	mg/dl	1490	1222	1758	134	268	
	g/l	14.8	12.1	17.5	1.35	2.70	Turbidimetric (IFCC Cal.)
	mg/dl	1480	1214	1746	133	266	
	g/l	15.0	12.3	17.7	1.35	2.70	Turbidimetric (Non IFCC Cal.)
	mg/dl	1500	1230	1770	135	270	
Immunoglobulin M	g/l	1.26	1.01	1.51	0.125	0.250	Nephelometric (IFCC Cal.)
	mg/dl	126	101	151	12.5	25.0	

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Method

Liquid Assayed Specific Protein Control - Level 2

Lot. No: 747LPC Cat. No: PS2683 Expiry: 2028/01/28

Size: 3 x 1 ml

			Range				
Analyte	**Unit**	**Target**	**Low**	**High**	**1SD**	**2SD**	**Method**
Immunoglobulin M	g/l	1.20	0.960	1.44	0.120	0.240	Turbidimetric (IFCC Cal.)
	mg/dl	120	96.0	144	12.0	24.0	
	g/l	1.21	0.968	1.45	0.120	0.240	Turbidimetric (Non IFCC Cal.)
	mg/dl	121	96.8	145	12.0	24.0	
Kappa Light Chain Total	g/l	3.55	2.84	4.26	0.355	0.710	Nephelometric - Siemens
	mg/dl	355	284	426	35.5	71.0	
	g/l	3.71	2.97	4.45	0.370	0.740	Turbidimetric
	mg/dl	371	297	445	37.0	74.0	
Lambda Light Chains Total	g/l	2.01	1.61	2.41	0.200	0.400	Nephelometric - Siemens
	mg/dl	201	161	241	20.0	40.0	
	g/l	2.02	1.62	2.42	0.200	0.400	Turbidimetric
	mg/dl	202	162	242	20.0	40.0	
Prealbumin	g/l	0.220	0.176	0.264	0.022	0.044	Nephelometric (IFCC Cal.)
	mg/dl	22.0	17.6	26.4	2.20	4.40	
	g/l	0.222	0.178	0.266	0.022	0.044	Turbidimetric (IFCC Cal.)
	mg/dl	22.2	17.8	26.6	2.20	4.40	
	g/l	0.229	0.183	0.275	0.023	0.046	Turbidimetric (Non IFCC Cal.)
	mg/dl	22.9	18.3	27.5	2.30	4.60	
Retinol Binding Protein	mg/l	43.7	35.0	52.4	4.35	8.70	Nephelometric (IFCC Cal.)
Rheumatoid Factor	U/ml	33.5	26.8	40.2	3.35	6.70	Latex (Non IFCC Cal.)
	U/ml	26.0	20.8	31.2	2.60	5.20	Nephelometric (Non IFCC Cal.)
	U/ml	30.1	24.1	36.1	3.00	6.00	Ortho Vitros Microtip
	U/ml	48.0	38.4	57.6	4.80	9.60	Turbidimetric (Abbott Cal 6K44)
	U/ml	34.8	27.8	41.8	3.50	7.00	Turbidimetric (Non IFCC Cal.)
Transferrin	g/l	3.09	2.47	3.71	0.310	0.620	Nephelometric (IFCC Cal.)
	mg/dl	309	247	371	31.0	62.0	
	g/l	3.26	2.61	3.91	0.325	0.650	Turbidimetric (IFCC Cal.)
	mg/dl	326	261	391	32.5	65.0	
	g/l	3.30	2.64	3.96	0.330	0.660	Turbidimetric (Non IFCC Cal.)
	mg/dl	330	264	396	33.0	66.0	

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