

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

CAT. NO. PS2684
SIZE: 3 x 1 ml

LOT NO. 635LPC
EXPIRY: 2023-09-28

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. Note: Free Lambda light chains are not for use in the U.S.

SAFETY PRECAUTIONS AND WARNINGS

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

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 is present in the Liquid Assayed Specific Protein Control material but no claim is made for the expected value or stability of this analyte.

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.

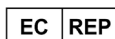
LIMITATIONS

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

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.

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



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

Rev. 21 Nov '22 me

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

Cat. No. PS2684 Lot. No. 635LPC Size 3 x 1ml Expiry 2023-09-28

Analyte	unit	Target	Range		methods	
			low	high		
Albumin	g/l	70.1	59.6	80.6	Bromocresol Green (IFCC Cal.)	
	g/dl	7.01	5.96	8.06		
	g/l	70.0	59.5	80.5	Bromocresol Purple (IFCC Cal.)	
	g/dl	7.00	5.95	8.05		
	g/l	69.5	59.1	79.9	Nephelometric (IFCC Cal.)	
	g/dl	6.95	5.91	7.99		
	g/l	71.6	60.9	82.3	Bromocresol Green (Non IFCC Cal.)	
	g/dl	7.16	6.09	8.23		
	g/l	74.2	63.1	85.3	Turbidimetric Assays (IFCC Cal.)	
	g/dl	7.42	6.31	8.53		
Alpha-1-Acid Glycoprotein	g/l	1.63	1.30	1.96	Turbidimetric (IFCC Cal.)	
	mg/dl	163	130	196		
	g/l	1.75	1.40	2.10	Nephelometric (IFCC Cal.)	
	mg/dl	175	140	210		
	g/l	1.66	1.33	1.99	Turbidimetric (Non IFCC Cal.)	
	mg/dl	166	133	199		
	Alpha-1-Antitrypsin	g/l	2.13	1.70	2.56	Turbidimetric (IFCC Cal.)
		mg/dl	213	170	256	
g/l		2.26	1.81	2.71	Nephelometric (IFCC Cal.)	
mg/dl		226	181	271		
g/l		2.12	1.70	2.54	Turbidimetric (Non IFCC Cal.)	
mg/dl		212	170	254		
Alpha-2-Macroglobulin	g/l	3.25	2.60	3.90	Nephelometric (IFCC Cal.)	
	mg/dl	325	260	390		
Alphafoetoprotein	KIU/l = IU/ml	42.8	34.2	51.4	Chemiluminescence (IFCC Cal.)	
	ng/ml	51.8	41.4	62.2		
	KIU/l = IU/ml	45.3	36.2	54.4	Chemiluminescence (Non IFCC Cal.)	
	ng/ml	54.8	43.8	65.8		
Anti Streptolysin O	IU/ml	356	285	427	Turbidimetric (IFCC Cal.)	
	IU/ml	382	306	458	Turbidimetric (Non IFCC Cal.)	
	IU/ml	209	167	251	Neph. Beckman (Non IFCC Cal.)	
	IU/ml	367	294	440	Siemens Nephelometric (Non IFCC Cal.)	
Antithrombin III	mg/l	432	324	540	Turbidimetric (Non IFCC Cal.)	
	mg/dl	43.2	32.4	54.0		
Beta-2-microglobulin	µg/ml = mg/l	4.97	3.98	5.96	Nephelometric (IFCC Cal.)	
	µg/ml = mg/l	5.03	4.02	6.04	Nephelometric (Non IFCC Cal.)	
	µg/ml = mg/l	5.66	4.53	6.79	Turbidimetric (IFCC Cal.)	
	µg/ml = mg/l	5.70	4.56	6.84	Turbidimetric (Non IFCC Cal.)	
C-Reactive Protein	mg/l	45.7	36.6	54.8	Vitros (IFCC Cal.)	
	mg/l	68.2	54.6	81.8	Turbidimetric (IFCC Cal.)	

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

Cat. No. PS2684 Lot. No. 635LPC Size 3 x 1ml Expiry 2023-09-28

Analyte	unit	Target	Range		methods	
			low	high		
C-Reactive Protein	mg/l	66.8	53.4	80.2	Nephelometric (IFCC Cal.)	
	mg/l	69.5	55.6	83.4	Turbidimetric (Non IFCC Cal.)	
	mg/l	70.5	56.4	84.6	Roche Turbidimetric Gen 3 (IFCC Cal.)	
	mg/l	67.0	53.6	80.4	Roche Turbidimetric Gen 3 (non-IFCC Cal.)	
	mg/l	66.8	53.4	80.2	Roche Turbidimetric Latex (IFCC Cal.)	
	mg/l	67.9	54.3	81.5	Roche Turbidimetric Latex (non-IFCC Cal.)	
	mg/l	73.2	58.6	87.8	Beckman Turb Latex (IFCC Cal)	
	mg/l	69.3	55.4	83.2	Roche Turbidimetric CRP4 (IFCC Cal.)	
Caeruloplasmin	g/l	0.688	0.516	0.860	Nephelometric (IFCC Cal.)	
	mg/dl	68.8	51.6	86.0		
	g/l	0.570	0.428	0.712	Turbidimetric (IFCC Cal.)	
	mg/dl	57.0	42.8	71.2		
	g/l	0.595	0.446	0.744	Nephelometric (Non IFCC Cal.)	
	mg/dl	59.5	44.6	74.4		
	g/l	0.475	0.356	0.594	Turbidimetric (Non IFCC Cal.)	
	mg/dl	47.5	35.6	59.4		
Complement C3	g/l	3.08	2.46	3.70	Turbidimetric (IFCC Cal.)	
	mg/dl	308	246	370		
	g/l	3.05	2.44	3.66	Nephelometric (IFCC Cal.)	
	mg/dl	305	244	366		
	g/l	2.95	2.36	3.54	Nephelometric (Non IFCC Cal.)	
	mg/dl	295	236	354		
	g/l	3.20	2.56	3.84	Turbidimetric (Non IFCC Cal.)	
	mg/dl	320	256	384		
Complement C4	g/l	0.587	0.470	0.704	Turbidimetric (IFCC Cal.)	
	mg/dl	58.7	47.0	70.4		
	g/l	0.580	0.464	0.696	Nephelometric (IFCC Cal.)	
	mg/dl	58.0	46.4	69.6		
	g/l	0.556	0.445	0.667	Nephelometric (Non IFCC Cal.)	
	mg/dl	55.6	44.5	66.7		
	g/l	0.569	0.455	0.683	Turbidimetric (Non IFCC Cal.)	
	mg/dl	56.9	45.5	68.3		
Ferritin	ng/ml = µg/l	323	258	388	Turbidimetric (IFCC Cal.)	
	ng/ml = µg/l	297	238	356	Turbidimetric (Non IFCC Cal.)	
	ng/ml = µg/l	375	300	450	Chemiluminescence (IFCC Cal.)	
	ng/ml = µg/l	385	308	462	Chemiluminescence (Non IFCC Cal.)	
	ng/ml = µg/l	293	234	352	Nephelometric (IFCC Cal.)	
	Free Lambda Light Chains	mg/L	23.3	18.6	28.0	Nephelometric - Binding Site
	mg/L	19.1	15.3	22.9	Nephelometric - Siemens	
	mg/L	21.3	17.0	25.6	Turbidimetric	
Haptoglobin	g/l	1.63	1.30	1.96	Nephelometric (IFCC Cal.)	
	mg/dl	163	130	196		

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

Cat. No. PS2684 Lot. No. 635LPC Size 3 x 1ml Expiry 2023-09-28

Analyte	unit	Target	Range		methods
			low	high	
Haptoglobin	g/l	1.61	1.29	1.93	Turbidimetric (IFCC Cal.)
	mg/dl	161	129	193	
	g/l	1.62	1.30	1.94	Turbidimetric (Non IFCC Cal.)
	mg/dl	162	130	194	
Immunoglobulin A	g/l	5.88	4.41	7.35	Turbidimetric (IFCC Cal.)
	mg/dl	588	441	735	
	g/l	6.15	4.61	7.69	Nephelometric (IFCC Cal.)
	mg/dl	615	461	769	
	g/l	6.19	4.64	7.74	Nephelometric (Non IFCC Cal.)
	mg/dl	619	464	774	
	g/l	6.03	4.52	7.54	Turbidimetric (Non IFCC Cal.)
	mg/dl	603	452	754	
Immunoglobulin E	g/l	5.92	4.44	7.40	Vitros 5.1 FS Microtip (IFCC)
	mg/dl	592	444	740	
	KIU/l = IU/ml	267	214	320	Chemiluminescence (Non IFCC Cal.)
	KIU/l = IU/ml	244	195	293	Nephelometric (Non IFCC Cal.)
	KIU/l = IU/ml	217	174	260	Turbidimetric (Non IFCC Cal.)
Immunoglobulin G	g/l	27.4	22.5	32.3	Turbidimetric (IFCC Cal.)
	mg/dl	2740	2250	3230	
	g/l	27.6	22.6	32.6	Nephelometric (IFCC Cal.)
	mg/dl	2760	2260	3260	
	g/l	27.5	22.6	32.5	Nephelometric (Non IFCC Cal.)
	mg/dl	2750	2260	3240	
	g/l	28.3	23.2	33.4	Turbidimetric (Non IFCC Cal.)
	mg/dl	2830	2320	3340	
	g/l	30.6	25.1	36.1	Vitros 5.1 FS Microtip (IFCC)
	mg/dl	3060	2510	3610	
Immunoglobulin M	g/l	2.12	1.70	2.54	Turbidimetric (IFCC Cal.)
	mg/dl	212	170	254	
	g/l	2.20	1.76	2.64	Nephelometric (IFCC Cal.)
	mg/dl	220	176	264	
	g/l	2.16	1.73	2.59	Nephelometric (Non IFCC Cal.)
	mg/dl	216	173	259	
	g/l	2.16	1.73	2.59	Turbidimetric (Non IFCC Cal.)
	mg/dl	216	173	259	
Kappa Light Chain	g/l	2.17	1.74	2.60	Vitros 5.1 FS Microtip (IFCC)
	mg/dl	217	174	260	
	g/l	22.5	18.0	27.0	Nephelometric - Beckman
	mg/dl	2253	1800	2700	
	g/l	6.53	5.22	7.84	Nephelometric - Siemens
	mg/dl	653	522	784	
Lambda Light Chain	g/l	7.29	5.83	8.75	Turbidimetric
	mg/dl	729	583	875	
	g/l	13.1	10.5	15.8	Nephelometric - Beckman
	mg/dl	1313	1050	1580	
Lambda Light Chain	g/l	3.68	2.94	4.42	Nephelometric - Siemens
	mg/dl	368	294	442	

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

Cat. No. PS2684 Lot. No. 635LPC Size 3 x 1ml Expiry 2023-09-28

		Range				
Analyte	unit	Target	low	high	methods	
Lambda Light Chain	g/l	3.96	3.17	4.75	Turbidimetric	
	mg/dl	396	317	475		
Prealbumin	g/l	0.450	0.360	0.540	Nephelometric (IFCC Cal.)	
	mg/dl	45.0	36.0	54.0		
	g/l	0.414	0.331	0.497	Turbidimetric (IFCC Cal.)	
	mg/dl	41.4	33.1	49.7		
	g/l	0.419	0.335	0.503	Turbidimetric (Non IFCC Cal.)	
mg/dl	41.9	33.5	50.3			
Protein Total	g/l	113	90.4	136	Biuret reaction end point	
	g/dl	11.3	9.04	13.6		
Retinol Binding Protein	mg/l	75.0	60.0	90.0	Nephelometric (IFCC Cal.)	
Rheumatoid Factor	U/ml	54.6	41.0	68.3	Turbidimetric (Non IFCC Cal.)	
	U/ml	42.5	31.9	53.1	Siemens Nephelometric (Non IFCC Cal.)	
Transferrin	g/l	5.01	4.01	6.01	Turbidimetric (IFCC Cal.)	
	mg/dl	501	401	601		
	g/l	5.08	4.06	6.10	Turbidimetric (Non IFCC Cal.)	
	mg/dl	508	406	610		
	g/l	5.16	4.13	6.19	Nephelometric (IFCC Cal.)	
mg/dl	516	413	619			