

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

Cat. No. PS2682 **Lot No.** 401LPC
Size: 3 x 1 ml **Expiry:** 2018-01

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 Kappa and 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.

PREPARATION

The Liquid Protein Controls are supplied ready for use.

MATERIALS PROVIDED

Liquid Assayed Specific Protein Control - Level I 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 Liquid 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

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LIQUID ASSAYED SPECIFIC PROTEIN CONTROL - LEVEL 1 (SP CONTROL 1)

Cat. No. PS2682 Lot. No. 401LPC Size 3 x 1ml Expiry 2018-01

Range					
Analyte	unit	Target	low	high	methods
Albumin	g/l	17.8	15.1	20.5	Bromocresol Green (IFCC Cal.)
	g/dl	1.78	1.51	2.05	
	g/l	18.0	15.3	20.7	Bromocresol Purple (IFCC Cal.)
	g/dl	1.80	1.53	2.07	
	g/l	17.6	15.0	20.2	Nephelometric (IFCC Cal.)
	g/dl	1.76	1.50	2.02	
	g/l	18.2	15.5	20.9	Bromocresol Green (Non IFCC Cal.)
	g/dl	1.82	1.55	2.09	
	g/l	17.0	14.5	19.6	Bromocresol Purple (Non IFCC Cal.)
	g/dl	1.70	1.45	1.95	
	g/l	17.5	14.9	20.1	Turbidimetric Assays (IFCC Cal.)
	g/dl	1.75	1.49	2.01	
	g/l	17.9	15.2	20.6	Turbidimetric Assays (Non IFCC Cal.)
	g/dl	1.79	1.52	2.06	
Alpha-1-Acid Glycoprotein	g/l	0.410	0.328	0.492	Turbidimetric (IFCC Cal.)
	mg/dl	41.0	32.8	49.2	
	g/l	0.460	0.368	0.552	Nephelometric (IFCC Cal.)
	mg/dl	46.0	36.8	55.2	
	g/l	0.410	0.328	0.492	Turbidimetric (Non IFCC Cal.)
	mg/dl	41.0	32.8	49.2	
Alpha-1-Antitrypsin	g/l	0.700	0.560	0.840	Agappe - Nephelometry
	mg/dl	70.0	56.0	84.0	
	g/l	0.760	0.608	0.912	Turbidimetric (IFCC Cal.)
	mg/dl	76.0	60.8	91.2	
	g/l	0.800	0.640	0.960	Nephelometric (IFCC Cal.)
	mg/dl	80.0	64.0	96.0	
Alpha-1-Antitrypsin	g/l	0.820	0.656	0.984	Nephelometric (Non IFCC Cal.)
	mg/dl	82.0	65.6	98.4	
	g/l	0.730	0.584	0.876	Turbidimetric (Non IFCC Cal.)
	mg/dl	73.0	58.4	87.6	
	g/l	0.750	0.600	0.900	Agappe - Nephelometry
	mg/dl	75.0	60.0	90.0	
Alpha-2-Macroglobulin	g/l	1.11	0.888	1.33	Turbidimetric (IFCC Cal.)
	mg/dl	111	88.8	133	
	g/l	1.05	0.840	1.26	Nephelometric (IFCC Cal.)
	mg/dl	105	84.0	126	
	g/l	1.05	0.840	1.26	Agappe - Nephelometry
	mg/dl	105	84.0	126	
Alphafoetoprotein	KIU/l = IU/ml	1.01	0.808	1.21	Chemiluminescence (IFCC Cal.)
	ng/ml	1.22	0.978	1.46	
Anti Streptolysin O	IU/ml	121	84.7	157	Turbidimetric (IFCC Cal.)
	IU/ml	128	96.0	160	Turbidimetric (Non IFCC Cal.)

%

LIQUID ASSAYED SPECIFIC PROTEIN CONTROL - LEVEL 1 (SP CONTROL 1)

Cat. No. PS2682 Lot. No. 401LPC Size 3 x 1ml Expiry 2018-01

Range					
Analyte	unit	Target	low	high	methods
Anti Streptolysin O	IU/ml	88.1	66.1	110	Neph. Beckman (IFCC Cal.)
	IU/ml	84.0	63.0	105	Neph. Beckman (Non IFCC Cal.)
	IU/ml	106	79.5	133	Agappe - Nephelometry
	IU/ml	145	116	174	Neph. Behring (IFCC Cal.)
	IU/ml	150	120	180	Neph. Behring (Non IFCC Cal.)
Antithrombin III	mg/l	129	110	148	Nephelometric (Non IFCC Cal.)
	mg/dl	12.9	11.0	14.8	
Beta-2-microglobulin	µg/ml = mg/l	1.97	1.58	2.36	Chemiluminescence (IFCC Cal.)
	µg/ml = mg/l	2.00	1.60	2.40	Chemiluminescence (Non IFCC Cal.)
	µg/ml = mg/l	1.87	1.50	2.24	Nephelometric (IFCC Cal.)
	µg/ml = mg/l	1.94	1.55	2.33	Nephelometric (Non IFCC Cal.)
	µg/ml = mg/l	2.09	1.67	2.51	Turbidimetric (IFCC Cal.)
	µg/ml = mg/l	2.03	1.62	2.44	Turbidimetric (Non IFCC Cal.)
	µg/ml = mg/l	1.84	1.47	2.21	Randox Immunoturbidimetric
C-Reactive Protein	mg/l	38.8	31.0	46.6	Vitros (IFCC Cal.)
	mg/l	24.0	19.2	28.8	Turbidimetric (IFCC Cal.)
	mg/l	21.8	17.4	26.2	Nephelometric (IFCC Cal.)
	mg/l	36.0	28.8	43.2	Vitros (Non IFCC Cal.)
	mg/l	22.1	17.7	26.5	Nephelometric (Non IFCC Cal.)
	mg/l	23.2	18.6	27.8	Turbidimetric (Non IFCC Cal.)
	mg/l	29.2	23.4	35.0	Agappe - Nephelometry
Caeruloplasmin	g/l	0.116	0.093	0.139	Nephelometric (IFCC Cal.)
	mg/dl	11.6	9.30	13.9	
	g/l	0.175	0.113	0.237	Turbidimetric (IFCC Cal.)
	mg/dl	17.5	13.3	23.7	
	g/l	0.120	0.096	0.144	Nephelometric (Non IFCC Cal.)
	mg/dl	12.0	9.60	14.4	
	g/l	0.182	0.118	0.246	Turbidimetric (Non IFCC Cal.)
	mg/dl	18.2	11.8	24.6	
	g/l	0.119	0.095	0.143	Neph. Beckman (IFCC Cal.)
	mg/dl	11.9	9.50	14.3	
	g/l	0.160	0.128	0.192	Agappe - Nephelometry
	mg/dl	16.0	12.8	19.2	
Complement C3	g/l	0.167	0.142	0.192	Randox Immunoturbidimetric
	mg/dl	16.7	14.2	19.2	
	g/l	0.710	0.568	0.852	Turbidimetric (IFCC Cal.)
	mg/dl	71.0	56.8	85.2	
	g/l	0.718	0.574	0.862	Nephelometric (IFCC Cal.)
	mg/dl	71.8	57.4	86.2	
	g/l	0.719	0.575	0.863	Nephelometric (Non IFCC Cal.)
	mg/dl	71.9	57.5	86.3	
	g/l	0.718	0.574	0.862	Turbidimetric (Non IFCC Cal.)
	mg/dl	71.8	57.4	86.2	
	g/l	0.687	0.550	0.824	Vitros 5.1 FS microtip assay
	mg/dl	68.7	55.0	82.4	
	g/l	0.669	0.535	0.803	Vitros 5.1 FS Microtip (Non IFCC)
	mg/dl	66.9	53.5	80.3	

%

LIQUID ASSAYED SPECIFIC PROTEIN CONTROL - LEVEL 1 (SP CONTROL 1)

Cat. No. PS2682 Lot. No. 401LPC Size 3 x 1ml Expiry 2018-01

Range					
Analyte	unit	Target	low	high	methods
Complement C3	g/l	0.704	0.563	0.845	Agappe - Nephelometry
	mg/dl	70.4	56.3	84.5	
Complement C4	g/l	0.159	0.127	0.191	Turbidimetric (IFCC Cal.)
	mg/dl	15.9	12.7	19.1	
	g/l	0.177	0.142	0.212	Nephelometric (IFCC Cal.)
	mg/dl	17.7	14.2	21.2	
	g/l	0.173	0.138	0.208	Nephelometric (Non IFCC Cal.)
	mg/dl	17.3	13.8	20.8	
	g/l	0.155	0.124	0.186	Turbidimetric (Non IFCC Cal.)
	mg/dl	15.5	12.4	18.6	
	g/l	0.151	0.121	0.181	Vitros 5.1 FS microtip assay
	mg/dl	15.1	12.1	18.1	
	g/l	0.160	0.128	0.192	Vitros 5.1 FS Microtip (Non IFCC)
	mg/dl	16.0	12.8	19.2	
	g/l	0.172	0.138	0.206	Agappe - Nephelometry
	mg/dl	17.2	13.8	20.6	
Ferritin	ng/ml = µg/l	112	89.6	134	Turbidimetric (IFCC Cal.)
	ng/ml = µg/l	113	90.4	136	Turbidimetric (Non IFCC Cal.)
	ng/ml = µg/l	113	90.4	136	Chemiluminescence (IFCC Cal.)
	ng/ml = µg/l	112	89.6	134	Chemiluminescence (Non IFCC Cal.)
	ng/ml = µg/l	102	81.6	122	Enzyme Immunoassay (IFCC Cal.)
	ng/ml = µg/l	106	84.8	127	Nephelometric (IFCC Cal.)
	ng/ml = µg/l	113	90.4	136	Agappe - Nephelometry
Free Kappa Light Chains	mg/L	15.9	11.9	19.9	Nephelometric (Non IFCC Cal.)
	mg/L	14.5	10.9	18.1	Turbidimetric (Non IFCC Cal.)
Free Lambda Light Chains	mg/L	17.3	12.1	22.5	Nephelometric (Non IFCC Cal.)
	mg/L	16.7	12.5	20.9	Turbidimetric (Non IFCC Cal.)
	mg/L	16.5	12.4	20.6	Nephelometric (IFCC Cal.)
Haptoglobin	g/l	0.680	0.544	0.816	Nephelometric (IFCC Cal.)
	mg/dl	68.0	54.4	81.6	
	g/l	0.689	0.551	0.827	Turbidimetric (IFCC Cal.)
	mg/dl	68.9	55.1	82.7	
	g/l	0.715	0.572	0.858	Nephelometric (Non IFCC Cal.)
	mg/dl	71.5	57.2	85.8	
	g/l	0.680	0.544	0.816	Turbidimetric (Non IFCC Cal.)
	mg/dl	68.0	54.4	81.6	
Immunoglobulin A	g/l	0.690	0.552	0.828	Agappe - Nephelometry
	mg/dl	69.0	55.2	82.8	
	g/l	1.24	0.930	1.55	Turbidimetric (IFCC Cal.)
	mg/dl	124	93.0	155	
	g/l	1.27	0.953	1.59	Nephelometric (IFCC Cal.)
	mg/dl	127	95.3	159	
	g/l	1.32	0.990	1.65	Nephelometric (Non IFCC Cal.)
	mg/dl	132	99.0	165	
	g/l	1.22	0.915	1.53	Turbidimetric (Non IFCC Cal.)
	mg/dl	122	91.5	153	

%

LIQUID ASSAYED SPECIFIC PROTEIN CONTROL - LEVEL 1 (SP CONTROL 1)

Cat. No. PS2682 Lot. No. 401LPC Size 3 x 1ml Expiry 2018-01

Range					
Analyte	unit	Target	low	high	methods
Immunoglobulin A	g/l	1.14	0.855	1.43	Vitros 5.1 FS Microtip (IFCC)
	mg/dl	114	85.5	143	
	g/l	1.15	0.863	1.44	Vitros 5.1 FS Microtip (Non IFCC)
	mg/dl	115	86.3	144	
	g/l	1.25	0.938	1.56	Agappe - Nephelometry
	mg/dl	125	93.8	156	
Immunoglobulin E	KIU/l = IU/ml	70.7	56.6	84.8	Fluorimetric (Non IFCC Cal.)
	KIU/l = IU/ml	72.5	58.0	87.0	Chemiluminescence (Non IFCC Cal.)
	KIU/l = IU/ml	75.6	60.5	90.7	Nephelometric (Non IFCC Cal.)
	KIU/l = IU/ml	69.9	55.9	83.9	Enzyme Immunoassay (Non IFCC Cal.)
	KIU/l = IU/ml	77.2	61.8	92.6	Turbidimetric (Non IFCC Cal.)
	KIU/l = IU/ml	69.9	55.9	83.9	Agappe - Nephelometry
	KIU/l = IU/ml	90.7	72.6	109	Randox Immunoturbidimetric
Immunoglobulin G	g/l	6.96	5.71	8.21	Turbidimetric (IFCC Cal.)
	mg/dl	696	571	821	
	g/l	7.31	5.99	8.63	Nephelometric (IFCC Cal.)
	mg/dl	731	599	863	
	g/l	7.26	5.95	8.57	Nephelometric (Non IFCC Cal.)
	mg/dl	726	595	857	
	g/l	6.94	5.69	8.19	Turbidimetric (Non IFCC Cal.)
	mg/dl	694	569	819	
	g/l	6.82	5.59	8.05	Vitros 5.1 FS Microtip (IFCC)
	mg/dl	682	559	805	
	g/l	7.34	6.02	8.66	Vitros 5.1 FS Microtip (Non IFCC)
	mg/dl	734	602	866	
	g/l	6.44	5.28	7.60	Agappe - Nephelometry
	mg/dl	644	528	760	
Immunoglobulin M	g/l	0.930	0.744	1.12	Turbidimetric (IFCC Cal.)
	mg/dl	93.0	74.4	112	
	g/l	0.980	0.784	1.18	Nephelometric (IFCC Cal.)
	mg/dl	98.0	78.4	118	
	g/l	0.980	0.784	1.18	Nephelometric (Non IFCC Cal.)
	mg/dl	98.0	78.4	118	
	g/l	0.930	0.744	1.12	Turbidimetric (Non IFCC Cal.)
	mg/dl	93.0	74.4	112	
	g/l	0.880	0.704	1.06	Vitros 5.1 FS Microtip (IFCC)
	mg/dl	88.0	70.4	106	
	g/l	0.860	0.688	1.03	Vitros 5.1 FS Microtip (Non IFCC)
	mg/dl	86.0	68.8	103	
	g/l	1.14	0.912	1.37	Agappe - Nephelometry
	mg/dl	114	91.2	137	
Kappa Light Chain	g/l	1.78	1.34	2.23	Neph. Behring (IFCC Cal.)
	mg/dl	178	134	222	
	g/l	1.80	1.35	2.25	Neph. Behring (Non IFCC Cal.)
	mg/dl	180	135	225	

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LIQUID ASSAYED SPECIFIC PROTEIN CONTROL - LEVEL 1 (SP CONTROL 1)

Cat. No. PS2682 Lot. No. 401LPC Size 3 x 1ml Expiry 2018-01

Range					
Analyte	unit	Target	low	high	methods
Kappa Light Chain	g/l	6.02	4.52	7.53	Neph. Beckman (IFCC Cal.)
	mg/dl	602	452	752	
	g/l	1.80	1.35	2.25	Turbidimetric (IFCC Cal.)
	mg/dl	180	135	225	
	g/l	1.88	1.41	2.35	Turbidimetric (Non IFCC Cal.)
	mg/dl	188	141	235	
	g/l	1.78	1.34	2.23	Agappe - Nephelometry
	mg/dl	178	134	222	
Lambda Light Chain	g/l	0.910	0.683	1.14	Neph. Behring (IFCC Cal.)
	mg/dl	91.0	68.3	114	
	g/l	0.929	0.697	1.16	Neph. Behring (Non IFCC Cal.)
	mg/dl	92.9	69.7	116	
	g/l	3.04	2.28	3.80	Neph. Beckman (IFCC Cal.)
	mg/dl	304	228	380	
	g/l	0.856	0.642	1.07	Turbidimetric (IFCC Cal.)
	mg/dl	85.6	64.2	107	
	g/l	0.923	0.692	1.15	Turbidimetric (Non IFCC Cal.)
	mg/dl	92.3	69.2	115	
	g/l	0.960	0.720	1.20	Agappe - Nephelometry
	mg/dl	96.0	72.0	120	
Prealbumin	g/l	0.155	0.109	0.202	Nephelometric (IFCC Cal.)
	mg/dl	15.5	10.9	20.1	
	g/l	0.147	0.103	0.191	Turbidimetric (IFCC Cal.)
	mg/dl	14.7	10.3	19.1	
	g/l	0.164	0.115	0.213	Nephelometric (Non IFCC Cal.)
	mg/dl	16.4	11.5	21.3	
	g/l	0.144	0.101	0.187	Turbidimetric (Non IFCC Cal.)
	mg/dl	14.4	10.1	18.7	
	g/l	0.159	0.111	0.207	Agappe - Nephelometry
	mg/dl	15.9	11.1	20.7	
Protein Total	g/l	36.1	28.9	43.3	Biuret reaction end point
	g/dl	3.61	2.89	4.33	
Retinol Binding Protein	mg/l	22.0	17.6	26.4	Nephelometric (IFCC Cal.)
	mg/l	22.2	17.8	26.6	Nephelometric (Non IFCC Cal.)
Rheumatoid Factor	U/ml	30.3	24.2	36.4	Turbidimetric (Non IFCC Cal.)
	U/ml	22.5	18.0	27.0	Behring Nephelometer
	U/ml	23.8	19.0	28.6	Neph. Beckman (IFCC Cal.)
Transferrin	g/l	1.29	1.03	1.55	Turbidimetric (IFCC Cal.)
	mg/dl	129	103	155	
	g/l	0.353	0.282	0.424	ELISA (IFCC Cal.)
	mg/dl	35.3	28.2	42.4	
	g/l	1.30	1.04	1.56	Turbidimetric (Non IFCC Cal.)
	mg/dl	130	104	156	
	g/l	1.26	1.01	1.51	Nephelometric (IFCC Cal.)
	mg/dl	126	101	151	
	g/l	1.28	1.02	1.54	Nephelometric (Non IFCC Cal.)
	mg/dl	128	102	154	

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LIQUID ASSAYED SPECIFIC PROTEIN CONTROL - LEVEL 1(SP CONTROL 1)

Cat. No. PS2682 Lot. No. 401LPC Size 3 x 1ml Expiry 2018-01

Range					
Analyte	unit	Target	low	high	methods
Transferrin	g/l	1.37	1.10	1.64	Radial Immunodiffusion (IFCC Cal.)
	mg/dl	137	110	164	