

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

Cat. No. PS2683 **Lot No.** 431LPC
Size: 3 x 1 ml **Expiry:** 2017-10

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 2 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 2 (SP CONTROL 2)

Cat. No. PS2683 Lot No. 431LPC Size: 3 x 1 ml Expiry: 2017-10

Range					
Analyte	unit	Target	low	high	methods
Albumin	g/l	36.0	30.6	41.4	Bromocresol Green (IFCC Cal.)
	g/dl	3.60	3.06	4.14	
	g/l	35.1	29.8	40.4	Bromocresol Purple (IFCC Cal.)
	g/dl	3.51	2.98	4.04	
	g/l	36.3	30.9	41.7	Nephelometric (IFCC Cal.)
	g/dl	3.63	3.09	4.17	
	g/l	36.6	31.1	42.1	Bromocresol Green (Non IFCC Cal.)
	g/dl	3.66	3.11	4.21	
	g/l	34.5	29.3	39.7	Bromocresol Purple (Non IFCC Cal.)
	g/dl	3.45	2.93	3.97	
	g/l	34.3	29.2	39.4	Turbidimetric Assays (IFCC Cal.)
	g/dl	3.43	2.92	3.94	
Alpha-1-Acid Glycoprotein	g/l	36.9	31.4	42.4	Turbidimetric Assays (Non IFCC Cal.)
	g/dl	3.69	3.14	4.24	
	g/l	0.845	0.676	1.01	Turbidimetric (IFCC Cal.)
	mg/dl	84.5	67.6	101	
	g/l	0.894	0.715	1.07	Nephelometric (IFCC Cal.)
	mg/dl	89.4	71.5	107	
Alpha-1-Antitrypsin	g/l	0.870	0.696	1.04	Turbidimetric (Non IFCC Cal.)
	mg/dl	87.0	69.6	104	
	g/l	1.09	0.872	1.31	Agappe - Nephelometry
	mg/dl	109	87.2	131	
	g/l	1.51	1.21	1.81	Turbidimetric (IFCC Cal.)
	mg/dl	151	121	181	
Alpha-2-Macroglobulin	g/l	1.66	1.33	1.99	Nephelometric (IFCC Cal.)
	mg/dl	166	133	199	
	g/l	1.68	1.34	2.02	Nephelometric (Non IFCC Cal.)
	mg/dl	168	134	202	
	g/l	1.49	1.19	1.79	Turbidimetric (Non IFCC Cal.)
	mg/dl	149	119	179	
	g/l	1.25	1.00	1.50	Agappe - Nephelometry
	mg/dl	125	100	150	
	g/l	2.24	1.79	2.69	Turbidimetric (IFCC Cal.)
	mg/dl	224	179	269	
	g/l	2.17	1.74	2.60	Nephelometric (IFCC Cal.)
	mg/dl	217	174	260	
Alpha-2-Macroglobulin	g/l	2.19	1.75	2.63	Nephelometric (Non IFCC Cal.)
	mg/dl	219	175	263	
	g/l	2.24	1.79	2.69	Turbidimetric (Non IFCC Cal.)
	mg/dl	224	179	269	
	g/l	2.05	1.64	2.46	Agappe - Nephelometry
	mg/dl	205	164	246	

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

Cat. No. PS2683 Lot No. 431LPC Size: 3 x 1 ml Expiry: 2017-10

Range					
Analyte	unit	Target	low	high	methods
Alphafoetoprotein	KIU/l = IU/ml	2.02	1.62	2.42	Chemiluminescence (IFCC Cal.)
	ng/ml	2.44	1.96	2.92	
	KIU/l = IU/ml	2.10	1.68	2.52	Chemiluminescence (Non IFCC Cal.)
	ng/ml	2.54	2.03	3.05	
Anti Streptolysin O	IU/ml	245	196	294	Turbidimetric (IFCC Cal.)
	IU/ml	263	210	316	Turbidimetric (Non IFCC Cal.)
	IU/ml	165	132	198	Neph. Beckman (IFCC Cal.)
	IU/ml	156	125	187	Neph. Beckman (Non IFCC Cal.)
	IU/ml	218	174	262	Agappe - Nephelometry
	IU/ml	279	223	335	Neph. Behring (IFCC Cal.)
	IU/ml	280	224	336	Neph. Behring (Non IFCC Cal.)
Antithrombin III	mg/l	271	203	339	Nephelometric (Non IFCC Cal.)
	mg/dl	27.1	20.3	33.9	
Beta-2-microglobulin	µg/ml = mg/l	3.98	3.18	4.78	Chemiluminescence (Non IFCC Cal.)
	µg/ml = mg/l	3.79	3.03	4.55	Nephelometric (IFCC Cal.)
	µg/ml = mg/l	3.83	3.06	4.60	Nephelometric (Non IFCC Cal.)
	µg/ml = mg/l	4.14	3.31	4.97	Turbidimetric (IFCC Cal.)
	µg/ml = mg/l	4.10	3.28	4.92	Turbidimetric (Non IFCC Cal.)
	µg/ml = mg/l	3.75	3.00	4.50	Randox Immunoturbidimetric
C-Reactive Protein	mg/l	53.1	42.5	63.7	Vitros (IFCC Cal.)
	mg/l	48.4	38.7	58.1	Turbidimetric (IFCC Cal.)
	mg/l	45.9	36.7	55.1	Nephelometric (IFCC Cal.)
	mg/l	50.7	40.6	60.8	Vitros (Non IFCC Cal.)
	mg/l	48.4	38.7	58.1	Nephelometric (Non IFCC Cal.)
	mg/l	47.4	37.9	56.9	Turbidimetric (Non IFCC Cal.)
	mg/l	45.3	36.2	54.4	Agappe - Nephelometry
Caeruloplasmin	g/l	0.288	0.230	0.350	Nephelometric (IFCC Cal.)
	mg/dl	28.8	23.0	34.6	
	g/l	0.399	0.279	0.519	Turbidimetric (IFCC Cal.)
	mg/dl	39.9	27.9	51.9	
	g/l	0.287	0.230	0.344	Nephelometric (Non IFCC Cal.)
	mg/dl	28.7	23.0	34.4	
	g/l	0.243	0.194	0.292	Neph. Beckman (IFCC Cal.)
	mg/dl	24.3	19.4	29.2	
	g/l	0.334	0.270	0.400	Agappe - Nephelometry
	mg/dl	33.4	27.0	39.8	
Complement C3	g/l	0.332	0.266	0.398	Randox Immunoturbidimetric
	mg/dl	33.2	26.6	39.8	
	g/l	1.44	1.15	1.73	Turbidimetric (IFCC Cal.)
	mg/dl	144	115	173	
	g/l	1.48	1.18	1.78	Nephelometric (IFCC Cal.)
	mg/dl	148	118	178	
	g/l	1.46	1.17	1.75	Nephelometric (Non IFCC Cal.)
	mg/dl	146	117	175	
	g/l	1.45	1.16	1.74	Turbidimetric (Non IFCC Cal.)
	mg/dl	145	116	174	

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Analyte	unit	Target	low	high	methods
Complement C3	g/l	1.39	1.11	1.67	Vitros 5.1 FS microtip assay
	mg/dl	139	111	167	
	g/l	1.36	1.09	1.63	Vitros 5.1 FS Microtip (Non IFCC)
	mg/dl	136	109	163	
	g/l	1.06	0.848	1.27	Agappe - Nephelometry
	mg/dl	106	84.8	127	
Complement C4	g/l	0.330	0.264	0.396	Turbidimetric (IFCC Cal.)
	mg/dl	33.0	26.4	39.6	
	g/l	0.370	0.296	0.444	Nephelometric (IFCC Cal.)
	mg/dl	37.0	29.6	44.4	
	g/l	0.360	0.288	0.432	Nephelometric (Non IFCC Cal.)
	mg/dl	36.0	28.8	43.2	
	g/l	0.310	0.248	0.372	Turbidimetric (Non IFCC Cal.)
	mg/dl	31.0	24.8	37.2	
	g/l	0.300	0.240	0.360	Vitros 5.1 FS microtip assay
	mg/dl	30.0	24.0	36.0	
	g/l	0.310	0.248	0.372	Vitros 5.1 FS Microtip (Non IFCC)
	mg/dl	31.0	24.8	37.2	
	g/l	0.271	0.217	0.325	Agappe - Nephelometry
	mg/dl	27.1	21.7	32.5	
Ferritin	ng/ml = µg/l	213	170	256	Turbidimetric (IFCC Cal.)
	ng/ml = µg/l	225	180	270	Turbidimetric (Non IFCC Cal.)
	ng/ml = µg/l	224	179	269	Chemiluminescence (IFCC Cal.)
	ng/ml = µg/l	232	186	278	Chemiluminescence (Non IFCC Cal.)
	ng/ml = µg/l	225	180	270	Nephelometric (IFCC Cal.)
	ng/ml = µg/l	212	170	254	Agappe - Nephelometry
Free Kappa Light Chains	mg/L	26.3	19.7	32.9	Nephelometric (Non IFCC Cal.)
	mg/L	25.5	19.1	31.9	Turbidimetric (Non IFCC Cal.)
Free Lambda Light Chains	mg/L	29.3	24.9	33.7	Nephelometric (Non IFCC Cal.)
	mg/L	29.5	25.1	33.9	Turbidimetric (Non IFCC Cal.)
	mg/L	27.5	23.4	31.6	Nephelometric (IFCC Cal.)
Haptoglobin	g/l	1.35	1.08	1.62	Nephelometric (IFCC Cal.)
	mg/dl	135	108	162	
	g/l	1.36	1.09	1.63	Turbidimetric (IFCC Cal.)
	mg/dl	136	109	163	
	g/l	1.37	1.10	1.64	Nephelometric (Non IFCC Cal.)
	mg/dl	137	110	164	
	g/l	1.35	1.08	1.62	Turbidimetric (Non IFCC Cal.)
	mg/dl	135	108	162	
Immunoglobulin A	g/l	1.29	1.03	1.55	Agappe - Nephelometry
	mg/dl	129	103	155	
	g/l	2.43	1.82	3.04	Turbidimetric (IFCC Cal.)
	mg/dl	243	182	304	
	g/l	2.63	1.97	3.29	Nephelometric (IFCC Cal.)
	mg/dl	263	197	329	
	g/l	2.69	2.02	3.36	Nephelometric (Non IFCC Cal.)
	mg/dl	269	202	336	

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Range					
Analyte	unit	Target	low	high	methods
Immunoglobulin A	g/l	2.40	1.80	3.00	Turbidimetric (Non IFCC Cal.)
	mg/dl	240	180	300	
	g/l	2.45	1.84	3.06	Vitros 5.1 FS Microtip (IFCC)
	mg/dl	245	184	306	
	g/l	2.51	1.88	3.14	Vitros 5.1 FS Microtip (Non IFCC)
	mg/dl	251	188	314	
Immunoglobulin E	g/l	2.14	1.61	2.68	Agappe - Nephelometry
	mg/dl	214	161	267	
Immunoglobulin E	KIU/I = IU/ml	131	105	157	Fluorimetric (Non IFCC Cal.)
	KIU/I = IU/ml	145	116	174	Chemiluminescence (Non IFCC Cal.)
	KIU/I = IU/ml	150	120	180	Nephelometric (Non IFCC Cal.)
	KIU/I = IU/ml	138	110	166	Enzyme Immunoassay (Non IFCC Cal.)
	KIU/I = IU/ml	157	126	188	Turbidimetric (Non IFCC Cal.)
	KIU/I = IU/ml	136	109	163	Agappe - Nephelometry
	KIU/I = IU/ml	177	141	212	Randox Immunoturbidimetric
Immunoglobulin G	g/l	13.8	11.3	16.3	Turbidimetric (IFCC Cal.)
	mg/dl	1380	1130	1630	
	g/l	14.3	11.7	16.9	Nephelometric (IFCC Cal.)
	mg/dl	1430	1170	1690	
	g/l	14.4	11.8	17.0	Nephelometric (Non IFCC Cal.)
	mg/dl	1440	1180	1700	
	g/l	13.8	11.3	16.3	Turbidimetric (Non IFCC Cal.)
	mg/dl	1380	1130	1630	
	g/l	13.4	11.0	15.8	Vitros 5.1 FS Microtip (IFCC)
	mg/dl	1340	1100	1580	
Immunoglobulin G	g/l	14.2	11.6	16.8	Vitros 5.1 FS Microtip (Non IFCC)
	mg/dl	1420	1160	1680	
	g/l	13.7	11.2	16.2	Agappe - Nephelometry
	mg/dl	1370	1120	1620	
Immunoglobulin M	g/l	1.86	1.49	2.23	Turbidimetric (IFCC Cal.)
	mg/dl	186	149	223	
	g/l	1.97	1.58	2.36	Nephelometric (IFCC Cal.)
	mg/dl	197	158	236	
	g/l	1.95	1.56	2.34	Nephelometric (Non IFCC Cal.)
	mg/dl	195	156	234	
	g/l	1.90	1.52	2.28	Turbidimetric (Non IFCC Cal.)
	mg/dl	190	152	228	
	g/l	1.85	1.48	2.22	Vitros 5.1 FS Microtip (IFCC)
Immunoglobulin M	mg/dl	185	148	222	
	g/l	1.84	1.47	2.21	Vitros 5.1 FS Microtip (Non IFCC)
	mg/dl	184	147	221	
	g/l	1.82	1.46	2.18	Agappe - Nephelometry
	mg/dl	182	146	218	
Kappa Light Chain	g/l	3.52	2.64	4.40	Neph. Behring (IFCC Cal.)
	mg/dl	352	264	440	

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

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Range					
Analyte	unit	Target	low	high	methods
Kappa Light Chain	g/l	3.57	2.68	4.46	Neph. Behring (Non IFCC Cal.)
	mg/dl	357	268	446	
	g/l	11.8	8.85	14.8	Neph. Beckman (IFCC Cal.)
	mg/dl	1180	885	1475	
	g/l	3.73	2.80	4.66	Turbidimetric (IFCC Cal.)
	mg/dl	373	280	466	
	g/l	3.64	2.73	4.55	Turbidimetric (Non IFCC Cal.)
	mg/dl	364	273	455	
	g/l	2.66	2.00	3.33	Agappe - Nephelometry
	mg/dl	266	200	332	
Lambda Light Chain	g/l	1.86	1.40	2.33	Neph. Behring (IFCC Cal.)
	mg/dl	186	140	232	
	g/l	1.96	1.47	2.45	Neph. Behring (Non IFCC Cal.)
	mg/dl	196	147	245	
	g/l	5.91	4.43	7.39	Neph. Beckman (IFCC Cal.)
	mg/dl	591	443	739	
	g/l	1.92	1.44	2.40	Turbidimetric (IFCC Cal.)
	mg/dl	192	144	240	
	g/l	1.90	1.43	2.38	Turbidimetric (Non IFCC Cal.)
	mg/dl	190	143	237	
	g/l	1.22	0.915	1.53	Agappe - Nephelometry
	mg/dl	122	91.5	153	
Prealbumin	g/l	0.333	0.266	0.400	Nephelometric (IFCC Cal.)
	mg/dl	33.3	26.6	40.0	
	g/l	0.304	0.243	0.365	Turbidimetric (IFCC Cal.)
	mg/dl	30.4	24.3	36.5	
	g/l	0.360	0.288	0.432	Nephelometric (Non IFCC Cal.)
	mg/dl	36.0	28.8	43.2	
	g/l	0.298	0.238	0.358	Turbidimetric (Non IFCC Cal.)
	mg/dl	29.8	23.8	35.8	
	g/l	0.270	0.216	0.324	Agappe - Nephelometry
	mg/dl	27.0	21.6	32.4	
Protein Total	g/l	65.1	52.1	78.1	Biuret reaction end point
	g/dl	6.51	5.21	7.81	
Retinol Binding Protein	mg/l	48.3	41.1	55.5	Nephelometric (IFCC Cal.)
	mg/l	50.6	43.0	58.2	Nephelometric (Non IFCC Cal.)
Rheumatoid Factor	U/ml	59.3	47.4	71.2	Turbidimetric (Non IFCC Cal.)
	U/ml	61.8	49.4	74.2	Neph. Beckman (Non IFCC Cal.)
	U/ml	39.8	31.8	47.8	Neph. Behring (Non IFCC Cal.)
Transferrin	g/l	2.56	2.05	3.07	Turbidimetric (IFCC Cal.)
	mg/dl	256	205	307	
	g/l	2.85	2.28	3.42	ELISA (IFCC Cal.)
	mg/dl	285	228	342	
	g/l	2.60	2.08	3.12	Turbidimetric (Non IFCC Cal.)
	mg/dl	260	208	312	
	g/l	2.49	1.99	2.99	Nephelometric (IFCC Cal.)
	mg/dl	249	199	299	

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Range					
Analyte	unit	Target	low	high	methods
Transferrin	g/l	2.46	1.97	2.95	Nephelometric (Non IFCC Cal.)
	mg/dl	246	197	295	
	g/l	2.54	2.03	3.05	Radial Immunodiffusion (IFCC Cal.)
	mg/dl	254	203	305	