

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

CAT. NO. PS2682**LOT NO.** 538LPC**SIZE:** 3 x 1 ml**EXPIRY:** 2021-02-28**GTIN:** 05055273204896

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.

MATERIALS PROVIDED

Liquid 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 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 94451070 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. 538LPC Size: 3 x 1 ml Expiry: 2021-02-28

Range					
Analyte	unit	Target	low	high	methods
Albumin	g/l	18.8	16.0	21.6	Bromocresol Green (IFCC Cal.)
	g/dl	1.88	1.60	2.16	
	g/l	18.4	15.6	21.2	Bromocresol Purple (IFCC Cal.)
	g/dl	1.84	1.56	2.12	
	g/l	19.2	16.3	22.1	Nephelometric (IFCC Cal.)
	g/dl	1.92	1.63	2.21	
	g/l	19.2	16.3	22.1	Bromocresol Green (Non IFCC Cal.)
	g/dl	1.92	1.63	2.21	
	g/l	21.4	18.2	24.6	Bromocresol Purple (Non IFCC Cal.)
	g/dl	2.14	1.82	2.46	
	g/l	18.9	16.1	21.7	Turbidimetric Assays (IFCC Cal.)
	g/dl	1.89	1.61	2.17	
Alpha-1-Acid Glycoprotein	g/l	19.4	16.5	22.3	Turbidimetric Assays (Non IFCC Cal.)
	g/dl	1.94	1.65	2.23	
	g/l	0.428	0.342	0.514	Turbidimetric (IFCC Cal.)
	mg/dl	42.8	34.2	51.4	
	g/l	0.460	0.368	0.552	Nephelometric (IFCC Cal.)
Alpha-1-Antitrypsin	mg/dl	46.0	36.8	55.2	
	g/l	0.415	0.332	0.498	Turbidimetric (Non IFCC Cal.)
	mg/dl	41.5	33.2	49.8	
	g/l	0.703	0.562	0.844	Turbidimetric (IFCC Cal.)
	mg/dl	70.3	56.2	84.4	
Alpha-1-Antitrypsin	g/l	0.739	0.591	0.887	Nephelometric (IFCC Cal.)
	mg/dl	73.9	59.1	88.7	
	g/l	0.728	0.582	0.874	Nephelometric (Non IFCC Cal.)
	mg/dl	72.8	58.2	87.4	
	g/l	0.722	0.578	0.866	Turbidimetric (Non IFCC Cal.)
Alpha-2-Macroglobulin	mg/dl	72.2	57.8	86.6	
	g/l	1.04	0.832	1.25	Turbidimetric (IFCC Cal.)
	mg/dl	104	83.2	125	
	g/l	1.03	0.824	1.24	Nephelometric (IFCC Cal.)
	mg/dl	103	82.4	124	
Alpha-2-Macroglobulin	g/l	1.05	0.840	1.26	Turbidimetric (Non IFCC Cal.)
	mg/dl	105	84.0	126	
Alpha-fetoprotein	KIU/l = IU/ml	18.6	14.9	22.3	Chemiluminescence (IFCC Cal.)
	ng/ml	22.5	18.0	27.0	
	KIU/l = IU/ml	18.8	15.0	22.6	Chemiluminescence (Non IFCC Cal.)
	ng/ml	22.7	18.2	27.2	
Anti-Streptolysin	IU/ml	120	96.0	144	Turbidimetric (IFCC Cal.)
	IU/ml	117	93.6	140	Turbidimetric (Non IFCC Cal.)
	IU/ml	138	110	166	Neph. others (IFCC Cal.)
	IU/ml	137	110	164	Neph. others (Non IFCC Cal.)

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

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Analyte	unit	Target	low	high	methods
Anti-Streptolysin O	IU/ml	84.2	67.4	101	Neph. Beckman (IFCC Cal.)
	IU/ml	84.6	67.7	102	Neph. Beckman (Non IFCC Cal.)
Antithrombin III	mg/l	121	84.7	157	Turbidimetric (IFCC Cal.)
	mg/dl	12.1	8.47	1.57	
Beta-2-microglobulin	µg/ml = mg/l	2.02	1.62	2.42	Chemiluminescence (Non IFCC Cal.)
	µg/ml = mg/l	1.96	1.57	2.35	Nephelometric (IFCC Cal.)
	µg/ml = mg/l	1.93	1.54	2.32	Nephelometric (Non IFCC Cal.)
	µg/ml = mg/l	2.17	1.74	2.60	Turbidimetric (IFCC Cal.)
	µg/ml = mg/l	2.11	1.69	2.53	Turbidimetric (Non IFCC Cal.)
C-Reactive Protein	mg/l	29.5	23.6	35.4	Vitros (IFCC Cal.)
	mg/l	23.1	18.5	27.7	Turbidimetric (IFCC Cal.)
	mg/l	20.6	16.5	24.7	Nephelometric (IFCC Cal.)
	mg/l	21.1	16.9	25.3	Nephelometric (Non IFCC Cal.)
	mg/l	22.5	18.0	27.0	Turbidimetric (Non IFCC Cal.)
	mg/l	21.7	17.4	26.0	Beckman Turb Latex (IFCC Cal)
Caeruloplasmin	g/l	0.134	0.101	0.167	Nephelometric (IFCC Cal.)
	mg/dl	13.4	10.1	16.7	
	g/l	0.148	0.111	0.185	Turbidimetric (IFCC Cal.)
	mg/dl	14.8	11.1	18.5	
	g/l	0.124	0.093	0.155	Nephelometric (Non IFCC Cal.)
	mg/dl	12.4	9.30	15.5	
	g/l	0.132	0.099	0.165	Turbidimetric (Non IFCC Cal.)
	mg/dl	13.2	9.90	16.5	
Complement C3	g/l	0.130	0.098	0.162	Neph. Beckman (IFCC Cal.)
	mg/dl	13.0	9.80	16.2	
	g/l	0.607	0.486	0.728	Turbidimetric (IFCC Cal.)
	mg/dl	60.7	48.6	72.8	
	g/l	0.600	0.480	0.720	Nephelometric (IFCC Cal.)
	mg/dl	60.0	48.0	72.0	
	g/l	0.615	0.492	0.738	Nephelometric (Non IFCC Cal.)
	mg/dl	61.5	49.2	73.8	
Complement C4	g/l	0.609	0.487	0.731	Turbidimetric (Non IFCC Cal.)
	mg/dl	60.9	48.7	73.1	
	g/l	0.606	0.485	0.727	Vitros 5.1 FS Microtip (Non IFCC)
	mg/dl	60.6	48.5	72.7	
	g/l	0.145	0.116	0.174	Turbidimetric (IFCC Cal.)
	mg/dl	14.5	11.6	17.4	
Complement C4	g/l	0.158	0.126	0.190	Nephelometric (IFCC Cal.)
	mg/dl	15.8	12.6	19.0	
	g/l	0.157	0.126	0.188	Nephelometric (Non IFCC Cal.)
	mg/dl	15.7	12.6	18.8	
	g/l	0.136	0.109	0.163	Turbidimetric (Non IFCC Cal.)
	mg/dl	13.6	10.9	16.3	
Ferritin	g/l	0.143	0.114	0.172	Vitros 5.1 FS Microtip (Non IFCC)
	mg/dl	14.3	11.4	17.2	
Ferritin	ng/ml = µg/l	102	81.6	122	Turbidimetric (IFCC Cal.)

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Analyte	unit	Target	low	high	methods
Ferritin	ng/ml = µg/l	103	82.4	124	Turbidimetric (Non IFCC Cal.)
	ng/ml = µg/l	106	84.8	127	Chemiluminescence (IFCC Cal.)
	ng/ml = µg/l	114	91.2	137	Chemiluminescence (Non IFCC Cal.)
	ng/ml = µg/l	95.5	76.4	115	Nephelometric (IFCC Cal.)
Free Lambda Light Chains	mg/L	13.8	11.0	16.6	Nephelometric - Beckman
	mg/L	11.4	9.12	13.7	Nephelometric - Binding Site
	mg/L	11.8	9.44	14.2	Nephelometric - Siemens
	mg/L	10.5	8.40	12.6	Turbidimetric
Haptoglobin	g/l	0.622	0.498	0.746	Nephelometric (IFCC Cal.)
	mg/dl	62.2	49.8	74.6	
	g/l	0.637	0.510	0.764	Turbidimetric (IFCC Cal.)
	mg/dl	63.7	51.0	76.4	
	g/l	0.636	0.509	0.763	Nephelometric (Non IFCC Cal.)
	mg/dl	63.6	50.9	76.3	
Haptoglobin	g/l	0.634	0.507	0.761	Turbidimetric (Non IFCC Cal.)
	mg/dl	63.4	50.7	76.1	
Immunoglobulin A	g/l	1.22	0.915	1.53	Turbidimetric (IFCC Cal.)
	mg/dl	122	91.5	153	
	g/l	1.18	0.885	1.48	Nephelometric (IFCC Cal.)
	mg/dl	118	88.5	148	
	g/l	1.28	0.960	1.60	Nephelometric (Non IFCC Cal.)
	mg/dl	128	96.0	160	
Immunoglobulin A	g/l	1.21	0.908	1.51	Turbidimetric (Non IFCC Cal.)
	mg/dl	121	90.8	151	
	g/l	1.16	0.870	1.45	Vitros 5.1 FS Microtip (Non IFCC)
	mg/dl	116	87.0	145	
Immunoglobulin E	KIU/l = IU/ml	64.6	51.7	77.5	Fluorimetric (Non IFCC Cal.)
	KIU/l = IU/ml	63.6	50.9	76.3	Chemiluminescence (Non IFCC Cal.)
	KIU/l = IU/ml	63.7	51.0	76.4	Nephelometric (Non IFCC Cal.)
	KIU/l = IU/ml	58.7	47.0	70.4	Enzyme Immunoassay (Non IFCC Cal.)
	KIU/l = IU/ml	63.5	50.8	76.2	Turbidimetric (Non IFCC Cal.)
Immunoglobulin G	g/l	6.07	4.98	7.16	Turbidimetric (IFCC Cal.)
	mg/dl	607	498	716	
	g/l	6.33	5.19	7.47	Nephelometric (IFCC Cal.)
	mg/dl	633	519	747	
	g/l	6.42	5.26	7.58	Nephelometric (Non IFCC Cal.)
	mg/dl	642	526	758	
	g/l	6.03	4.94	7.12	Turbidimetric (Non IFCC Cal.)
	mg/dl	603	494	712	
Immunoglobulin G	g/l	6.17	5.06	7.28	Vitros 5.1 FS Microtip (Non IFCC)
	mg/dl	617	506	728	
Immunoglobulin M	g/l	0.898	0.718	1.08	Turbidimetric (IFCC Cal.)
	mg/dl	89.8	71.8	108	
	g/l	0.935	0.748	1.12	Nephelometric (IFCC Cal.)
	mg/dl	93.5	74.8	112	
	g/l	0.956	0.765	1.15	Nephelometric (Non IFCC Cal.)
	mg/dl	95.6	76.5	115	

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Range					
Analyte	unit	Target	low	high	methods
Immunoglobulin M	g/l	0.893	0.714	1.07	Turbidimetric (Non IFCC Cal.)
	mg/dl	89.3	71.4	107	
	g/l	0.870	0.696	1.04	Vitros 5.1 FS Microtip (Non IFCC)
	mg/dl	87.0	69.6	104	
Kappa Light Chain	g/l	5.36	4.29	6.43	Nephelometric - Beckman
	mg/dl	536	429	643	
	g/l	1.63	1.30	1.96	Nephelometric - Siemens
	mg/dl	163	130	196	
	g/l	1.69	1.35	2.03	Turbidimetric
	mg/dl	169	135	203	
Lambda Light Chain	g/l	2.73	2.18	3.28	Nephelometric - Beckman
	mg/dl	273	218	328	
	g/l	0.831	0.660	1.00	Nephelometric - Siemens
	mg/dl	83.1	66.0	100	
	g/l	0.807	0.650	0.970	Turbidimetric
	mg/dl	80.7	65.0	97.0	
Prealbumin	g/l	0.158	0.126	0.190	Nephelometric (IFCC Cal.)
	mg/dl	15.8	12.6	19.0	
	g/l	0.153	0.122	0.184	Turbidimetric (IFCC Cal.)
	mg/dl	15.3	12.2	18.4	
	g/l	0.155	0.124	0.186	Nephelometric (Non IFCC Cal.)
	mg/dl	15.5	12.4	18.6	
Protein Total	g/l	34.3	27.4	41.2	Biuret reaction end point
	g/dl	3.43	2.74	4.12	
Retinol Binding Protein	mg/l	21.4	17.1	25.7	Nephelometric (IFCC Cal.)
	mg/l	21.6	17.3	25.9	Nephelometric (Non IFCC Cal.)
Rheumatoid Factor	U/ml	28.7	23.0	34.4	Turbidimetric (Non IFCC Cal.)
	U/ml	24.1	19.3	28.9	Nephelometric (Non IFCC Cal.)
	U/ml	29.5	23.6	35.4	Latex (Non-IFCC Cal.)
Transferrin	g/l	1.13	0.904	1.36	Turbidimetric (IFCC Cal.)
	mg/dl	113	90.4	136	
	g/l	1.14	0.912	1.37	Turbidimetric (Non IFCC Cal.)
	mg/dl	114	91.2	137	
	g/l	1.11	0.888	1.33	Nephelometric (IFCC Cal.)
	mg/dl	111	88.8	133	
	g/l	1.10	0.880	1.32	Nephelometric (Non IFCC Cal.)
	mg/dl	110	88.0	132	