

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

CAT. NO. PS2682

LOT NO. 531LPC

SIZE: 3 x 1 ml

EXPIRY: 2020-09-28

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.

(S) 14 Oct 19 pq

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

Cat. No. PS2682 Lot No. 531LPC Size: 3 x 1 ml Expiry: 2020-09-28

Range					
Analyte	unit	Target	low	high	methods
Albumin	g/l	19.0	16.2	21.9	Bromocresol Green (IFCC Cal.)
	g/dl	1.90	1.62	2.18	
	g/l	18.6	15.8	21.4	Bromocresol Purple (IFCC Cal.)
	g/dl	1.86	1.58	2.14	
	g/l	18.5	15.7	21.3	Nephelometric (IFCC Cal.)
	g/dl	1.85	1.57	2.13	
	g/l	19.5	16.6	22.4	Bromocresol Green (Non IFCC Cal.)
	g/dl	1.95	1.66	2.24	
	g/l	18.0	15.3	20.7	Bromocresol Purple (Non IFCC Cal.)
	g/dl	1.80	1.53	2.07	
	g/l	18.3	15.6	21.0	Nephelometric (Non IFCC Cal.)
	g/dl	1.83	1.56	2.10	
	g/l	19.0	16.2	21.9	Turbidimetric Assays (IFCC Cal.)
	g/dl	1.90	1.62	2.18	
g/l	19.0	16.2	21.9	Turbidimetric Assays (Non IFCC Cal.)	
g/dl	1.90	1.62	2.18		
Alpha-1-Acid Glycoprotein	g/l	0.358	0.286	0.430	Turbidimetric (IFCC Cal.)
	mg/dl	35.8	28.6	43.0	Nephelometric (IFCC Cal.)
	g/l	0.410	0.328	0.492	
	mg/dl	41.0	32.8	49.2	Nephelometric (Non IFCC Cal.)
	g/l	0.425	0.340	0.510	
	mg/dl	42.5	34.0	51.0	
Alpha-1-Antitrypsin	g/l	0.729	0.583	0.875	Turbidimetric (IFCC Cal.)
	mg/dl	72.9	58.3	87.5	Nephelometric (IFCC Cal.)
	g/l	0.766	0.613	0.919	
	mg/dl	76.6	61.3	91.9	Nephelometric (Non IFCC Cal.)
	g/l	0.791	0.633	0.949	
	mg/dl	79.1	63.3	94.9	
Alpha-2-Macroglobulin	g/l	1.07	0.856	1.28	Turbidimetric (IFCC Cal.)
	mg/dl	107	85.6	128	Nephelometric (IFCC Cal.)
	g/l	1.04	0.832	1.25	
	mg/dl	104	83.2	125	Nephelometric (Non IFCC Cal.)
	g/l	1.08	0.864	1.30	
	mg/dl	108	86.4	130	
Alphafoetoprotein	KIU/l = IU/ml	18.3	14.6	22.0	Chemiluminescence (IFCC Cal.)
	ng/ml	22.1	17.7	26.5	

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

Cat. No. PS2682 Lot No. 531LPC Size: 3 x 1 ml Expiry: 2020-09-28

Range					
Analyte	unit	Target	low	high	methods
Alphafoetoprotein	KIU/l = IU/ml	18.1	14.5	21.7	Chemiluminescence (Non IFCC Cal.)
	ng/ml	21.9	17.5	26.3	
Anti Streptolysin O	IU/ml	120	90.0	150	Turbidimetric (IFCC Cal.)
	IU/ml	120	90.0	150	Turbidimetric (Non IFCC Cal.)
	IU/ml	139	104	174	Neph. others (IFCC Cal.)
	IU/ml	142	107	178	Neph. others (Non IFCC Cal.)
	IU/ml	84.5	63.4	106	Neph. Beckman (IFCC Cal.)
	IU/ml	84.4	63.3	106	Neph. Beckman (Non IFCC Cal.)
Antithrombin III	mg/l	134	101	168	Turbidimetric (IFCC Cal.)
	mg/dl	13.4	10.1	16.8	
Beta-2-microglobulin	µg/ml = mg/l	2.01	1.61	2.41	Chemiluminescence (Non IFCC Cal.)
	µg/ml = mg/l	1.87	1.50	2.24	Nephelometric (IFCC Cal.)
	µg/ml = mg/l	1.92	1.54	2.30	Nephelometric (Non IFCC Cal.)
	µg/ml = mg/l	2.04	1.63	2.45	Turbidimetric (IFCC Cal.)
	µg/ml = mg/l	2.03	1.62	2.44	Turbidimetric (Non IFCC Cal.)
	µg/ml = mg/l	1.82	1.46	2.18	Randox Immunoturbidimetric
C-Reactive Protein	mg/l	28.8	23.0	34.6	Vitros (IFCC Cal.)
	mg/l	22.8	18.2	27.4	Turbidimetric (IFCC Cal.)
	mg/l	20.4	16.3	24.5	Nephelometric (IFCC Cal.)
	mg/l	28.7	23.0	34.4	Vitros (Non IFCC Cal.)
	mg/l	20.7	16.6	24.8	Nephelometric (Non IFCC Cal.)
	mg/l	21.8	17.4	26.2	Turbidimetric (Non IFCC Cal.)
	mg/l	21.5	17.2	25.8	Beckman Turb Latex (IFCC Cal)
Caeruloplasmin	g/l	0.176	0.132	0.220	Nephelometric (IFCC Cal.)
	mg/dl	17.6	13.2	22.0	Turbidimetric (IFCC Cal.)
	g/l	0.181	0.136	0.226	
	mg/dl	18.1	13.6	22.6	Nephelometric (Non IFCC Cal.)
	g/l	0.175	0.131	0.219	
	mg/dl	17.5	13.1	21.9	Turbidimetric (Non IFCC Cal.)
	g/l	0.169	0.127	0.211	
	mg/dl	16.9	12.7	21.1	Neph. Beckman (IFCC Cal.)
	g/l	0.155	0.116	0.194	
	mg/dl	15.5	11.6	19.4	Randox Immunoturbidimetric
g/l	0.202	0.152	0.252		
mg/dl	20.2	15.2	25.2		
Complement C3	g/l	0.742	0.594	0.890	Turbidimetric (IFCC Cal.)
	mg/dl	74.2	59.4	89.0	
	g/l	0.720	0.576	0.864	Nephelometric (IFCC Cal.)
	mg/dl	72.0	57.6	86.4	
	g/l	0.746	0.597	0.895	Nephelometric (Non IFCC Cal.)
	mg/dl	74.6	59.7	89.5	
	g/l	0.745	0.596	0.894	Turbidimetric (Non IFCC Cal.)
	mg/dl	74.5	59.6	89.4	
Complement C4	g/l	0.160	0.128	0.192	Turbidimetric (IFCC Cal.)
	mg/dl	16.0	12.8	19.2	

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Analyte	unit	Target	Range		methods
			low	high	
Complement C4	g/l	0.173	0.138	0.208	Nephelometric (IFCC Cal.)
	mg/dl	17.3	13.8	20.8	
	g/l	0.171	0.137	0.205	Nephelometric (Non IFCC Cal.)
	mg/dl	17.1	13.7	20.5	
	g/l	0.152	0.122	0.182	Turbidimetric (Non IFCC Cal.)
	mg/dl	15.2	12.2	18.2	
Ferritin	g/l	0.162	0.130	0.194	Vitros 5.1 FS Microtip (Non IFCC)
	mg/dl	16.2	13.0	19.4	
	ng/ml = µg/l	102	81.6	122	Turbidimetric (IFCC Cal.)
	ng/ml = µg/l	103	82.4	124	Turbidimetric (Non IFCC Cal.)
	ng/ml = µg/l	103	82.4	124	Chemiluminescence (IFCC Cal.)
	ng/ml = µg/l	112	89.6	134	Chemiluminescence (Non IFCC Cal.)
Free Lambda Light Chains	ng/ml = µg/l	100	80.0	120	Nephelometric (Non IFCC Cal.)
	mg/L	13.8	11.0	16.6	Nephelometric - Beckman
	mg/L	11.5	9.20	13.8	Nephelometric - Binding Site
	mg/L	10.0	8.00	12.0	Nephelometric - Siemens
Haptoglobin	mg/L	11.4	9.12	13.7	Turbidimetric
	g/l	0.626	0.501	0.751	Nephelometric (IFCC Cal.)
	mg/dl	62.6	50.1	75.1	
	g/l	0.662	0.530	0.794	Turbidimetric (IFCC Cal.)
	mg/dl	66.2	53.0	79.4	
	g/l	0.642	0.514	0.770	Nephelometric (Non IFCC Cal.)
Immunoglobulin A	mg/dl	64.2	51.4	77.0	
	g/l	0.666	0.533	0.799	Turbidimetric (Non IFCC Cal.)
	mg/dl	66.6	53.3	79.9	
	g/l	1.16	0.870	1.45	Turbidimetric (IFCC Cal.)
	mg/dl	116	87.0	145	
	g/l	1.12	0.840	1.40	Nephelometric (IFCC Cal.)
Immunoglobulin E	mg/dl	112	84.0	140	
	g/l	1.19	0.893	1.49	Nephelometric (Non IFCC Cal.)
	mg/dl	119	89.3	149	
	g/l	1.16	0.870	1.45	Turbidimetric (Non IFCC Cal.)
	mg/dl	116	87.0	145	
	g/l	1.15	0.863	1.44	Vitros 5.1 FS Microtip (Non IFCC)
Immunoglobulin G	mg/dl	115	86.3	144	
	KIU/l = IU/ml	70.4	56.3	84.5	Fluorimetric (Non IFCC Cal.)
	KIU/l = IU/ml	68.5	54.8	82.2	Chemiluminescence (Non IFCC Cal.)
	KIU/l = IU/ml	65.8	52.6	79.0	Nephelometric (Non IFCC Cal.)
	KIU/l = IU/ml	68.9	55.1	82.7	Enzyme Immunoassay (Non IFCC Cal.)
Immunoglobulin G	KIU/l = IU/ml	71.6	57.3	85.9	Turbidimetric (Non IFCC Cal.)
	g/l	6.16	5.05	7.27	Turbidimetric (IFCC Cal.)
	mg/dl	616	505	727	

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Range					
Analyte	unit	Target	low	high	methods
Immunoglobulin G	g/l	6.38	5.23	7.53	Nephelometric (IFCC Cal.)
	mg/dl	638	523	753	
	g/l	6.50	5.33	7.67	Nephelometric (Non IFCC Cal.)
	mg/dl	650	533	767	
	g/l	6.06	4.97	7.15	Turbidimetric (Non IFCC Cal.)
	mg/dl	606	497	715	
Immunoglobulin M	g/l	6.59	5.40	7.78	Vitros 5.1 FS Microtip (Non IFCC)
	mg/dl	659	540	778	
	g/l	0.875	0.700	1.05	Turbidimetric (IFCC Cal.)
	mg/dl	87.5	70.0	105	
	g/l	0.899	0.719	1.08	Nephelometric (IFCC Cal.)
	mg/dl	89.9	71.9	108	
Kappa Light Chain	g/l	0.923	0.738	1.11	Nephelometric (Non IFCC Cal.)
	mg/dl	92.3	73.8	111	
	g/l	0.882	0.706	1.06	Turbidimetric (Non IFCC Cal.)
	mg/dl	88.2	70.6	106	
	g/l	0.915	0.732	1.10	Vitros 5.1 FS Microtip (Non IFCC)
	mg/dl	91.5	73.2	110	
Lambda Light Chain	g/l	6.10	4.88	7.32	Nephelometric - Beckman
	mg/dl	610	488	732	
	g/l	1.59	1.27	1.91	Nephelometric - Siemens
	mg/dl	159	127	191	
Prealbumin	g/l	1.66	1.33	1.99	Turbidimetric
	mg/dl	166	133	199	
	g/l	2.77	2.22	3.32	Nephelometric - Beckman
	mg/dl	277	222	332	
Protein Total	g/l	0.803	0.683	0.923	Nephelometric - Siemens
	mg/dl	80.3	68.3	92.3	
	g/l	0.815	0.650	0.980	Turbidimetric
	mg/dl	81.5	65.0	98.0	
Retinol Binding Protein	g/l	0.164	0.115	0.213	Nephelometric (IFCC Cal.)
	mg/dl	16.4	11.5	21.3	
	g/l	0.161	0.113	0.209	Turbidimetric (IFCC Cal.)
	mg/dl	16.1	11.3	20.9	
	g/l	0.162	0.113	0.211	Nephelometric (Non IFCC Cal.)
Rheumatoid Factor	mg/dl	16.2	11.3	21.1	
	g/l	0.161	0.113	0.209	Turbidimetric (Non IFCC Cal.)
Protein Total	mg/dl	16.1	11.3	20.9	
	g/dl	35.3	28.2	42.4	Biuret reaction end point
Retinol Binding Protein	g/dl	3.53	2.82	4.24	
	mg/l	21.0	16.8	25.2	Nephelometric (IFCC Cal.)
Rheumatoid Factor	mg/l	21.1	16.9	25.3	Nephelometric (Non IFCC Cal.)
	U/ml	30.0	24.0	36.0	Turbidimetric (Non IFCC Cal.)
	U/ml	30.5	24.4	36.6	Latex (Non-IFCC Cal.)



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Range					
Analyte	unit	Target	low	high	methods
Rheumatoid Factor	U/ml	26.5	21.2	31.8	Neph. Behring (Non IFCC Cal.)
	U/ml	23.8	19.0	28.6	Neph. Beckman (Non IFCC Cal.)
Transferrin	g/l	1.22	0.976	1.46	Turbidimetric (IFCC Cal.)
	mg/dl	122	97.6	146	
	g/l	1.22	0.976	1.46	Turbidimetric (Non IFCC Cal.)
	mg/dl	122	97.6	146	
	g/l	1.12	0.896	1.34	Nephelometric (IFCC Cal.)
	mg/dl	112	89.6	134	
	g/l	1.19	0.952	1.43	Nephelometric (Non IFCC Cal.)
	mg/dl	119	95.2	143	