

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

CAT. NO. PS2682 **LOT NO.** 589LPC
SIZE: 3 x 1 ml **EXPIRY:** 2022-02-28
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.

26 May 20 pq

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

Cat. No. PS2682 Lot. No. 589LPC

Size 3 x 1 ml Expiry 2022-02-28

Analyte	unit	Target	Range		methods
			low	high	
Albumin	g/l	19.7	16.7	22.7	Bromocresol Green (IFCC Cal.)
	g/dl	1.97	1.67	2.27	
	g/l	18.9	16.1	21.7	Bromocresol Purple (IFCC Cal.)
	g/dl	1.89	1.61	2.17	
	g/l	19.4	16.5	22.3	Nephelometric (IFCC Cal.)
	g/dl	1.94	1.65	2.23	
	g/l	20.3	17.3	23.3	Bromocresol Green (Non IFCC Cal.)
	g/dl	2.03	1.73	2.33	
	g/l	19.3	16.4	22.2	Bromocresol Purple (Non IFCC Cal.)
	g/dl	1.93	1.64	2.22	
	g/l	19.5	16.6	22.4	Nephelometric (Non IFCC Cal.)
	g/dl	1.95	1.66	2.24	
	g/l	19.9	16.9	22.9	Turbidimetric Assays (IFCC Cal.)
	g/dl	1.99	1.69	2.29	
g/l	19.7	16.7	22.7	Turbidimetric Assays (Non IFCC Cal.)	
g/dl	1.97	1.67	2.27		
Alpha-1-Acid Glycoprotein	g/l	0.450	0.360	0.540	Turbidimetric (IFCC Cal.)
	mg/dl	45.0	36.0	54.0	Nephelometric (IFCC Cal.)
	g/l	0.467	0.374	0.560	
	mg/dl	46.7	37.4	56.0	
Alpha-1-Antitrypsin	g/l	0.410	0.328	0.492	Turbidimetric (Non IFCC Cal.)
	mg/dl	41.0	32.8	49.2	
	g/l	0.856	0.685	1.03	Turbidimetric (IFCC Cal.)
	mg/dl	85.6	68.5	103	
	g/l	0.890	0.712	1.07	Nephelometric (IFCC Cal.)
	mg/dl	89.0	71.2	107	
Alpha-2-Macroglobulin	g/l	0.846	0.677	1.02	Nephelometric (Non IFCC Cal.)
	mg/dl	84.6	67.7	102	
	g/l	0.848	0.678	1.02	Turbidimetric (Non IFCC Cal.)
	mg/dl	84.8	67.8	102	
	g/l	1.00	0.800	1.20	Turbidimetric (IFCC Cal.)
	mg/dl	100	80.0	120	
	g/l	0.984	0.787	1.18	Nephelometric (IFCC Cal.)
	mg/dl	98.4	78.7	118	
Alphafoetoprotein	KIU/l = IU/ml	17.9	14.3	21.5	Chemiluminescence (IFCC Cal.)
	ng/ml	21.7	17.3	26.1	
	KIU/l = IU/ml	18.0	14.4	21.6	Chemiluminescence (Non IFCC Cal.)
	ng/ml	21.8	17.4	26.2	
Anti Streptolysin O	IU/ml	113	90.4	136	Turbidimetric (IFCC Cal.)
	IU/ml	117	93.6	140	Turbidimetric (Non IFCC Cal.)

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

Cat. No. PS2682 Lot. No. 589LPC

Size 3 x 1 ml Expiry 2022-02-28

Analyte	unit	Target	Range		methods
			low	high	
Anti Streptolysin O	IU/ml	94.5	75.6	113	Neph. Beckman (IFCC Cal.)
	IU/ml	123	98.4	148	Neph. Behring (IFCC Cal.)
	IU/ml	120	96.0	144	Neph. Behring (Non IFCC Cal.)
Beta-2-microglobulin	µg/ml = mg/l	1.96	1.57	2.35	Nephelometric (IFCC Cal.)
	µg/ml = mg/l	2.12	1.70	2.54	Nephelometric (Non IFCC Cal.)
	µg/ml = mg/l	2.20	1.76	2.64	Turbidimetric (IFCC Cal.)
	µg/ml = mg/l	2.24	1.79	2.69	Turbidimetric (Non IFCC Cal.)
C-Reactive Protein	mg/l	28.9	23.1	34.7	Vitros (IFCC Cal.)
	mg/l	23.9	19.1	28.7	Turbidimetric (IFCC Cal.)
	mg/l	20.5	16.4	24.6	Nephelometric (IFCC Cal.)
	mg/l	23.6	18.9	28.3	Turbidimetric (Non IFCC Cal.)
	mg/l	21.8	17.4	26.2	Beckman Turb Latex (IFCC Cal)
Caeruloplasmin	g/l	0.175	0.131	0.219	Nephelometric (IFCC Cal.)
	mg/dl	17.5	13.1	21.9	
	g/l	0.176	0.132	0.220	Turbidimetric (IFCC Cal.)
	mg/dl	17.6	13.2	22.0	
	g/l	0.155	0.116	0.194	Nephelometric (Non IFCC Cal.)
	mg/dl	15.5	11.6	19.4	
	g/l	0.164	0.123	0.205	Turbidimetric (Non IFCC Cal.)
	mg/dl	16.4	12.3	20.5	
Complement C3	g/l	0.737	0.590	0.884	Turbidimetric (IFCC Cal.)
	mg/dl	73.7	59.0	88.4	
	g/l	0.726	0.581	0.871	Nephelometric (IFCC Cal.)
	mg/dl	72.6	58.1	87.1	
	g/l	0.746	0.597	0.895	Nephelometric (Non IFCC Cal.)
	mg/dl	74.6	59.7	89.5	
	g/l	0.725	0.580	0.870	Turbidimetric (Non IFCC Cal.)
	mg/dl	72.5	58.0	87.0	
Complement C4	g/l	0.744	0.595	0.893	Vitros 5.1 FS microtip assay
	mg/dl	74.4	59.5	89.3	
	g/l	0.182	0.146	0.218	Turbidimetric (IFCC Cal.)
	mg/dl	18.2	14.6	21.8	
	g/l	0.196	0.157	0.235	Nephelometric (IFCC Cal.)
	mg/dl	19.6	15.7	23.5	
	g/l	0.187	0.150	0.224	Nephelometric (Non IFCC Cal.)
	mg/dl	18.7	15.0	22.4	
Ferritin	g/l	0.173	0.138	0.208	Turbidimetric (Non IFCC Cal.)
	mg/dl	17.3	13.8	20.8	
	g/l	0.183	0.146	0.220	Vitros 5.1 FS microtip assay
	mg/dl	18.3	14.6	22.0	
	ng/ml = µg/l	93.2	74.6	112	Turbidimetric (IFCC Cal.)
	ng/ml = µg/l	102	81.6	122	Turbidimetric (Non IFCC Cal.)
	ng/ml = µg/l	105	84.0	126	Chemiluminescence (IFCC Cal.)
	ng/ml = µg/l	105	84.0	126	Chemiluminescence (Non IFCC Cal.)

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

Cat. No. PS2682 Lot. No. 589LPC Size 3 x 1 ml Expiry 2022-02-28

Analyte	unit	Target	Range		methods
			low	high	
Free Lambda Light Chains	mg/L	12.1	9.68	14.5	Nephelometric - Binding Site
	mg/L	9.95	7.96	11.9	Nephelometric - Siemens
	mg/L	11.8	9.44	14.2	Turbidimetric
Haptoglobin	g/l	0.716	0.573	0.859	Nephelometric (IFCC Cal.)
	mg/dl	71.6	57.3	85.9	
	g/l	0.771	0.617	0.925	Turbidimetric (IFCC Cal.)
	mg/dl	77.1	61.7	92.5	
	g/l	0.705	0.564	0.846	Nephelometric (Non IFCC Cal.)
	mg/dl	70.5	56.4	84.6	
Immunoglobulin A	g/l	0.769	0.615	0.923	Turbidimetric (Non IFCC Cal.)
	mg/dl	76.9	61.5	92.3	
	g/l	1.24	0.930	1.55	Turbidimetric (IFCC Cal.)
	mg/dl	124	93.0	155	
	g/l	1.25	0.938	1.56	Nephelometric (IFCC Cal.)
	mg/dl	125	93.8	156	
Immunoglobulin E	g/l	1.24	0.930	1.55	Nephelometric (Non IFCC Cal.)
	mg/dl	124	93.0	155	
	g/l	1.21	0.908	1.51	Turbidimetric (Non IFCC Cal.)
	mg/dl	121	90.8	151	
	g/l	1.19	0.893	1.49	Vitros 5.1 FS Microtip (IFCC)
	mg/dl	119	89.3	149	
Immunoglobulin G	KIU/l = IU/ml	84.3	67.4	101	Fluorimetric (Non IFCC Cal.)
	KIU/l = IU/ml	82.9	66.3	99.0	Chemiluminescence (Non IFCC Cal.)
	KIU/l = IU/ml	79.7	63.8	95.6	Nephelometric (Non IFCC Cal.)
	KIU/l = IU/ml	72.8	58.2	87.4	Turbidimetric (Non IFCC Cal.)
Immunoglobulin M	g/l	7.01	5.75	8.27	Turbidimetric (IFCC Cal.)
	mg/dl	701	575	827	
	g/l	7.02	5.76	8.28	Nephelometric (IFCC Cal.)
	mg/dl	702	576	828	
	g/l	7.19	5.90	8.48	Nephelometric (Non IFCC Cal.)
	mg/dl	719	590	848	
Immunoglobulin M	g/l	7.10	5.82	8.38	Turbidimetric (Non IFCC Cal.)
	mg/dl	710	582	838	
	g/l	7.06	5.79	8.33	Vitros 5.1 FS Microtip (IFCC)
	mg/dl	706	579	833	
	g/l	0.845	0.676	1.01	Turbidimetric (IFCC Cal.)
	mg/dl	84.5	67.6	101	
Kappa Light Chain	g/l	0.845	0.676	1.01	Nephelometric (IFCC Cal.)
	mg/dl	84.5	67.6	101	
	g/l	0.874	0.699	1.05	Nephelometric (Non IFCC Cal.)
	mg/dl	87.4	69.9	105	
	g/l	0.839	0.671	1.01	Turbidimetric (Non IFCC Cal.)
	mg/dl	83.9	67.1	101	
Kappa Light Chain	g/l	0.854	0.683	1.02	Vitros 5.1 FS Microtip (IFCC)
	mg/dl	85.4	68.3	103	
Kappa Light Chain	g/l	5.44	4.35	6.53	Nephelometric - Beckman
	mg/dl	544	435	653	

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

Cat. No. PS2682 Lot. No. 589LPC Size 3 x 1 ml Expiry 2022-02-28

Analyte	unit	Target	Range		methods
			low	high	
Kappa Light Chain	g/l	1.81	1.45	2.17	Nephelometric - Siemens
	mg/dl	181	145	217	
	g/l	1.76	1.41	2.11	Turbidimetric
	mg/dl	176	141	211	
Lambda Light Chain	g/l	2.66	2.13	3.19	Nephelometric - Beckman
	mg/dl	266	213	319	
	g/l	0.942	0.750	1.13	Nephelometric - Siemens
	mg/dl	94.2	75.0	113	
	g/l	0.856	0.680	1.03	Turbidimetric
	mg/dl	85.6	68.0	103	
Prealbumin	g/l	0.202	0.162	0.242	Nephelometric (IFCC Cal.)
	mg/dl	20.2	16.2	24.2	
	g/l	0.199	0.159	0.239	Turbidimetric (IFCC Cal.)
	mg/dl	19.9	15.9	23.9	
	g/l	0.198	0.158	0.238	Turbidimetric (Non IFCC Cal.)
	mg/dl	19.8	15.8	23.8	
Protein Total	g/l	36.2	29.0	43.4	Biuret reaction end point
	g/dl	3.62	2.90	4.34	
Retinol Binding Protein	mg/l	31.2	25.0	37.4	Nephelometric (Non IFCC Cal.)
Rheumatoid Factor	U/ml	39.0	31.2	46.8	Turbidimetric (Non IFCC Cal.)
	U/ml	38.5	30.8	46.2	Latex (Non-IFCC Cal.)
	U/ml	29.2	23.4	35.0	Neph. Beckman (Non IFCC Cal.)
	U/ml	33.5	26.8	40.2	Neph. Behring (Non IFCC Cal.)
Transferrin	g/l	1.30	1.04	1.56	Turbidimetric (IFCC Cal.)
	mg/dl	130	104	156	
	g/l	1.30	1.04	1.56	Turbidimetric (Non IFCC Cal.)
	mg/dl	130	104	156	
	g/l	1.24	0.992	1.49	Nephelometric (IFCC Cal.)
	mg/dl	124	99.2	149	
g/l	1.32	1.06	1.58	Nephelometric (Non IFCC Cal.)	
mg/dl	132	106	158		