

PRODUCT INFORMATION

PS2682

584LPC

Please note that while Antithrombin III is present in PS2682 - Liquid Assayed Specific Protein Control Level 1 - lot 584LPC, targets and ranges are not available for this analyte.

CCS6790

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

CAT. NO. PS2682

LOT NO. 584LPC

SIZE: 3 x 1 ml

EXPIRY: 2023-06-28

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.



Randox Teoranta, Meenmore,
Dungloe, Donegal,
F94 TV06, Ireland

Rev. 18 Nov '22 me

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

Cat. No. PS2682 Lot No. 584LPC Size: 3 x 1 ml Expiry: 2023-06-28

Range					
Analyte	unit	Target	low	high	methods
Albumin	g/l	22.3	19.0	25.6	Bromocresol Green (IFCC Cal.)
	g/dl	2.23	1.90	2.56	
	g/l	20.9	17.8	24.0	Bromocresol Purple (IFCC Cal.)
	g/dl	2.09	1.78	2.40	
	g/l	22.5	19.1	25.9	Nephelometric (IFCC Cal.)
	g/dl	2.25	1.91	2.59	
	g/l	23.0	19.6	26.5	Bromocresol Green (Non IFCC Cal.)
	g/dl	2.30	1.96	2.64	
	g/l	21.8	18.5	25.1	Bromocresol Purple (Non IFCC Cal.)
	g/dl	2.18	1.85	2.51	
Alpha-1-Acid Glycoprotein	g/l	0.454	0.363	0.545	Turbidimetric (IFCC Cal.)
	mg/dl	45.4	36.3	54.5	
	g/l	0.486	0.389	0.583	Nephelometric (IFCC Cal.)
	mg/dl	48.6	38.9	58.3	
	g/l	0.446	0.357	0.535	Turbidimetric (Non IFCC Cal.)
	mg/dl	44.6	35.7	53.5	
Alpha-1-Antitrypsin	g/l	0.666	0.533	0.799	Turbidimetric (IFCC Cal.)
	mg/dl	66.6	53.3	79.9	
	g/l	0.694	0.555	0.833	Nephelometric (IFCC Cal.)
	mg/dl	69.4	55.5	83.3	
	g/l	0.672	0.538	0.806	Turbidimetric (Non IFCC Cal.)
mg/dl	67.2	53.8	80.6		
Alpha-2-Macroglobulin	g/l	0.975	0.780	1.17	Nephelometric (IFCC Cal.)
	mg/dl	97.5	78.0	117	
Alpha-fetoprotein	KIU/l = IU/ml	14.0	11.2	16.8	Chemiluminescence (IFCC Cal.)
	ng/ml	16.9	13.6	20.2	
	KIU/l = IU/ml	14.2	11.4	17.0	Chemiluminescence (Non IFCC Cal.)
	ng/ml	17.2	13.8	20.6	
Anti Streptolysin O	IU/ml	106	84.8	127	Turbidimetric (IFCC Cal.)
	IU/ml	112	89.6	134	Turbidimetric (Non IFCC Cal.)
	IU/ml	76.0	60.8	91.2	Neph. Beckman (IFCC Cal.)
	IU/ml	123	98.4	148	Siemens Nephelometric (IFCC Cal.)
	IU/ml	121	96.8	145	Siemens Nephelometric (Non IFCC Cal.)
Beta-2-microglobulin	µg/ml = mg/l	1.77	1.42	2.12	Chemiluminescence (IFCC Cal.)
	µg/ml = mg/l	1.55	1.24	1.86	Nephelometric (IFCC Cal.)
	µg/ml = mg/l	1.50	1.20	1.80	Nephelometric (Non IFCC Cal.)
	µg/ml = mg/l	1.81	1.45	2.17	Turbidimetric (IFCC Cal.)
	µg/ml = mg/l	1.78	1.42	2.14	Turbidimetric (Non IFCC Cal.)
C-Reactive Protein	mg/l	23.4	18.7	28.1	Vitros (IFCC Cal.)
	mg/l	24.7	19.8	29.6	Turbidimetric (IFCC Cal.)

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

Cat. No. PS2682 Lot No. 584LPC Size: 3 x 1 ml Expiry: 2023-06-28

Range					
Analyte	unit	Target	low	high	methods
C-Reactive Protein	mg/l	22.3	17.8	26.8	Nephelometric (IFCC Cal.)
	mg/l	24.5	19.6	29.4	Turbidimetric (Non IFCC Cal.)
	mg/l	22.7	18.2	27.2	Beckman Turb Latex (IFCC Cal)
Caeruloplasmin	g/l	0.184	0.138	0.230	Nephelometric (IFCC Cal.)
	mg/dl	18.4	13.8	23.0	
	g/l	0.174	0.131	0.217	Nephelometric (Non IFCC Cal.)
	mg/dl	17.4	13.1	21.7	
	g/l	0.146	0.110	0.182	Turbidimetric (Non IFCC Cal.)
	mg/dl	14.6	11.0	18.2	
Complement C3	g/l	0.168	0.126	0.210	Neph. Beckman (IFCC Cal.)
	mg/dl	16.8	12.6	21.0	
	g/l	0.844	0.675	1.01	Turbidimetric (IFCC Cal.)
	mg/dl	84.4	67.5	101	
	g/l	0.827	0.662	0.992	Nephelometric (IFCC Cal.)
	mg/dl	82.7	66.2	99.2	
Complement C4	g/l	0.845	0.676	1.01	Nephelometric (Non IFCC Cal.)
	mg/dl	84.5	67.6	101	
	g/l	0.856	0.685	1.03	Turbidimetric (Non IFCC Cal.)
	mg/dl	85.6	68.5	103	
	g/l	0.874	0.699	1.05	Vitros 5.1 FS microtip assay
	mg/dl	87.4	69.9	105	
Complement C4	g/l	0.139	0.111	0.167	Turbidimetric (IFCC Cal.)
	mg/dl	13.9	11.1	16.7	
	g/l	0.150	0.120	0.180	Nephelometric (IFCC Cal.)
	mg/dl	15.0	12.0	18.0	
	g/l	0.145	0.116	0.174	Nephelometric (Non IFCC Cal.)
	mg/dl	14.5	11.6	17.4	
Ferritin	g/l	0.132	0.106	0.158	Turbidimetric (Non IFCC Cal.)
	mg/dl	13.2	10.6	15.8	
	g/l	0.146	0.117	0.175	Vitros 5.1 FS microtip assay
	mg/dl	14.6	11.7	17.5	
Free Lambda Light Chains	ng/ml = µg/l	89.9	71.9	108	Turbidimetric (IFCC Cal.)
	ng/ml = µg/l	92.7	74.2	111	Turbidimetric (Non IFCC Cal.)
	ng/ml = µg/l	113	90.4	136	Chemiluminescence (IFCC Cal.)
	ng/ml = µg/l	124	99.0	149	Chemiluminescence (Non IFCC Cal.)
Free Lambda Light Chains	mg/L	7.62	6.10	9.14	Nephelometric - Binding Site
	mg/L	7.55	6.04	9.06	Nephelometric - Siemens
	mg/L	7.27	5.82	8.72	Turbidimetric
Haptoglobin	g/l	0.506	0.405	0.607	Nephelometric (IFCC Cal.)
	mg/dl	50.6	40.5	60.7	
	g/l	0.521	0.417	0.625	Turbidimetric (IFCC Cal.)
	mg/dl	52.1	41.7	62.5	
Immunoglobulin A	g/l	0.531	0.425	0.637	Turbidimetric (Non IFCC Cal.)
	mg/dl	53.1	42.5	63.7	
	g/l	1.53	1.15	1.91	Turbidimetric (IFCC Cal.)
mg/dl	153	115	191		

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

Cat. No. PS2682 Lot No. 584LPC Size: 3 x 1 ml Expiry: 2023-06-28

Analyte	unit	Target	Range		methods
			low	high	
Immunoglobulin A	g/l	1.57	1.18	1.96	Nephelometric (IFCC Cal.)
	mg/dl	157	118	196	
	g/l	1.57	1.18	1.96	Nephelometric (Non IFCC Cal.)
	mg/dl	157	118	196	
	g/l	1.51	1.13	1.89	Turbidimetric (Non IFCC Cal.)
	mg/dl	151	113	189	
Immunoglobulin E	g/l	1.56	1.17	1.95	Vitros 5.1 FS Microtip (IFCC)
	mg/dl	156	117	195	
	KIU/l = IU/ml	83.4	66.7	100	Chemiluminescence (Non IFCC Cal.)
	KIU/l = IU/ml	82.7	66.2	99.0	Nephelometric (Non IFCC Cal.)
	KIU/l = IU/ml	74.3	59.4	89.2	Turbidimetric (Non IFCC Cal.)
	Immunoglobulin G	g/l	7.79	6.39	9.19
mg/dl		779	639	919	
g/l		7.85	6.44	9.26	Nephelometric (IFCC Cal.)
mg/dl		785	644	926	
g/l		7.86	6.45	9.27	Nephelometric (Non IFCC Cal.)
mg/dl		786	645	927	
g/l		7.86	6.45	9.27	Turbidimetric (Non IFCC Cal.)
mg/dl		786	645	927	
g/l		8.43	6.91	9.95	Vitros 5.1 FS Microtip (IFCC)
mg/dl		843	691	995	
Immunoglobulin M	g/l	0.591	0.473	0.709	Turbidimetric (IFCC Cal.)
	mg/dl	59.1	47.3	70.9	
	g/l	0.615	0.492	0.738	Nephelometric (IFCC Cal.)
	mg/dl	61.5	49.2	73.8	
	g/l	0.638	0.510	0.766	Nephelometric (Non IFCC Cal.)
	mg/dl	63.8	51.0	76.6	
	g/l	0.591	0.473	0.709	Turbidimetric (Non IFCC Cal.)
	mg/dl	59.1	47.3	70.9	
	g/l	0.616	0.493	0.739	Vitros 5.1 FS Microtip (IFCC)
	mg/dl	61.6	49.3	73.9	
Kappa Light Chain	g/l	6.51	5.21	7.81	Nephelometric - Beckman
	mg/dl	651	521	781	
	g/l	1.88	1.50	2.26	Nephelometric - Siemens
	mg/dl	188	150	226	
	g/l	1.86	1.49	2.23	Turbidimetric
	mg/dl	186	149	223	
Lambda Light Chain	g/l	3.59	2.87	4.31	Nephelometric - Beckman
	mg/dl	359	287	431	
	g/l	1.08	0.860	1.30	Nephelometric - Siemens
	mg/dl	108	86.0	130	
	g/l	1.02	0.820	1.22	Turbidimetric
	mg/dl	102	82.0	122	
Prealbumin	g/l	0.133	0.106	0.160	Nephelometric (IFCC Cal.)
	mg/dl	13.3	10.6	16.0	
	g/l	0.127	0.102	0.152	Turbidimetric (IFCC Cal.)
	mg/dl	12.7	10.2	15.2	

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

Cat. No. PS2682 Lot. No. 584LPC Size 3 x 1ml Expiry 2023-06-28

Range					
Analyte	unit	Target	low	high	methods
Prealbumin	g/l	0.129	0.103	0.155	Nephelometric (Non IFCC Cal.)
	mg/dl	12.9	10.3	15.5	
	g/l	0.133	0.106	0.160	Turbidimetric (Non IFCC Cal.)
	mg/dl	13.3	10.6	16.0	
Protein Total	g/l	39.4	31.5	47.3	Biuret reaction end point
	g/dl	3.94	3.15	4.73	
Retinol Binding Protein	mg/l	20.5	16.4	24.6	Nephelometric (Non IFCC Cal.)
Rheumatoid Factor	U/ml	12.7	9.53	15.9	Turbidimetric (Non IFCC Cal.)
	U/ml	12.4	9.30	15.5	Siemens Nephelometric (Non IFCC Cal.)
Transferrin	g/l	1.55	1.24	1.86	Turbidimetric (IFCC Cal.)
	mg/dl	155	124	186	
	g/l	1.57	1.26	1.88	Turbidimetric (Non IFCC Cal.)
	mg/dl	157	126	188	
	g/l	1.54	1.23	1.85	Nephelometric (IFCC Cal.)
	mg/dl	154	123	185	
	g/l	1.52	1.22	1.82	Nephelometric (Non IFCC Cal.)
	mg/dl	152	122	182	