

PRODUCT INFORMATION

PS2684

587LPC

Please note that the target and range for Antithrombin III are currently not available. This will be updated in due course when values become available.

CCS6416

LIQUID ASSAYED SPECIFIC PROTEIN CONTROL - LEVEL 3 (SP CONTROL 3)

CAT. NO. PS2684
SIZE: 3 x 1 ml

LOT NO. 587LPC
EXPIRY: 2022-02-28

GTIN: 05055273204919

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 3 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 9445 1070 or email Technical.Services@randox.com.

22 Apr 20 pl

LIQUID ASSAYED SPECIFIC PROTEIN CONTROL LEVEL 3 (SP CONTROL 3)

Cat. No. PS2684 Lot. No. 587LPC Size 3 x 1ml Expiry 2022-02-28

Range						
Analyte	unit	Target	low	high	methods	
Albumin	g/l	57.2	48.6	65.8	Bromocresol Green (IFCC Cal.)	
	g/dl	5.72	4.86	6.58		
	g/l	57.3	48.7	65.9	Bromocresol Purple (IFCC Cal.)	
	g/dl	5.73	4.87	6.59		
	g/l	56.9	48.4	65.4	Nephelometric (IFCC Cal.)	
	g/dl	5.69	4.84	6.54		
	g/l	57.9	49.2	66.6	Bromocresol Green (Non IFCC Cal.)	
	g/dl	5.79	4.92	6.66		
	g/l	59.0	50.2	67.9	Bromocresol Purple (Non IFCC Cal.)	
	g/dl	5.90	5.02	6.78		
Alpha-1-Acid Glycoprotein	g/l	56.7	48.2	65.2	Turbidimetric Assays (IFCC Cal.)	
	g/dl	5.67	4.82	6.52		
	g/l	56.8	48.3	65.3	Turbidimetric Assays (Non IFCC Cal.)	
	g/dl	5.68	4.83	6.53		
	Alpha-1-Acid Glycoprotein	g/l	1.39	1.11	1.67	Turbidimetric (IFCC Cal.)
		mg/dl	139	111	167	Nephelometric (IFCC Cal.)
		g/l	1.36	1.09	1.63	
		mg/dl	136	109	163	
Alpha-1-Acid Glycoprotein	g/l	1.37	1.10	1.64	Turbidimetric (Non IFCC Cal.)	
	mg/dl	137	110	164		
	Alpha-1-Antitrypsin	g/l	2.49	1.99	2.99	Turbidimetric (IFCC Cal.)
		mg/dl	249	199	299	
g/l		2.85	2.28	3.42	Nephelometric (IFCC Cal.)	
mg/dl		285	228	342		
Alpha-1-Antitrypsin	g/l	2.51	2.01	3.01	Turbidimetric (Non IFCC Cal.)	
	mg/dl	251	201	301		
	Alpha-2-Macroglobulin	g/l	2.94	2.35	3.53	Turbidimetric (IFCC Cal.)
		mg/dl	294	235	353	
g/l		3.01	2.41	3.61	Nephelometric (IFCC Cal.)	
mg/dl		301	241	361		
Alpha-2-Macroglobulin	g/l	2.97	2.38	3.56	Turbidimetric (Non IFCC Cal.)	
	mg/dl	297	238	356		
	Alphafoetoprotein	KIU/l = IU/ml	56.4	45.1	67.7	Chemiluminescence (IFCC Cal.)
		ng/ml	68.2	54.6	81.8	
KIU/l = IU/ml		52.7	42.2	63.2	Chemiluminescence (Non IFCC Cal.)	
ng/ml		63.8	51.1	76.5		
Anti Streptolysin O	IU/ml	352	282	422	Turbidimetric (IFCC Cal.)	
	IU/ml	363	290	436	Turbidimetric (Non IFCC Cal.)	
	IU/ml	244	195	293	Neph. Beckman (IFCC Cal.)	
	IU/ml	236	189	283	Neph. Beckman (Non IFCC Cal.)	
	IU/ml	343	274	412	Neph. Behring (IFCC Cal.)	
	IU/ml	336	269	403	Neph. Behring (Non IFCC Cal.)	

LIQUID ASSAYED SPECIFIC PROTEIN CONTROL LEVEL 3 (SP CONTROL 3)

Cat. No. PS2684 Lot. No. 587LPC Size 3 x 1ml Expiry 2022-02-28

Range					
Analyte	unit	Target	low	high	methods
Beta-2-microglobulin	µg/ml = mg/l	6.09	4.87	7.31	Nephelometric (IFCC Cal.)
	µg/ml = mg/l	6.58	5.26	7.90	Nephelometric (Non IFCC Cal.)
	µg/ml = mg/l	6.65	5.32	7.98	Turbidimetric (IFCC Cal.)
	µg/ml = mg/l	6.43	5.14	7.72	Turbidimetric (Non IFCC Cal.)
C-Reactive Protein	mg/l	68.9	55.1	82.7	Turbidimetric (IFCC Cal.)
	mg/l	65.0	52.0	78.0	Nephelometric (IFCC Cal.)
	mg/l	68.8	55.0	82.6	Turbidimetric (Non IFCC Cal.)
	mg/l	72.3	57.8	86.8	Beckman Turb Latex (IFCC Cal)
Caeruloplasmin	g/l	0.733	0.550	0.916	Nephelometric (IFCC Cal.)
	mg/dl	73.3	55.0	91.6	
	g/l	0.581	0.436	0.726	Turbidimetric (IFCC Cal.)
	mg/dl	58.1	43.6	72.6	
	g/l	0.567	0.425	0.709	Turbidimetric (Non IFCC Cal.)
mg/dl	56.7	42.5	70.9		
Complement C3	g/l	2.22	1.78	2.66	Turbidimetric (IFCC Cal.)
	mg/dl	222	178	266	
	g/l	2.19	1.75	2.63	Nephelometric (IFCC Cal.)
	mg/dl	219	175	263	
	g/l	2.29	1.83	2.75	Nephelometric (Non IFCC Cal.)
	mg/dl	229	183	275	
	g/l	2.20	1.76	2.64	Turbidimetric (Non IFCC Cal.)
	mg/dl	220	176	264	
Complement C4	g/l	2.27	1.82	2.72	Vitros 5.1 FS microtip assay
	mg/dl	227	182	272	
	g/l	0.549	0.439	0.659	Turbidimetric (IFCC Cal.)
	mg/dl	54.9	43.9	65.9	
	g/l	0.581	0.465	0.697	Nephelometric (IFCC Cal.)
	mg/dl	58.1	46.5	69.7	
	g/l	0.594	0.475	0.713	Nephelometric (Non IFCC Cal.)
	mg/dl	59.4	47.5	71.3	
Ferritin	g/l	0.539	0.431	0.647	Turbidimetric (Non IFCC Cal.)
	mg/dl	53.9	43.1	64.7	
	ng/ml = µg/l	266	213	319	Turbidimetric (IFCC Cal.)
	ng/ml = µg/l	277	222	332	Turbidimetric (Non IFCC Cal.)
Free Lambda Light Chains	ng/ml = µg/l	303	242	364	Chemiluminescence (IFCC Cal.)
	ng/ml = µg/l	299	239	359	Chemiluminescence (Non IFCC Cal.)
	mg/L	29.3	23.4	35.2	Nephelometric - Binding Site
Haptoglobin	mg/L	19.1	15.3	22.9	Nephelometric - Siemens
	mg/L	28.1	22.5	33.7	Turbidimetric
	g/l	2.17	1.74	2.60	Nephelometric (IFCC Cal.)
Haptoglobin	mg/dl	217	174	260	
	g/l	2.27	1.82	2.72	Turbidimetric (IFCC Cal.)
	mg/dl	227	182	272	
	g/l	2.25	1.80	2.70	Nephelometric (Non IFCC Cal.)
	mg/dl	225	180	270	
	g/l	2.29	1.83	2.75	Turbidimetric (Non IFCC Cal.)
mg/dl	229	183	275		

LIQUID ASSAYED SPECIFIC PROTEIN CONTROL LEVEL 3 (SP CONTROL 3)

Cat. No. PS2684 Lot. No. 587LPC Size 3 x 1ml Expiry 2022-02-28

Analyte	unit	Target	Range		methods
			low	high	
Immunoglobulin A	g/l	3.61	2.71	4.51	Turbidimetric (IFCC Cal.)
	mg/dl	361	271	451	
	g/l	3.92	2.94	4.90	Nephelometric (IFCC Cal.)
	mg/dl	392	294	490	
	g/l	3.99	2.99	4.99	Nephelometric (Non IFCC Cal.)
	mg/dl	399	299	499	
Immunoglobulin E	g/l	3.60	2.70	4.50	Turbidimetric (Non IFCC Cal.)
	mg/dl	360	270	450	
	g/l	3.50	2.63	4.38	Vitros 5.1 FS Microtip (IFCC)
	mg/dl	350	263	437	
	KIU/l = IU/ml	256	205	307	Fluorimetric (Non IFCC Cal.)
	KIU/l = IU/ml	243	194	292	Chemiluminescence (Non IFCC Cal.)
Immunoglobulin G	KIU/l = IU/ml	236	189	283	Nephelometric (Non IFCC Cal.)
	KIU/l = IU/ml	241	193	289	Enzyme Immunoassay (Non IFCC Cal.)
	KIU/l = IU/ml	220	176	264	Turbidimetric (Non IFCC Cal.)
	g/l	20.4	16.7	24.1	Turbidimetric (IFCC Cal.)
	mg/dl	2040	1670	2410	
	g/l	20.4	16.7	24.1	Nephelometric (IFCC Cal.)
Immunoglobulin M	mg/dl	2040	1670	2410	
	g/l	20.2	16.6	23.8	Nephelometric (Non IFCC Cal.)
	mg/dl	2020	1660	2380	
	g/l	20.7	17.0	24.4	Turbidimetric (Non IFCC Cal.)
	mg/dl	2070	1700	2440	
	g/l	20.3	16.6	24.0	Vitros 5.1 FS Microtip (IFCC)
Kappa Light Chain	mg/dl	2030	1660	2400	
	g/l	2.50	2.00	3.00	Turbidimetric (IFCC Cal.)
	mg/dl	250	200	300	
	g/l	2.59	2.07	3.11	Nephelometric (IFCC Cal.)
	mg/dl	259	207	311	
	g/l	2.51	2.01	3.01	Nephelometric (Non IFCC Cal.)
Lambda Light Chain	mg/dl	251	201	301	
	g/l	2.54	2.03	3.05	Turbidimetric (Non IFCC Cal.)
	mg/dl	254	203	305	
	g/l	2.57	2.06	3.08	Vitros 5.1 FS Microtip (IFCC)
	mg/dl	257	206	308	
	g/l	5.21	4.17	6.25	Nephelometric - Siemens
Kappa Light Chain	mg/dl	521	417	625	
	g/l	5.67	4.54	6.80	Turbidimetric
	mg/dl	567	454	680	
Lambda Light Chain	g/l	8.27	6.62	9.92	Nephelometric - Beckman
	mg/dl	827	662	992	
	g/l	2.72	2.18	3.26	Nephelometric - Siemens
	mg/dl	272	218	326	
Kappa Light Chain	g/l	2.93	2.34	3.52	Turbidimetric
	mg/dl	293	234	352	

LIQUID ASSAYED SPECIFIC PROTEIN CONTROL LEVEL 3 (SP CONTROL 3)

Cat. No. PS2684 Lot. No. 587LPC Size 3 x 1ml Expiry 2022-02-28

Range					
Analyte	unit	Target	low	high	methods
Prealbumin	g/l	0.600	0.480	0.720	Nephelometric (IFCC Cal.)
	mg/dl	60.0	48.0	72.0	
	g/l	0.587	0.470	0.704	Turbidimetric (IFCC Cal.)
	mg/dl	58.7	47.0	70.4	
Protein Total	g/l	0.593	0.474	0.712	Turbidimetric (Non IFCC Cal.)
	mg/dl	59.3	47.4	71.2	
Protein Total	g/l	98.4	78.7	118	Biuret reaction end point
	g/dl	9.84	7.87	11.8	
Retinol Binding Protein	mg/l	97.8	78.2	117	Nephelometric (IFCC Cal.)
	mg/l	102	81.6	122	Nephelometric (Non IFCC Cal.)
Rheumatoid Factor	U/ml	109	87.2	131	Turbidimetric (Non IFCC Cal.)
	U/ml	119	95.2	143	Latex (Non-IFCC Cal.)
	U/ml	126	101	151	Neph. Beckman (Non IFCC Cal.)
	U/ml	94.1	75.3	113	Neph. Behring (Non IFCC Cal.)
Transferrin	g/l	3.83	3.06	4.60	Turbidimetric (IFCC Cal.)
	mg/dl	383	306	460	
	g/l	3.90	3.12	4.68	Turbidimetric (Non IFCC Cal.)
	mg/dl	390	312	468	
Transferrin	g/l	3.79	3.03	4.55	Nephelometric (IFCC Cal.)
	mg/dl	379	303	455	