



## CONE IMMUNOASSAY CONTROL, LYOPHILIZED – 3 LEVELS

Product	Lot Number	Contents	Expiration Date
CONE Lyophilized Immunoassay Control, 3 Levels	5635F001	3 Levels x 3 Vials	3 Years DOM
CONE Lyophilized Immunoassay Control, Level 1	5597F001	3 Vials x 5 mL	3 Years DOM
CONE Lyophilized Immunoassay Control, Level 2	5598F001	3 Vials x 5 mL	3 Years DOM
CONE Lyophilized Immunoassay Control, Level 3	5599F001	3 Vials x 5 mL	3 Years DOM

### INTENDED USE

CONE Lyophilized Immunoassay Control is intended for use as a human lyophilized control serum to monitor the precision of laboratory testing procedures for the analytes listed in the package insert.

### SUMMARY AND PRINCIPLE

The use of independent quality control materials is indicated as an objective assessment of the precision of methods and techniques in use and is an integral part of good laboratory practices. Three levels of control are available to allow performance monitoring within the clinical range.

### REAGENT

CONE Lyophilized Immunoassay Control is prepared from human serum to which human biochemical material, chemicals, stabilizers and preservatives are added. The control is provided in lyophilized form for increased stability.

### STORAGE AND STABILITY

To achieve maximum shelf life for the CONE Lyophilized Immunoassay Control, store unopened at 2-8°C until the expiration date. Store vials away from the light. Upon opening, the control can be used for up to 7 days with most analytes after reconstitution. Do not refreeze after reconstitution, and discard any unused control after the 7-day reuse period.

### PROCEDURE

CONE Lyophilized Immunoassay Control should be treated in the same manner as patient samples and in accordance with local, state, and/or federal regulations or accreditation requirements. Reconstitute product using a volumetric pipette with 5.0mL of deionized water. Replace the stopper allowing the product to sit for 15 minutes after reconstitution. Gently swirl occasionally. After reconstitution, store tightly capped at 2-8°C when not in use. Before each use, gently swirl to ensure even mixture of product. Dispose of product after expiration according to local waste authority procedures.

### LIMITATIONS

Different values from those obtained with reagents available at the time of assay may be obtained as a result of changes in manufacturer's reagents or lot-to-lot reagent variability. CONE Lyophilized Immunoassay Control should not be used past its expiration date or after improper handling. Microbial contamination will affect performance of this product.

### ANALYTE VALUES

In accordance with good laboratory practices, each laboratory should establish its own analyte means and acceptable performance ranges.

### SPECIFIC PERFORMANCE CHARACTERISTICS

CONE Lyophilized Immunoassay Control is manufactured in accordance with industry guidelines and standards. To perform as intended, the control requires proper storage and handling as described in this package insert.

### WARNINGS

Individual donor units used in the preparation of this product have been tested and found to be non-reactive for HBsAg, Anti-HIV I/II, Anti-HCV, HIV-1 RNA, and HCV RNA. Donors of human plasma units used in making this product were tested and found negative for syphilis. However, no test method can offer complete assurance that products derived from human source material will not transmit infectious diseases. Therefore, this product should be considered potentially infectious and be treated in the same manner as a patient specimen.

This product contains 0.09% sodium azide as a preservative. Sodium azide may react with lead and copper plumbing to form potentially explosive compounds. Flush with copious amounts of water upon disposal.



## CONE IMMUNOASSAY CONTROL, LYOPHILIZED – 3 LEVELS

**For In Vitro Diagnostic Use Only**

**Assigned Values and Ranges Lot #5635F001 (Representative Values)**

**Containing Vial Lots L1 #5597F001 & L2 #5598F001 & L3 #5599F001**

*Analyte* - Instrument		LEVEL 1 – 5597F001			LEVEL 2 – 5598F001			LEVEL 3 – 5599F001		
	UNITS	MEAN	Expected Range		MEAN	Expected Range		MEAN	Expected Range	
*25-OH Vitamin D*	ng/mL	38.9	32.7	45.1	17.9	15.0	20.8	54.5	45.7	63.2
*CA 15-3*										
Tosoh AIA	U/mL	16.3	13.7	16.9	28.0	23.5	32.4	41.8	35.1	48.5
*AFP*										
Tosoh AIA	ng/mL	7.3	6.2	8.5	34.7	29.2	40.3	116.1	97.5	134.7
*Vitamin B12*										
Tosoh AIA	pg/mL	385	308	453	882	705	1058	1180	944	1415
*BMG*										
Tosoh AIA	mg/L	0.822	0.657	0.986	2.226	1.870	2.582	3.735	3.137	4.333
*bHCG II*										
Tosoh AIA	mIU/mL	2.5	1.0	4.0	94.4	79.3	109.5	290.4	244.0	336.9
*CEA*										
Tosoh AIA	ng/mL	6.7	5.6	7.8	18.3	15.4	21.3	36.8	30.9	42.7
*CKMB*										
Tosoh AIA	ng/mL	4.1	3.5	4.8	10.0	8.4	11.6	49.8	41.8	57.7
*Cortisol*										
Tosoh AIA	µg/dL	8.7	6.96	10.44	13.42	11.27	15.56	27.42	23.03	31.61
*C-Peptide*										
Tosoh AIA	ng/mL	0.7	0.6	0.9	4.9	4.1	5.6	15.1	12.7	17.5
*C-Peptide II*										
Tosoh AIA	ng/mL	0.83	0.66	0.99	4.75	3.99	5.51	15.06	12.7	17.5
*cTnl 3 <sup>rd</sup> -Gen*										
Tosoh AIA	ng/mL	0.27	0.21	0.34	10.04	8.03	12.04	21.24	17.84	24.64
*DHEA-S*										
Tosoh AIA	µg/dL	59.1	49.6	68.5	303.0	254.5	351.4	566.6	475.0	657.3
*hsE2*										
Tosoh AIA	pg/mL	203.7	142.6	264.8	335.4	281.7	389.0	515.8	433.3	598.3
*iE2*										
Tosoh AIA	pg/mL	168.0	117.6	218.4	290.4	243.9	336.9	445.0	373.8	516.2
*Ferritin*										
Tosoh AIA	ng/mL	53.1	44.6	61.6	199.0	167.2	230.9	499.2	419.3	579.0
*Folate*										
Tosoh AIA	ng/mL	2.5	1.5	3.5	5.9	4.1	7.6	15.1	10.6	19.7
*FSH*										
Tosoh AIA	mIU/mL	7.9	6.6	9.1	14.7	12.3	17.1	44.5	37.3	51.6



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<b>*Analyte* - Instrument</b>		<b>LEVEL 1 – 5597F001</b>			<b>LEVEL 2 – 5598F001</b>			<b>LEVEL 3 – 5599F001</b>		
<b>*iFT3*</b>	<b>UNITS</b>	<b>MEAN</b>	<b>Expected Range</b>		<b>MEAN</b>	<b>Expected Range</b>		<b>MEAN</b>	<b>Expected</b>	
Tosoh AIA	pg/mL	2.27	1.82	2.73	3.44	2.89	3.99	15.29	12.85	17.74
<b>*FT4*</b>										
Tosoh AIA	ng/dL	0.73	0.55	0.90	1.40	1.18	1.63	4.74	3.96	5.50
<b>*hCG II*</b>										
Tosoh AIA	mIU/mL	2.5	1.0	4.0	95.7	80.4	111.0	297.2	249.7	344.8
<b>*HGH*</b>										
Tosoh AIA	ng/mL	3.7	3.1	4.3	9.2	7.7	10.7	23.9	20.1	27.7
<b>*IgE II*</b>										
Tosoh AIA	IU/mL	61.2	51.4	71.0	115.5	97.0	134.0	351.6	295.3	407.9
<b>*IRI*</b>										
Tosoh AIA	μU/mL	17.6	14.1	21.2	142.5	119.7	165.3	260.5	218.9	302.2
<b>*LH II*</b>										
Tosoh AIA	mIU/mL	4.1	3.5	4.8	25.6	21.5	29.7	104.3	87.6	121.0
<b>*Myoglobin*</b>										
Tosoh AIA	ng/mL	53.2	44.7	61.7	121.9	102.4	141.4	296.1	248.8	343.5
<b>*CA 125*</b>										
Tosoh AIA	U/mL	15.1	12.7	17.5	42.3	35.5	49.1	88.0	73.9	102.1
<b>*PAP*</b>										
Tosoh AIA	ng/mL	7.9	6.7	9.2	24.3	20.4	28.2	5.2	4.4	6.1
<b>*Prolactin*</b>										
Tosoh AIA	ng/mL	3.0	2.5	3.5	13.8	11.6	16.0	56.7	47.6	65.8
<b>*Progesterone*</b>										
Tosoh AIA	ng/mL	4.01	3.37	4.66	11.44	9.61	13.28	26.81	22.52	31.09
<b>*Progesterone 2<sup>nd</sup> gen*</b>										
Tosoh AIA	ng/mL	2.97	2.50	3.45	10.51	8.83	12.20	26.88	20.43	33.34
<b>*PSA II*</b>										
Tosoh AIA	ng/mL	3.068	2.578	3.559	29.455	24.727	34.168	0.474	0.379	0.568
<b>*Free PSA*</b>										
Tosoh AIA	ng/mL	1.097	0.921	1.272	13.617	11.438	15.796	0.290	0.254	0.336
<b>*iPTH*</b>										
Tosoh AIA	pg/mL	12.0	9.6	14.4	32.9	27.6	38.1	193.1	162.2	224.0
<b>*wPTH*</b>										
Tosoh AIA	pg/mL	8.7	6.9	10.4	20.8	16.6	24.9	123.6	98.9	148.3
<b>*CA 19-9*</b>										
Tosoh AIA	U/mL	16.4	13.8	19.0	37.5	31.5	43.4	86.7	72.8	100.5
<b>*T4*</b>										
Tosoh AIA	μg/dL	3.9	3.1	4.6	7.0	5.6	8.4	18.7	15.0	22.5
<b>*Testosterone*</b>										
Tosoh AIA	ng/dL	112.76	85.11	140.42	480.22	399.35	561.08	983.08	819.32	1146.84
<b>*TSH*</b>										
Tosoh AIA	μIU/mL	0.453	0.380	0.525	5.959	5.006	6.913	28.877	24.257	33.498



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*TT3*	UNITS	MEAN	Expected Range		MEAN	Expected Range		MEAN	Expected	
Tosoh AIA	ng/mL	0.83	0.66	1.00	1.14	0.91	1.37	3.80	3.04	4.55