BGT BioGenTechnologies GmbH
Von-Langen-Weg 10
D-48565 Steinfurt
Tel.: 02551/4090 Fax.: 02551/1298

Cytokine Controls
(CTK CONTROL)
KG5006 CE

Art.-Nr.:	KG5006
Ch.-B.:	2450 (3081EV, 3004EV, 3005EV) v1
Inhalt:	3 x 3 x 1 ml
Verw. bis:	2010-04
Darreichungsform:	Lyophilised

LABELLING GUIDE

CTK	Cytokine
CONTROL	Control

INTENDED USE
BGT Cytokine controls are *in-vitro* diagnostic products intended for use as an assayed quality control in the routine monitoring of accuracy and precision for the analytes listed in this insert.
The BGT Cytokine Controls are multi-analyte. Each control contains all of the analytes listed overleaf. There are 3 levels of control: low, medium and high; Level 1, 2 and 3 respectively.

REAGENT COMPOSITION
Lyophilised human serum, pH 7.5 containing preservatives and a range of cytokines and growth factors as listed overleaf.

STORAGE AND STABILITY

Unopened:	Lyophilised cytokine controls are stable up to the expiration date when stored at +2 to +8°C.
Opened:	Once reconstituted, the controls are stable for 10 - 12 hours when stored at +2 to +8°C in the original vial, or up to 2 weeks at -20°C. Only the required amount of product should be removed. After use, any residual product should NOT BE RETURNED to the original vial.

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.

The reagents must be used only for the purpose intended by suitably qualified laboratory personnel, under appropriate laboratory conditions.

MATERIALS PROVIDED
Batch Specific barcodes for use with Evidence and Investigator analysers
Batch Specific control settings for the Evidence and Investigator analysers and Instructions for Use CD

CTK CONTROL 1	3 x 1 ml
CTK CONTROL 2	3 x 1 ml
CTK CONTROL 3	3 x 1 ml

MATERIALS REQUIRED BUT NOT PROVIDED
Volumetric Pipette

FOR EVIDENCE SYSTEMS

Evidence Cytokine Array	EV3508 or EV3544
Investigator Cytokine Array	EV3513
2 ml Sample cups	EV3574
16 mm Sample tubes	EV3633

PROCEDURAL NOTES

EVIDENCE / INVESTIGATOR CD ROM INSTALLATION

Insert disc into CDROM drive
Double click on **MY COMPUTER** icon on Windows desktop
Double click on CD drive icon
Double click on **UPDATE CONTROLS.EXE**
Select the box next to either evidence® or evidence investigator™ controls for the relevant array
Click on **UPDATE**
A progress bar will appear and once complete will say 'Update Complete'
Click on **EXIT**
Control information (lot, target, SD, barcode, display name) for this lot of controls has now been updated.

PREPARATION

Procedure

1. Open the vial very carefully, avoiding any loss of material.
2. Reconstitute with 1 ml accurately measured distilled water at +20 to +25°C.
3. Replace the rubber stopper, close vial and leave to stand for 15 minutes out of bright light before use.
4. Make sure all dry material has dissolved then place the vial on a roller for 15 minutes.
5. Do not shake the vial.

The control should only be reconstituted using this procedure.

FOR THE evidence® ANALYSER ONLY

Label appropriate sample tubes with the batch specific control barcodes provided. Using a volumetric pipette, transfer the required amount of control to the appropriate barcode labelled tube or sample cup to be used on the evidence® analyser.

LIMITATIONS

1. Do not use the product past the expiry date.
2. Control settings are lot specific. Do not mix lots of reagents.
3. Do not use the product if there is evidence of contamination.
4.

VALUE ASSIGNMENT

Controls are assigned using a minimum of 36 replicates over multiple analysers. For each control level, the outliers are removed from the data set using Chauvenet's exclusion principle and the remaining values are averaged to produce a target. The ranges are provided as the target ± 2 standard deviations. The assignment is then validated on three different analysers.

ABBREVIATIONS

IL	Interleukin
VEGF	Vascular Endothelial Growth Factor
TNFα	Tumour Necrosis Factor alpha
IFNγ	Interferon gamma
MCP-1	Monocyte Chemoattractant Protein-1
EGF	Epidermal Growth Factor

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evidence® ANALYSER CONTROL RANGES (KITS EV3508 and EV3544)

IL2	pg/ml	Target	Range		SD	IFNy	pg/ml	Target	Range		SD
	Control 1	29.51	19.19	39.83	5.16		Control 1	33.01	21.45	44.57	5.78
	Control 2	113.72	73.92	153.52	19.90		Control 2	128.65	83.63	173.67	22.51
	Control 3	501.87	326.21	677.53	87.83		Control 3	596.77	387.91	805.63	104.43
IL4						TNFα					
	Control 1	36.79	23.91	49.67	6.44		Control 1	24.51	15.93	33.09	4.29
	Control 2	134.22	87.24	181.20	23.49		Control 2	90.13	58.59	121.67	15.77
	Control 3	623.99	405.59	842.39	109.20		Control 3	354.17	320.21	478.13	61.98
IL6						IL-1α					
	Control 1	15.14	9.84	20.44	2.65		Control 1	14.28	9.28	19.28	2.50
	Control 2	61.82	40.18	83.46	10.82		Control 2	61.08	39.70	82.46	10.69
	Control 3	251.65	163.57	339.73	44.04		Control 3	200.35	130.23	270.47	35.06
IL8						IL-1β					
	Control 1	28.68	18.64	38.72	5.02		Control 1	11.07	7.19	14.95	1.94
	Control 2	141.20	91.78	190.62	24.71		Control 2	39.83	25.89	53.77	6.97
	Control 3	647.76	421.04	874.48	113.36		Control 3	130.27	84.67	175.87	22.80
IL10						MCP-1					
	Control 1	22.75	14.79	30.71	3.98		Control 1	25.98	16.88	35.08	4.55
	Control 2	85.56	55.62	115.50	14.97		Control 2	124.17	77.09	171.25	23.54
	Control 3	371.96	204.46	539.46	83.75		Control 3	556.11	361.47	750.75	97.32
VEGF						EGF					
	Control 1	58.95	38.31	79.59	10.32		Control 1	24.56	15.96	33.16	4.30
	Control 2	231.29	150.33	312.25	40.48		Control 2	113.21	73.59	152.83	19.81
	Control 3	620.00	403.00	837.00	108.50		Control 3	689.10	422.10	956.10	133.50

evidence® INVESTIGATOR CONTROL RANGES (KIT EV3513)

IL2	pg/ml	Target	Range		SD	IFNy	pg/ml	Target	Range		SD
	Control 1	29.76	19.34	40.18	5.21		Control 1	30.61	17.07	44.15	6.77
	Control 2	102.79	66.81	138.77	17.99		Control 2	119.85	76.15	163.55	21.85
	Control 3	418.39	271.95	564.83	73.22		Control 3	534.81	347.63	721.99	93.59
IL4						TNFα					
	Control 1	32.20	20.92	43.48	5.64		Control 1	22.68	14.74	30.62	3.97
	Control 2	114.81	71.15	158.47	21.83		Control 2	84.79	55.11	114.47	14.84
	Control 3	498.14	323.80	672.48	87.17		Control 3	317.66	206.48	428.84	55.59
IL6						IL-1α					
	Control 1	14.53	9.45	19.61	2.54		Control 1	12.88	8.38	17.38	2.25
	Control 2	60.09	39.05	81.13	10.52		Control 2	52.37	34.03	70.71	9.17
	Control 3	239.44	155.64	323.24	41.90		Control 3	165.26	107.42	223.10	28.92
IL8						IL-1β					
	Control 1	31.55	19.57	43.53	5.99		Control 1	9.61	6.25	12.97	1.68
	Control 2	134.99	83.29	186.69	25.85		Control 2	33.68	21.90	45.46	5.89
	Control 3	623.81	388.73	858.89	117.54		Control 3	113.50	73.78	153.22	19.86
IL10						MCP-1					
	Control 1	20.70	13.64	27.94	3.62		Control 1	26.62	17.30	35.94	4.66
	Control 2	75.30	45.54	105.06	14.88		Control 2	113.12	73.52	152.72	19.80
	Control 3	313.59	203.83	423.35	54.88		Control 3	464.86	302.16	627.56	81.35
VEGF						EGF					
	Control 1	61.91	40.25	83.57	10.83		Control 1	23.32	15.16	31.48	4.08
	Control 2	209.34	136.08	282.60	36.63		Control 2	101.61	66.05	137.17	17.78
	Control 3	532.19	324.85	739.53	103.67		Control 3	525.20	281.38	769.02	121.91

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