

Art.-Nr.: KG5005
Ch.-B.: 2101 (3081EV, 3004EV, 3005EV) v2
Inhalt: 3 x 3 x 2 ml
Verw. bis: 2010-04
Darreichungsform: Lyophilised

LABELLING GUIDE

CTK Cytokine
HS High Sensitivity
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 re-constituted, the controls can be used for up to 4 hours when stored at +2 to +8°C in the original vial or up to 1 week 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 HS CONTROL 1	3 x 2 ml
CTK HS CONTROL 2	3 x 2 ml
CTK HS CONTROL 3	3 x 2 ml

MATERIALS REQUIRED BUT NOT PROVIDED

Volumetric Pipette

FOR THE EVIDENCE INVESTIGATOR ANALYSER

Evidence Investigator Cytokine High Sensitivity Array Kit (EV3623)

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 2ml 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 \pm 2 standard deviations. The assignment is then validated on three different analysers.

ABBREVIATIONS

IL	Interleukin
VEGF	Vascular Endothelial Growth Factor
TNF α	Tumour Necrosis Factor alpha
IFN γ	Interferon gamma
MCP-1	Monocyte Chemoattractant Protein-1
EGF	Epidermal Growth Factor

evidence[®] INVESTIGATOR CONTROL RANGES (KIT EV3623)

	pg/ml	Target	Range		SD		pg/ml	Target	Range		SD
IL2	Control 1	16.87	10.97	22.77	2.95	IFN γ	Control 1	17.25	11.21	23.29	3.02
	Control 2	60.26	39.16	81.36	10.55		Control 2	70.4	45.76	95.04	12.32
	Control 3	259.08	168.4	349.76	45.34		Control 3	322.88	209.88	435.88	56.5
IL4	Control 1	20.45	13.29	27.61	3.58	TNF α	Control 1	10.78	7	14.56	1.89
	Control 2	74.39	48.25	100.43	13.02		Control 2	41.08	26.7	55.46	7.19
	Control 3	353.28	229.64	476.92	61.82		Control 3	161.19	104.77	217.61	28.21
IL6	Control 1	8.6	5.58	11.62	1.51	IL-1a	Control 1	8.39	5.45	11.33	1.47
	Control 2	36.75	23.89	49.61	6.43		Control 2	32.55	21.15	43.95	5.7
	Control 3	158.16	102.8	213.52	27.68		Control 3	97.22	63.2	131.24	17.01
IL8	Control 1	16.92	11	22.84	2.96	IL-1b	Control 1	6.65	4.33	8.97	1.16
	Control 2	76.27	49.57	102.97	13.35		Control 2	22.02	14.32	29.72	3.85
	Control 3	381.61	248.05	515.17	66.78		Control 3	71.36	46.38	96.34	12.49
IL10	Control 1	11.33	7.37	15.29	1.98	MCP-1	Control 1	15.92	10.34	21.5	2.79
	Control 2	44.29	28.79	59.79	7.75		Control 2	88.08	57.26	118.9	15.41
	Control 3	195.6	127.14	264.06	34.23		Control 3	351.21	228.29	474.13	61.46
VEGF	Control 1	31.46	20.44	42.48	5.51	EGF	Control 1	15.41	10.01	20.81	2.7
	Control 2	110.54	71.86	149.22	19.34		Control 2	62.03	40.31	83.75	10.86
	Control 3	309.36	201.08	417.64	54.14		Control 3	344.92	224.2	465.64	60.36

Revised 29 Oct '08