

## Quality control of Hexanpyl-Lys (HEL) ELISA (code: KHL-700/E)

### 1) Comparison of standard curves of different production lot.

Lot #	HEL standards (absorbance at 450nm)					
	2.6 nmol/L	7.7 nmol/L	22.7 nmol/L	69.7 nmol/L	207 nmol/L	624 nmol/L
Lot. 007	1.239	1.055	0.817	0.466	0.238	0.128
Lot. 008	1.321	1.204	1.018	0.655	0.333	0.184
Lot. 009	1.385	1.225	1.033	0.692	0.356	0.177

### 2) Preparation of QC samples.

Prepare three normal human urine samples. Add HEL standard to prepare QC sample with high concentration of HEL. Please repeat freeze-thaw cycle at least three times and remove insoluble materials by centrifugation. Store the aliquots below -80 degree C. Before use, QC samples should be thawed out by incubation at 37 degree C for 1 hour or 4 degree C for over night.

### 3) Result of QC samples.

Lot #	QC samples (nmol/L)			
	S-1	S-2	S-3	S-4
Lot. 007	26.5	44.5	98.6	143.0
Lot. 008	28.3	45.3	114.6	140.7
Lot. 009	23.7	43.0	116.8	141.8

### 4) Intra-assay variation of HEL standards (N=6).

	HEL ELISA kit, lot.009 (absorbance at 450nm)					
	2.6 nmol/L	7.7 nmol/L	22.7 nmol/L	69.7 nmol/L	207 nmol/L	624 nmol/L
1	1.400	1.240	1.112	0.685	0.388	0.172
2	1.403	1.233	1.038	0.696	0.325	0.179
3	1.357	1.210	1.035	0.723	0.358	0.182
4	1.376	1.232	1.000	0.683	0.356	0.174
5	1.364	1.229	1.011	0.692	0.342	0.178
6	1.408	1.208	0.999	0.675	0.365	0.175
Mean	1.385	1.225	1.033	0.692	0.356	0.177
S.D.	0.022	0.013	0.042	0.017	0.021	0.004
C.V.	1.6%	1.1%	4.1%	2.4%	6.0%	2.1%

**5) Intra-assay variation of QC samples (N=6).**

	HEL ELISA kit, lot.009 (absorbance at 450nm)			
	S-1	S-2	S-3	S-4
1	1.058	0.874	0.504	0.511
2	1.031	0.850	0.583	0.447
3	1.019	0.841	0.497	0.489
4	0.995	0.842	0.498	0.464
5	1.002	0.818	0.505	0.448
6	0.990	0.849	0.597	0.470
Mean	1.016	0.846	0.531	0.472
S.D.	0.026	0.018	0.046	0.025
C.V.	2.5%	2.1%	8.7%	5.2%

**6) Inter-assay variation of QC samples (N=6).**

	QC samples (nmol/L)			
	S-1	S-2	S-3	S-4
Lot.006	24.0	41.3	105.5	136.1
Lot. 007	26.5	44.5	98.6	143.0
Lot. 008	28.3	45.3	114.6	140.7
Lot. 009	23.7	43.0	116.8	141.8
Mean	25.6	43.5	108.9	140.4
S.D.	2.2	1.8	8.4	3.0
C.V.	8.5%	4.1%	7.7%	2.1%

Samples were assayed in N=6 for each days.