



### PRECISION

#### **Intra-assay Precision (Precision within an assay): CV%<8%**

Three samples of known concentration were tested twenty times on one plate to assess.

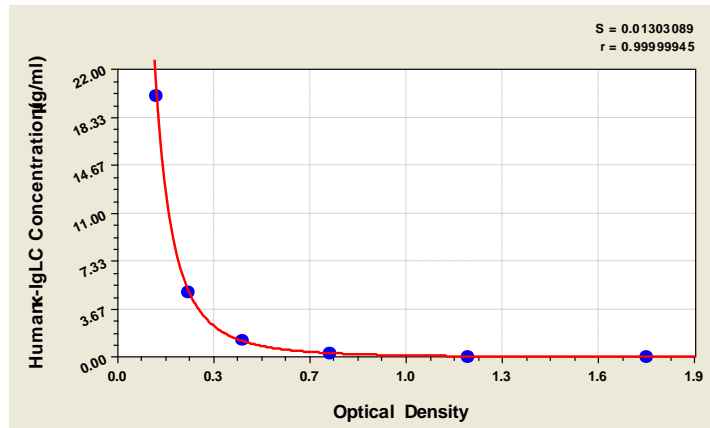
#### **Inter-assay Precision (Precision between assays): CV%<10%**

Three samples of known concentration were tested in twenty assays to assess.

| Sample      | Intra-Assay Precision |       |       | Inter-Assay Precision |       |       |
|-------------|-----------------------|-------|-------|-----------------------|-------|-------|
|             | 1                     | 2     | 3     | 1                     | 2     | 3     |
| n           | 20                    | 20    | 20    | 20                    | 20    | 20    |
| Mean(µg/ml) | 1.174                 | 1.276 | 1.239 | 1.406                 | 1.253 | 1.324 |
| SD          | 0.030                 | 0.020 | 0.027 | 0.033                 | 0.028 | 0.038 |
| CV(%)       | 6.833                 | 4.725 | 6.34  | 8.149                 | 6.574 | 9.044 |

### TYPICAL DATA

These standard curves are provided for demonstration only. A standard curve should be generated for each set of samples assayed.



| µg/ml | OD1   | OD2   | Average |
|-------|-------|-------|---------|
| 20    | 0.149 | 0.139 | 0.144   |
| 5     | 0.251 | 0.249 | 0.250   |
| 1.25  | 0.427 | 0.425 | 0.426   |
| 0.313 | 0.723 | 0.708 | 0.716   |
| 0.078 | 1.191 | 1.148 | 1.170   |
| 0     | 1.750 | 1.771 | 1.761   |

### LOD

0.046µg/ml

### LINEARITY

To assess the linearity of the assay, samples were spiked with high concentrations of human κ-IgLC in various matrices and diluted with the Sample Diluent to produce samples with values within the dynamic range of the assay.

| Sample  | Sample    | Serum(n=4) |
|---------|-----------|------------|
| 1:200   | Average % | 92         |
|         | Range %   | 84-97      |
| 1:800   | Average % | 95         |
|         | Range %   | 84-103     |
| 1:3200  | Average % | 93         |
|         | Range %   | 85-99      |
| 1:12800 | Average % | 97         |
|         | Range %   | 90-104     |