

**OC-SENSOR PLEDIA**

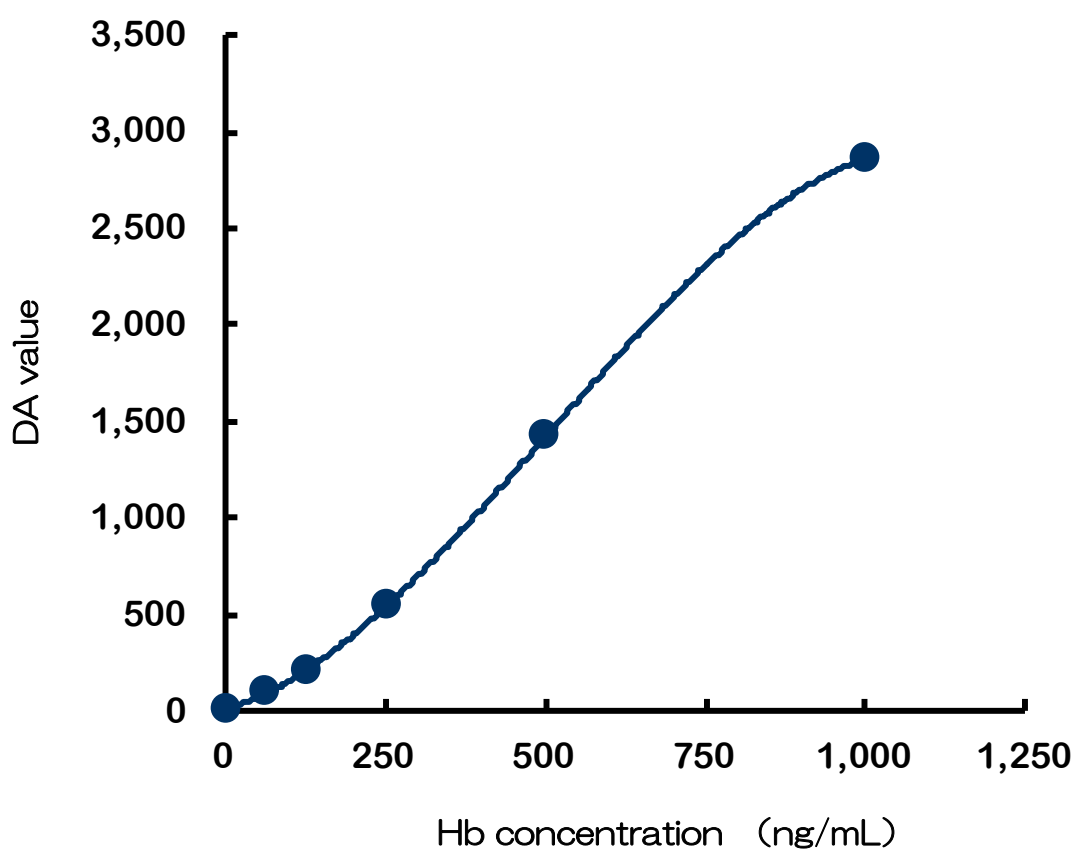
# **Analytical Performance Report**

**EIKEN CHEMICAL CO., LTD.**

**2015.2.**

## Calibration curve

|       | Theoretical Hb concentration (ng/mL) | DA value | Back Fit value (ng/mL) |        |
|-------|--------------------------------------|----------|------------------------|--------|
| Std.1 | 0                                    | 8        | 0                      |        |
| Std.2 | 62.5                                 | 94       | 63                     | 101.0% |
| Std.3 | 125                                  | 206      | 122                    | 97.4%  |
| Std.4 | 250                                  | 542      | 254                    | 101.7% |
| Std.5 | 500                                  | 1,420    | 497                    | 99.4%  |
| Std.6 | 1,000                                | 2,860    | 1,001                  | 100.1% |

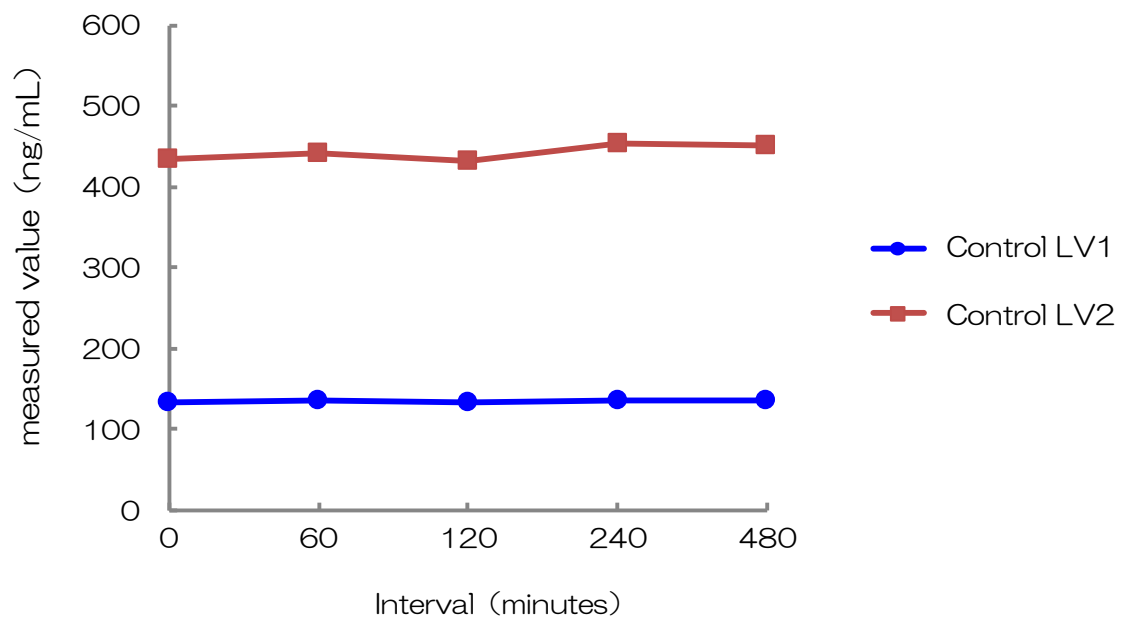


## Intra-day reproducibility

|          | (ng/mL)     |             |
|----------|-------------|-------------|
|          | Control LV1 | Control LV2 |
| 1        | 130         | 446         |
| 2        | 131         | 451         |
| 3        | 132         | 456         |
| 4        | 133         | 447         |
| 5        | 135         | 447         |
| 6        | 135         | 445         |
| 7        | 133         | 450         |
| 8        | 134         | 440         |
| 9        | 135         | 446         |
| 10       | 135         | 447         |
| 11       | 134         | 441         |
| 12       | 134         | 443         |
| 13       | 133         | 454         |
| 14       | 131         | 457         |
| 15       | 132         | 453         |
| 16       | 131         | 452         |
| 17       | 131         | 454         |
| 18       | 136         | 458         |
| 19       | 136         | 459         |
| 20       | 133         | 459         |
| Mean     | 133         | 450         |
| S.D.     | 1.82        | 5.94        |
| C.V. (%) | 1.37%       | 1.32%       |
| Range    | 6           | 19          |
| MAX.     | 136         | 459         |
| MIN.     | 130         | 440         |

## Reproducibility within a day

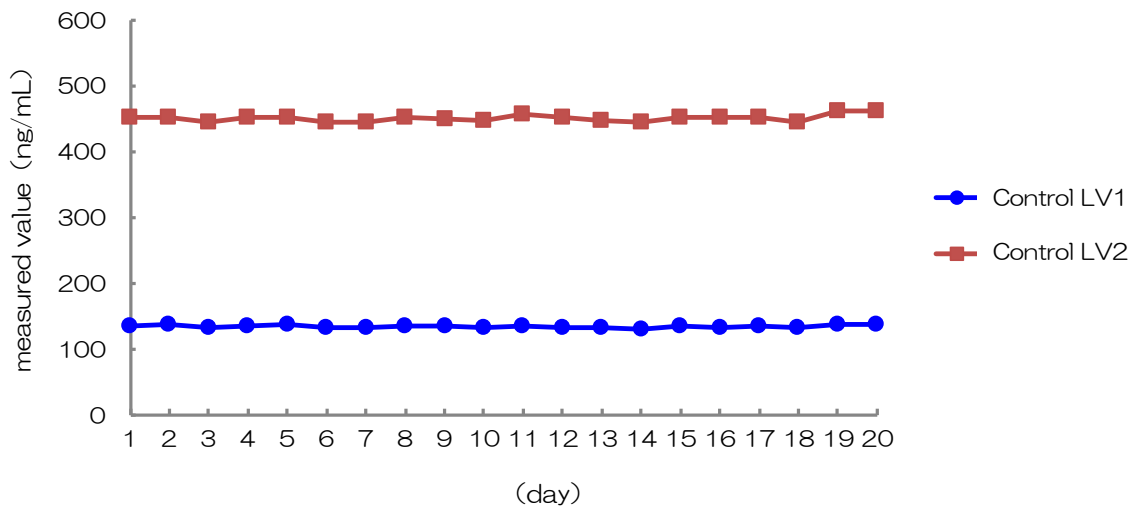
| Interval (min) | 0   | 60  | 120 | 240 | 480 |
|----------------|-----|-----|-----|-----|-----|
| Control LV1    | 133 | 136 | 134 | 136 | 135 |
| Control LV2    | 435 | 441 | 431 | 453 | 451 |



# Inter-day reproducibility

(ng/mL)

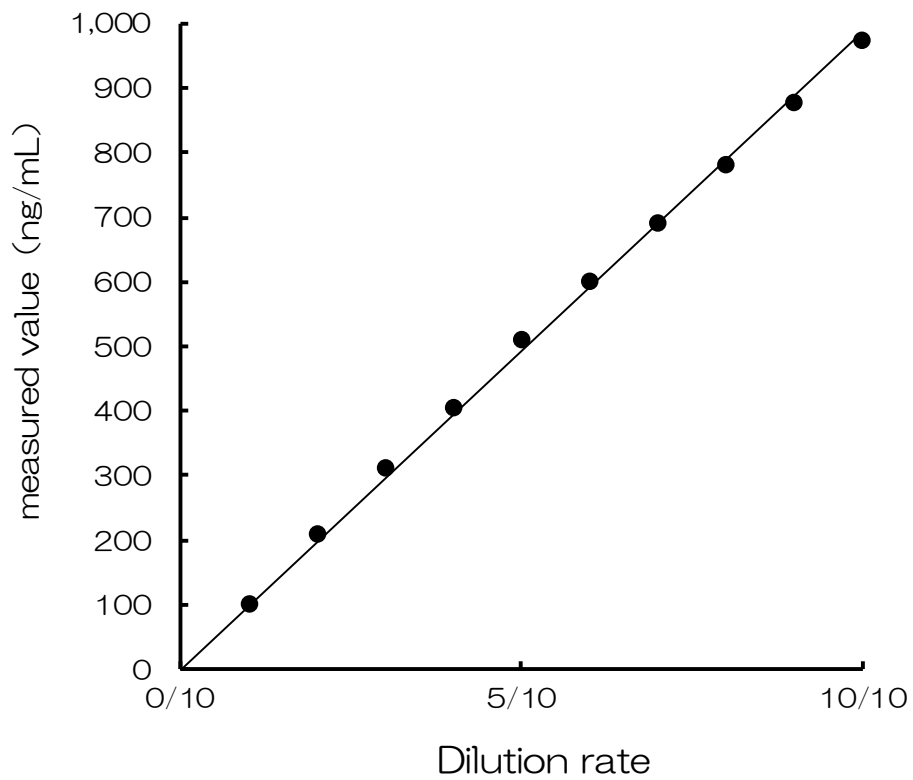
| Measurement day | 1   | 2   | 3   | 4   | 5   |
|-----------------|-----|-----|-----|-----|-----|
| Control LV1     | 135 | 137 | 133 | 135 | 137 |
| Control LV2     | 452 | 453 | 445 | 452 | 453 |
| Measurement day | 6   | 7   | 8   | 9   | 10  |
| Control LV1     | 133 | 132 | 135 | 134 | 132 |
| Control LV2     | 445 | 445 | 452 | 450 | 448 |
| Measurement day | 11  | 12  | 13  | 14  | 15  |
| Control LV1     | 136 | 134 | 134 | 132 | 135 |
| Control LV2     | 456 | 452 | 448 | 445 | 453 |
| Measurement day | 16  | 17  | 18  | 19  | 20  |
| Control LV1     | 134 | 135 | 134 | 139 | 138 |
| Control LV2     | 453 | 453 | 444 | 463 | 461 |



# Dilution linearity

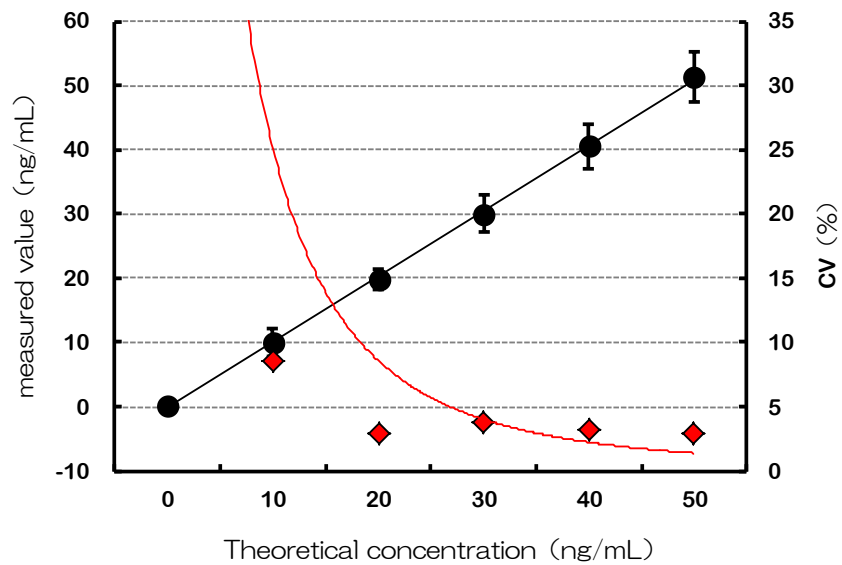
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| Dilution rate | Measured value (ng/mL) |
|---------------|------------------------|
| 1/10          | 101                    |
| 2/10          | 208                    |
| 3/10          | 313                    |
| 4/10          | 406                    |
| 5/10          | 510                    |
| 6/10          | 601                    |
| 7/10          | 690                    |
| 8/10          | 782                    |
| 9/10          | 879                    |
| 10/10         | 975                    |



# Hb detection limit - 2.6SD method

|                           |        | (ng/mL) |      |      |      |      |  |
|---------------------------|--------|---------|------|------|------|------|--|
| Theoretical concentration | 0      | 10      | 20   | 30   | 40   | 50   |  |
| Measured value            | 0      | 11      | 19   | 31   | 43   | 50   |  |
|                           | 0      | 10      | 19   | 30   | 41   | 53   |  |
|                           | 0      | 10      | 20   | 31   | 42   | 52   |  |
|                           | 0      | 10      | 20   | 31   | 40   | 52   |  |
|                           | 0      | 9       | 19   | 31   | 39   | 53   |  |
|                           | 1      | 9       | 20   | 31   | 40   | 52   |  |
|                           | 0      | 11      | 20   | 31   | 40   | 52   |  |
|                           | 0      | 10      | 20   | 31   | 38   | 51   |  |
|                           | 0      | 9       | 20   | 29   | 39   | 51   |  |
|                           | 0      | 9       | 21   | 31   | 42   | 53   |  |
|                           | 0      | 9       | 20   | 29   | 40   | 49   |  |
|                           | 0      | 11      | 20   | 29   | 40   | 52   |  |
|                           | 0      | 9       | 20   | 28   | 40   | 51   |  |
|                           | 0      | 10      | 21   | 29   | 41   | 54   |  |
|                           | 0      | 11      | 20   | 28   | 40   | 50   |  |
|                           | 0      | 11      | 20   | 30   | 42   | 49   |  |
|                           | 0      | 11      | 20   | 29   | 43   | 51   |  |
|                           | 0      | 10      | 20   | 31   | 40   | 51   |  |
|                           | 0      | 9       | 19   | 29   | 41   | 48   |  |
|                           | 0      | 11      | 19   | 31   | 40   | 52   |  |
| N                         | 20     | 20      | 20   | 20   | 20   | 20   |  |
| Mean                      | 0.1    | 10.0    | 19.9 | 30.0 | 40.6 | 51.3 |  |
| S.D.                      | 0.22   | 0.86    | 0.59 | 1.12 | 1.32 | 1.53 |  |
| C.V. (%)                  | 447.21 | 8.58    | 2.96 | 3.75 | 3.25 | 2.97 |  |

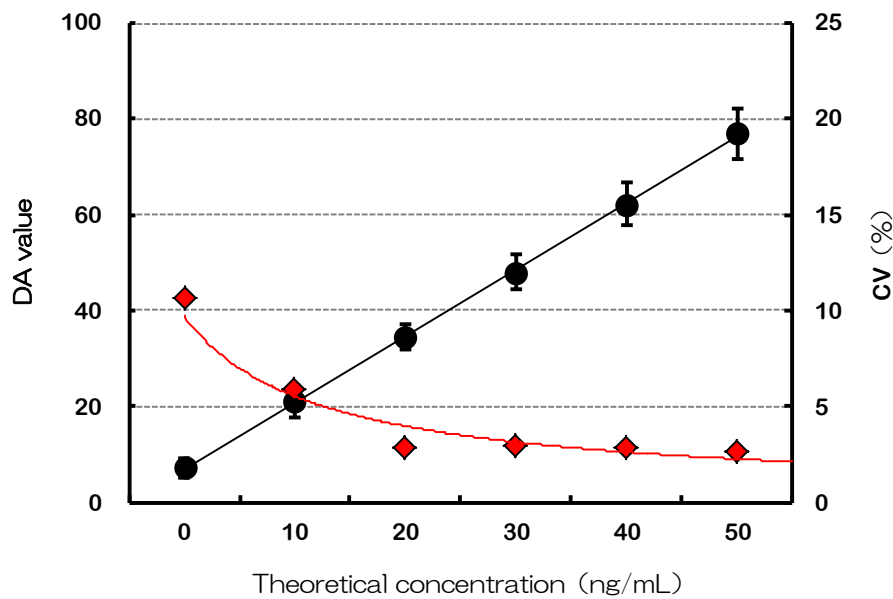


Hb detection limit : 10ng/mL

Hb acceptable limit : 10ng/mL

## Hb detection limit - 2.6SD method

| Theoretical concentration | 0     | 10   | 20   | 30   | 40   | 50   |
|---------------------------|-------|------|------|------|------|------|
| DA value                  | 7     | 22   | 33   | 49   | 66   | 75   |
|                           | 7     | 21   | 33   | 48   | 63   | 79   |
|                           | 8     | 21   | 34   | 49   | 64   | 78   |
|                           | 8     | 21   | 35   | 50   | 61   | 78   |
|                           | 8     | 20   | 33   | 50   | 60   | 79   |
|                           | 9     | 19   | 35   | 49   | 62   | 78   |
|                           | 7     | 22   | 35   | 49   | 62   | 78   |
|                           | 7     | 21   | 35   | 49   | 59   | 77   |
|                           | 7     | 19   | 35   | 47   | 60   | 76   |
|                           | 8     | 19   | 36   | 50   | 64   | 79   |
|                           | 6     | 20   | 35   | 47   | 61   | 74   |
|                           | 7     | 23   | 34   | 47   | 62   | 78   |
|                           | 7     | 20   | 35   | 45   | 61   | 77   |
|                           | 6     | 21   | 36   | 47   | 63   | 81   |
|                           | 7     | 22   | 34   | 46   | 62   | 75   |
|                           | 7     | 23   | 35   | 48   | 64   | 74   |
|                           | 8     | 22   | 35   | 47   | 65   | 76   |
|                           | 6     | 21   | 34   | 49   | 62   | 77   |
|                           | 7     | 20   | 33   | 47   | 63   | 73   |
|                           | 7     | 22   | 33   | 49   | 62   | 78   |
| N                         | 20    | 20   | 20   | 20   | 20   | 20   |
| Mean                      | 7.2   | 21.0 | 34.4 | 48.1 | 62.3 | 77.0 |
| S.D.                      | 0.77  | 1.23 | 0.99 | 1.41 | 1.75 | 2.03 |
| C.V. (%)                  | 10.66 | 5.89 | 2.89 | 2.93 | 2.81 | 2.63 |



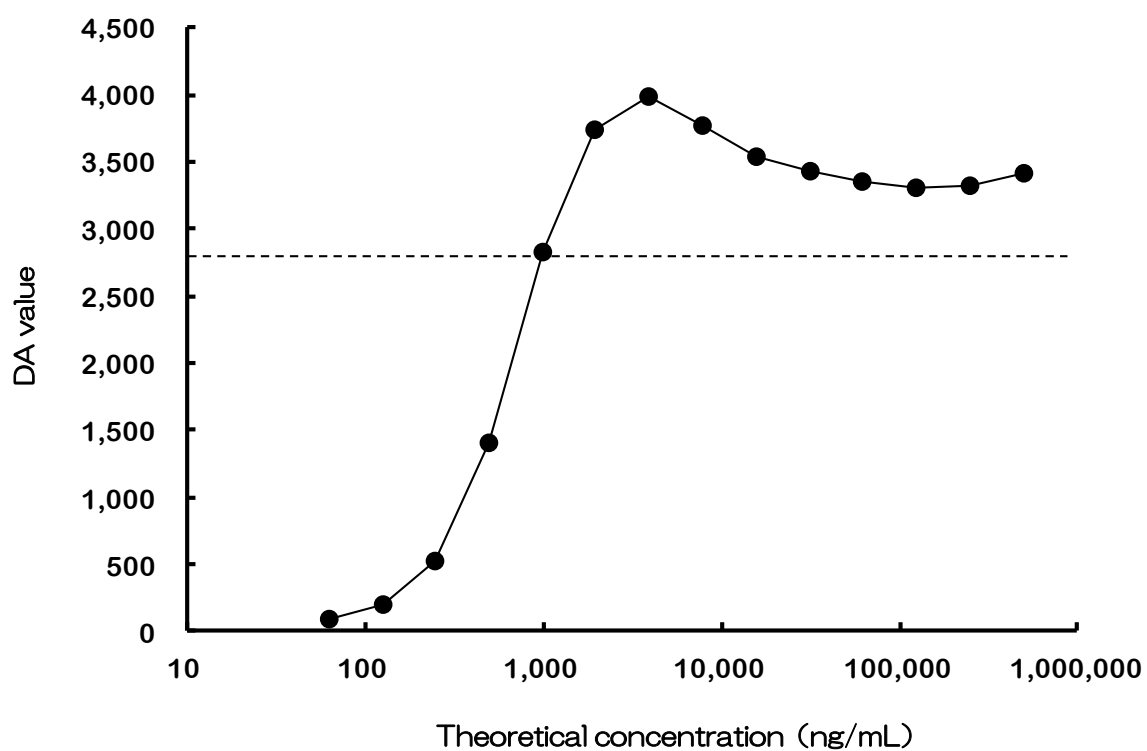
Hb detection limit : 10ng/mL

Hb acceptable limit : 10ng/mL



# Prozone phenomenon

| Theoretical concentration (ng/mL) | DA value | Measured value (ng/mL)<br>[ OR/PRC flag ] |
|-----------------------------------|----------|---|
| 0                                 | 6        | 0   |
| 62.5                              | 89       | 63  |
| 125                               | 201      | 124                                       |
| 250                               | 523      | 253                                       |
| 500                               | 1,403    | 499                                       |
| 1,000                             | 2,830    | 1,001                                     |
| 1,953                             | 3,740    | OR  |
| 3,906                             | 3,996    | OR  |
| 7,813                             | 3,777    | OR  |
| 15,625                            | 3,543    | OR  |
| 31,250                            | 3,427    | OR  |
| 62,500                            | 3,362    | OR  |
| 125,000                           | 3,310    | OR  |
| 250,000                           | 3,325    | OR  |
| 500,000                           | 3,415    | OR  |



## Recovery test

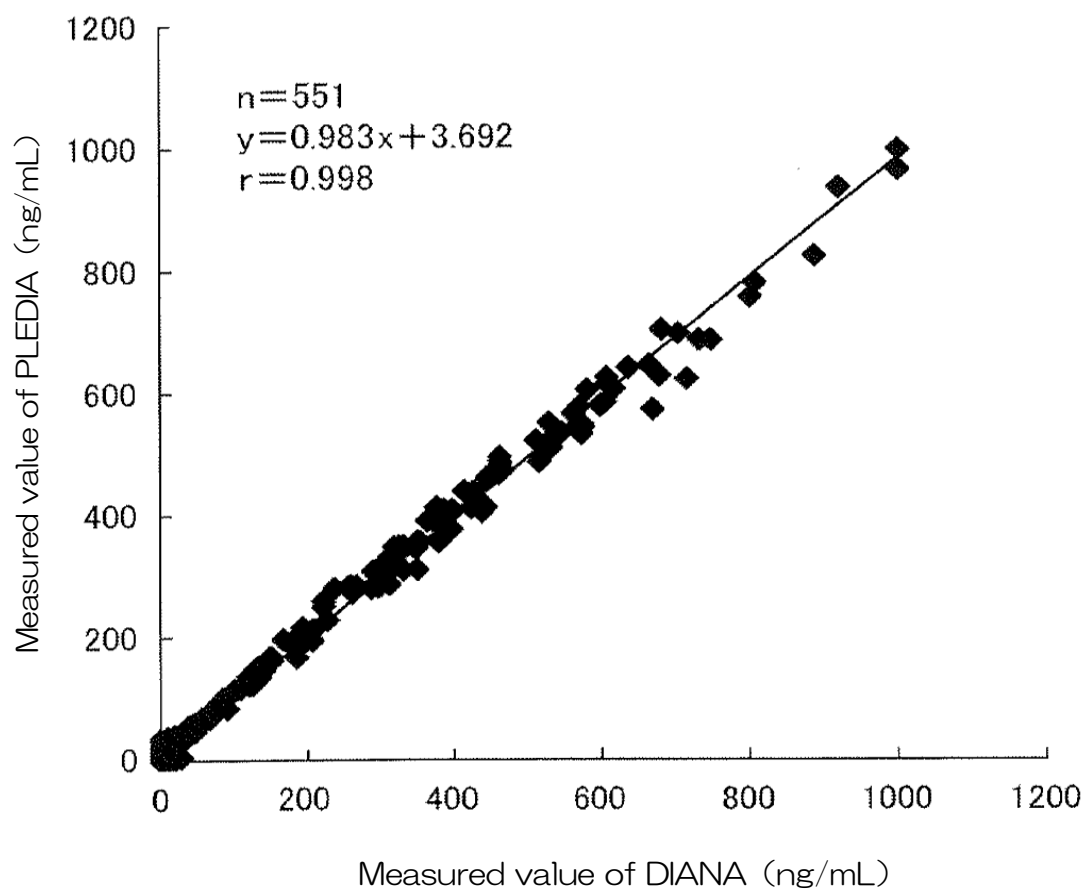
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Ratio of 9:1 (sample : added Hb)

| Sample No.             | Added sample (ng/mL) | Measured value (ng/mL) | Theoretical concentration (ng/mL) | Recovery (%) |
|------------------------|----------------------|------------------------|-----------------------------------|--------------|
| Specimen A<br>82ng/mL  | 0                    | 82                     | —                                 | —            |
|                        | 109                  | 199                    | 191                               | 104.2        |
|                        | 210                  | 298                    | 292                               | 102.1        |
|                        | 316                  | 399                    | 398                               | 100.3        |
| Specimen B<br>188ng/mL | 0                    | 188                    | —                                 | —            |
|                        | 109                  | 288                    | 297                               | 97.0         |
|                        | 210                  | 385                    | 398                               | 96.7         |
|                        | 316                  | 486                    | 504                               | 96.4         |
| Specimen C<br>274ng/mL | 0                    | 274                    | —                                 | —            |
|                        | 109                  | 372                    | 383                               | 97.1         |
|                        | 210                  | 470                    | 484                               | 97.1         |
|                        | 316                  | 562                    | 590                               | 95.3         |

## Correlative examination (External evaluation)

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TAKU KUSAKA\*, et al. : Basic Measurement Performance Evaluation of Fecal Occult Blood Analyzer OC Sensor PLEDIA.

The Journal of Clinical Laboratory Instruments and Reagents, 2014, vol.37 (5), 643-648

\* Tokai University Hospital

# Carry over

| No.       | Cell No. | Sample                                   | Measured value (ng/mL) | Carry over percentage |
|-----------|----------|--|------------------------|-----------------------|
| ①         | 1        | High concentration specimen 500,000ng/mL | OR                     |                       |
|           | 2        | Buffer                                   | 4                      | 0.0008%               |
|           | 3        | Buffer                                   | 2                      | 0.0004%               |
|           | 4        | Buffer                                   | 3                      | 0.0006%               |
|           | 5        | High concentration specimen 500,000ng/mL | OR                     |                       |
|           | 6        | Buffer                                   | 2                      | 0.0004%               |
|           | 7        | Buffer                                   | 0                      | 0.0000%               |
|           | 8        | Buffer                                   | 1                      | 0.0002%               |
|           | 9        | High concentration specimen 500,000ng/mL | OR                     |                       |
|           | 10       | Buffer                                   | 2                      | 0.0004%               |
|           | AVG      |  |                        | 0.0004%               |
| ②         | 1        | High concentration specimen 250,000ng/mL | OR                     |                       |
|           | 2        | Buffer                                   | 0                      | 0.0000%               |
|           | 3        | Buffer                                   | 0                      | 0.0000%               |
|           | 4        | Buffer                                   | 0                      | 0.0000%               |
|           | 5        | High concentration specimen 250,000ng/mL | OR                     |                       |
|           | 6        | Buffer                                   | 0                      | 0.0000%               |
|           | 7        | Buffer                                   | 1                      | 0.0004%               |
|           | 8        | Buffer                                   | 2                      | 0.0008%               |
|           | 9        | High concentration specimen 250,000ng/mL | OR                     |                       |
|           | 10       | Buffer                                   | 1                      | 0.0004%               |
|           | AVG      |  |                        | 0.0002%               |
| ③         | 1        | High concentration specimen 125,000ng/mL | OR                     |                       |
|           | 2        | Buffer                                   | 1                      | 0.0008%               |
|           | 3        | Buffer                                   | 0                      | 0.0000%               |
|           | 4        | Buffer                                   | 0                      | 0.0000%               |
|           | 5        | High concentration specimen 125,000ng/mL | OR                     |                       |
|           | 6        | Buffer                                   | 1                      | 0.0008%               |
|           | 7        | Buffer                                   | 0                      | 0.0000%               |
|           | 8        | Buffer                                   | 0                      | 0.0000%               |
|           | 9        | High concentration specimen 125,000ng/mL | OR                     |                       |
|           | 10       | Buffer                                   | 0                      | 0.0000%               |
|           | AVG      |  |                        | 0.0002%               |
| Total AVG |          |  |                        | 0.0003%               |