**Acknowledgement**

*A special thank to all investigators at the various locations for performing the study: Dr. J. Lotz, UNIVERSITÄTSMEDIZIN Mainz, D-Mainz, Dr. M. Trummler, Bio-Analytica AG, CH- Luzern, Dr. L. Esmilaire, Hôpital Henri Mondor, F- Creteil. Thanks also to the Roche colleagues for their dedicated support.*

**References**

1 Passing, H., Bablok, W. (1983). A new biometrical procedure for testing the equality of measurements from two different analytical methods. *J Clin Chem Clin Biochem; 21/11*:709-720.

2 Kunst, A., Busse Grawitz, A., Engeldinger, W., Koch, W., Luthe, H., Stockmann, W. (2005). WinCAEv – A new program supporting evaluations of reagents and analysers. *Clinica Chimica Acta; 355S (Abstr-No WP6.04)*:S361.

3 Bablok, W., Barembruch, R., Stockmann, W., Brauer, P., Graber, P., Michel, R., Vonderschmitt, D. (1991). CAEv - A program for computer aided evaluation. *J Autom Chem; 13/5*:167-179.



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# Correlation study turbidimetry versus nephelometry

## *Turbidimetry setting new standards: Consolidation without compromise*

**Lotz, J.[1], Trummler, M.[2], Esmilaire, L.[3]**
[1] UNIVERSITÄTSMEDIZIN Mainz (D)
[2] Bio-Analytica AG Luzern (CH)
[3] Henri Mondor Hospital Creteil (F)

### Introduction

The testing of "specific proteins" continues to be one of the key routines in laboratories due to their wide ranging clinical utility.

In the past, specific proteins were analyzed using a variety of specialized methods, such as radial immunodiffusion, immunoelectrophoresis or dedicated nephelometers. This incremental investment and the resulting additional costs, handling complexity and reductions in throughput were accepted due to the perceived benefits in performance of these methods.

Today, specific protein determinations are frequently carried out on consolidated, random-access clinical chemistry systems utilizing turbidimetric technology. Therewith, routine efficiencies such as reduced turnaround time for these parameters are captured.

The correlation study between turbidimetric and nephelometric technologies was completed on the Roche **cobas c** 501 module, the Siemens BN II and the Abbott Architect systems for 22 applications at three European sites (Table 1):

| Evaluator | Laboratory | Country |
|---|---|---|
| Lotz J. | Universitätsmedizin Mainz | Germany |
| Trummler M. | Bio-Analytica AG | Switzerland |
| Esmilaire L. | Henri Mondor Hospital for AAGP | France |

*Table 1: Evaluation sites*

### Key conclusions

The study clearly demonstrates the analytical performance parity between turbidimetric and nephelometric methods.

The technological advancements both in detection methods as well as in assay design over the past years have made turbidimetry a equal detection method to nephelometry. The harmonization of standardization contributes to good comparability of various methods.

In addition, the ability to perform specific protein analyses on an integrated clinical chemistry/immunoassay system can allow for consolidation of testing on a single platform, resulting in improved laboratory operations efficiency and significant cost savings. High result quality, high reliability and convenient operation improves ease of handling and makes it attractive both for routine and emergency usage.

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## Study design

The study objective is to confirm performance parity between turbidimetry and nephelometry under routine laboratory conditions. Exemplary the following analytical systems for turbidimetry and nephelometry were selected: The Roche **cobas c** platform and the Siemens BN II system. 22 assays have been evaluated (of the possible 32 specific protein determinations that can currently be performed on **cobas c** analyzers).
The obtained routine results from the Abbott Architect have also been used in order to receive further correlation measurements.
The correlation experiments were performed by analyzing on average 90 routine samples per parameter at levels corresponding to low, normal, and high physiologic concentrations. The parameters evaluated were $\alpha$1-acid glycoprotein, $\alpha$1-antitrypsin, albumin, apolipoprotein A-1 and B, antistreptolysin O, $\beta$2-microglobulin, C3c, C4, ceruloplasmin, CRP high sensitive, CRP, ferritin, haptoglobin, IgA, IgG, IgM, prealbumin, RF II, soluble transferrin receptor and transferrin (Table 2).
The assay results were compared to immunonephelometric methods on the Siemens BN II.
The comparison of the methods was performed by calculation of the Passing/Bablok regression analysis.[1]
Both the slope and intercept from the relevant medical level are presented. The study was supported by WINCAEv, a Windows® based program for computer aided evaluation[2,3], which allows the definition of protocols, the sample and test request for on-line data capture as well as statistical evaluation of the results.

### Correlation results of cobas c 501 module versus BN II

| Short Name | Long Name | Short Name | Long Name |
|---|---|---|---|
| AAGP2 | $\alpha$-Acid Glycoprotein Gen.2 | CRPHS | C-Reactive Protein (Latex) high sensitive |
| AAT2 | $\alpha$-Antitrypsin Ver.2 | CRPL3 | C-Reactive Protein Gen.3 |
| ALBS2 | Tina-quant® Albumin Gen.2 Serum | FERR3 | Tina-quant® Ferritin Gen.3 |
| ALBU2 | Tina-quant® Albumin Gen.2 Urine | HAPT2 | Tina-quant® Haptoglobin Ver.2 |
| APOAT | Tina-quant® Apolipoprotein A-1 Ver.2 | IGA-2 | Tina-quant® IGA Gen. 2 Standard application |
| APOBT | Tina-quant® Apolipoprotein B Ver.2 | IGG-2 | Tina-quant® IGG Gen. 2 Standard application |
| ASLOT | Tina-quant® Antistreptolysin O | IGM-2 | Tina-quant® IGM Gen. 2 Standard application |
| B2MG | Tina-quant® $\beta$2 Microglobulin | PREA | Prealbumin |
| C3C-2 | Tina-quant® Complement C3/C3c Ver.2 | RF-II | Rheumatoid Factors II |
| C4-2 | Tina-quant® Complement C4 Ver.2 | STFR | Tina-quant® Soluble Transferrin Receptor |
| CERU | Ceruloplasmin | TRSF2 | Tina-quant® Transferrin Ver.2 |

*Table 2: Overview about used assays and available correlation results.*

## Detailed results

In total, ~6,000 results from ~2,000 samples and 2 different methods (turbidimetry, nephelometry) were generated.
For nearly all selected assays the performed method comparisons versus Siemens BN II and Abbott Architect demonstrated an excellent correlation (> 0.975) and did not show a "method" effect. Turbidimetric and nephelometric methods compared closely in analytical performance. Methods were precise and correlated well between the involved sites and the different used systems.

However, some of these assays show discrepant results regarding slope and correlation coefficient:

### cobas c 501 module versus BN II

AAT2: For values higher than the clinical cutoff (> 2.0 g/L) a scatter can be observed for $\alpha$1-Antitrypsin (r = 0.9452).
Good agreement obtained between **cobas c** 501 module and Architect (r = 0.9861).

### cobas c 501 module versus Architect

ASLOT: Because of the different assay formats a scatter can be observed for antistreptolysin O (r = 0.9613).
Correlation and slope are good between **cobas c** 501 module and BN II.

CERU: The ceruloplasmin method comparison shows a correlation of r = 0.8713. This is presumably caused by varying assay designs regarding detection of copper bound and copper free ceruloplasmin. This is covered by different reference ranges.
Though, good comparability between **cobas c** 501 module and BN II is shown (r = 0.9850).

RF-II: Due to varying assay design the performed method comparison for rheumatoid factor resulted in a correlation of r = 0.9065. This lack of correlation is well known and described in many references.
Though, good comparability between **cobas c** 501 and BN II is shown (r = 0.9810).

## Conclusion and observation

**Dr. J. Lotz, UNIVERSITÄTSMEDIZIN Mainz, D-Mainz**

The aim of the study was to compare the determination of several specific proteins analysed by a nephelometric (BN II) and two turbidimetric (**cobas c** 501 module/Architect c8000) assays. In general, the comparison of the turbidimetric assays, as well as the turbidimetric versus nephelometric assays are excellent ($r > 0.98$), except for RF, ASL and $\alpha$1-antitrypsin ($r > 0.93$). This indicates a strong coherence between the assay results. However, some of these assays show differences in the linear regression's slope. For the turbidimetric ferritin assay (**cobas c** module) a slop $> 1.10$ was calculated for the nephelometric, as well as for the second turbidimetric assay (Architect). But this 10% deviation is not relevant for medical purposes. The ASL-titer and the haptoglobin concentrations (Architect) are significant lower than the results obtained by nephelometry or the compared turbidimetric test (**cobas c** module). Both turbidimetric assays result in lower concentrations of IgG (slope: 1.17, 1.25 resp.), but correlate excellent ($r = 0.99$ for both).
In summary, all methods and assays seem to detect the same analytes and show a very good correlation by the majority. Although, different assay principles, standardisations and variable antibodies are used, all assays are reliable for the clinical use.

**Dr. M. Trummler, Bio-Analytica AG, CH-Luzern**

The quantification of different specific proteins is a main part of the daily laboratory work load. Therefore, we were very pleased to see that for almost all measured parameters the fully automated **cobas**® 6000 analyzer series provided very reliable results compared with the other analyzers. There were a few discrepant results when comparing "difficult" analytes like rheumatoid factor, but nevertheless they are satisfactory for clinical purposes.

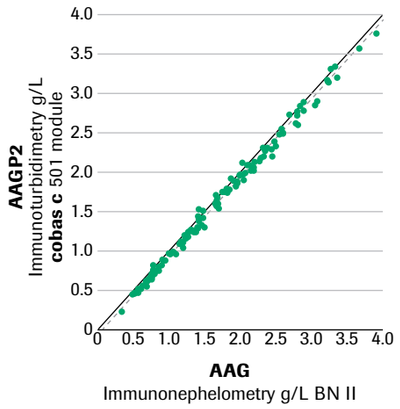
**Dr. L. Esmilaire, Henri Mondor Hospital, F-Creteil, for AAGP**

The correlation was carried out in 2 sets of 2 series, one on the **cobas**® 6000 analyzer series and the other on the BN II analyzer. The samples were thawed and centrifuged. The calibrations and controls were completed before the dosages.
The correlation is highly correct; $r = 0.9974$
Slope of the regression line = 1.000

**Correlation results of cobas c 501 module versus BN II**

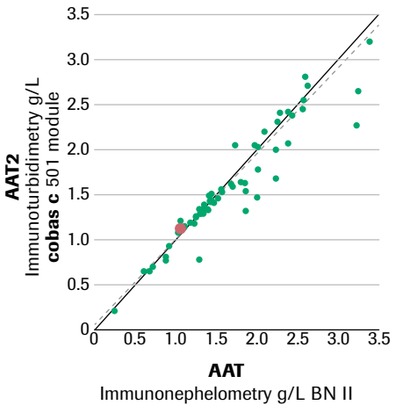
| Short Name | Unit | n | Min X | Max X | Passing / Bablok | | | Pearson's | Kendall's |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | Intercept | Slope | md(95) | r | Tau |
| AAGP2 | g/L | 126 | 0.34 | 3.91 | -0.070 | 1.000 | 0.085 | 0.9974 | 0.9641 |
| AAT2 | g/L | 62 | 0.25 | 3.38 | 0.043 | 0.956 | 0.358 | 0.9452 | 0.8773 |
| ALBS2 | g/L | 111 | 8.90 | 49.60 | 2.431 | 0.912 | 2.5397 | 0.9862 | 0.9027 |
| ALBU2 | mg/L | 74 | 11.70 | 348.00 | -1.778 | 0.999 | 21.213 | 0.9910 | 0.9018 |
| APOAT | g/L | 104 | 0.26 | 2.69 | -0.163 | 1.122 | 0.110 | 0.9899 | 0.9276 |
| APOBT | g/L | 105 | 0.28 | 2.48 | 0.020 | 0.917 | 0.085 | 0.9903 | 0.9307 |
| ASLOT | U/mL | 57 | 68.80 | 1190.00 | 4.609 | 0.943 | 101.266 | 0.9828 | 0.9009 |
| B2MG | mg/L | 111 | 1.09 | 33.19 | 0.027 | 0.884 | 0.935 | 0.9916 | 0.9150 |
| C3C-2 | g/L | 65 | 0.60 | 2.27 | 0.011 | 1.023 | 0.120 | 0.9772 | 0.8926 |
| C4-2 | g/L | 57 | 0.07 | 0.71 | -0.013 | 1.125 | 0.033 | 0.9945 | 0.9403 |
| CERU | g/L | 42 | 0.16 | 0.60 | -0.019 | 0.915 | 0.021 | 0.9850 | 0.8879 |
| CRPHS | mg/L | 111 | 0.16 | 44.84 | 0.116 | 1.060 | 1.065 | 0.9931 | 0.9472 |
| CRPL3 | mg/L | 111 | 0.22 | 417.19 | -0.460 | 1.027 | 27.094 | 0.9982 | 0.9849 |
| FERR3 | µg/L | 93 | 3.96 | 510.20 | 4.864 | 1.205 | 34.121 | 0.9929 | 0.9343 |
| HAPT2 | g/L | 83 | 0.39 | 6.83 | 0.019 | 1.020 | 0.278 | 0.9821 | 0.9278 |
| IGA-2 | g/L | 98 | 0.45 | 7.20 | -0.013 | 1.008 | 0.377 | 0.9887 | 0.9262 |
| IGG-2 | g/L | 94 | 3.89 | 53.30 | -2.138 | 1.167 | 2.682 | 0.9899 | 0.9494 |
| IGM-2 | g/L | 98 | 0.19 | 8.15 | -0.016 | 1.070 | 0.365 | 0.9916 | 0.9115 |
| PREA | g/L | 85 | 0.04 | 0.38 | -0.004 | 0.938 | 0.017 | 0.9888 | 0.9302 |
| RF-II | IU/mL | 77 | 10.31 | 599.98 | 6.996 | 0.903 | 50.615 | 0.9810 | 0.7472 |
| STFR | mg/L | 102 | 2.30 | 37.59 | -1.131 | 1.083 | 1.670 | 0.9960 | 0.9111 |
| TRSF2 | g/L | 111 | 0.29 | 4.39 | 0.033 | 1.093 | 0.163 | 0.9889 | 0.9203 |

*X = BN II, Y =* ***cobas c*** *501 module*




*P/B Regression*
*Y = 1.0 **
*X - 0.07*
*md(95) = 0.085*
*N = 126 r = 0.9974*
*t = 0.9641*

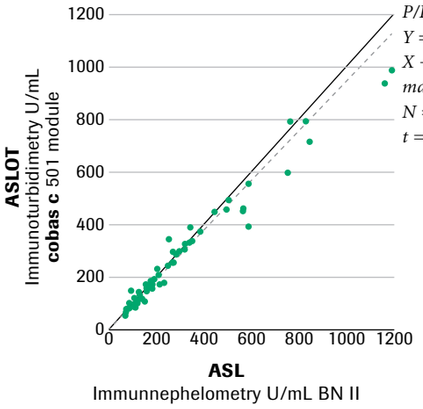
*Excellent slope and correlation is demonstrated (r = 0.9974, Y = 1.0).*




*P/B Regression*
*Y = 0.956 **
*X + 0.043*
*md(95) = 0.358*
*N = 62 r = 0.9452*
*t = 0.8773*

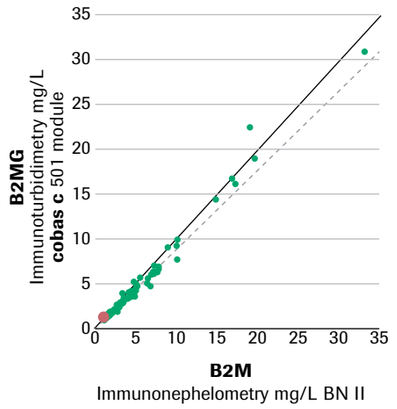
- *Reference standard claim: 1.12 g/L*
  *Obtained values:*
  *BN II: 1.05 g/L*
  ***cobas c** 501 module: 1.12 g/L*

*The reference standard claim of 1.12 g/L was exactly recovered by **cobas c** 501 module.*




*P/B Regression*
*Y = 0.943 **
*X + 4.609*
*md(95) = 101.266*
*N = 57 r = 0.9828*
*t = 0.9009*

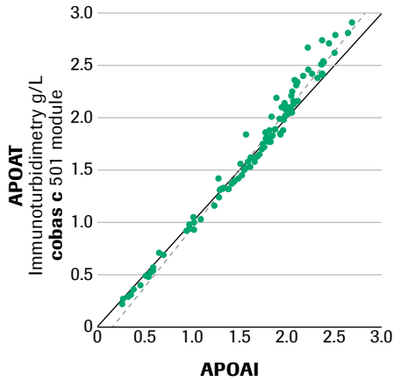
*Correlation and slope are good. However, due to different assay formats a scatter at high concentrations can be observed.*




*P/B Regression*
*Y = 0.884 **
*X + 0.027*
*md(95) = 0.935*
*N = 111 r = 0.9916*
*t = 0.9150*

- *Reference standard claim: 1.4 U/L*
  *Obtained values:*
  *BN II: 1.11 U/L*
  ***cobas c** 501 module: 1.25 U/L*

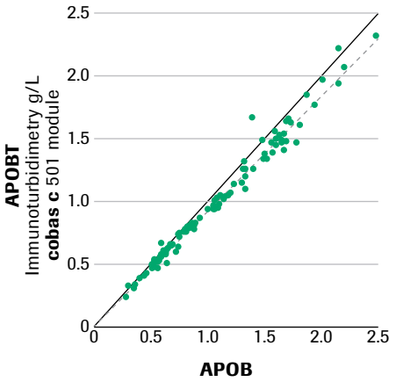
*Good correlation; lack of traceability due to old reference material. New reference material based on ERM-DA470k planned.*
*Excellent comparability between **cobas c** 501 module and Architect is shown (r = 0.9972).*
*To low recovery of reference material on BN II.*




*P/B Regression*
*Y = 0.912 **
*X + 2.431*
*md(95) = 2.54*
*N = 111 r = 0.9862*
*t = 0.9027*

- *Reference standard claim: 37.2 g/L*
  *BN II: 36.4 g/L*
  ***cobas c** 501 module: 36.9 g/L*

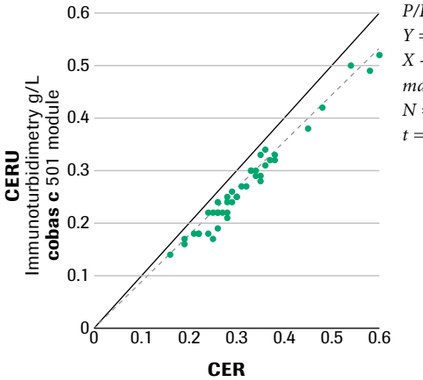
*Good comparability and recovery of reference standard ERM-DA470.*




*P/B Regression*
*Y = 0.999 **
*X - 1.778*
*md(95) = 21.213*
*N = 74 r = 0.9910*
*t = 0.9018*

- *Reference standard claim: 3720 mg/L*
  *BN II: 3499 mg/L*
  ***cobas c** 501 module: 3581 mg/L*

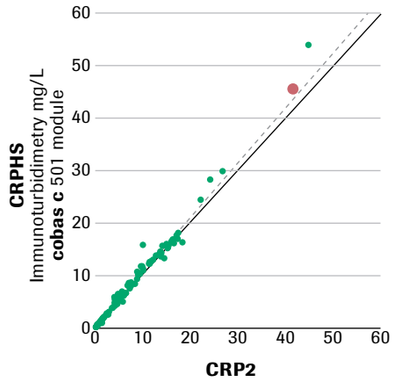
*Excellent comparability of methods at clinical cut-off (20 mg/L) is demonstrated (r = 0.9910).*




*P/B Regression*
*Y = 1.023 **
*X + 0.011*
*md(95) = 0.12*
*N = 65 r = 0.9772*
*t = 0.8926*

- *Reference standard claim: 1.00 g/L*
  *Obtained values:*
  *BN II: 1.07 g/L*
  ***cobas c** 501 module: 1.01 g/L*

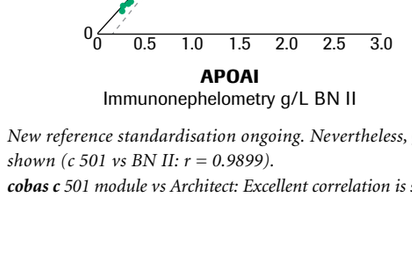
*Good agreement obtained between **cobas c** 501 module and BN II.*
***cobas c** 501 module has well recovered the reference standard.*




*P/B Regression*
*Y = 1.125 **
*X - 0.013*
*md(95) = 0.033*
*N = 57 r = 0.9945*
*t = 0.9403*

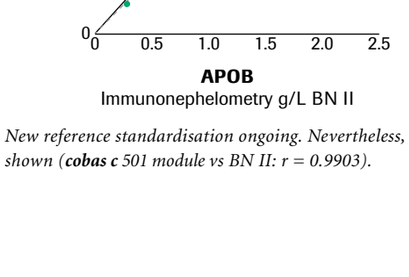
- *Reference standard claim: 0.162 g/L*
  *Obtained values:*
  *BN-II: 0.158 g/L*
  ***cobas c** 501 module: 0.157 g/L*

*The methode comparison vs BN II shows a deviation at the higher measuring range (>clinical cut off). Though a good correlation of methods is demonstrated (r = 0.9945).*
***cobas c** 501 module vs Architect: Excellent correlation and slope is shown. (r = 0.9973, Y = 1.0).*



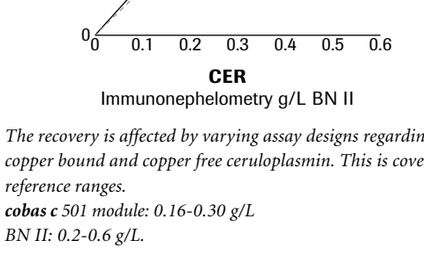

*P/B Regression*
*Y = 1.122 **
*X - 0.163*
*md(95) = 0.11*
*N = 104 r = 0.9899*
*t = 0.9276*

*New reference standardisation ongoing. Nevertheless, good correlation is shown (c 501 vs BN II: r = 0.9899).*
***cobas c** 501 module vs Architect: Excellent correlation is shown (r = 0.9954).*



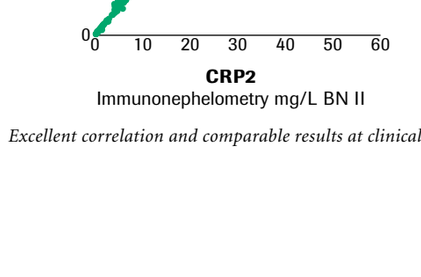

*P/B Regression*
*Y = 0.917 **
*X + 0.02*
*md(95) = 0.085*
*N = 105 r = 0.9903*
*t = 0.9307*

*New reference standardisation ongoing. Nevertheless, good correlation is shown (**cobas c** 501 module vs BN II: r = 0.9903).*




*P/B Regression*
*Y = 0.915 **
*X - 0.019*
*md(95) = 0.021*
*N = 42 r = 0.9850*
*t = 0.8879*

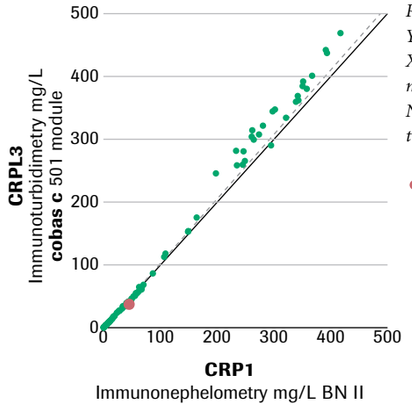
*The recovery is affected by varying assay designs regarding detection of copper bound and copper free ceruloplasmin. This is covered by different reference ranges.*
***cobas c** 501 module: 0.16-0.30 g/L*
*BN II: 0.2-0.6 g/L.*




*P/B Regression*
*Y = 1.06 **
*X + 0.116*
*md(95) = 1.064*
*N = 111 r = 0.9931*
*t = 0.9472*

- *Reference standard claim: 41.8 mg/L*
  *Obtained values:*
  *BN II: 41.6 mg/L*
  ***cobas c** 501 module: 45.5 mg/L*

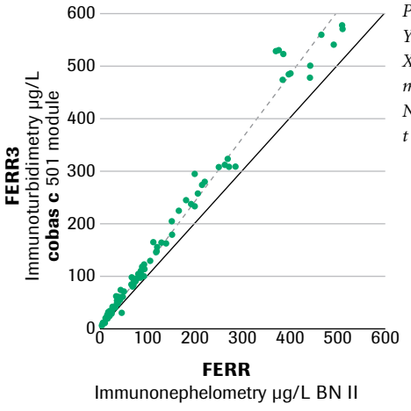
*Excellent correlation and comparable results at clinical cut-off.*




*P/B Regression*
*Y = 1.027 **
*X - 0.46*
*md(95) = 27.094*
*N = 111 r = 0.9982*
*t = 0.9849*

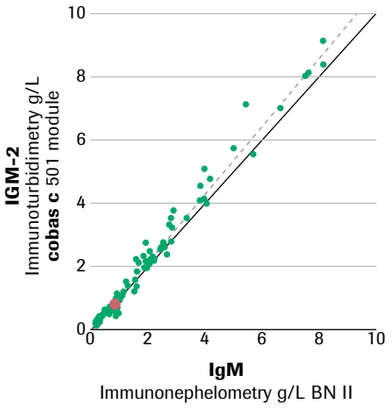
- *Reference standard claim: 41.8 mg/L*
  *Obtained values:*
  *BN-II: 40.6 mg/L*
  ***cobas c** 501 module: 34.3 mg/L*

*Shift can be observed due to higher dilution (1:400) on BN II with samples > test range (200 mg/L).*




*P/B Regression*
*Y = 1.205 **
*X + 4.864*
*md(95) = 34.121*
*N = 93 r = 0.9929*
*t = 0.9343*

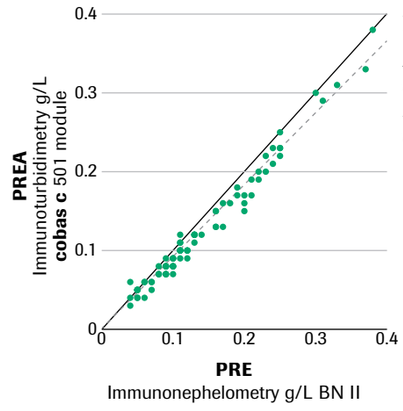
*The **cobas c** 501 module assay is traceable to the WHO international standard for ferritin.*




*P/B Regression*
*Y = 1.07 **
*X - 0.016*
*md(95) = 0.365*
*N = 98 r = 0.9916*
*t = 0.9115*

- *Reference standard claim: 0.72 g/L*
  *Obtained values:*
  *BN-II: 0.73 g/L*
  ***cobas c** 501 module: 0.75 g/L*

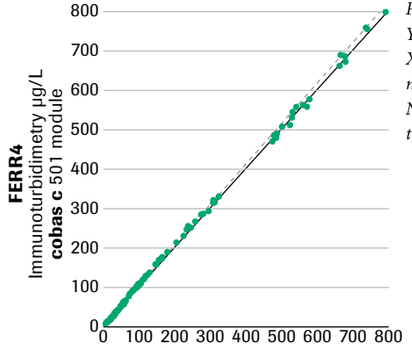
***cobas c** 501 module vs BN II: good correlation of methods is demonstrated (r = 0.9916).*
***cobas c** 501 module vs Architect: Excellent correlation is shown (r = 0.9953).*




*P/B Regression*
*Y = 0.938 **
*X - 0.004*
*md(95) = 0.017*
*N = 85 r = 0.9888*
*t = 0.9302*

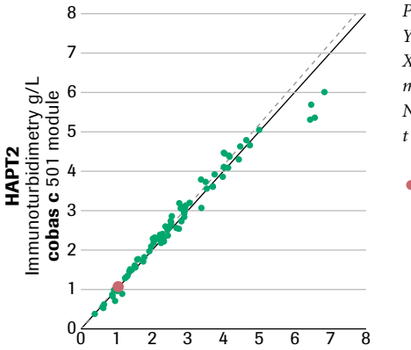
- *Reference standard claim: 0.22 g/L*
  *Obtained values:*
  ***cobas c** 501 module: 0.20 g/L*

*All results for slope, intercept and correlation coefficient fulfilled the specifications. Good recovery of reference standard ERM-DA470k on **cobas c** 501 module.*




*P/B Regression*
*Y = 1.024 **
*X + 1.757*
*md(95) = 12.061*
*N = 100 r = 0.9996*
*t = 0.9840*

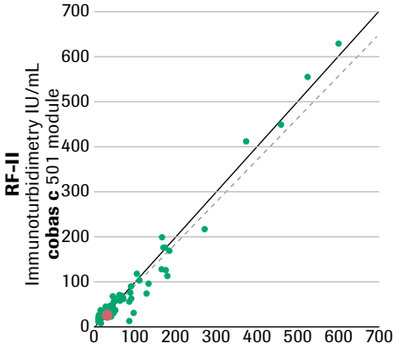
*Excellent slope and agreement of Roche Ferritin Gen.3 versus Roche Ferritin Gen. 4.*




*P/B Regression*
*Y = 1.02 **
*X + 0.019*
*md(95) = 0.278*
*N = 83 r = 0.9821*
*t = 0.9278*

- *Reference standard claim: 0.889 g/L*
  *Obtained values:*
  *BN-II: 0.93 g/L*
  ***cobas c** 501 module: 0.99 g/L*

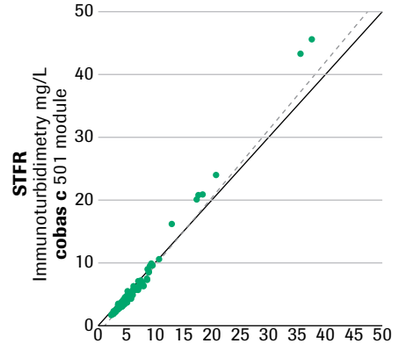
*Excellent slope (Y = 1.02) and good comparability of methods is demonstrated (r = 0.9821).*




*P/B Regression*
*Y = 0.903 **
*X + 6.996*
*md(95) = 50.615*
*N = 77 r = 0.9810*
*t = 0.7472*

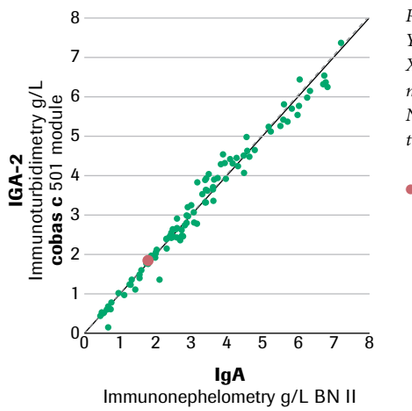
- *Reference standard claim: 25 IU/mL*
  *Obtained values:*
  *BN II: 32.7 IU/mL*
  ***cobas c** 501 module: 29.5 IU/mL*

*Despite that the lack of correlation is well known and described in many references the comparability is acceptable considering the varying assay design and the unavailability of global reference claim.*




*P/B Regression*
*Y = 1.083 **
*X - 1.131*
*md(95) = 1.67*
*N = 102 r = 0.9960*
*t = 0.9111*

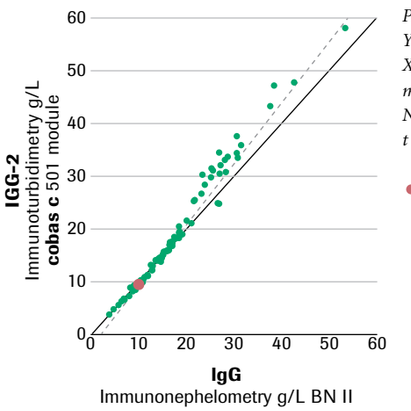
*No global reference standard available currently therefore different expected value ranges are valid.*
***cobas c** 501 module: 1.9-5.0 mg/L*
*BN II: 0.76-1.76 mg/L.*
*Results are calculated with a factor of 2.841 in order to compare both assays. This leads to a slope, intercept and correlation coefficient within specification.*




*P/B Regression*
*Y = 1.008 **
*X - 0.013*
*md(95) = 0.377*
*N = 98 r = 0.9887*
*t = 0.9262*

- *Reference standard claim: 1.80 g/L*
  *BN II: 1.74 g/L*
  ***cobas c** 501 module: 1.77 g/L*

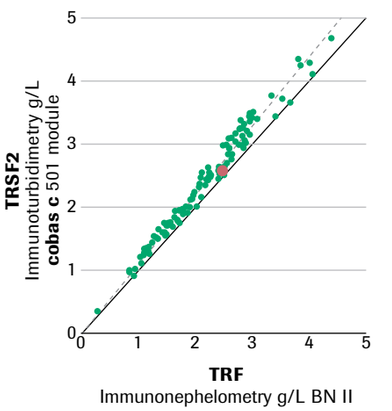
*Excellent slope, good correlation and good recovery of reference standard ERM-DA470.*




*P/B Regression*
*Y = 1.167 **
*X - 2.138*
*md(95) = 2.682*
*N = 94 r = 0.9899*
*t = 0.9494*

- *Reference standard claim: 9.17 g/L*
  *Obtained values:*
  *BN-II: 9.40 g/L*
  ***cobas c** 501 module: 8.47 g/L*

*Good comparability at clinical cut-off.*




*P/B Regression*
*Y = 1.093 **
*X + 0.033*
*md(95) = 0.163*
*N = 111 r = 0.9889*
*t = 0.9203*

- *Reference standard claim: 2.36 g/L*
  *Obtained values:*
  *BN-II: 2.41 g/L*
  ***cobas c** 501 module: 2.45 g/L*

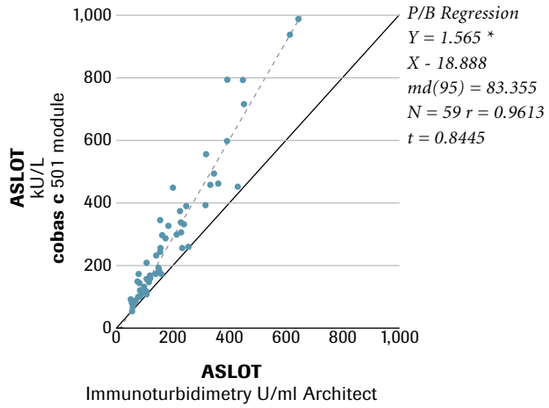
***cobas c** 501 module vs BN II: good comparability of methods is demonstrated (r = 0.9889). Scatter can be observed, presumably an issue caused by thawing of samples on BN II as mentioned in the Siemens Package Insert.*
***cobas c** 501 module vs Architect: excellent correlation (r = 0.9964) and slope (Y = 0.982) is demonstrated.*

## Correlation results of cobas c 501 module versus Architect

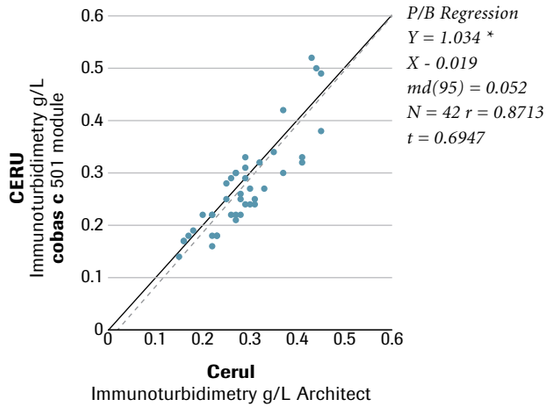
| Short Name | Unit | n | Min X | Max X | Passing / Bablok | | | Pearson's | Kendall's |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | Intercept | Slope | md(95) | r | Tau |
| AAT2 | g/L | 62 | 0.31 | 2.99 | -0.162 | 1.075 | 0.112 | 0.9861 | 0.9003 |
| ALBS2 | g/L | 111 | 9.00 | 47.00 | 0.878 | 0.994 | 2.828 | 0.9845 | 0.9130 |
| APOAT | g/L | 104 | 0.30 | 2.92 | -0.074 | 1.024 | 0.110 | 0.9954 | 0.9398 |
| APOBT | g/L | 105 | 0.27 | 2.89 | 0.028 | 0.891 | 0.093 | 0.9929 | 0.9436 |
| ASLOT | U/mL | 59 | 51.00 | 643.00 | -18.888 | 1.565 | 83.355 | 0.9613 | 0.8445 |
| B2MG | mg/L | 110 | 1.20 | 31.20 | -0.207 | 0.983 | 0.650 | 0.9972 | 0.9578 |
| C3C-2 | g/L | 65 | 0.47 | 2.10 | 0.098 | 1.047 | 0.093 | 0.9815 | 0.9168 |
| C4-2 | g/L | 65 | 0.03 | 0.75 | 0.000 | 1.000 | 0.028 | 0.9973 | 0.9738 |
| CERU | g/L | 42 | 0.15 | 0.45 | -0.019 | 1.034 | 0.052 | 0.8713 | 0.6947 |
| CRPHS | mg/L | 97 | 1.10 | 49.00 | -0.248 | 0.969 | 2.412 | 0.9908 | 0.9323 |
| CRPL3 | mg/L | 111 | 1.10 | 437.00 | -1.122 | 1.007 | 21.331 | 0.9987 | 0.9738 |
| FERR3 | µg/L | 100 | 5.90 | 757.00 | 6.448 | 1.143 | 70.596 | 0.9855 | 0.9363 |
| HAPT2 | g/L | 85 | 0.16 | 4.84 | -0.139 | 1.231 | 0.254 | 0.9923 | 0.9486 |
| IGG-2 | g/L | 94 | 3.76 | 64.47 | -0.421 | 0.930 | 1.643 | 0.9961 | 0.9708 |
| IGM-2 | g/L | 106 | 0.05 | 8.97 | -0.015 | 1.028 | 0.303 | 0.9953 | 0.9729 |
| RF-II | IU/mL | 86 | 20 | 865 | -9.208 | 1.022 | 112.245 | 0.9065 | 0.6852 |
| TRSF2 | g/L | 111 | 0.39 | 4.68 | 0.084 | 0.982 | 0.100 | 0.9964 | 0.9486 |

*X = Architect, Y = **cobas c** 501 module*

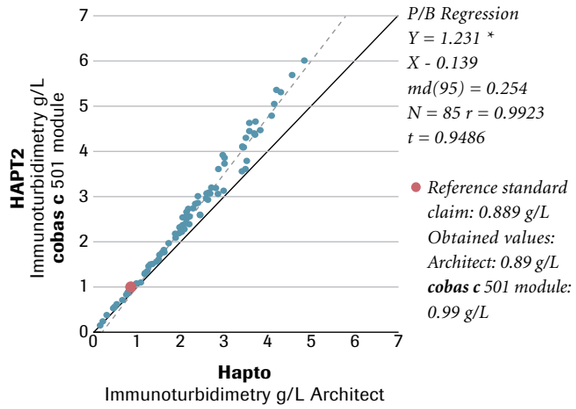
For nearly all selected assays the performed method comparisons versus Abbott Architect demonstrated an excellent correlation (> 0.975). However, some of these assays show discrepant results regarding slope and correlation coefficient. Even though an excellent comparability between **cobas c** 501 module and BN II is shown.



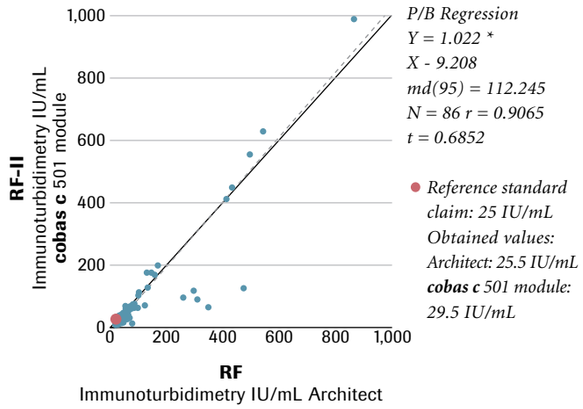

*Because of the different assay formats a scatter can be observed for antistreptolysin O (r = 0.9613).*
*Correlation and slope are good between **cobas c** 501 and BN II.*




*The ceruloplasmin method comparison shows a correlation of r = 0.8713. This is presumably caused by varying assay designs regarding detection of copper bound and copper free ceruloplasmin. This is covered by different reference ranges.*
*Though, good comparability between **cobas c** 501 module and BN II is shown (r = 0.9850).*




*Good comparability at clinical cut-off.*
***cobas c** 501 module vs BN II: Excellent slope and good comparability of methods is demonstrated (r = 0.9821).*




*Due to varying assay designs the performed method comparison for rheumatoid factor resulted in a correlation of r = 0.9065. This lack of correlation is well known and described in many references.*
*Though, good comparability between **cobas c** 501 module and BN II is shown (r = 0.9810).*