Validierungsbericht Aripiprazol

| Abteilung |  |  |
| --- | --- | --- |
|  | Spez. Klinische Chemie ZLM |  |
| Durchführung | FV BMA Amanda Ferlez |  |
|  | L-BMA Anina Kühne |  |
| Fachliche Leitung | Dr. Siegfried Stranders, FAMH |  |

| Analytik |  |  |
| --- | --- | --- |
| Material | Serum | Alternativ |
| Messgrösse | Aripiprazol | Synonym |
| Einheit | [ µmol/l ] |  |

| Bisher Methode x |  |  |
| --- | --- | --- |
| Labor | USZ TDM Klinische Chemie |  |
| Methode | LC-MS/MS quantitativ |  |
| Messinstrument | Sciex TQ System 4500 |  |
| Lieferant | Chromsystems |  |

| Neue Methode y |  |  |
| --- | --- | --- |
| Labor | ZLM Spez. Klinische Chemie |  |
| Methode | LC-MS/MS quantitativ |  |
| Messinstrument | Sciex TQ System 4500 |  |
| Lieferant | Chromsystems |  |
| Kit | Chromsystems |  |
| Messbereich | 0.1 - 3 µmol/l |  |
| Referenz Interval | 0.33 - 1.12 µmol/l |  |

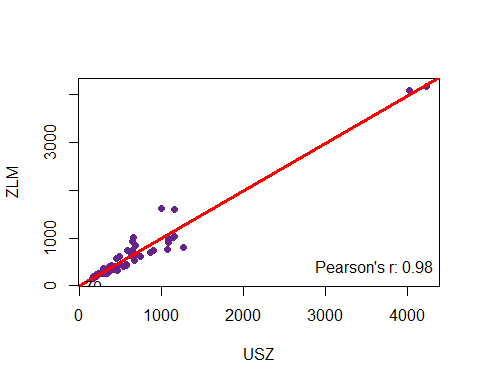
| Akzeptanzkriterien |  |  |
| --- | --- | --- |
| Anzahl Doppelmessungen | ≥ 20 |  |
| VK intra-Assay | < 10 % |  |
| VK inter-Assay | < 10 % |  |
| Korrelation r | ≥ 0.95 |  |
| PaBa Regression | Steigung m 1.0 ± 0.15 |  |

| QM-Dokumente |  |  |
| --- | --- | --- |
| Projekt | CL 4.4.004 | Einführung eines LC-MS/MS Systems |
| Mutation | CL 4.4.002 | Aripiprazol und Metabolit |

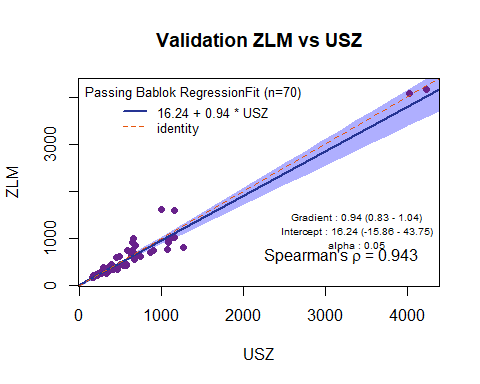
### Messdaten

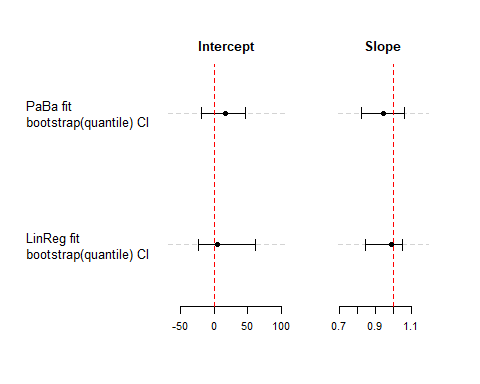
| # | USZ | ZLM | delta.% |
| --- | --- | --- | --- |
| 1 | 658.4 | 706.0 | 4.0 |
| 2 | 253.6 | 265.1 | 1.0 |
| 3 | 411.1 | 379.7 | -2.6 |
| 4 | 413.1 | 346.5 | -5.6 |
| 5 | 407.3 | 374.0 | -2.8 |
| 6 | 4032.5 | 4092.8 | 5.0 |
| 7 | 368.0 | 356.3 | -1.0 |
| 8 | 173.8 | 190.9 | 1.4 |
| 9 | 437.0 | 384.9 | -4.4 |
| 10 | 320.7 | 286.3 | -2.9 |
| 11 | 347.2 | 360.4 | 1.1 |
| 12 | 368.6 | 395.4 | 2.2 |
| 13 | 294.8 | 373.2 | 6.5 |
| 14 | 203.2 | 231.7 | 2.4 |
| 15 | 569.5 | 454.8 | -9.6 |
| 16 | 337.5 | 307.9 | -2.5 |
| 17 | 165.2 | 163.3 | -0.2 |
| 18 | 662.5 | 635.4 | -2.3 |
| 19 | 406.9 | 403.7 | -0.3 |
| 20 | 1147.9 | 1009.9 | -11.5 |
| 21 | 344.0 | 268.9 | -6.3 |
| 22 | 651.3 | 1006.4 | 29.6 |
| 23 | 1158.4 | 1588.9 | 35.9 |
| 24 | 482.3 | 612.5 | 10.9 |
| 25 | 681.4 | 842.5 | 13.4 |
| 26 | 1264.4 | 806.3 | -38.2 |
| 27 | 211.3 | 215.8 | 0.4 |
| 28 | 366.9 | 382.7 | 1.3 |
| 29 | 1151.3 | 1029.8 | -10.1 |
| 30 | 385.8 | 354.7 | -2.6 |
| 31 | 261.9 | 250.6 | -0.9 |
| 32 | 736.8 | 612.7 | -10.4 |
| 33 | 894.6 | 752.4 | -11.9 |
| 34 | 387.6 | 438.3 | 4.2 |
| 35 | 565.1 | 431.3 | -11.2 |
| 36 | 644.5 | 737.4 | 7.8 |
| 37 | 233.0 | 259.0 | 2.2 |
| 38 | 401.7 | 354.5 | -3.9 |
| 39 | 458.0 | 332.3 | -10.5 |
| 40 | 366.6 | 397.5 | 2.6 |
| 41 | 4233.7 | 4173.4 | -5.0 |
| 42 | 333.4 | 366.1 | 2.7 |
| 43 | 170.5 | 177.1 | 0.5 |
| 44 | 405.0 | 374.6 | -2.5 |
| 45 | 289.8 | 265.1 | -2.1 |
| 46 | 345.6 | 333.8 | -1.0 |
| 47 | 361.3 | 377.0 | 1.3 |
| 48 | 287.0 | 361.5 | 6.2 |
| 49 | 171.9 | 208.6 | 3.1 |
| 50 | 502.2 | 454.8 | -4.0 |
| 51 | 324.9 | 303.5 | -1.8 |
| 52 | 149.6 | 158.6 | 0.7 |
| 53 | 628.4 | 637.6 | 0.8 |
| 54 | 377.6 | 390.1 | 1.0 |
| 55 | 1087.8 | 918.4 | -14.1 |
| 56 | 330.2 | 252.2 | -6.5 |
| 57 | 645.2 | 923.2 | 23.2 |
| 58 | 999.2 | 1625.5 | 52.3 |
| 59 | 453.5 | 584.2 | 10.9 |
| 60 | 587.9 | 745.2 | 13.1 |
| 61 | 1076.1 | 760.5 | -26.3 |
| 62 | 199.1 | 207.4 | 0.7 |
| 63 | 329.2 | 336.4 | 0.6 |
| 64 | 1078.2 | 975.9 | -8.5 |
| 65 | 361.7 | 312.5 | -4.1 |
| 66 | 205.7 | 225.6 | 1.7 |
| 67 | 664.6 | 542.0 | -10.2 |
| 68 | 859.8 | 699.7 | -13.4 |
| 69 | 361.0 | 390.2 | 2.4 |
| 70 | 537.9 | 414.3 | -10.3 |

### Korrelation

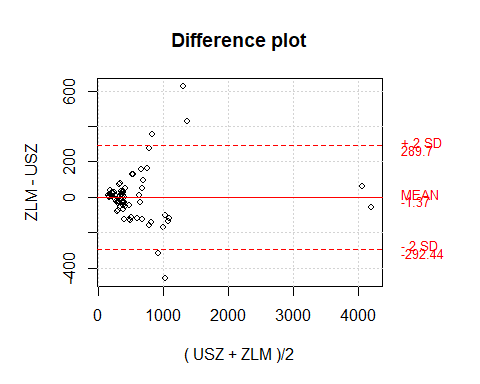


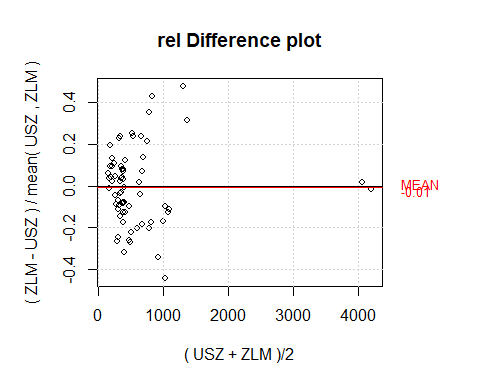
### Passing Bablok

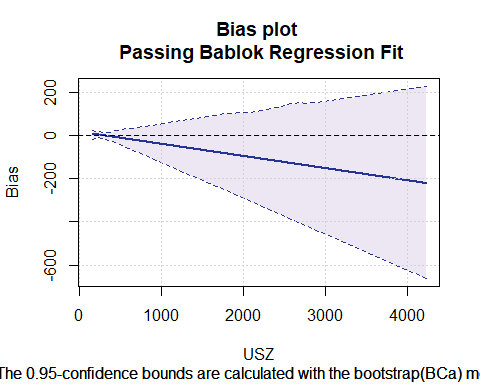


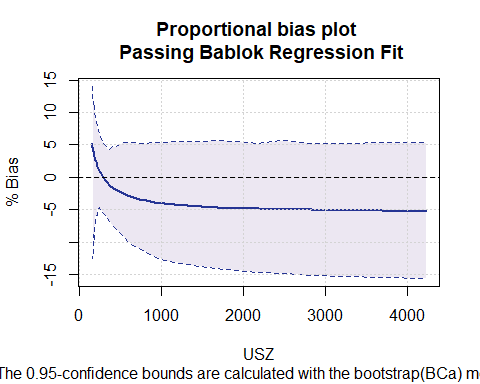


### Bland-Altman









### Schlussfolgerung und Freigabe

Bitte gib hier Deine Beurteilung der vorliegenden Verifikation/Validation ein:  
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|  
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**Zentrum für Labormedizin St. Gallen, Montag 13. März 2023**

#### Data is processed using R language1 and mcr package2. Rmarkdown3 is used for converting results into Word, PDF and HTML files. This project was inspired by Daniel Holmes (UBC, CA)4 and Burak Bahar (Washington, USA)5.

#### References and packages:

1. R: A language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria. Version: 4.2.2 URL: <https://www.R-project.org>
2. mcr: Method Comparison Regression. Version: 1.3.2 URL: <http://CRAN.R-project.org/package=mcr>
3. rmarkdown: Dynamic Documents for R. Version: 2.20 URL: <http://rmarkdown.rstudio.com>
4. The Lab-R-torian: URL: <https://labrtorian.com/>
5. An interactive website for analytical method comparison and bias estimation: URL: <https://bahar.shinyapps.io/method_compare/>