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 |  |

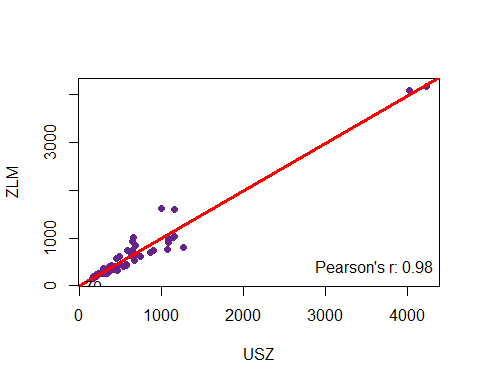
| QM-Dokumente |  |  |
| --- | --- | --- |
| Projekt | CL 4.4.004 | Einführung eines LC-MS/MS Systems |
| Mutation | CL 4.4.002 | Aripiprazol und Metabolit |

### Messdaten

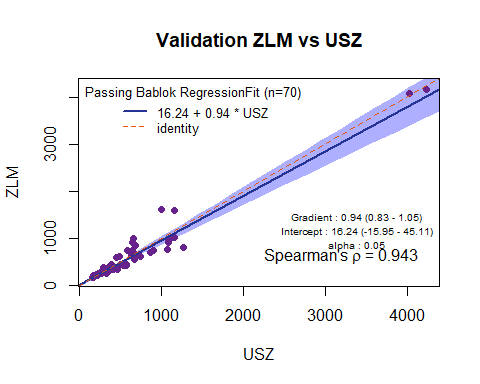
S: Sample Number;—x: USZ ;—y: ZLM

|  | X | Y |
| --- | --- | --- |
| S1 | 658.36 | 706.03 |
| S2 | 253.57 | 265.07 |
| S3 | 411.10 | 379.68 |
| S4 | 413.09 | 346.54 |
| S5 | 407.27 | 373.99 |
| S6 | 4032.53 | 4092.78 |
| S7 | 367.95 | 356.28 |
| S8 | 173.79 | 190.91 |
| S9 | 437.03 | 384.91 |
| S10 | 320.74 | 286.31 |
| S11 | 347.22 | 360.37 |
| S12 | 368.56 | 395.43 |
| S13 | 294.78 | 373.23 |
| S14 | 203.24 | 231.72 |
| S15 | 569.51 | 454.81 |
| S16 | 337.54 | 307.85 |
| S17 | 165.17 | 163.28 |
| S18 | 662.47 | 635.41 |
| S19 | 406.94 | 403.68 |
| S20 | 1147.94 | 1009.91 |
| S21 | 343.95 | 268.88 |
| S22 | 651.30 | 1006.38 |
| S23 | 1158.40 | 1588.88 |
| S24 | 482.28 | 612.50 |
| S25 | 681.42 | 842.48 |
| S26 | 1264.45 | 806.27 |
| S27 | 211.29 | 215.80 |
| S28 | 366.94 | 382.68 |
| S29 | 1151.27 | 1029.75 |
| S30 | 385.84 | 354.69 |
| S31 | 261.85 | 250.62 |
| S32 | 736.78 | 612.71 |
| S33 | 894.62 | 752.42 |
| S34 | 387.61 | 438.28 |
| S35 | 565.15 | 431.32 |
| S36 | 644.48 | 737.41 |
| S37 | 233.00 | 259.02 |
| S38 | 401.67 | 354.54 |
| S39 | 458.02 | 332.28 |
| S40 | 366.64 | 397.48 |
| S41 | 4233.67 | 4173.42 |
| S42 | 333.40 | 366.15 |
| S43 | 170.50 | 177.08 |
| S44 | 405.04 | 374.59 |
| S45 | 289.75 | 265.08 |
| S46 | 345.62 | 333.76 |
| S47 | 361.26 | 377.00 |
| S48 | 286.98 | 361.53 |
| S49 | 171.86 | 208.55 |
| S50 | 502.17 | 454.81 |
| S51 | 324.90 | 303.46 |
| S52 | 149.60 | 158.56 |
| S53 | 628.38 | 637.58 |
| S54 | 377.56 | 390.08 |
| S55 | 1087.81 | 918.35 |
| S56 | 330.21 | 252.20 |
| S57 | 645.22 | 923.19 |
| S58 | 999.20 | 1625.54 |
| S59 | 453.46 | 584.19 |
| S60 | 587.88 | 745.22 |
| S61 | 1076.09 | 760.45 |
| S62 | 199.05 | 207.42 |
| S63 | 329.16 | 336.36 |
| S64 | 1078.25 | 975.91 |
| S65 | 361.72 | 312.49 |
| S66 | 205.68 | 225.56 |
| S67 | 664.58 | 542.03 |
| S68 | 859.78 | 699.69 |
| S69 | 360.97 | 390.22 |
| S70 | 537.87 | 414.34 |

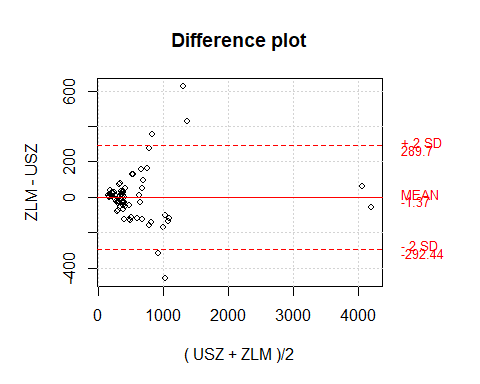
### Korrelation

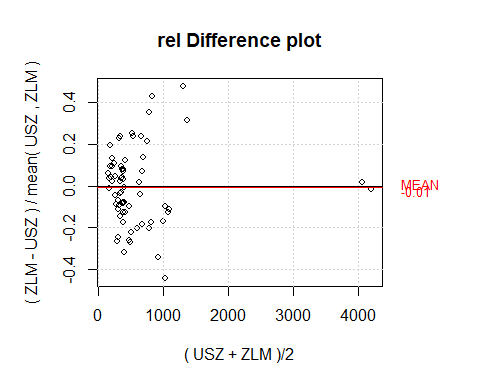


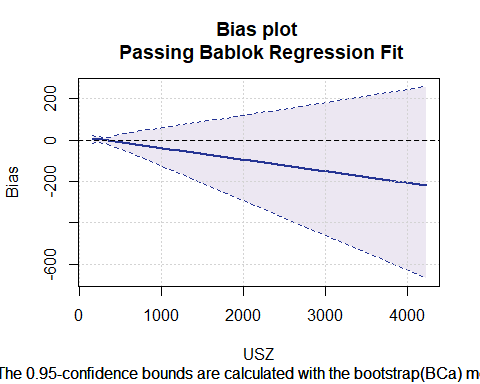
### Passing Bablok

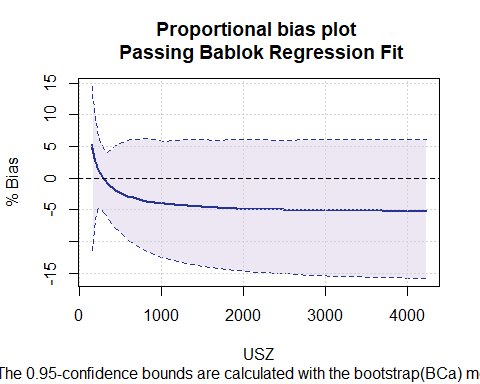


### Bland-Altman









### Schlussfolgerung und Freigabe

Bitte gib hier Deine Beurteilung der vorliegenden Verifikation/Validation ein:  
|  
|  
|  
|  
|  
—

**Zentrum für Labormedizin St. Gallen, Mittwoch 08. 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/>