

# Monitoring of the analytical performance of four different blood glucose monitoring systems: a post-market performance follow-up study

## Authors

Julia K. Mader<sup>1</sup>, MD; Annette Baumstark<sup>2</sup>, PhD; Johannes Tüting<sup>3</sup>, MD; Günter Sokol<sup>4</sup>, MD; Ruth Schuebel<sup>5</sup>, PhD; Yuhong Tong<sup>6</sup>, MD; Julia Roetschke<sup>5</sup>, PhD; Robbert Slingerland<sup>7</sup>, PhD

## Affiliations

<sup>1</sup>Division of Endocrinology and Diabetology, Medical University of Graz, Graz, Austria; <sup>2</sup>Institut für Diabetes-Technologie Forschungs- und Entwicklungsgesellschaft mbH an der Universität Ulm, Ulm, Germany; <sup>3</sup>Tüting Diabetologische Schwerpunktpraxis, Cloppenburg, Germany; <sup>4</sup>Diabetes Sokol Clinic, Vienna, Austria; <sup>5</sup>Roche Diabetes Care GmbH, ONEMedical, Mannheim, Germany; <sup>6</sup>Roche Diabetes Care, Roche Diagnostics (Shanghai) Ltd, Shanghai, China; <sup>7</sup>Department of Clinical Chemistry, Isala Hospital, Zwolle, The Netherlands

## Running title

Accuracy of four different blood glucose monitoring systems in a non-standardized setting

## Corresponding author

Dr Julia Roetschke, Roche Diabetes Care GmbH ONEMedical, Sandhofer Strasse 116, 68305 Mannheim, Germany

E-mail: [julia.roetschke@roche.com](mailto:julia.roetschke@roche.com)

## **Supplementary Tables**

**Supplementary Table S1. Assessment of evaluable data for BGM1, according to study period and site number**

| <b>Study period and site number</b> | <b>Strip lots</b> | <b>Number of participants</b> | <b>Number of participants removed due to reference drift</b> | <b>Number of participants with missing data</b> |
|-------------------------------------|-------------------|-------------------------------|--------------------------------------------------------------|-------------------------------------------------|
| <i>Fall 2020</i>                    |                   |                               |                                                              |                                                 |
| 01                                  | 1, 2, 3, 4        | 50                            | 10                                                           | 0                                               |
| 02                                  | 1, 2, 3, 4        | 50                            | 16                                                           | 1                                               |
| 03                                  | 1, 2, 3, 4        | 50                            | 3                                                            | 0                                               |
| 05                                  | 1, 2, 3, 4        | 50                            | 1                                                            | 0                                               |
| <i>Fall 2021</i>                    |                   |                               |                                                              |                                                 |
| 01                                  | 5, 6, 7, 8        | 50                            | 1                                                            | 0                                               |
| 05                                  | 5, 6, 7, 8        | 50                            | 1                                                            | 4                                               |
| 06                                  | 5, 6, 7, 8        | 50                            | 0                                                            | 0                                               |
| 07                                  | 5, 6, 7, 8        | 50                            | 0                                                            | 9                                               |
| <i>Fall 2022</i>                    |                   |                               |                                                              |                                                 |
| 04                                  | 9, 10, 11, 12     | 50                            | 2                                                            | 0                                               |
| 05                                  | 9, 10, 11, 12     | 50                            | 3                                                            | 2                                               |
| 06                                  | 9, 10, 11, 12     | 100                           | 1                                                            | 0                                               |
| 07                                  | 9, 10, 11, 12     | 50                            | 2                                                            | 0                                               |

*BGM1* Accu-Chek Guide [blood glucose meter]

Supplementary Table S2. Assessment of evaluable data for BGM2, according to study period and site number

| Study period and site number | Strip lots    | Number of participants | Number of participants removed due to reference drift | Number of participants with missing data |
|------------------------------|---------------|------------------------|-------------------------------------------------------|------------------------------------------|
| <i>Fall 2020</i>             |               |                        |                                                       |                                          |
| 01                           | 2, 4          | 50                     | 16                                                    | 0                                        |
| 02 <sup>a</sup>              | 1, 3          | 50                     | 17                                                    | 2                                        |
| 03                           | 2, 4          | 50                     | 3                                                     | 0                                        |
| 05                           | 3, 4          | 50                     | 6                                                     | 0                                        |
| <i>Fall 2021</i>             |               |                        |                                                       |                                          |
| 01 <sup>b</sup>              | 5, 6, 7, 8    | 50                     | 8                                                     | 0                                        |
| 05                           | 5, 6, 7, 8    | 50                     | 11                                                    | 4                                        |
| 06                           | 5, 6, 7, 8    | 50                     | 0                                                     | 0                                        |
| 07                           | 5, 6, 7, 8    | 50                     | 1                                                     | 9                                        |
| <i>Fall 2022</i>             |               |                        |                                                       |                                          |
| 04                           | 9, 10, 11, 12 | 50                     | 3                                                     | 0                                        |
| 05                           | 9, 10, 11, 12 | 50                     | 1                                                     | 2                                        |
| 06                           | 9, 10, 11, 12 | 100                    | 1                                                     | 0                                        |
| 07                           | 9, 10, 11, 12 | 50                     | 1                                                     | 0                                        |

BGM2 Accu-Chek GuideMe [blood glucose meter]

<sup>a</sup> Number of participants with missing data varied for different strip lots (lot 1, n=2; lot 3, n=1)

<sup>b</sup> Number of participants varied for different strip lots (lot 5, n=51; lot 6, n=51; lot 7, n=50; lot 8, n=48)

Supplementary Table S3. Assessment of evaluable data for BGM3, according to study period and site number

| Study period and site number | Strip lots | Number of participants | Number of participants removed due to reference drift | Number of participants with missing data |
|------------------------------|------------|------------------------|-------------------------------------------------------|------------------------------------------|
| <i>Fall 2021</i>             |            |                        |                                                       |                                          |
| 02                           | 1, 2, 3, 4 | 50                     | 1                                                     | 0                                        |
| 03                           | 1, 2, 3, 4 | 50                     | 0                                                     | 0                                        |
| 04                           | 1, 2, 3, 4 | 50                     | 2                                                     | 0                                        |
| 06                           | 1, 2, 3, 4 | 50                     | 1                                                     | 0                                        |
| <i>Fall 2022</i>             |            |                        |                                                       |                                          |
| 01 <sup>a</sup>              | 5, 6, 7, 8 | 100                    | 10                                                    | 0                                        |
| 02                           | 5, 6, 7, 8 | 50                     | 1                                                     | 0                                        |
| 04 <sup>b</sup>              | 5, 6, 7, 8 | 50                     | 1                                                     | 0                                        |
| 06                           | 5, 6, 7, 8 | 50                     | 6                                                     | 0                                        |

*BGM3* Accu-Chek Instant [blood glucose meter]

<sup>a</sup> Number of participants varied for different strip lots (lot 5, n=101; lot 6, n=99; lot 7, n=98; lot 8, n=102)

<sup>b</sup> Number of participants varied for different strip lots (lot 5, n=50; lot 6, n=51; lot 7, n=49; lot 8, n=50)

Supplementary Table S4. Assessment of evaluable data for BGM4, according to study period and site number

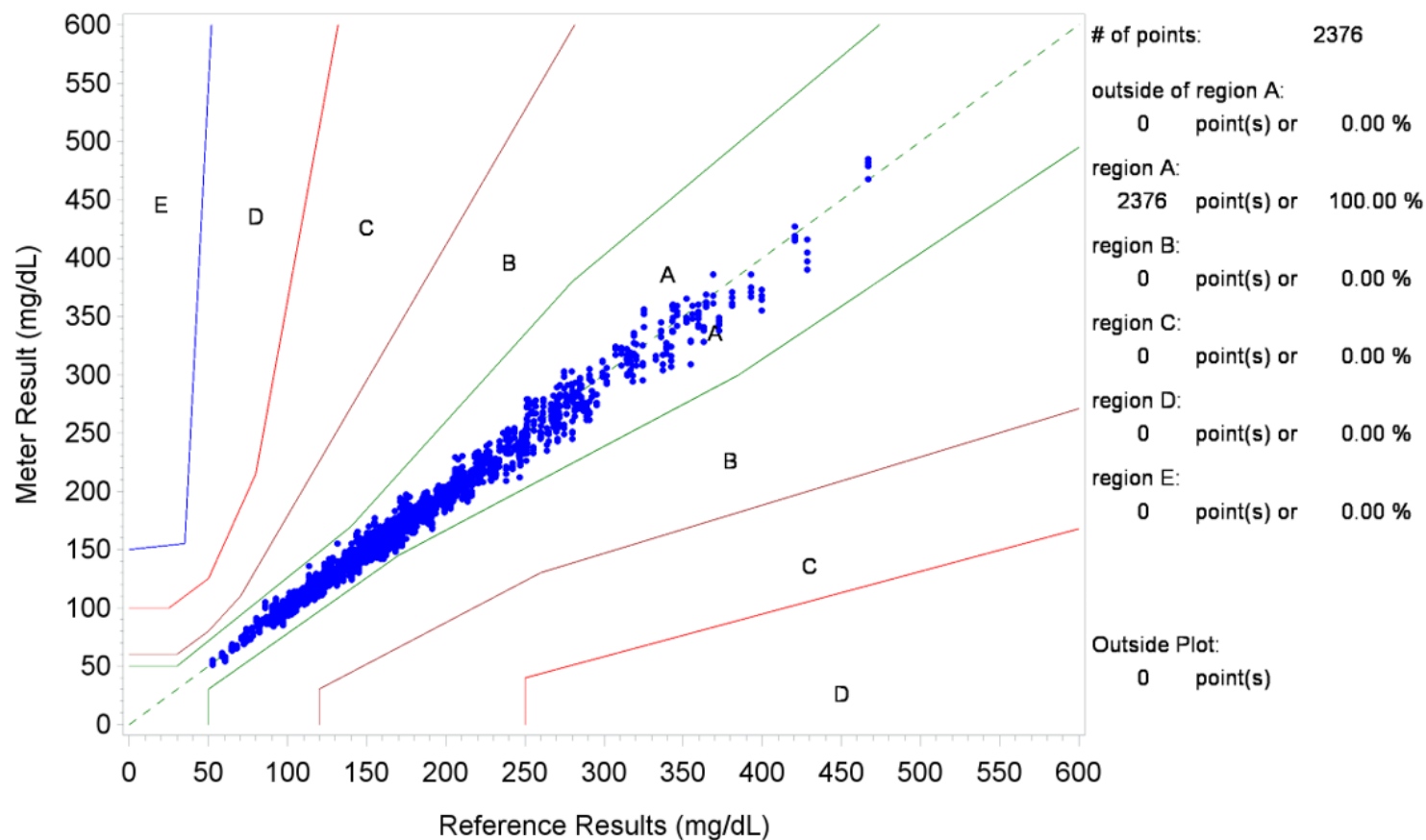
| Study period and site number | Strip lots  | Number of participants | Number of participants removed due to reference drift | Number of participants with missing data |
|------------------------------|-------------|------------------------|-------------------------------------------------------|------------------------------------------|
| <i>Fall 2020</i>             |             |                        |                                                       |                                          |
| 01                           | 1, 2        | 52                     | 10                                                    | 1                                        |
| 02                           | 1, 2        | 50                     | 25                                                    | 1                                        |
| 03                           | 1, 2        | 50                     | 2                                                     | 0                                        |
| 04                           | 1, 2        | 50                     | 5                                                     | 1                                        |
| <i>Fall 2021</i>             |             |                        |                                                       |                                          |
| 02                           | 3, 4, 5, 6  | 50                     | 1                                                     | 0                                        |
| 05                           | 3, 4, 5, 6  | 50                     | 0                                                     | 3                                        |
| 06                           | 3, 4, 5, 6  | 50                     | 1                                                     | 0                                        |
| 07                           | 3, 4, 5, 6  | 50                     | 0                                                     | 5                                        |
| <i>Fall 2022</i>             |             |                        |                                                       |                                          |
| 02                           | 7, 8, 9, 10 | 50                     | 2                                                     | 0                                        |
| 05                           | 7, 8, 9, 10 | 50                     | 2                                                     | 0                                        |
| 06 <sup>a</sup>              | 7, 8, 9, 10 | 50                     | 2                                                     | 0                                        |
| 08                           | 7, 8, 9, 10 | 50                     | 7                                                     | 6                                        |

BGM4 Accu-Chek Instant S [blood glucose meter]

<sup>a</sup> Number of participants varied for different strip lots (lot 7, n=49; lot 8, n=51; lot 9, n=50; lot 10, n=50)

## Supplementary Figures

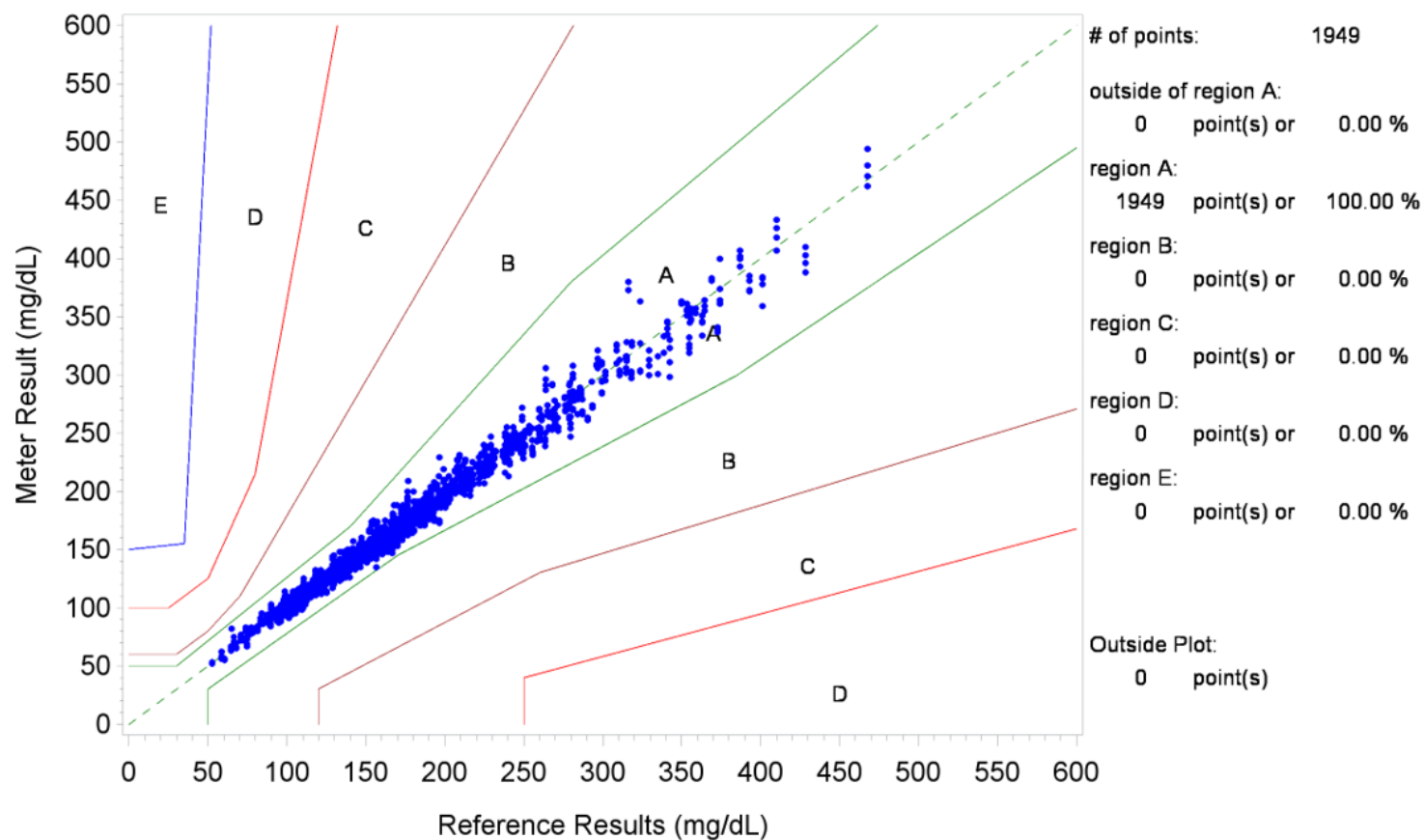
Supplementary Figure S1. Parkes Consensus Error Grid comparing results for BGM1 with results for the reference method



Each point represents a meter reading.

BGM1 Accu-Chek Guide [blood glucose meter]

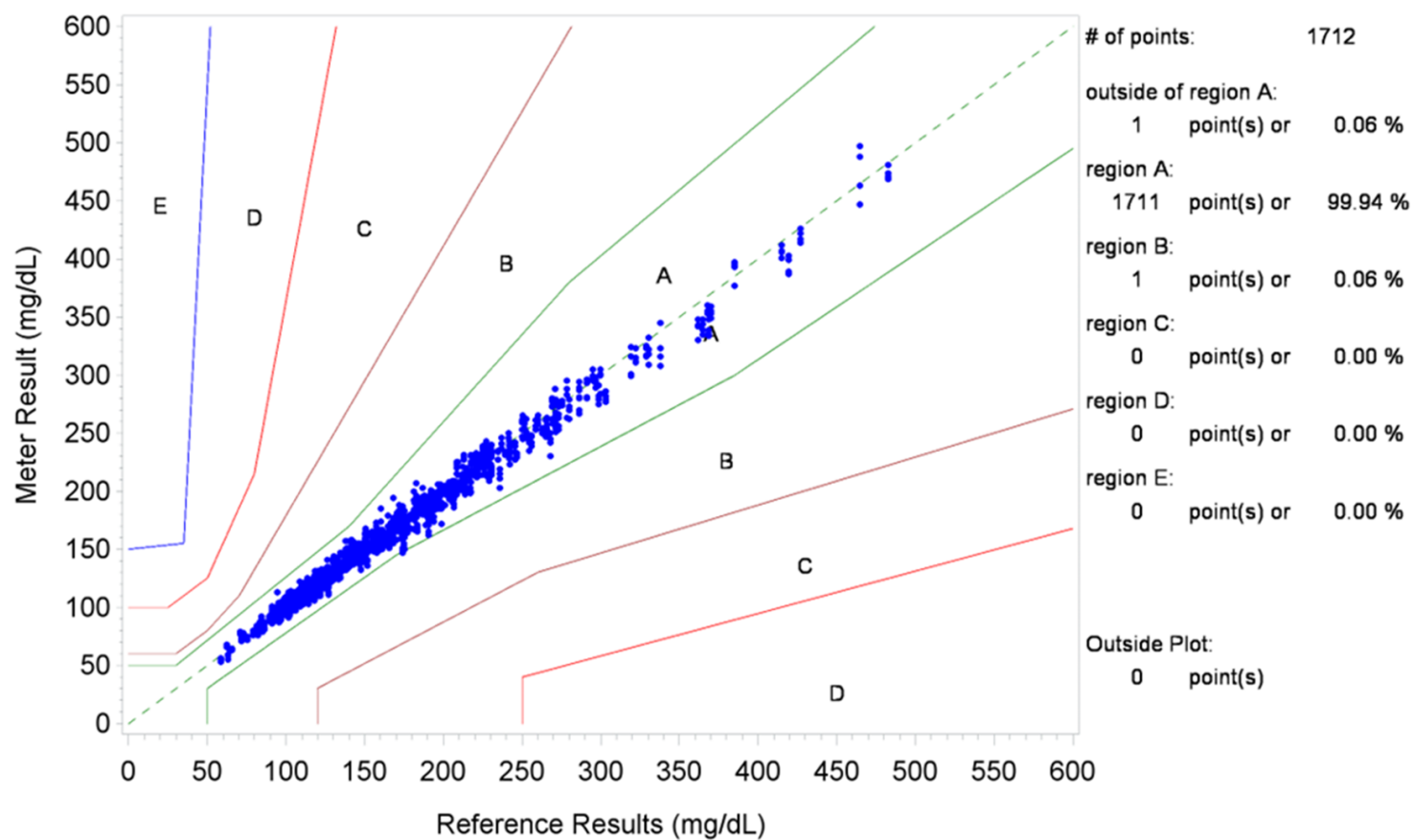
Supplementary Figure S2. Parkes Consensus Error Grid comparing results for BGM2 with results for the reference method



Each point represents a meter reading.

BGM2 Accu-Chek GuideMe [blood glucose meter]

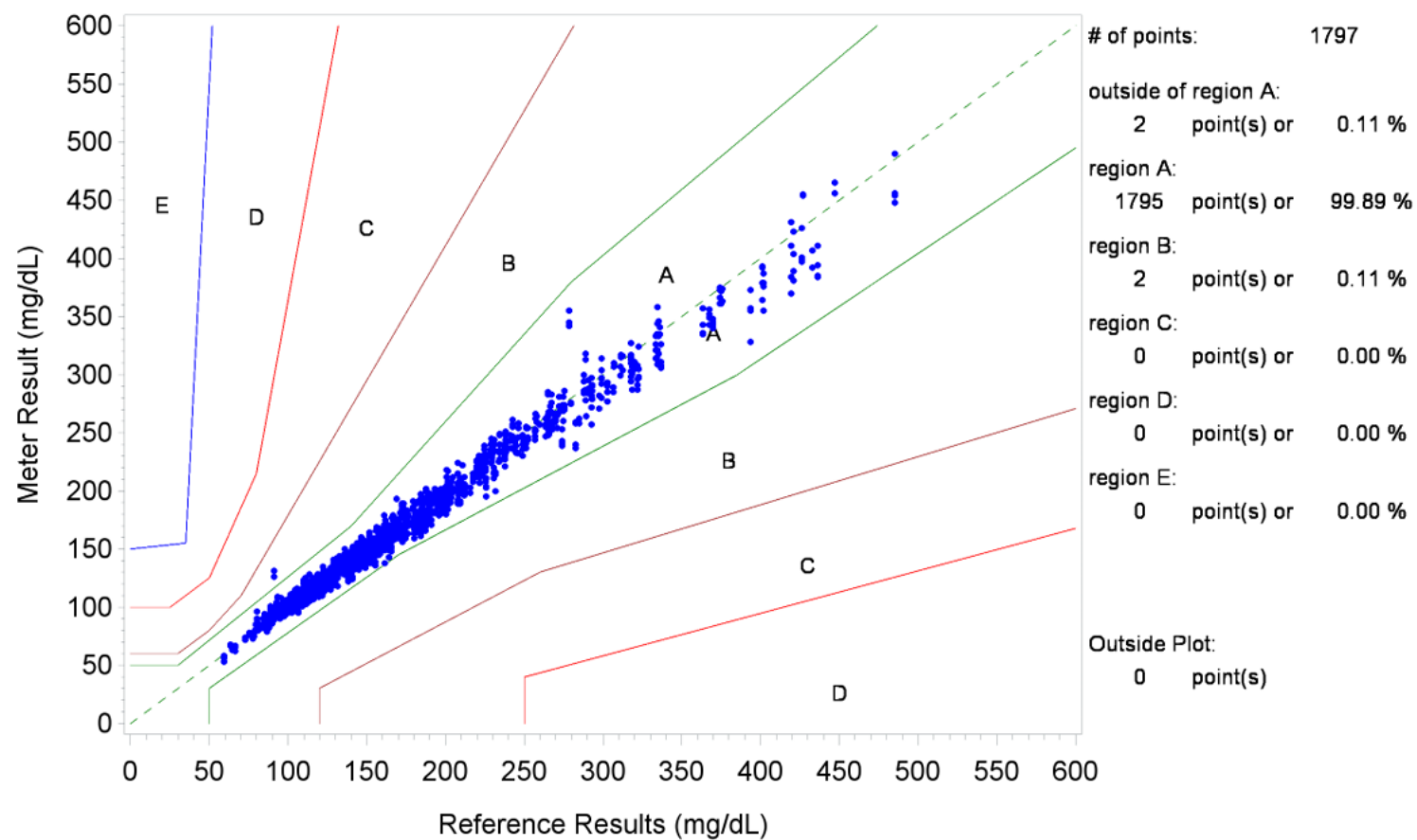
Supplementary Figure S3. Parkes Consensus Error Grid comparing results for BGM3 with results for the reference method



Each point represents a meter reading.

BGM3 Accu-Chek Instant [blood glucose meter]

Supplementary Figure S4. Parkes Consensus Error Grid comparing results for BGM4 with results for the reference method



Each point represents a meter reading.

BGM4 Accu-Chek Instant S [blood glucose meter]

## **Appendix**

### **Appendix 1. Calculations of the number of observations for each CE-marked blood glucose meter**

Participants were tested on multiple meter types, so the actual number of participants enrolled was less than it appears. A description of how much data was lost due to reference drift and missing values is listed below for each type of meter. The blood glucose meters tested were the Roche Accu-Chek Guide (BGM1), Accu-Chek GuideMe (BGM2), Accu-Chek Instant (BGM3), and Accu-Chek Instant S (BGM4).

#### *BGM1*

BGM1 was evaluated on 650 participants (**Supplementary Table 1**). Of the 650 participants, 40 were lost due to reference drift and 16 had missing data. The remaining 594 participants had data collected across 4 strip lots each, for a total of 2376 data points (**Supplementary Fig. 1**). During each of the three 6-month study periods, four strip lots were tested, representing a total of 12 strip lots.

#### *BGM2*

For BGM2, data collection was unbalanced in the first 6-month study period, which started in the fall of 2020 (**Supplementary Table 2**).

- Lot 1 was evaluated on 50 participants with 17 lost to reference drift and 2 with missing data (N=31)
- Lot 2 was evaluated on 100 participants with 19 lost to reference drift (N=81)
- Lot 3 was evaluated on 100 participants with 23 lost to reference drift and 1 with missing data (N=76)
- Lot 4 was evaluated on 150 participants with 25 lost to reference drift (N=125)

For the remaining data collection, there were 450 participants. Of the 450 participants, 26 were lost to reference drift and 15 had missing data. The remaining 409 participants were tested on 4 strip lots (N=1636 data points). Data were collected from four additional strip lots (lots 5 to 8) in the fall 2021 study period and four additional strip lots (lots 9 to 12) in the fall 2022 study period. BGM2 was tested on a total of 12 strip lots.

The total number of observations for BGM2 was 1949 (31 + 81 + 76 + 125 + 1636; **Supplementary Fig. 2**).

#### *BGM3*

BGM3 was evaluated on 450 participants (**Supplementary Table 3**). Of the 450 participants, 22 were lost due to reference drift. The remaining 428 participants had data collected across four lots each (N=1712; **Supplementary Fig. 3**). BGM3 was tested on a total of eight lots. Data were collected from four strip lots (lots 1 to 4) in the Fall 2021 study period and four different strip lots (lots 5 to 8) in the Fall 2022 study period.

#### *BGM4*

BGM4 was evaluated on 602 participants (**Supplementary Table 4**). In the 202 participants assessed in the Fall 2020 study period, 42 were lost due to reference drift and three had missing data. The remaining 157 participants were tested on 2 strip lots (lots 1 and 2; N=314). In the 400 participants assessed in the Fall 2021 and Fall 2022 study periods, 15 were lost to reference drift and 14 had missing data. The remaining 371 participants were tested on 4 strip lots. However, there was one additional missing value for one participant on only one lot, so the actual number of data points was one fewer (N=1483). Data were collected from four additional strip lots (lots 3 to 6) in the Fall 2021 study period and four additional strip lots (lots 7 to 10) in the Fall 2022 study period. BGM4 was tested on a total of 10 lots.

The total number of observations for BGM4 was 1797 (314+1483; **Supplementary Fig. 4**).