

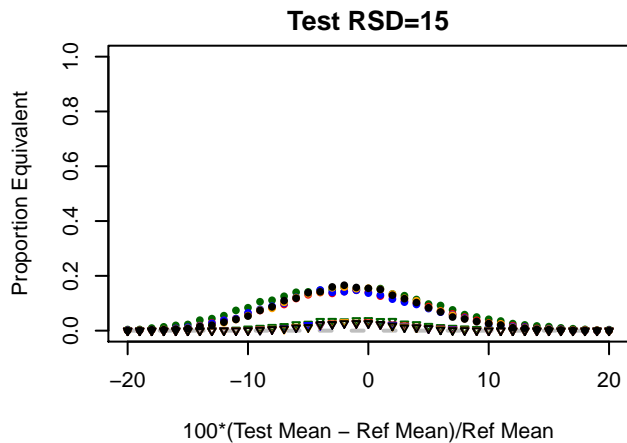
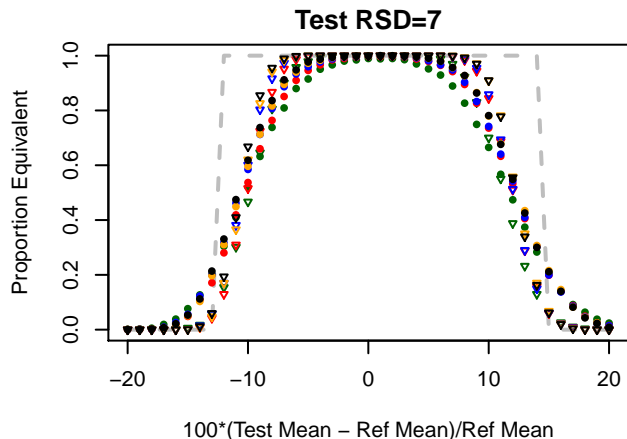
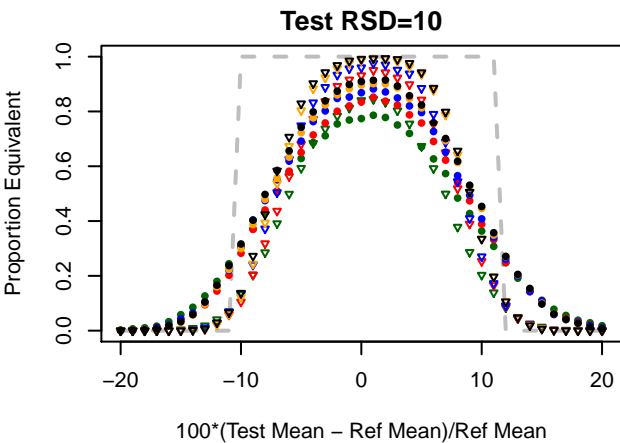
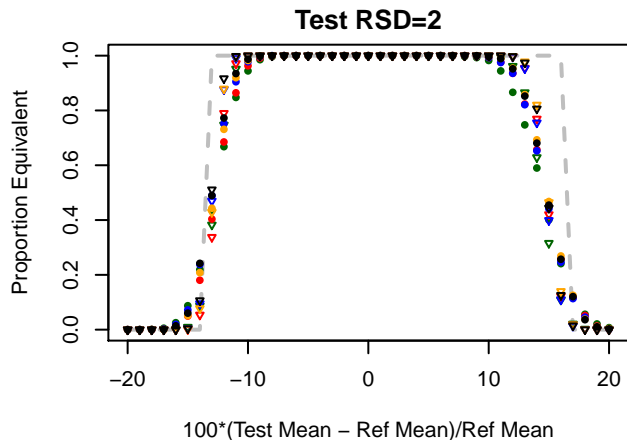
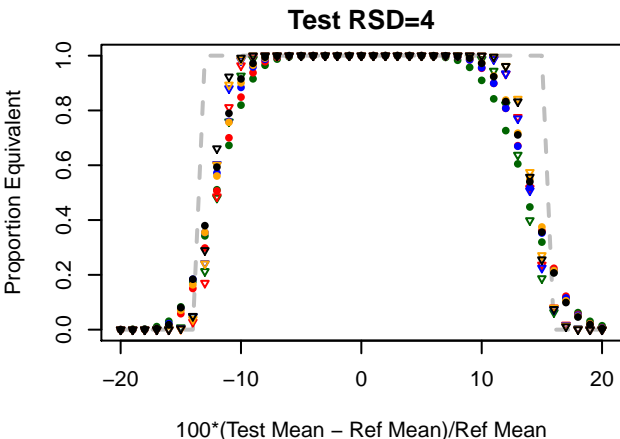
Operating Characteristic (OC) Curves from Simulation

IPAC-RS

August 17, 2017

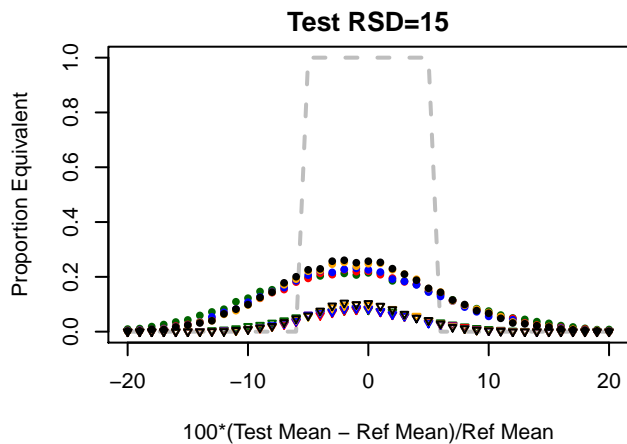
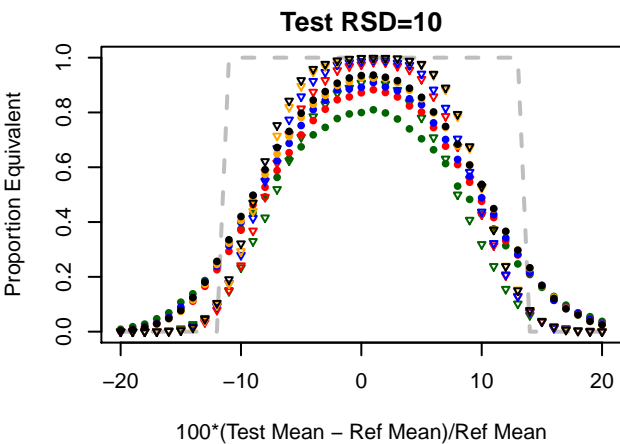
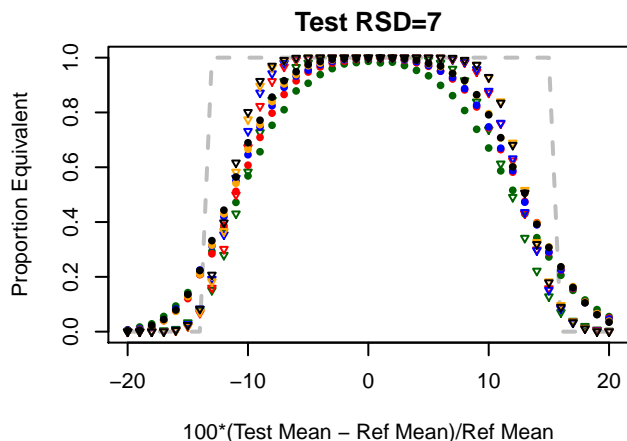
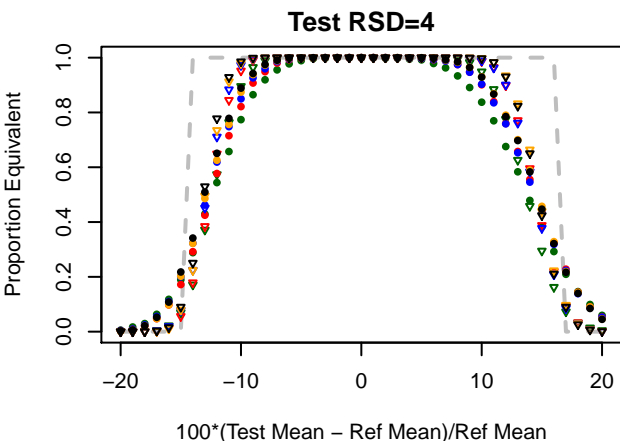
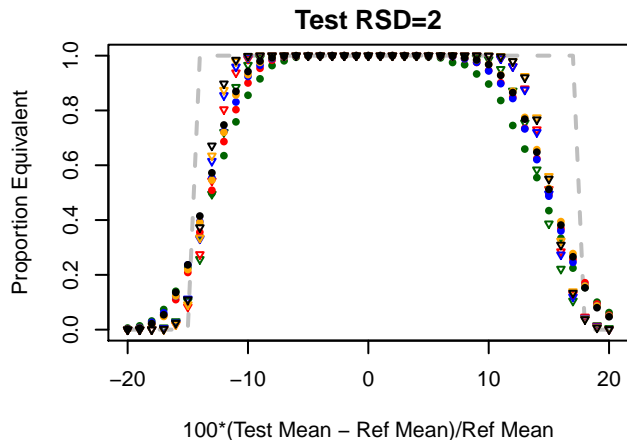
Extremes = NONE; T or R Ext = BOTH; Ref RSD = 4

- ▽ 10% Btwn-Batch Var
- 50% Btwn-Batch Var
- 1 LS
- 2 LS, no LS effect
- 2 LS, LS effect
- 3 LS, no LS effect
- 3 LS, LS effect
- +- PBE Region



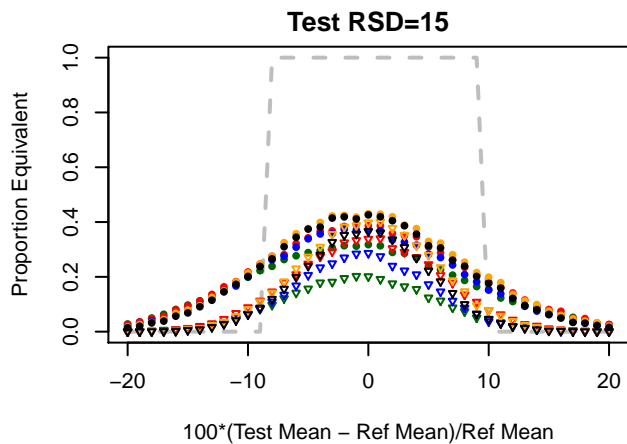
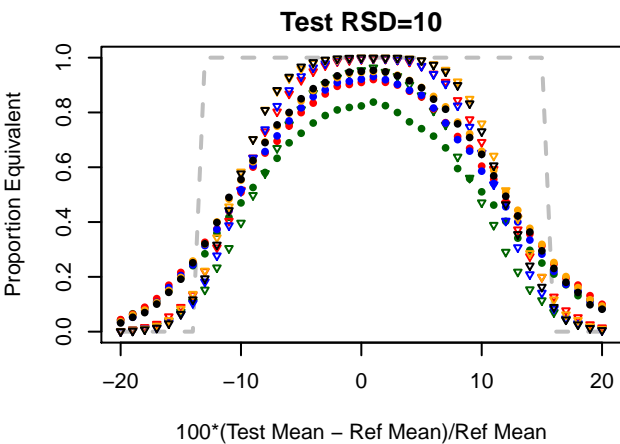
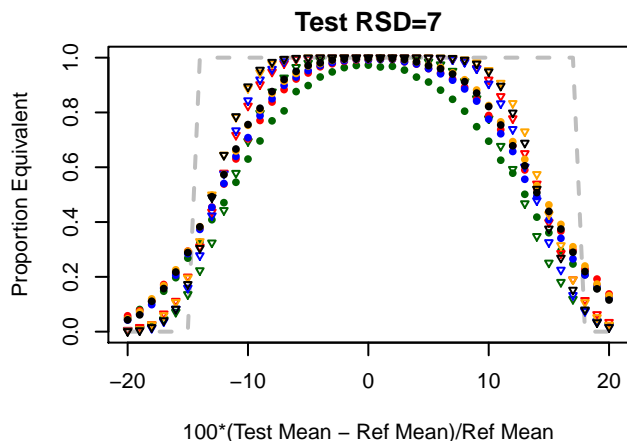
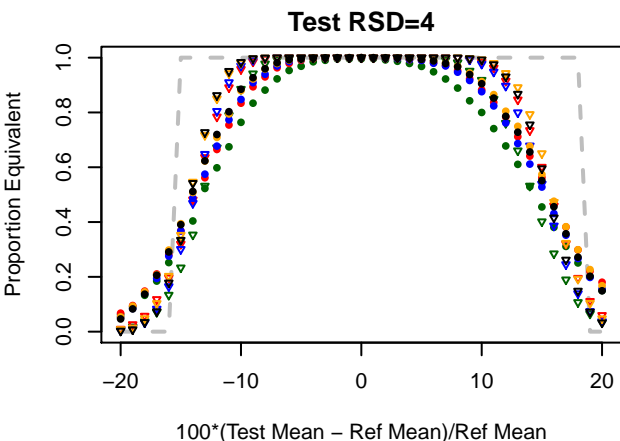
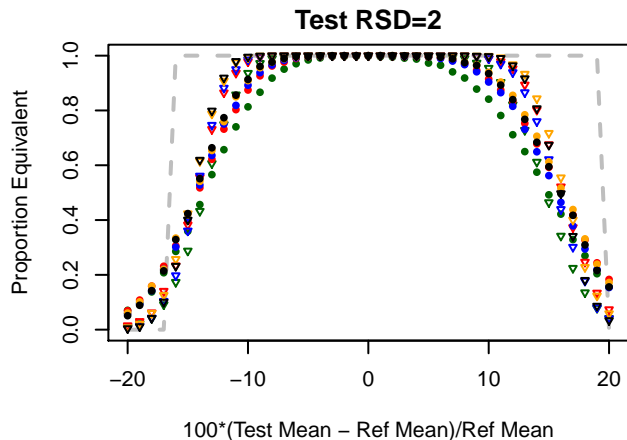
Extremes = NONE; T or R Ext = BOTH; Ref RSD = 7

- ▽ 10% Btwn-Batch Var
- 50% Btwn-Batch Var
- 1 LS
- 2 LS, no LS effect
- 2 LS, LS effect
- 3 LS, no LS effect
- 3 LS, LS effect
- +- PBE Region



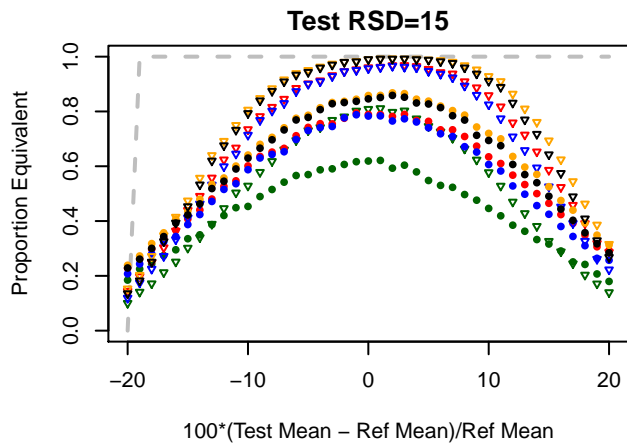
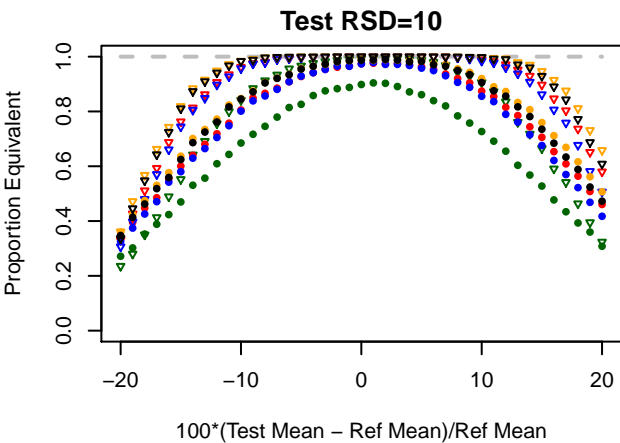
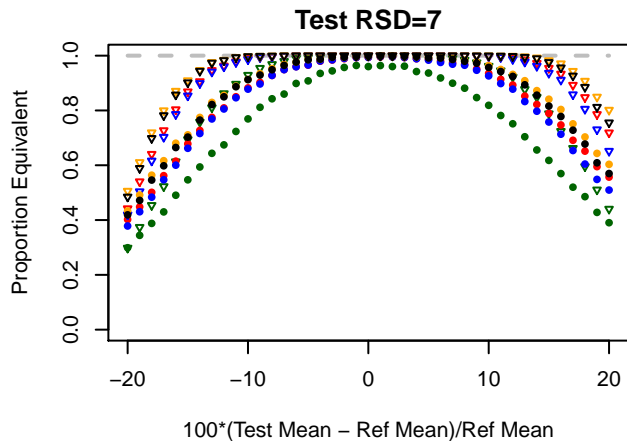
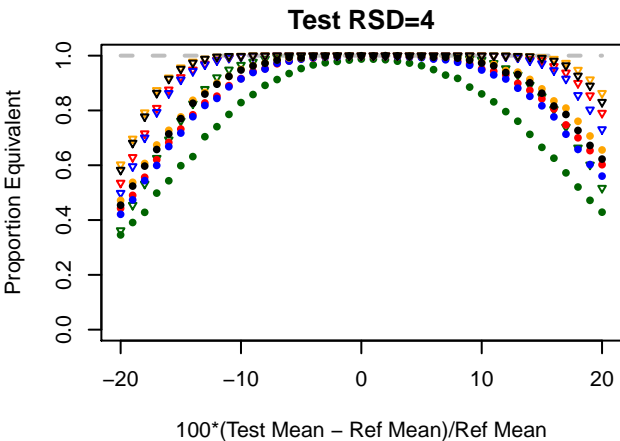
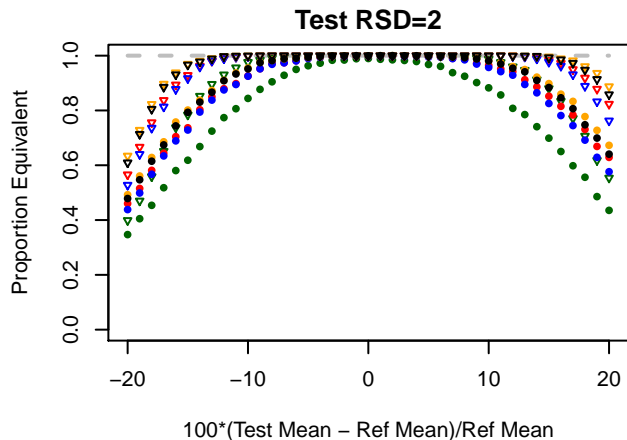
Extremes = NONE; T or R Ext = BOTH; Ref RSD = 10

- ▽ 10% Btwn-Batch Var
- 50% Btwn-Batch Var
- 1 LS
- 2 LS, no LS effect
- 2 LS, LS effect
- 3 LS, no LS effect
- 3 LS, LS effect
- +- PBE Region



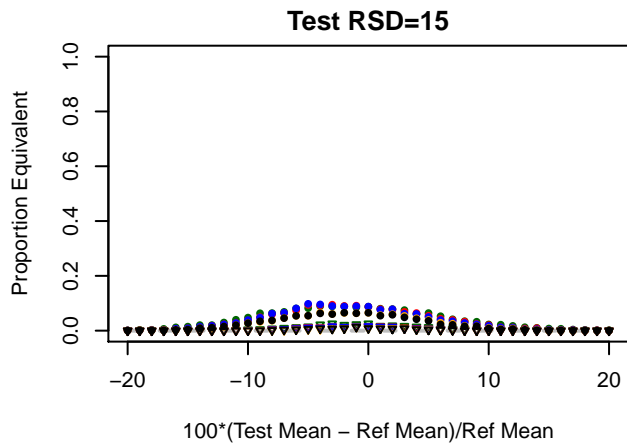
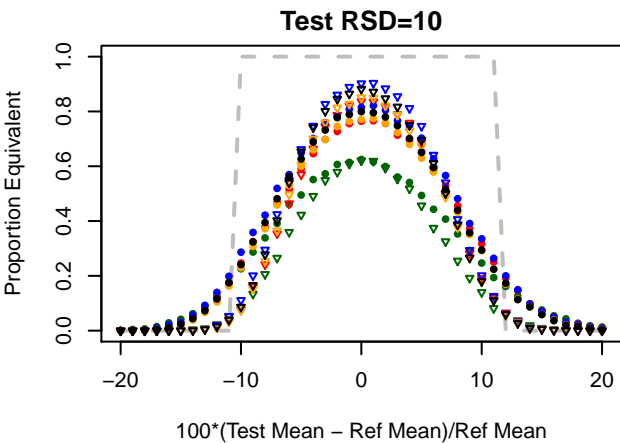
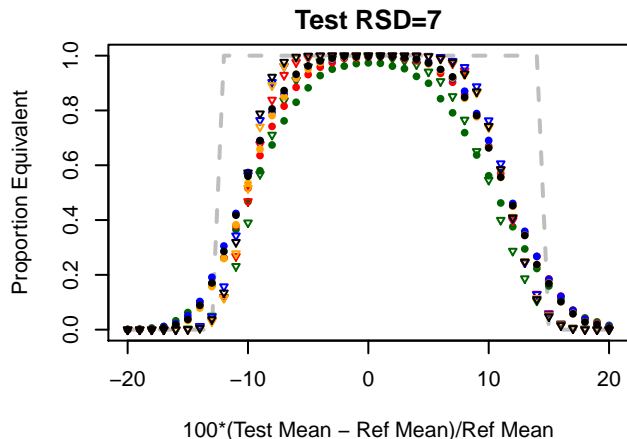
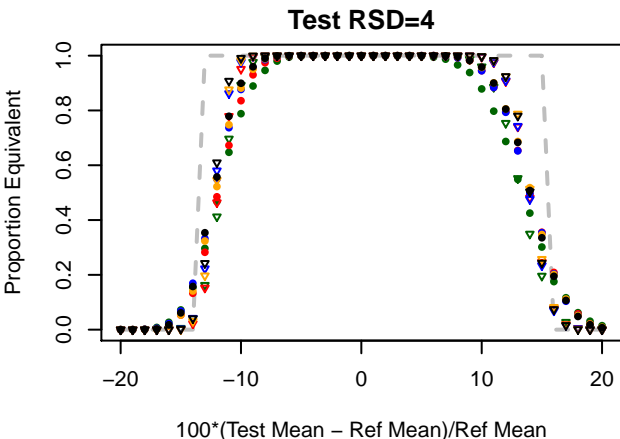
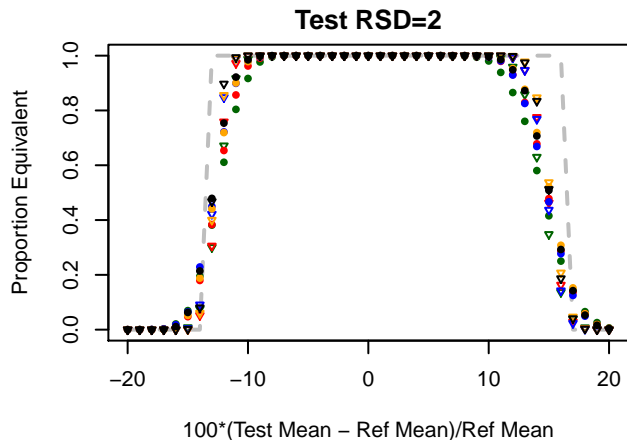
Extremes = NONE; T or R Ext = BOTH; Ref RSD = 15

- ▽ 10% Btwn-Batch Var
- 50% Btwn-Batch Var
- 1 LS
- 2 LS, no LS effect
- 2 LS, LS effect
- 3 LS, no LS effect
- 3 LS, LS effect
- +- PBE Region



Extremes = HIGH; T or R Ext = BOTH; Ref RSD = 4

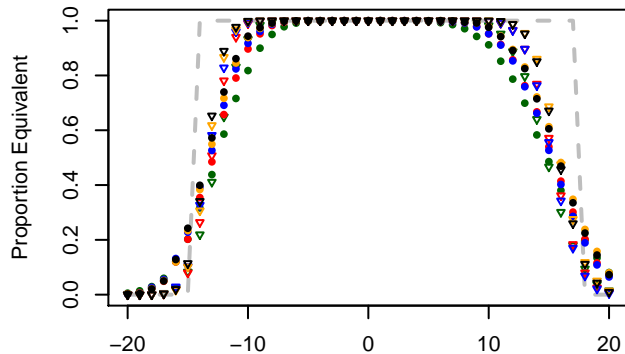
- ▽ 10% Btwn-Batch Var
- 50% Btwn-Batch Var
- 1 LS
- 2 LS, no LS effect
- 2 LS, LS effect
- 3 LS, no LS effect
- 3 LS, LS effect
- +- PBE Region



Extremes = HIGH; T or R Ext = BOTH; Ref RSD = 7

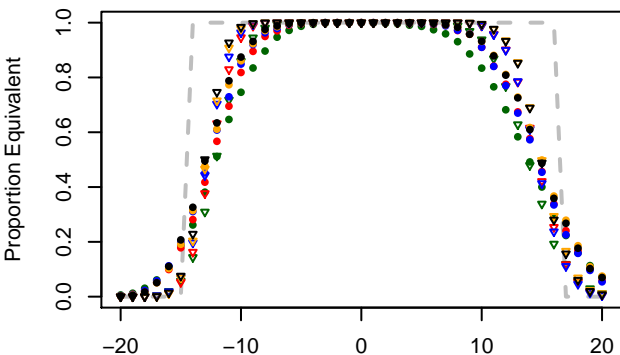
- ▽ 10% Btw-Batch Var
- 50% Btw-Batch Var
- 1 LS
- 2 LS, no LS effect
- 2 LS, LS effect
- 3 LS, no LS effect
- 3 LS, LS effect
- +- PBE Region

Test RSD=2



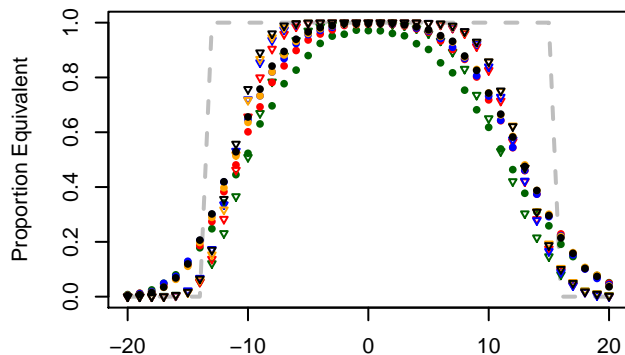
$100 \cdot (\text{Test Mean} - \text{Ref Mean}) / \text{Ref Mean}$

Test RSD=4



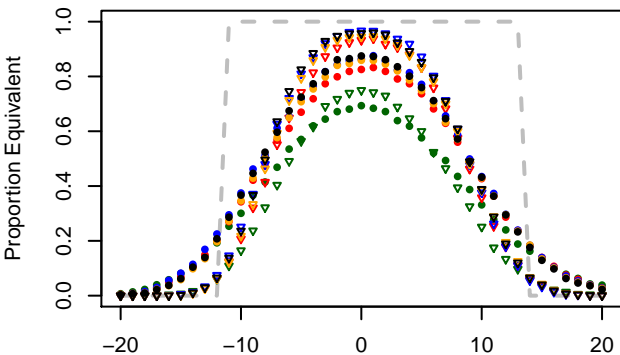
$100 \cdot (\text{Test Mean} - \text{Ref Mean}) / \text{Ref Mean}$

Test RSD=7



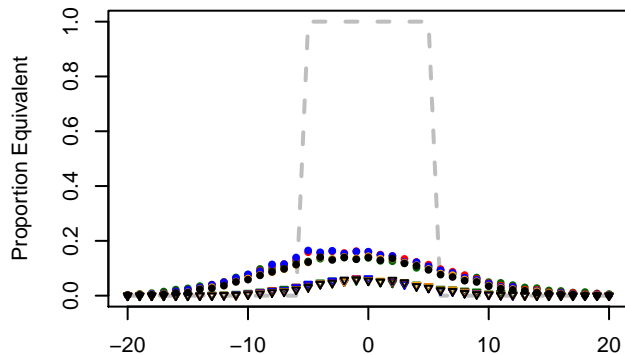
$100 \cdot (\text{Test Mean} - \text{Ref Mean}) / \text{Ref Mean}$

Test RSD=10



$100 \cdot (\text{Test Mean} - \text{Ref Mean}) / \text{Ref Mean}$

Test RSD=15

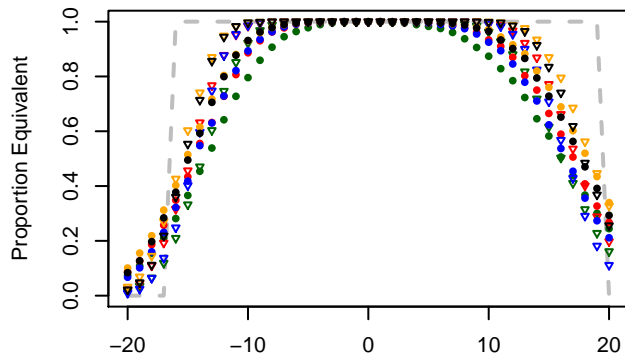


$100 \cdot (\text{Test Mean} - \text{Ref Mean}) / \text{Ref Mean}$

Extremes = HIGH; T or R Ext = BOTH; Ref RSD = 10

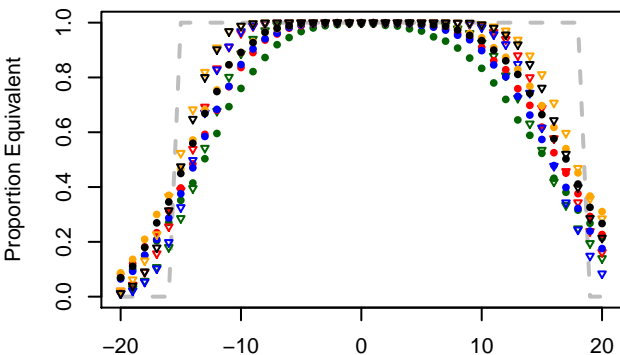
- ▽ 10% Btwn-Batch Var
- 50% Btwn-Batch Var
- 1 LS
- 2 LS, no LS effect
- 2 LS, LS effect
- 3 LS, no LS effect
- 3 LS, LS effect
- +- PBE Region

Test RSD=2



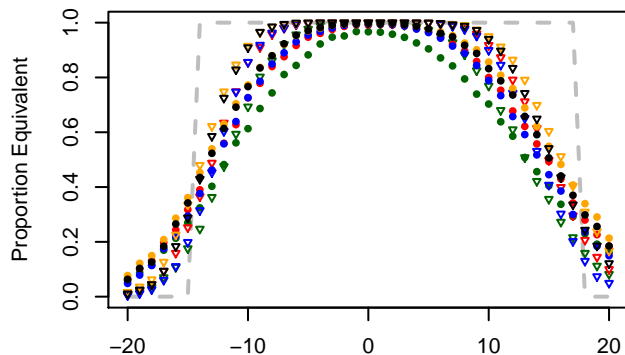
$100 \cdot (\text{Test Mean} - \text{Ref Mean}) / \text{Ref Mean}$

Test RSD=4



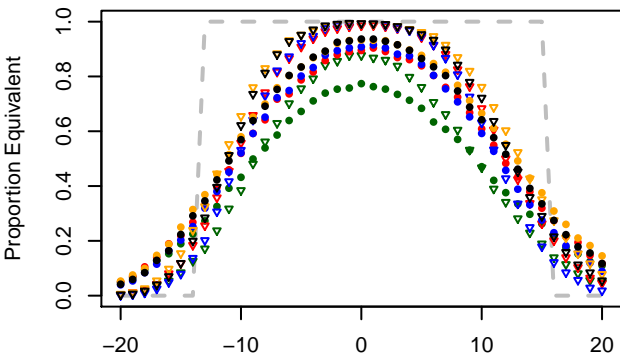
$100 \cdot (\text{Test Mean} - \text{Ref Mean}) / \text{Ref Mean}$

Test RSD=7



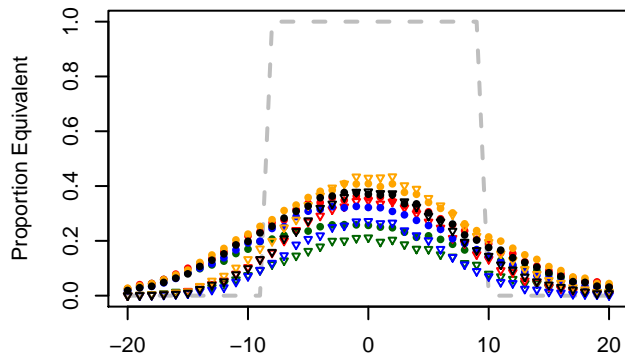
$100 \cdot (\text{Test Mean} - \text{Ref Mean}) / \text{Ref Mean}$

Test RSD=10



$100 \cdot (\text{Test Mean} - \text{Ref Mean}) / \text{Ref Mean}$

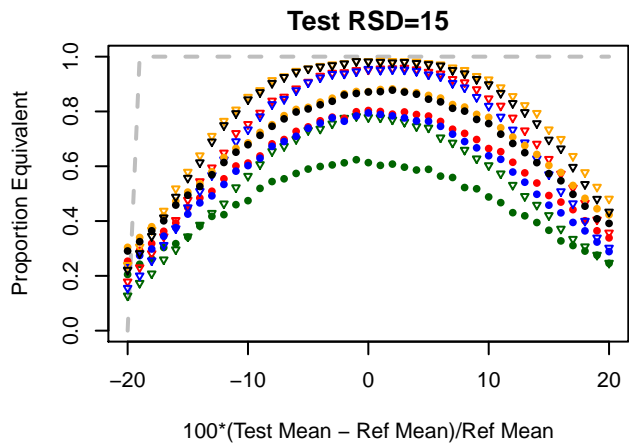
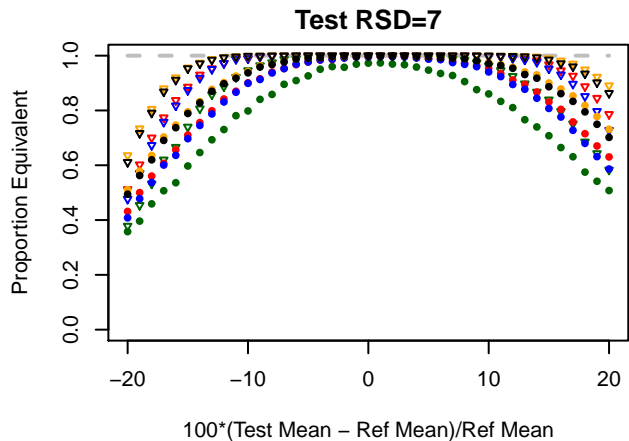
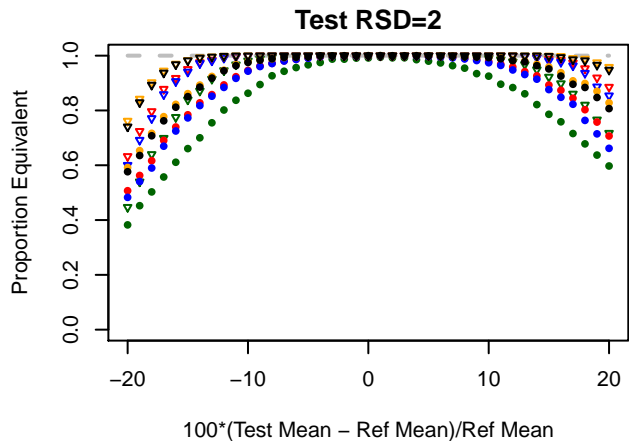
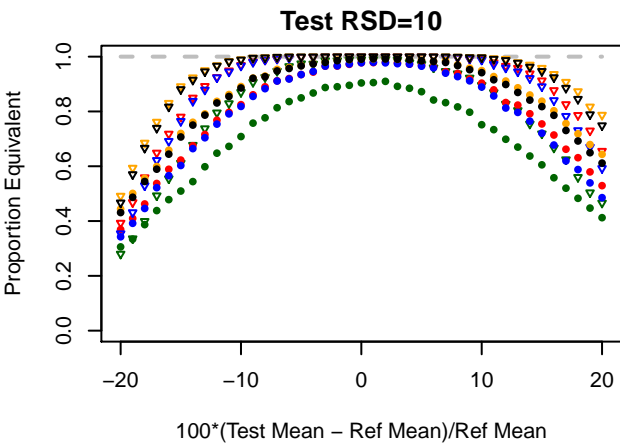
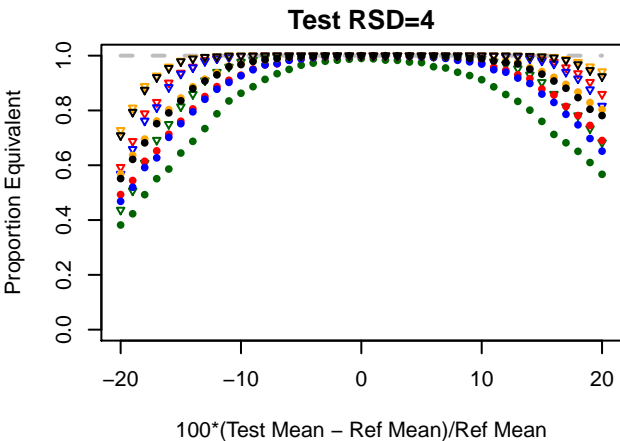
Test RSD=15



$100 \cdot (\text{Test Mean} - \text{Ref Mean}) / \text{Ref Mean}$

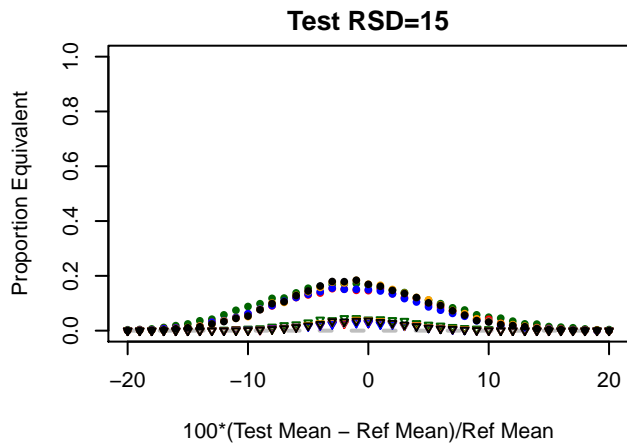
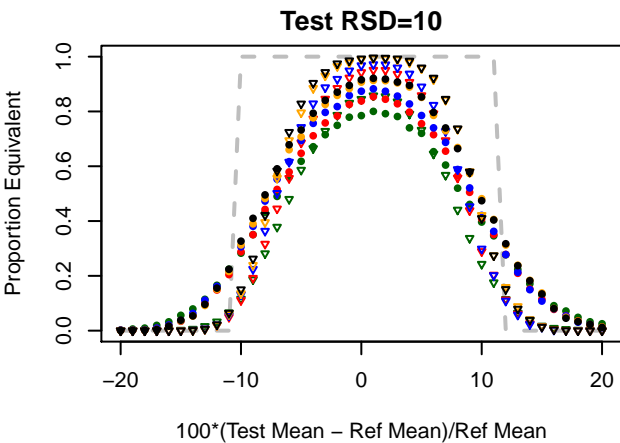
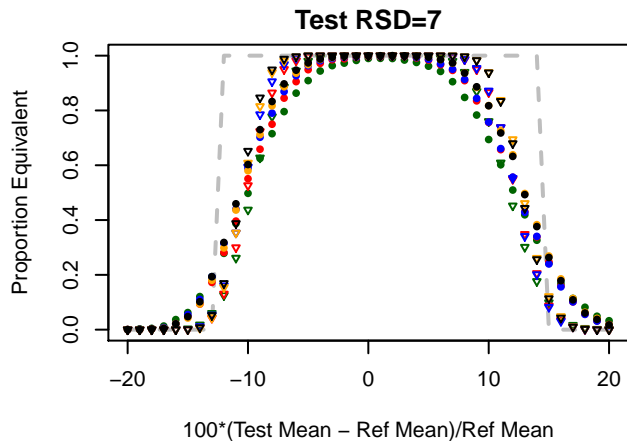
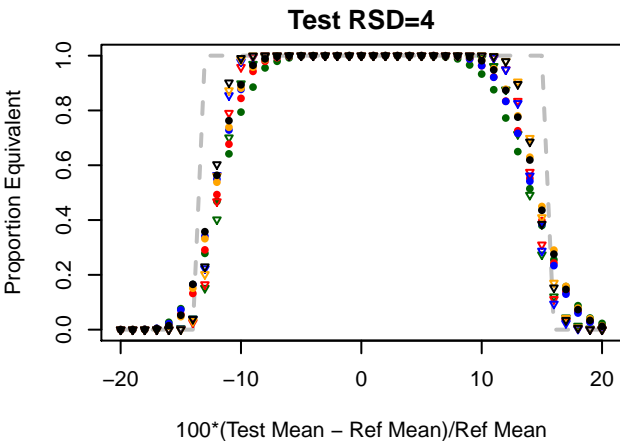
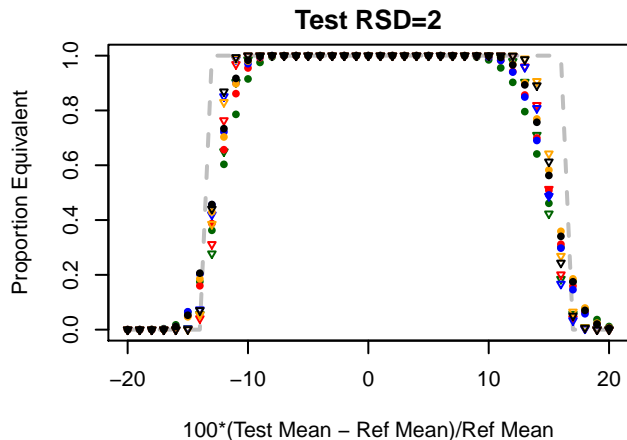
Extremes = HIGH; T or R Ext = BOTH; Ref RSD = 15

- ▽ 10% Btwn-Batch Var
- 50% Btwn-Batch Var
- 1 LS
- 2 LS, no LS effect
- 2 LS, LS effect
- 3 LS, no LS effect
- 3 LS, LS effect
- +- PBE Region



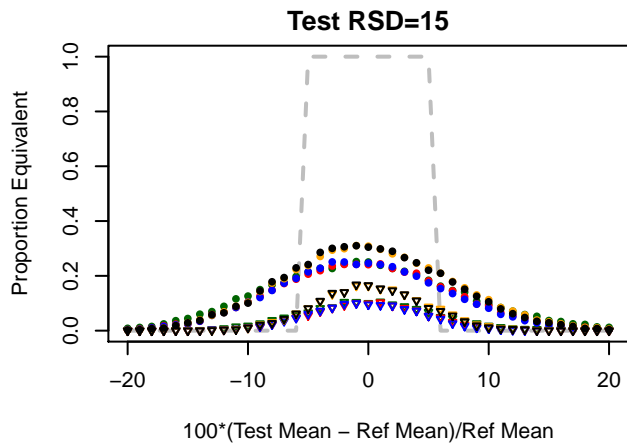
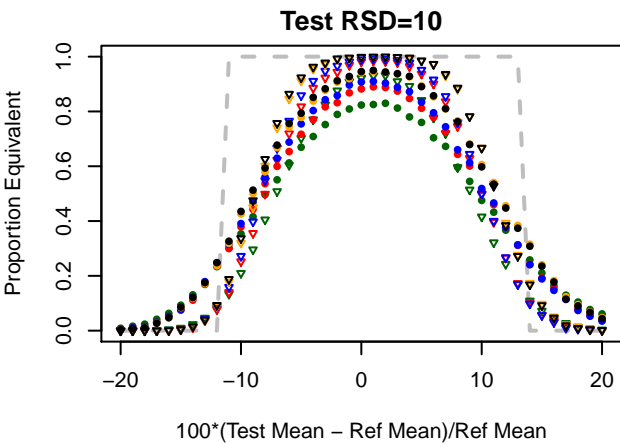
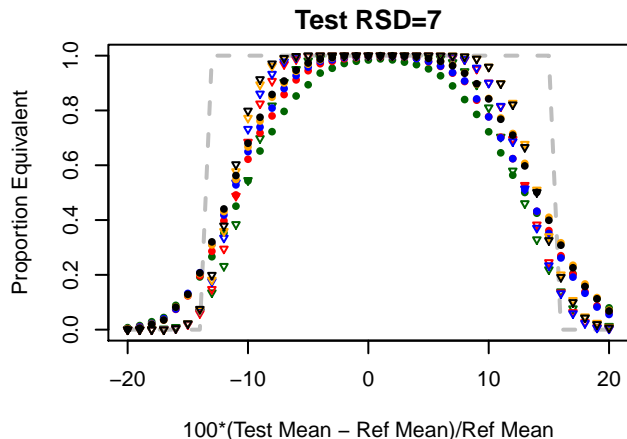
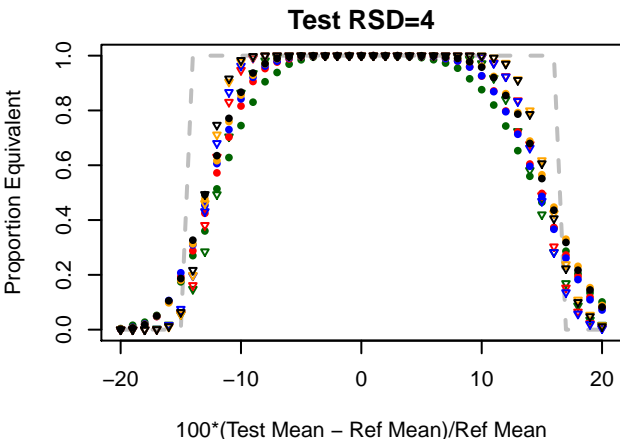
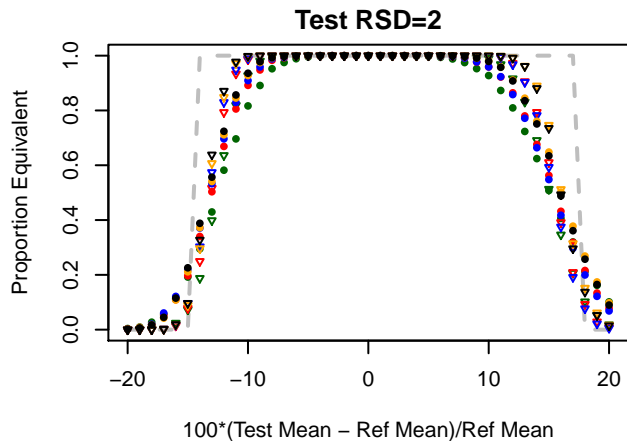
Extremes = HIGH; T or R Ext = REF; Ref RSD = 4

- ▽ 10% Btwn-Batch Var
- 50% Btwn-Batch Var
- 1 LS
- 2 LS, no LS effect
- 2 LS, LS effect
- 3 LS, no LS effect
- 3 LS, LS effect
- +- PBE Region



Extremes = HIGH; T or R Ext = REF; Ref RSD = 7

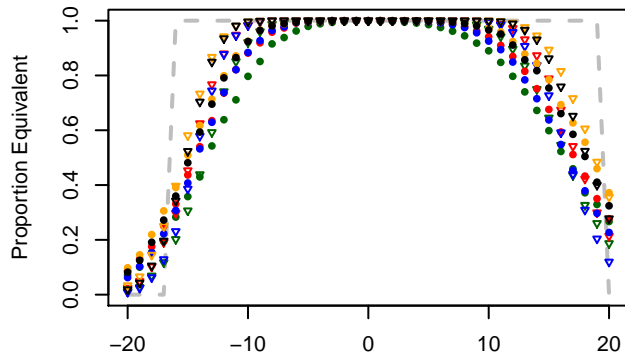
- ▽ 10% Btwn-Batch Var
- 50% Btwn-Batch Var
- 1 LS
- 2 LS, no LS effect
- 2 LS, LS effect
- 3 LS, no LS effect
- 3 LS, LS effect
- +- PBE Region



Extremes = HIGH; T or R Ext = REF; Ref RSD = 10

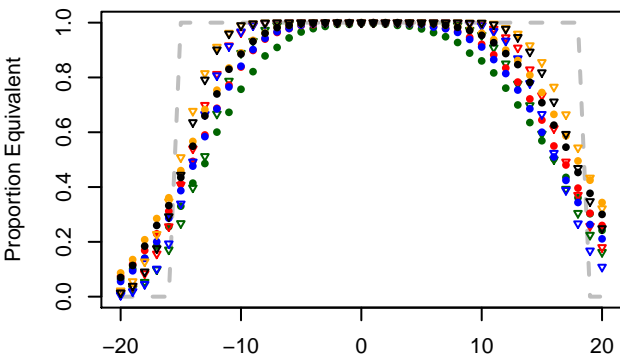
- ▽ 10% Btwn-Batch Var
- 50% Btwn-Batch Var
- 1 LS
- 2 LS, no LS effect
- 2 LS, LS effect
- 3 LS, no LS effect
- 3 LS, LS effect
- +- PBE Region

Test RSD=2



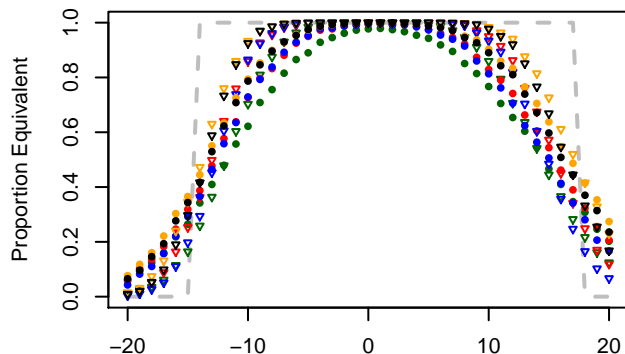
$100 \cdot (\text{Test Mean} - \text{Ref Mean}) / \text{Ref Mean}$

Test RSD=4



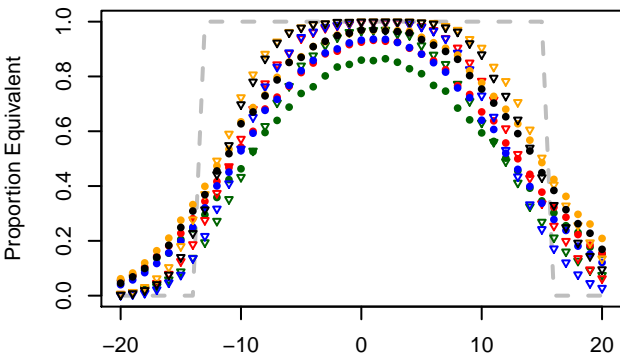
$100 \cdot (\text{Test Mean} - \text{Ref Mean}) / \text{Ref Mean}$

Test RSD=7



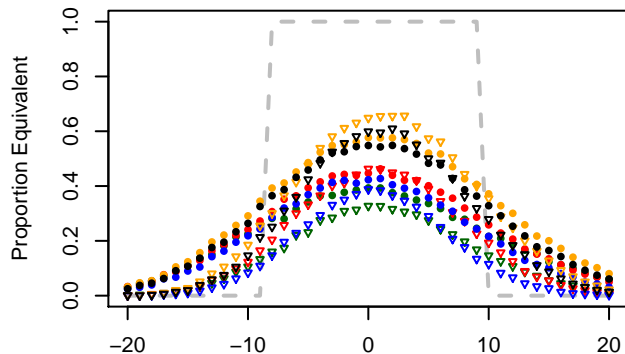
$100 \cdot (\text{Test Mean} - \text{Ref Mean}) / \text{Ref Mean}$

Test RSD=10



$100 \cdot (\text{Test Mean} - \text{Ref Mean}) / \text{Ref Mean}$

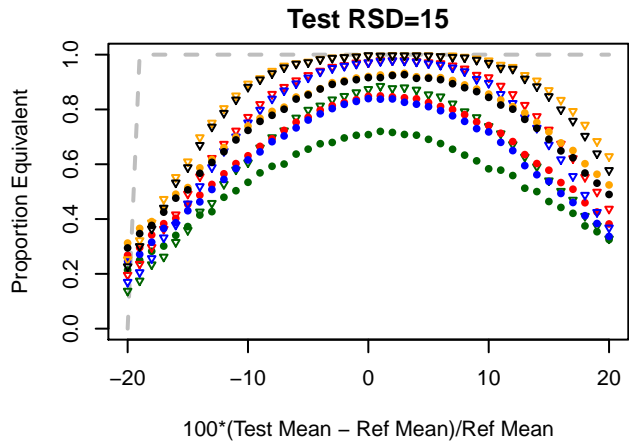
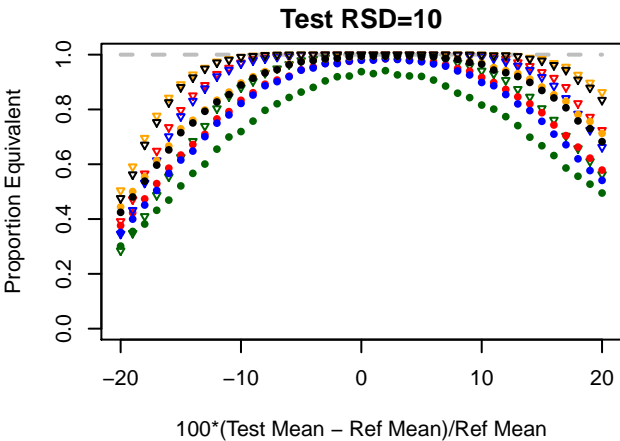
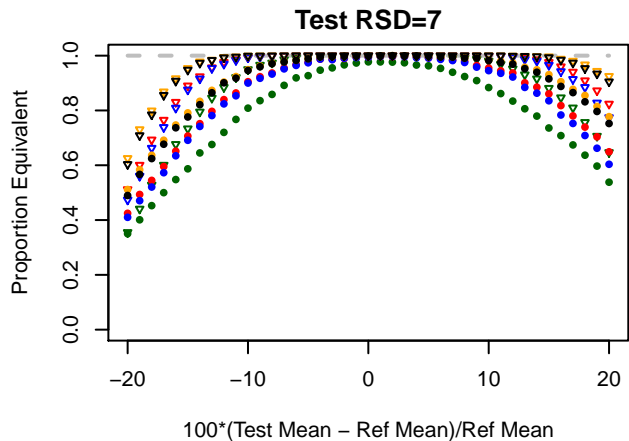
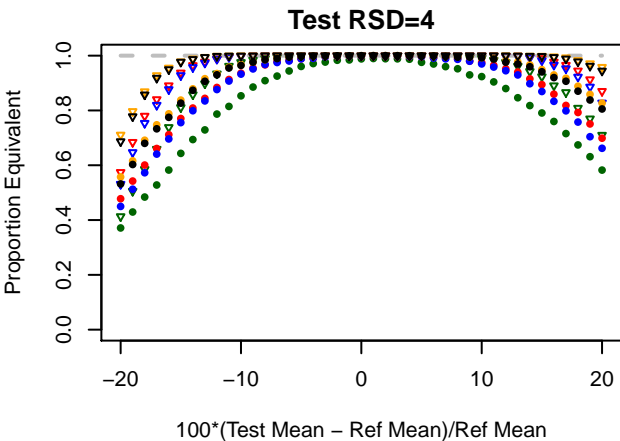
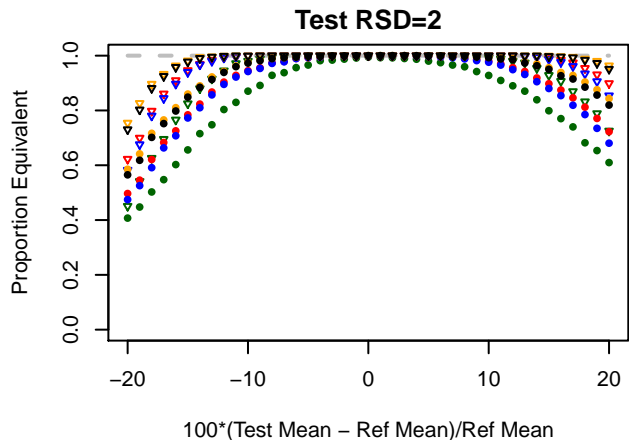
Test RSD=15



$100 \cdot (\text{Test Mean} - \text{Ref Mean}) / \text{Ref Mean}$

Extremes = HIGH; T or R Ext = REF; Ref RSD = 15

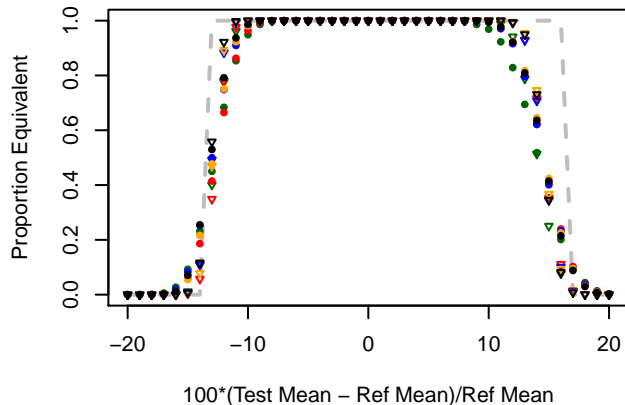
- ▽ 10% Btwn-Batch Var
- 50% Btwn-Batch Var
- 1 LS
- 2 LS, no LS effect
- 2 LS, LS effect
- 3 LS, no LS effect
- 3 LS, LS effect
- +- PBE Region



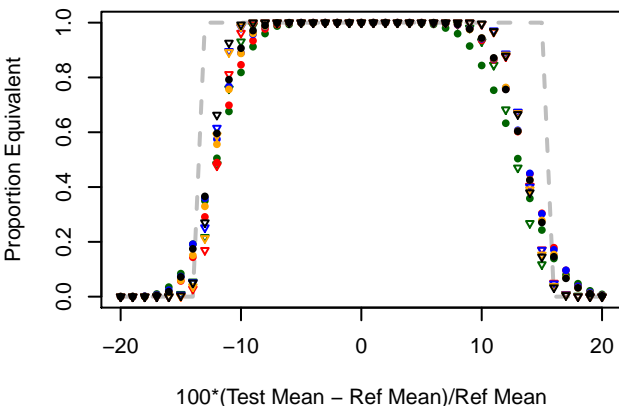
Extremes = HIGH; T or R Ext = TEST; Ref RSD = 4

- ▽ 10% Btwn-Batch Var
- 50% Btwn-Batch Var
- 1 LS
- 2 LS, no LS effect
- 2 LS, LS effect
- 3 LS, no LS effect
- 3 LS, LS effect
- +- PBE Region

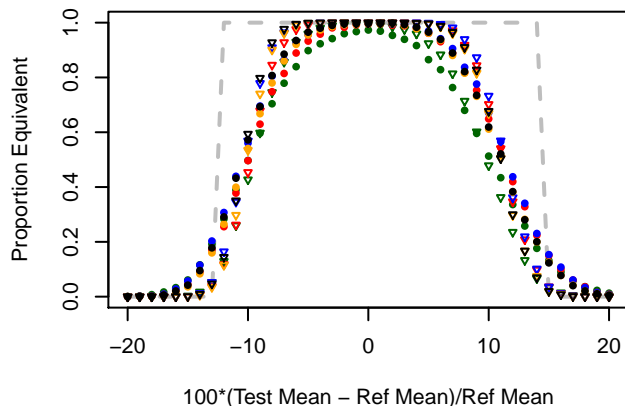
Test RSD=2



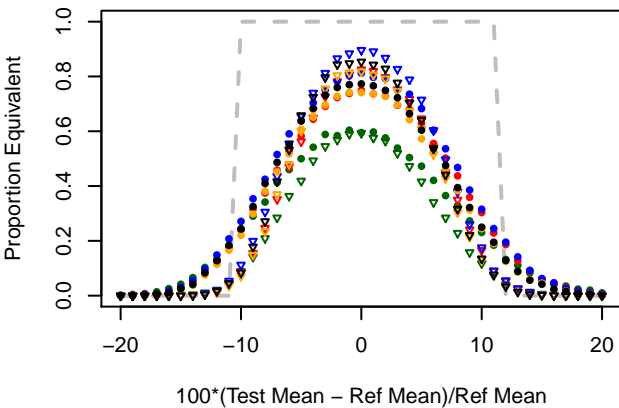
Test RSD=4



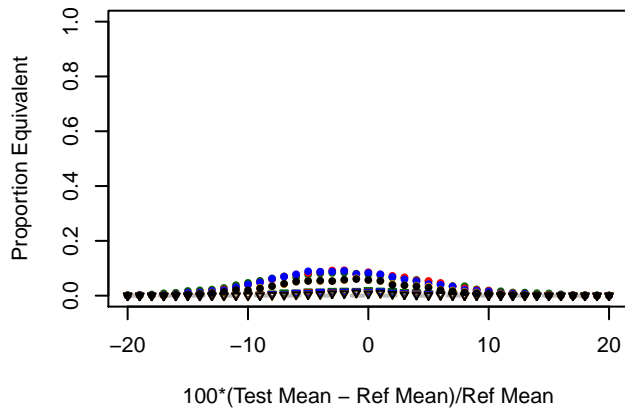
Test RSD=7



Test RSD=10



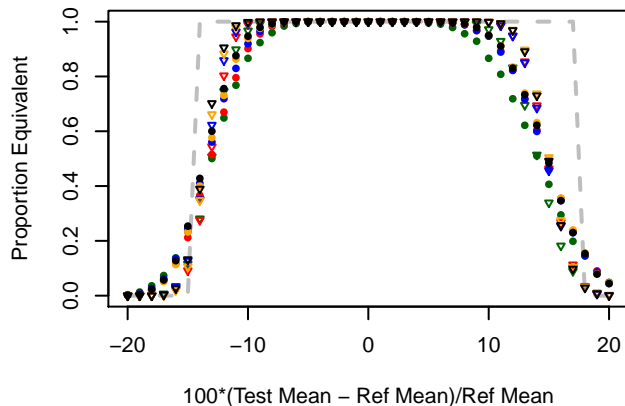
Test RSD=15



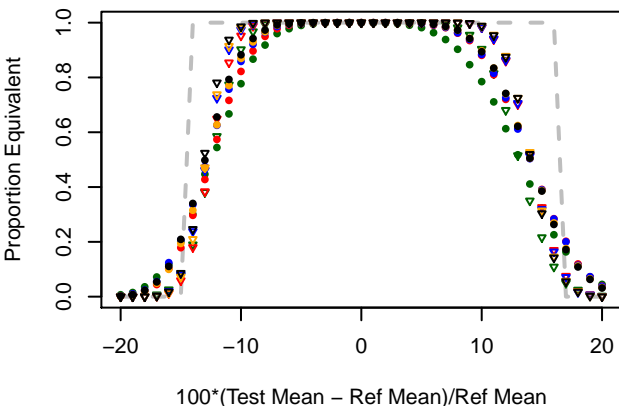
Extremes = HIGH; T or R Ext = TEST; Ref RSD = 7

- ▽ 10% Btwn-Batch Var
- 50% Btwn-Batch Var
- 1 LS
- 2 LS, no LS effect
- 2 LS, LS effect
- 3 LS, no LS effect
- 3 LS, LS effect
- +- PBE Region

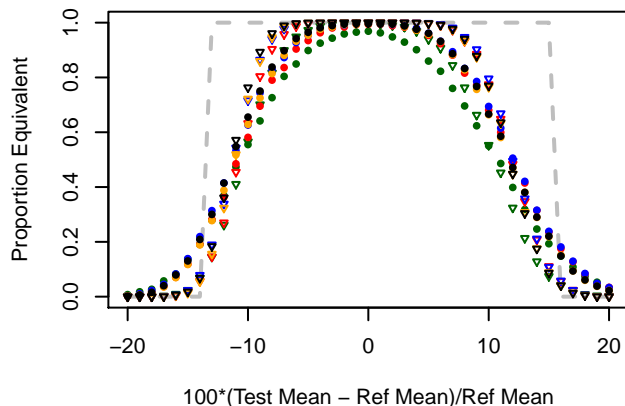
Test RSD=2



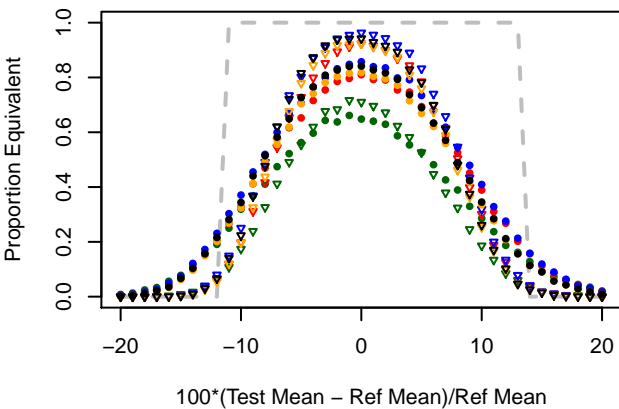
Test RSD=4



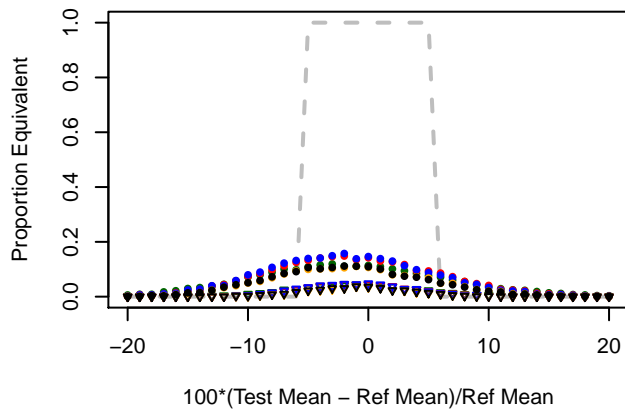
Test RSD=7



Test RSD=10

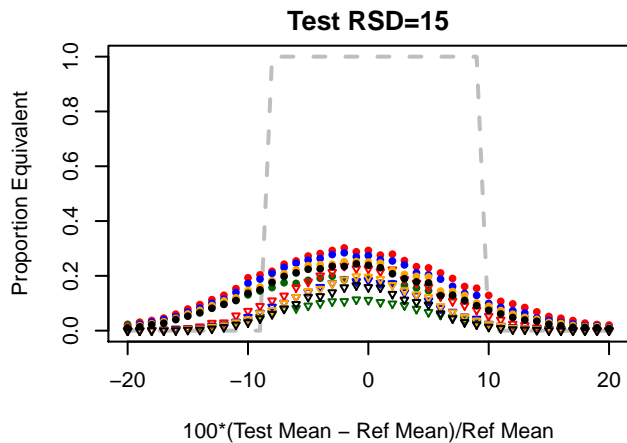
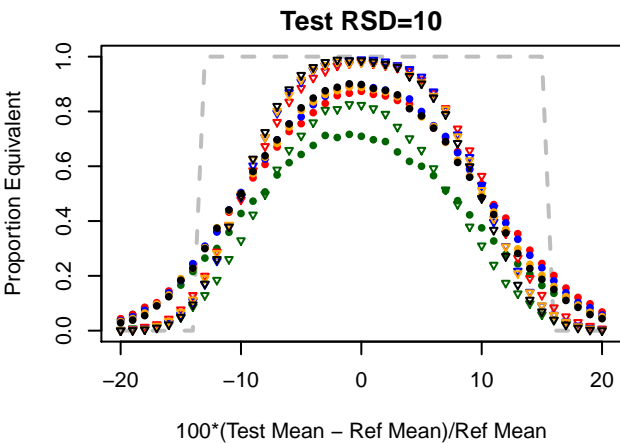
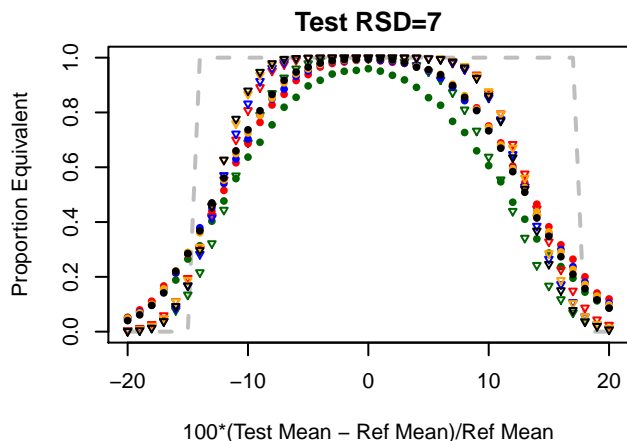
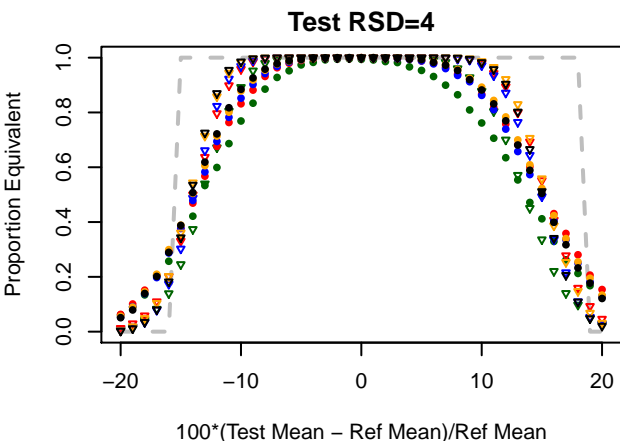
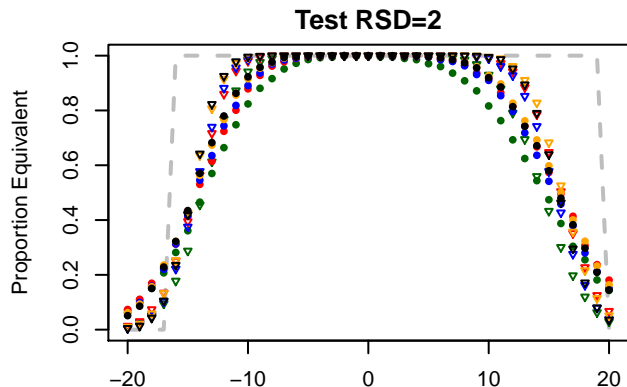


Test RSD=15



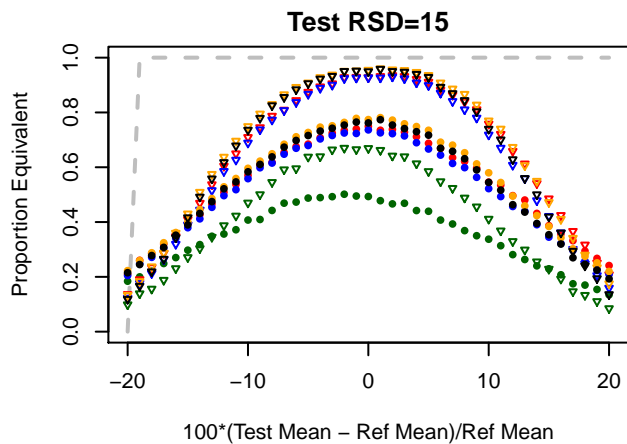
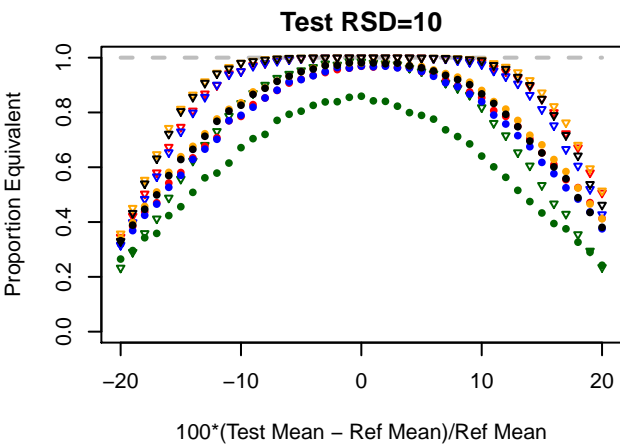
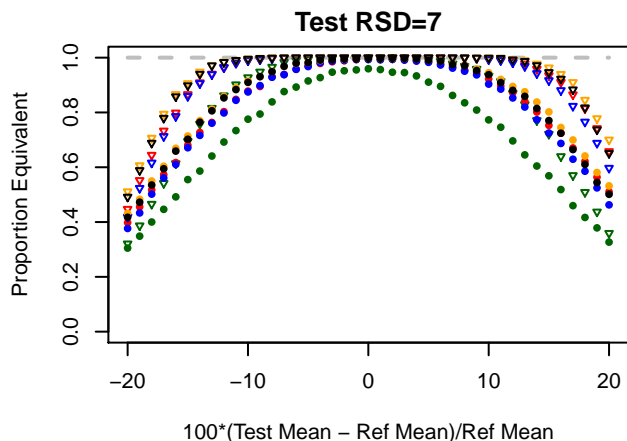
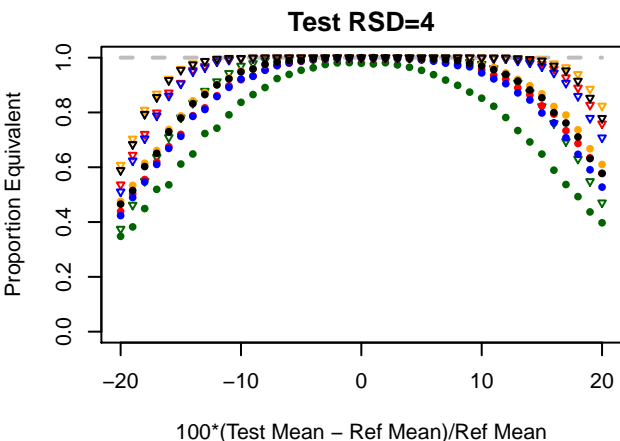
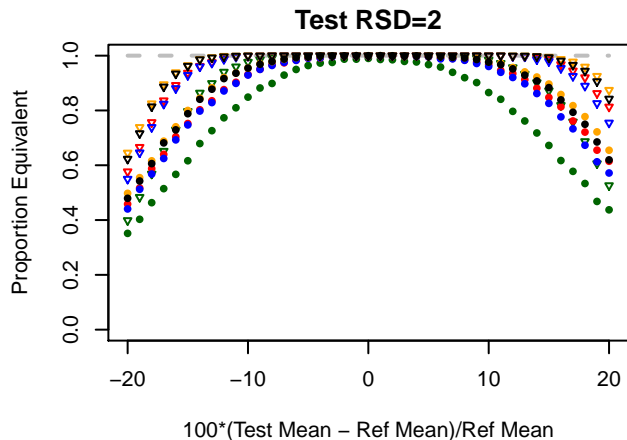
Extremes = HIGH; T or R Ext = TEST; Ref RSD = 10

- ▽ 10% Btwn-Batch Var
- 50% Btwn-Batch Var
- 1 LS
- 2 LS, no LS effect
- 2 LS, LS effect
- 3 LS, no LS effect
- 3 LS, LS effect
- +- PBE Region



Extremes = HIGH; T or R Ext = TEST; Ref RSD = 15

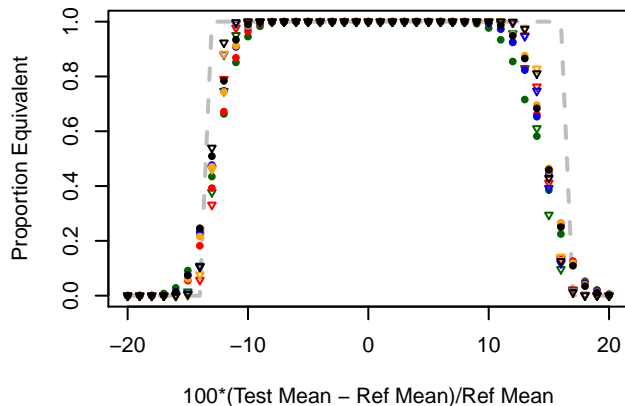
- ▽ 10% Btwn-Batch Var
- 50% Btwn-Batch Var
- 1 LS
- 2 LS, no LS effect
- 2 LS, LS effect
- 3 LS, no LS effect
- 3 LS, LS effect
- +- PBE Region



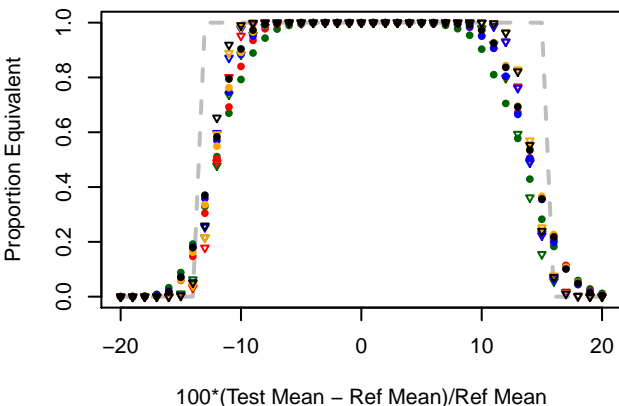
Extremes = LOW; T or R Ext = BOTH; Ref RSD = 4

- ▽ 10% Btwn-Batch Var
- 50% Btwn-Batch Var
- 1 LS
- 2 LS, no LS effect
- 2 LS, LS effect
- 3 LS, no LS effect
- 3 LS, LS effect
- +- PBE Region

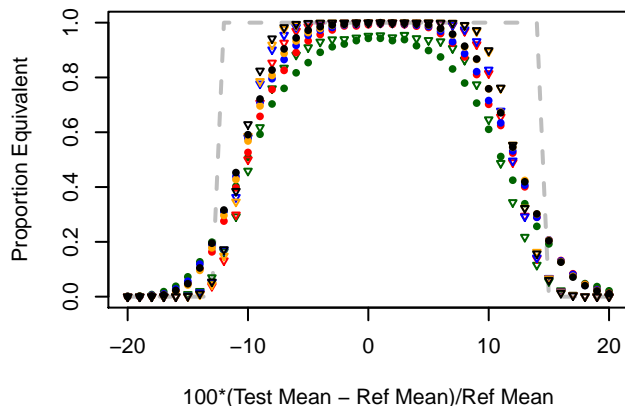
Test RSD=2



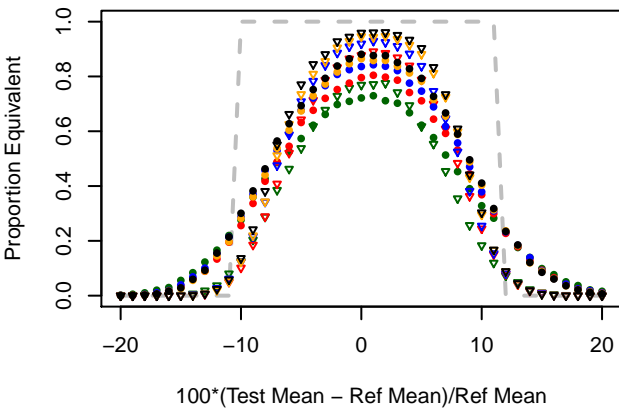
Test RSD=4



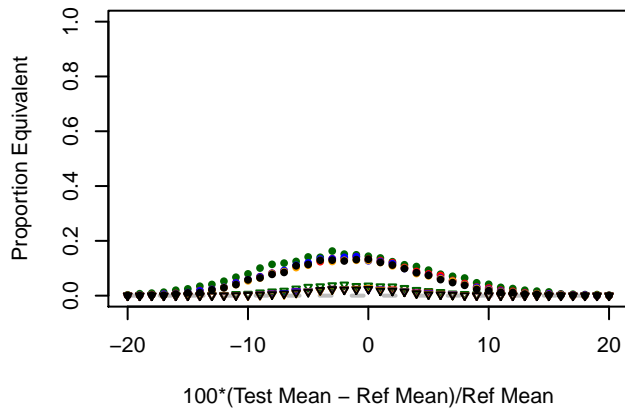
Test RSD=7



Test RSD=10

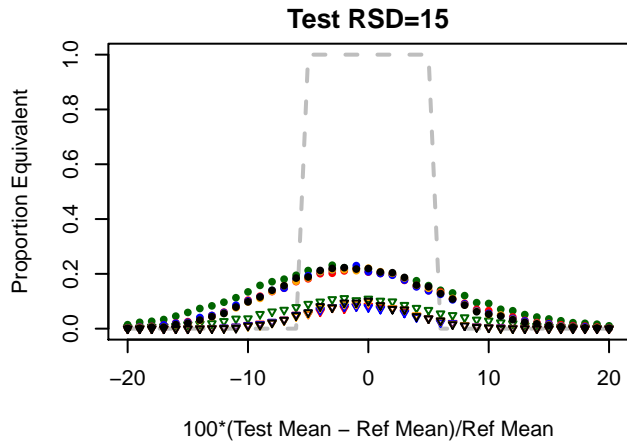
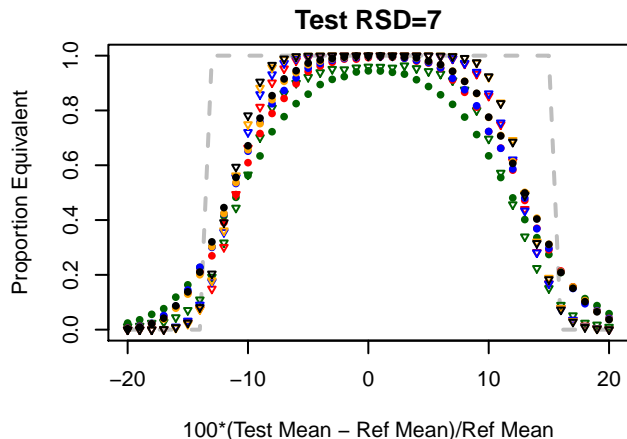
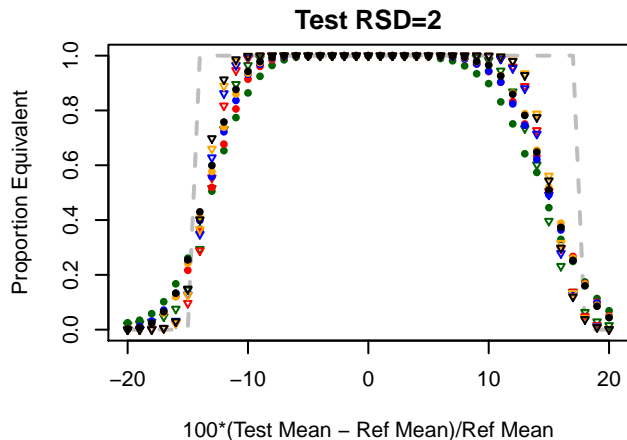
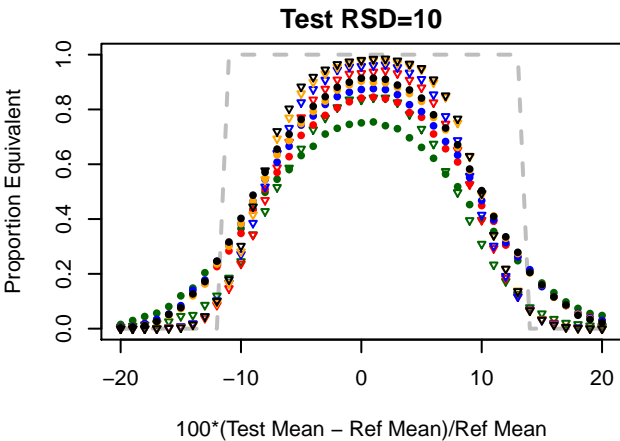
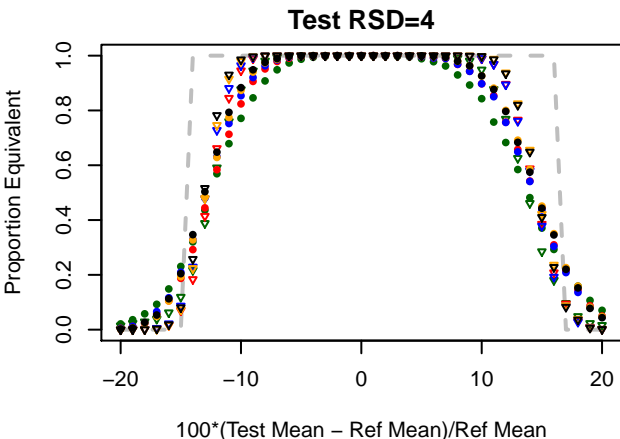


Test RSD=15



Extremes = LOW; T or R Ext = BOTH; Ref RSD = 7

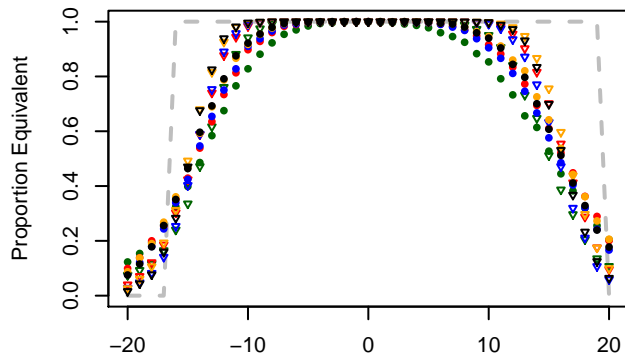
- ▽ 10% Btwn-Batch Var
- 50% Btwn-Batch Var
- 1 LS
- 2 LS, no LS effect
- 2 LS, LS effect
- 3 LS, no LS effect
- 3 LS, LS effect
- +- PBE Region



Extremes = LOW; T or R Ext = BOTH; Ref RSD = 10

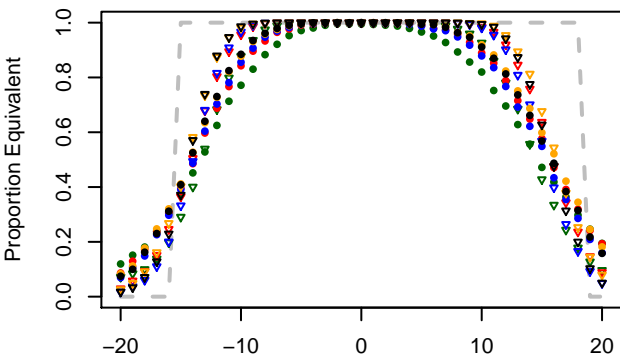
- ▽ 10% Btwn-Batch Var
- 50% Btwn-Batch Var
- 1 LS
- 2 LS, no LS effect
- 2 LS, LS effect
- 3 LS, no LS effect
- 3 LS, LS effect
- +- PBE Region

Test RSD=2



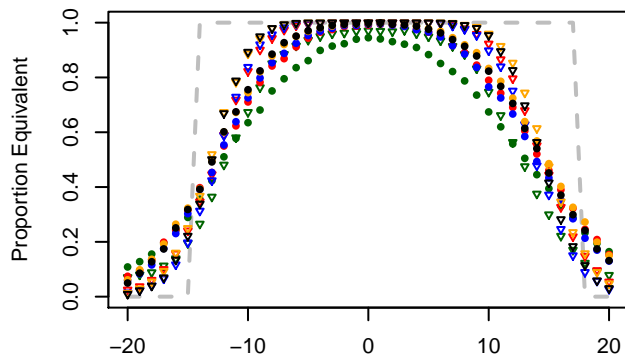
$100 \cdot (\text{Test Mean} - \text{Ref Mean}) / \text{Ref Mean}$

Test RSD=4



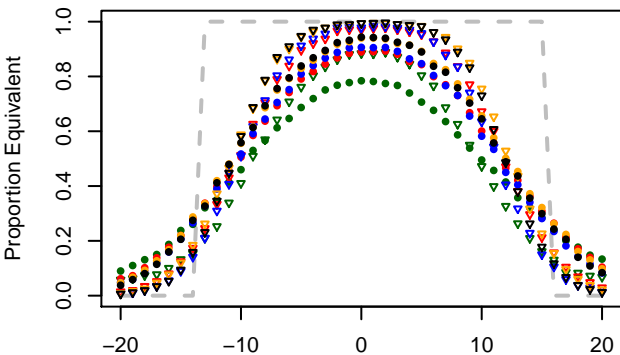
$100 \cdot (\text{Test Mean} - \text{Ref Mean}) / \text{Ref Mean}$

Test RSD=7



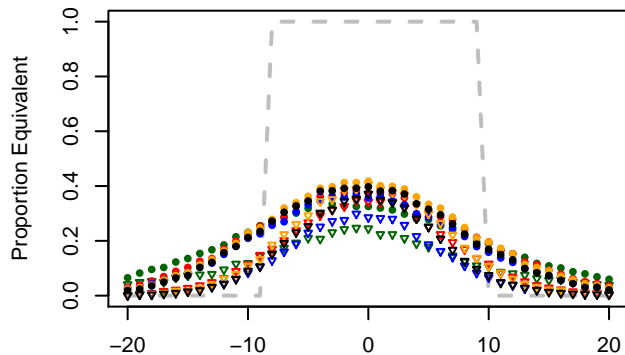
$100 \cdot (\text{Test Mean} - \text{Ref Mean}) / \text{Ref Mean}$

Test RSD=10



$100 \cdot (\text{Test Mean} - \text{Ref Mean}) / \text{Ref Mean}$

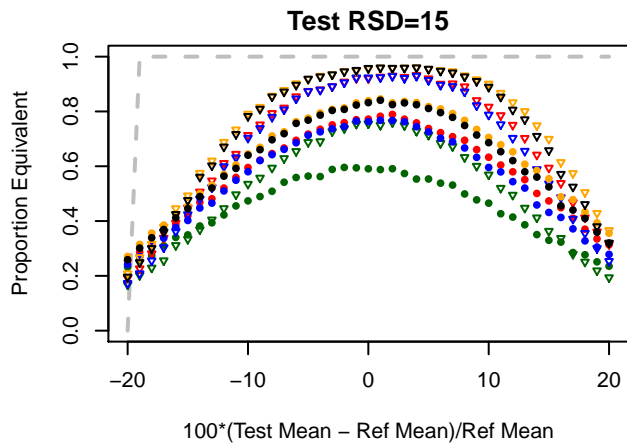
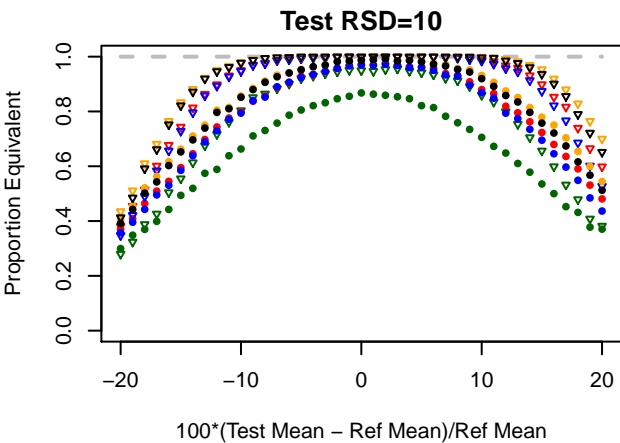
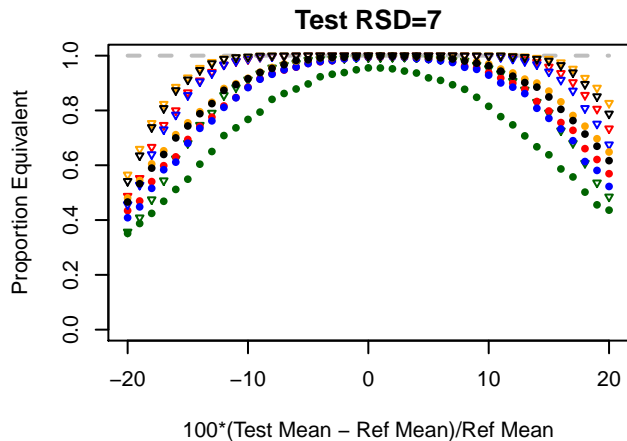
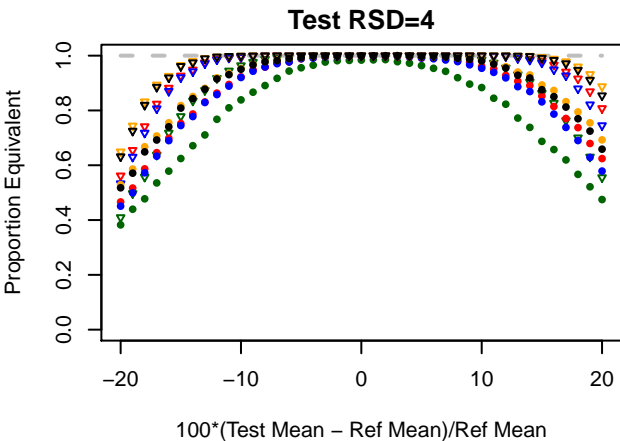
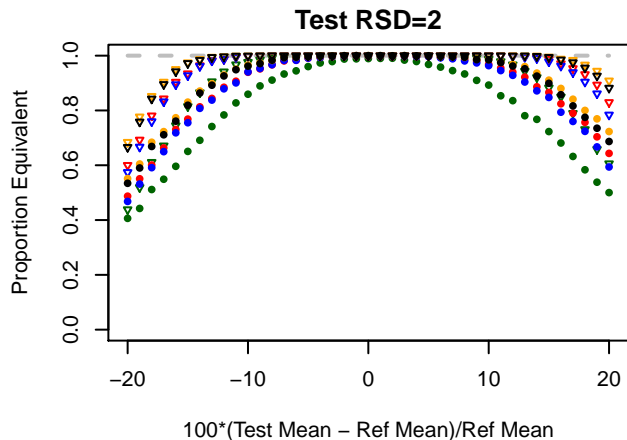
Test RSD=15



$100 \cdot (\text{Test Mean} - \text{Ref Mean}) / \text{Ref Mean}$

Extremes = LOW; T or R Ext = BOTH; Ref RSD = 15

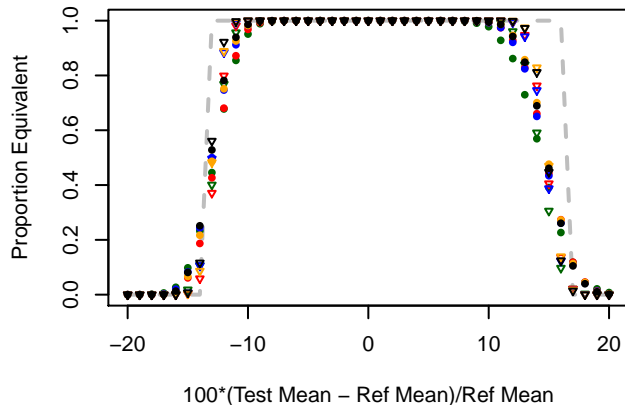
- ▽ 10% Btwn-Batch Var
- 50% Btwn-Batch Var
- 1 LS
- 2 LS, no LS effect
- 2 LS, LS effect
- 3 LS, no LS effect
- 3 LS, LS effect
- +- PBE Region



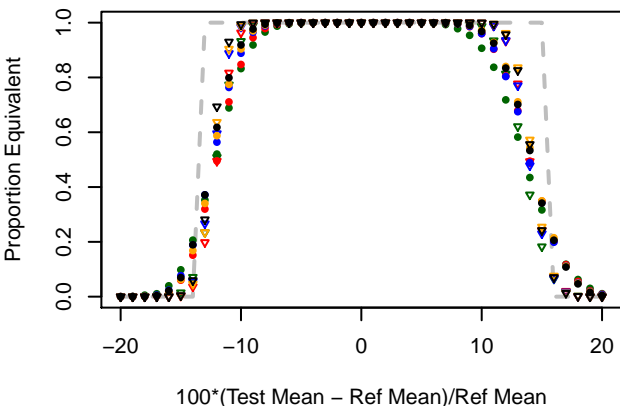
Extremes = LOW; T or R Ext = REF; Ref RSD = 4

- ▽ 10% Btwn-Batch Var
- 50% Btwn-Batch Var
- 1 LS
- 2 LS, no LS effect
- 2 LS, LS effect
- 3 LS, no LS effect
- 3 LS, LS effect
- +- PBE Region

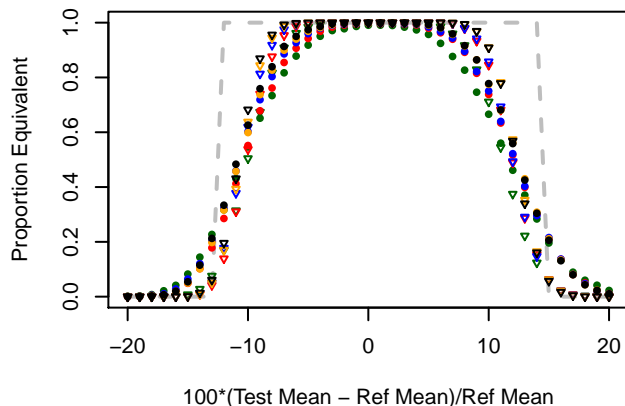
Test RSD=2



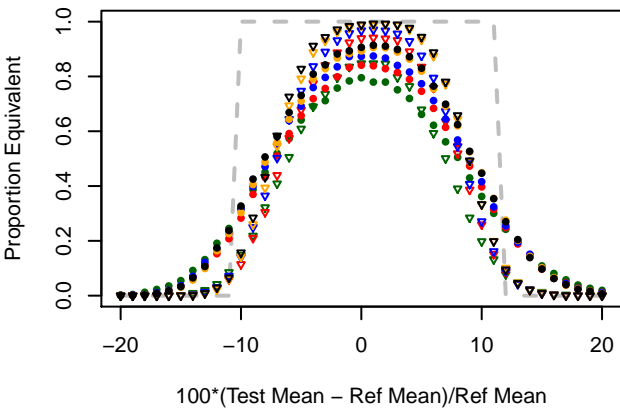
Test RSD=4



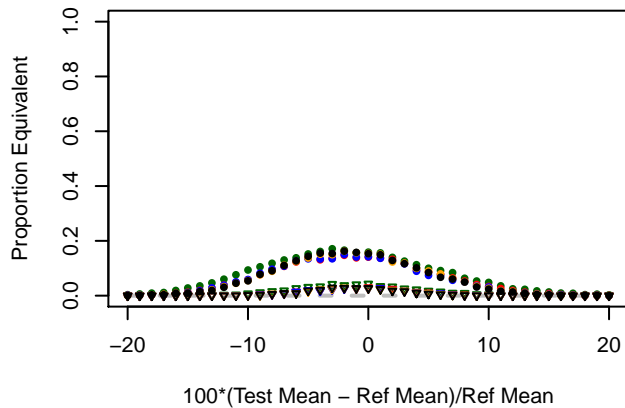
Test RSD=7



Test RSD=10

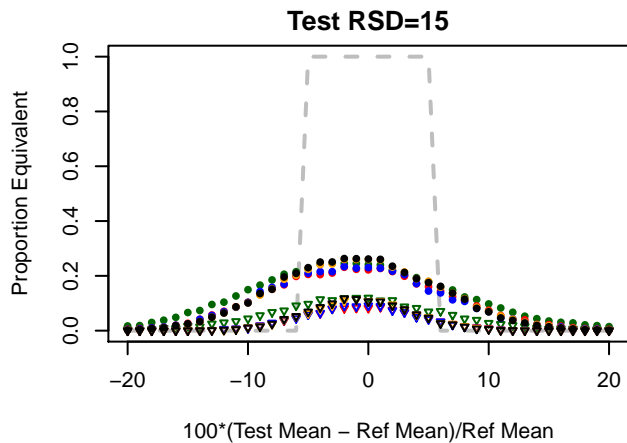
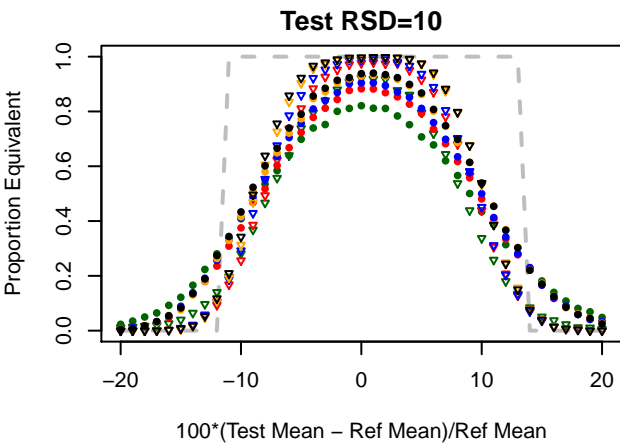
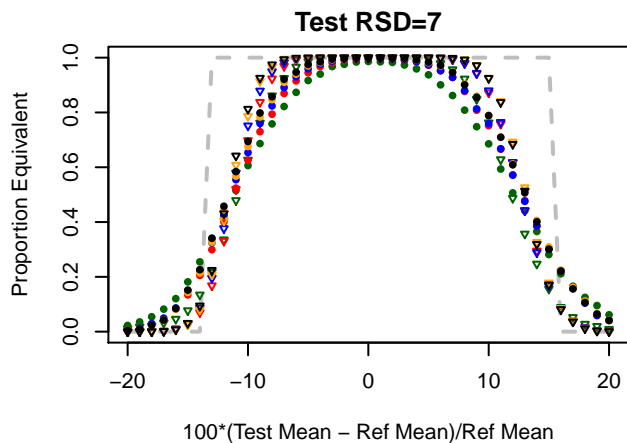
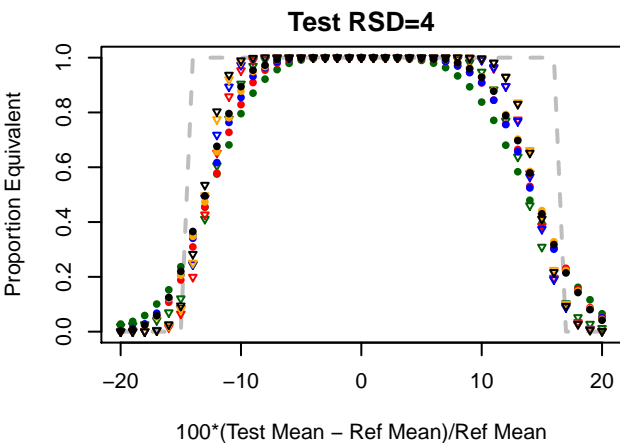
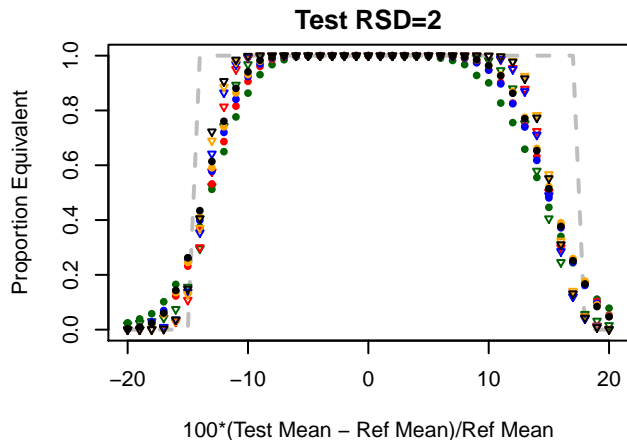


Test RSD=15



Extremes = LOW; T or R Ext = REF; Ref RSD = 7

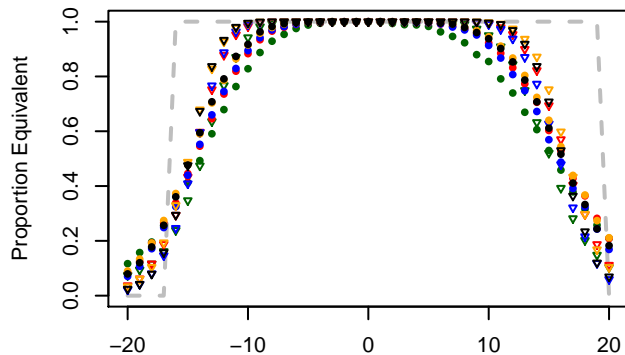
- ▽ 10% Btwn-Batch Var
- 50% Btwn-Batch Var
- 1 LS
- 2 LS, no LS effect
- 2 LS, LS effect
- 3 LS, no LS effect
- 3 LS, LS effect
- +- PBE Region



Extremes = LOW; T or R Ext = REF; Ref RSD = 10

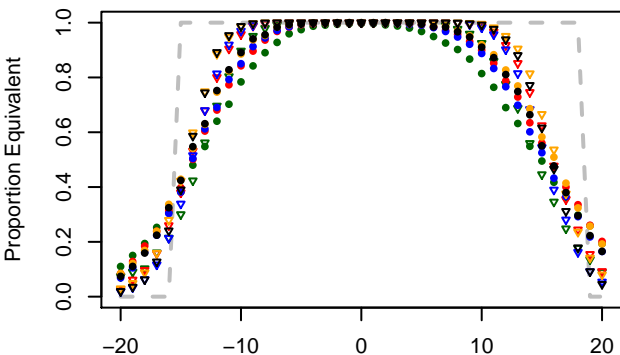
- ▽ 10% Btwn-Batch Var
- 50% Btwn-Batch Var
- 1 LS
- 2 LS, no LS effect
- 2 LS, LS effect
- 3 LS, no LS effect
- 3 LS, LS effect
- +- PBE Region

Test RSD=2



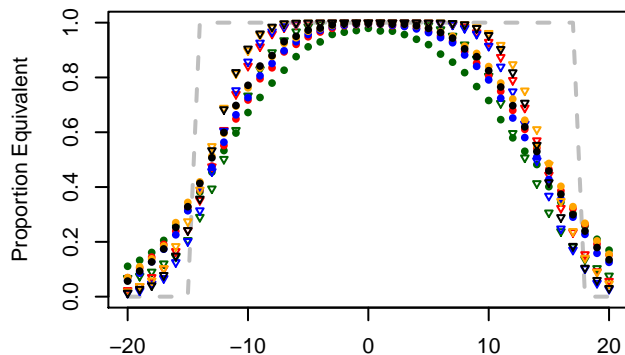
$100 \cdot (\text{Test Mean} - \text{Ref Mean}) / \text{Ref Mean}$

Test RSD=4



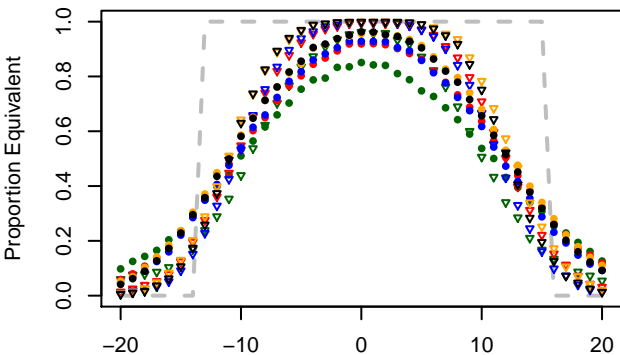
$100 \cdot (\text{Test Mean} - \text{Ref Mean}) / \text{Ref Mean}$

Test RSD=7



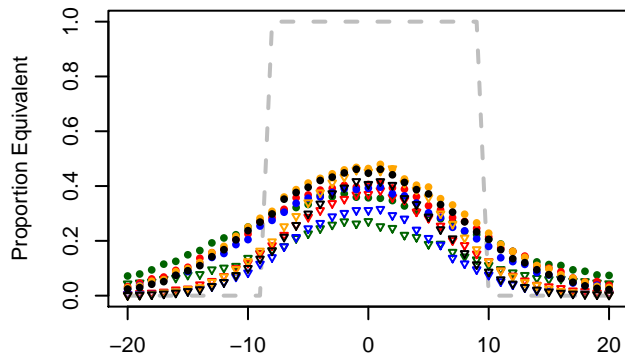
$100 \cdot (\text{Test Mean} - \text{Ref Mean}) / \text{Ref Mean}$

Test RSD=10



$100 \cdot (\text{Test Mean} - \text{Ref Mean}) / \text{Ref Mean}$

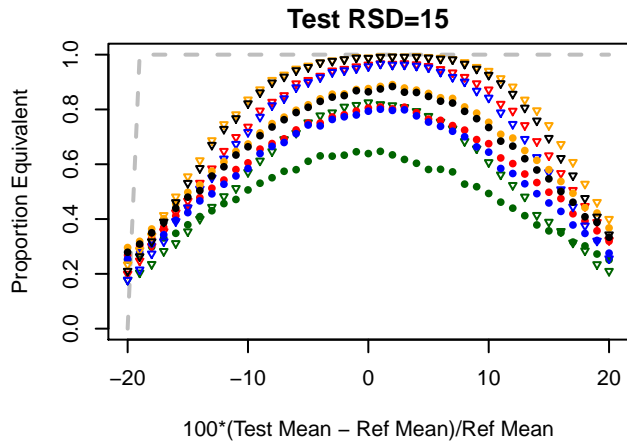
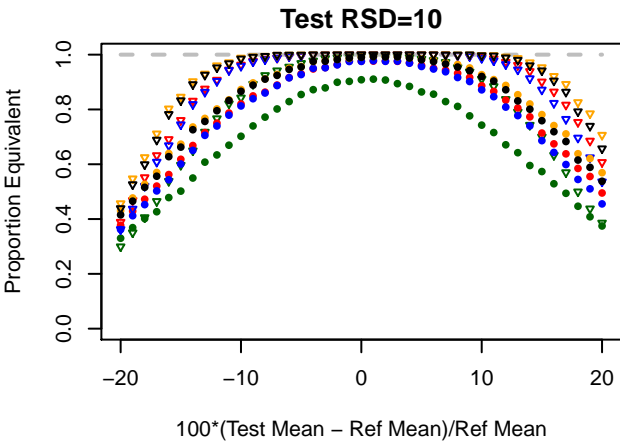
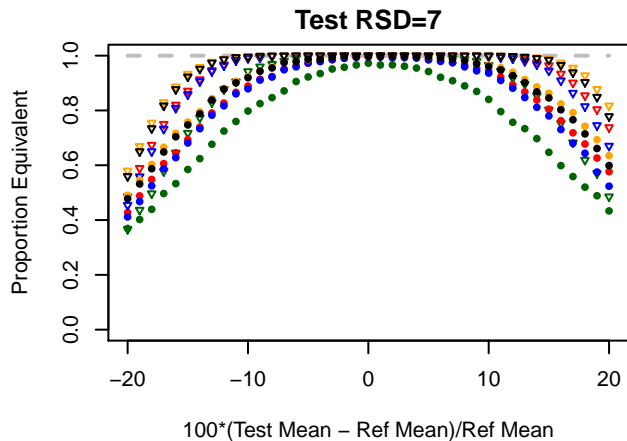
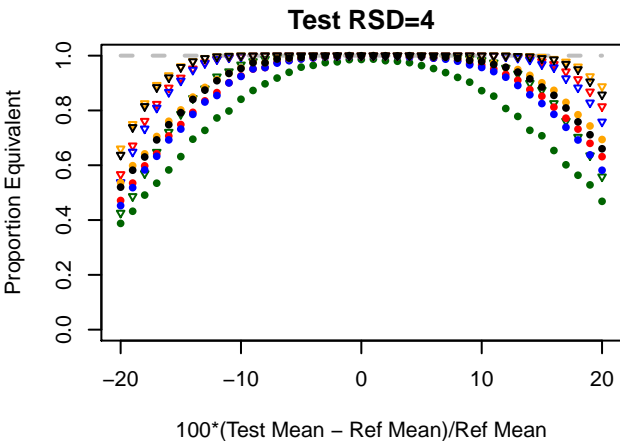
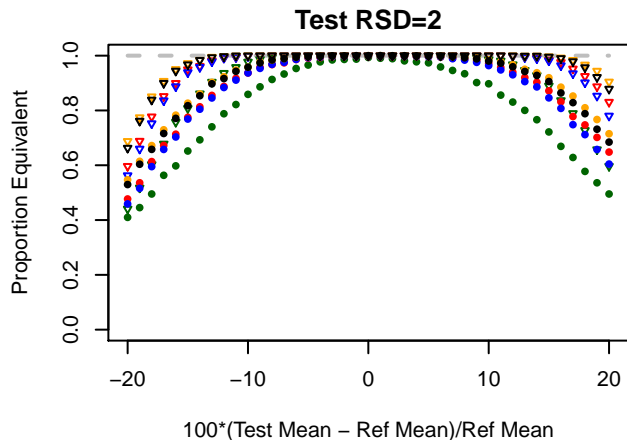
Test RSD=15



$100 \cdot (\text{Test Mean} - \text{Ref Mean}) / \text{Ref Mean}$

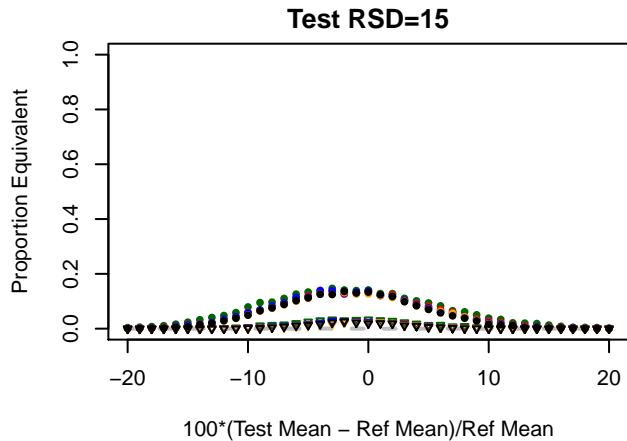
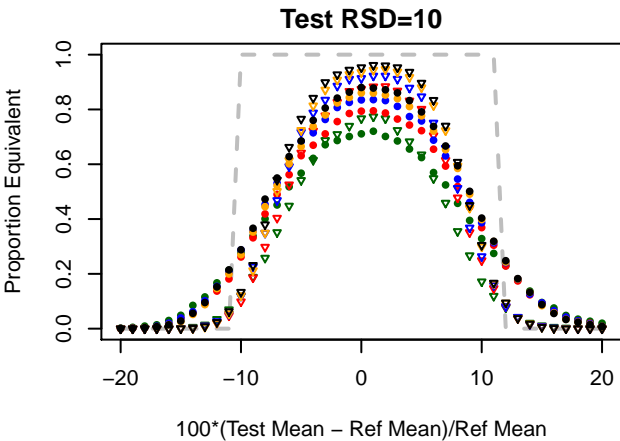
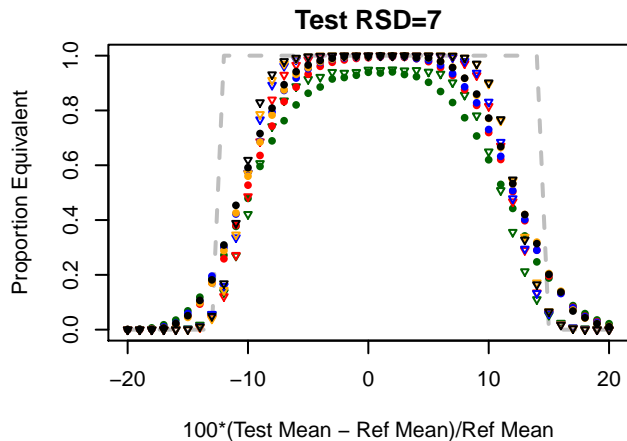
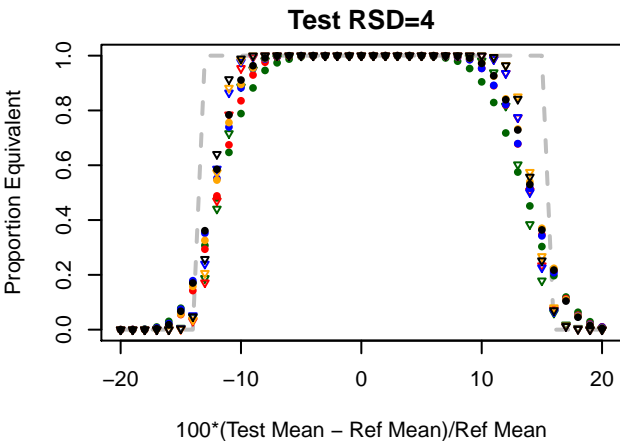
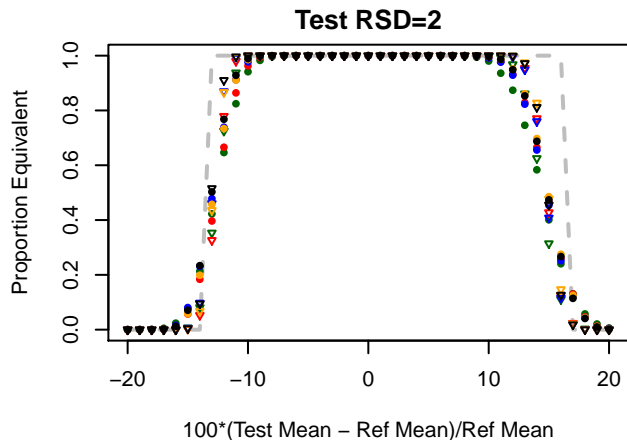
Extremes = LOW; T or R Ext = REF; Ref RSD = 15

- ▽ 10% Btwn-Batch Var
- 50% Btwn-Batch Var
- 1 LS
- 2 LS, no LS effect
- 2 LS, LS effect
- 3 LS, no LS effect
- 3 LS, LS effect
- +- PBE Region



Extremes = LOW; T or R Ext = TEST; Ref RSD = 4

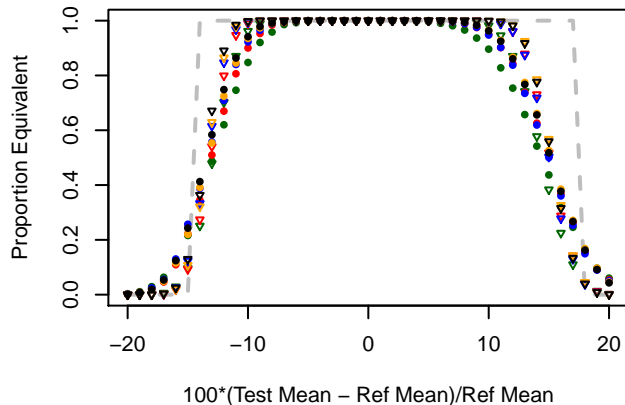
- ▽ 10% Btwn-Batch Var
- 50% Btwn-Batch Var
- 1 LS
- 2 LS, no LS effect
- 2 LS, LS effect
- 3 LS, no LS effect
- 3 LS, LS effect
- +- PBE Region



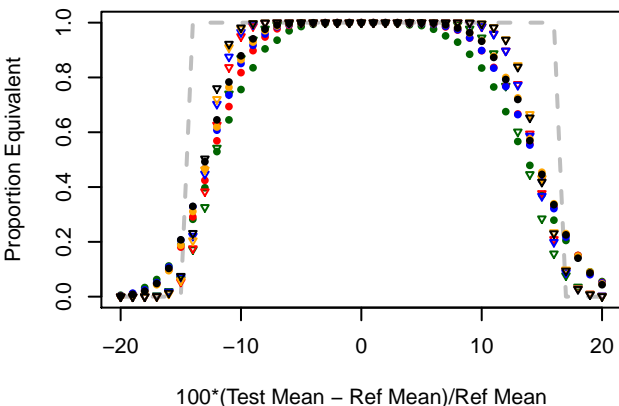
Extremes = LOW; T or R Ext = TEST; Ref RSD = 7

- ▽ 10% Btwn-Batch Var
- 50% Btwn-Batch Var
- 1 LS
- 2 LS, no LS effect
- 2 LS, LS effect
- 3 LS, no LS effect
- 3 LS, LS effect
- +- PBE Region

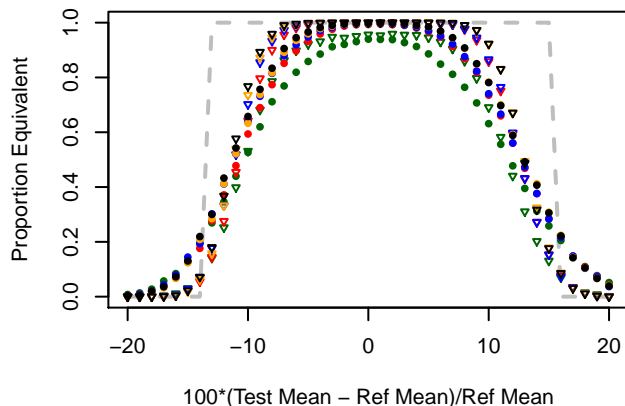
Test RSD=2



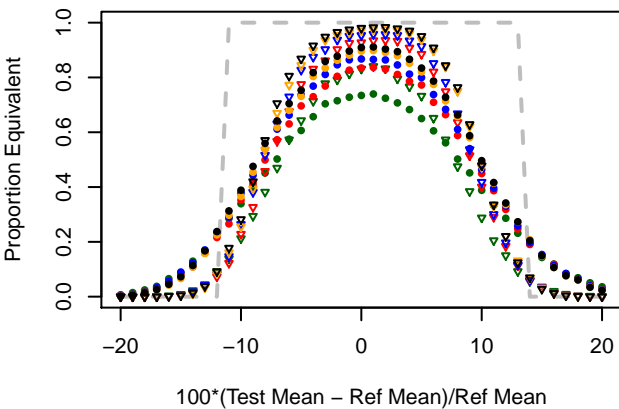
Test RSD=4



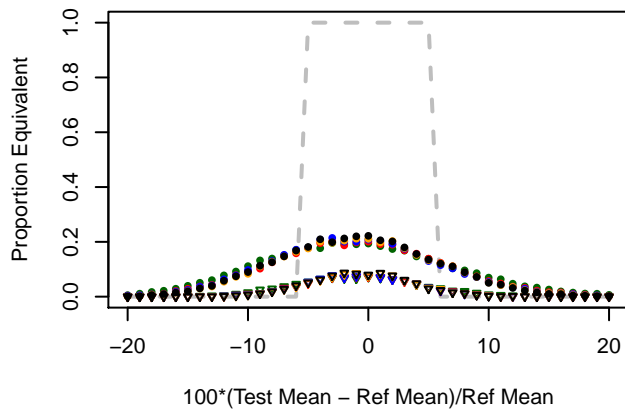
Test RSD=7



Test RSD=10

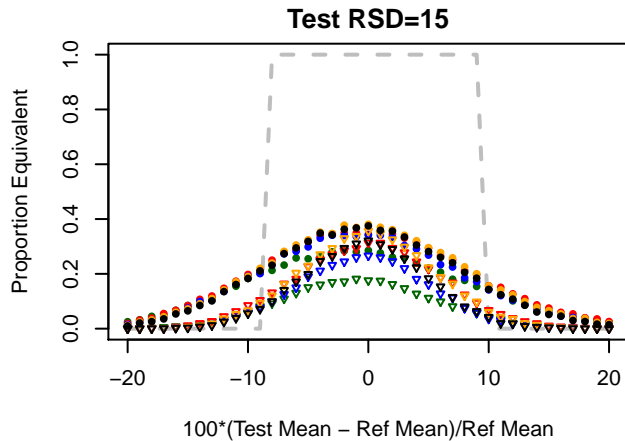
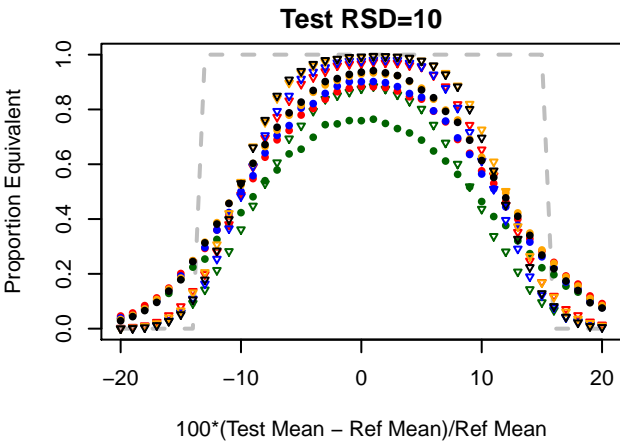
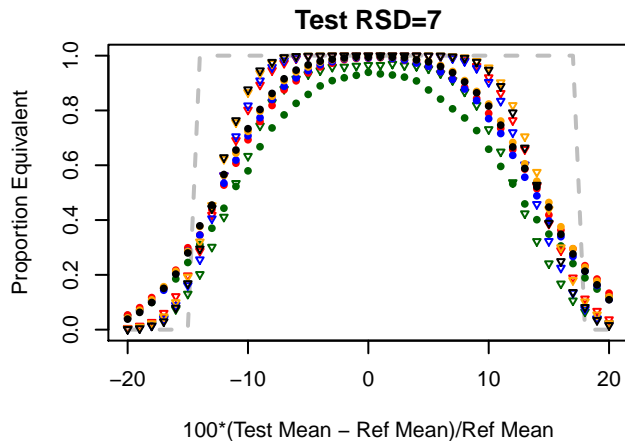
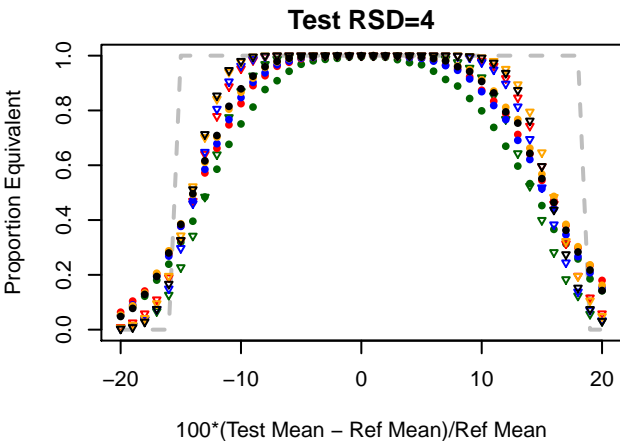
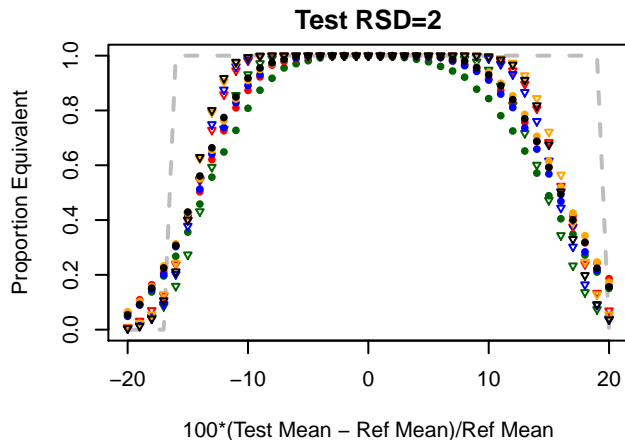


Test RSD=15



Extremes = LOW; T or R Ext = TEST; Ref RSD = 10

- ▽ 10% Btwn-Batch Var
- 50% Btwn-Batch Var
- 1 LS
- 2 LS, no LS effect
- 2 LS, LS effect
- 3 LS, no LS effect
- 3 LS, LS effect
- +- PBE Region



Extremes = LOW; T or R Ext = TEST; Ref RSD = 15

- ▽ 10% Btwn-Batch Var
- 50% Btwn-Batch Var
- 1 LS
- 2 LS, no LS effect
- 2 LS, LS effect
- 3 LS, no LS effect
- 3 LS, LS effect
- +- PBE Region

