QC of Biomarker Explorer RShiny Tool

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| --- | --- |
| **QC data set** | GS-379-1900 |
| **Path of data set** | Apollo\Development\Biometrics\Stat \PK\_Study\RshinyTool\PhaseI\_PKPD\Validation\PDplots\DataForQC |
| **Path of Rshiny\_output files** | Apollo\Development\Biometrics\Stat \PK\_Study\RshinyTool\PhaseI\_PKPD\Validation\PDplots\Rshiny\_output |
| **Path of QC output files** | Apollo\Development\Biometrics\Stat \PK\_Study\RshinyTool\PhaseI\_PKPD\Validation\PDplots |

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|  | **Data set** | **Test tab** | **Function** | **Parameter selected** | **Rshiny Output** | **QC output file** | **QC Result** | **Comment** |
| 1 | Biom\_univ.xls | Import Data | data import | NA | NA | NA | Pass |  |
| 2 | Biom\_univ.xls | Subject-level PKPD | summary table | % Baseline of CD63+ Cells FlowCast FCERI |  | PD\_univ\_summary.csv | Pass |  |
| 3 | Biom\_univ.xls | Subject-level PKPD | Boxplot | CD63+, % inhibition FlowCast FCERI |  | PD\_univ\_plot.pdf | Pass |  |
| 4 | Biom\_univ.xls | Subject-level PKPD | Summary line plot | CD63+, % inhibition FlowCast FCERI |  | PD\_univ\_plot.pdf | Pass |  |
| 5 | Biom\_univ.xls | Subject-level PKPD | PD-PD scatter plot | % Baseline of CD63+ Cells FlowCast FCERI vs CD63+, % inhibition FlowCast FCERI |  | PD\_univ\_plot.pdf | Pass |  |
| 6 | Biom\_univ.xls | Subject-level PKPD | 2D forest plot | % Baseline of CD63+ Cells FlowCast FCERI vs CD63+, % inhibition FlowCast FCERI |  | PD\_univ\_plot.pdf | Pass |  |
| 7 | Biom\_univ.xls | Subject-level PKPD | PD-PD forest plot | % Baseline of CD63+ Cells FlowCast FCERI vs CD63+, % inhibition FlowCast FCERI |  | PD\_univ\_plot.pdf | Pass |  |
| 8 | Biom\_univ.xls, PK\_param\_univ | Import Data | Merged PK-PD data | Merge | NA | NA | Pass |  |
| 9 | Biom\_univ.xls, PK\_param\_univ | Subject-level PKPD import data | PK-PD scatter plot | CD63+, % inhibition FlowCast FCERI vs Cmax, group by cohort | PK-PD scatter plot | PK\_PD\_subjectlevel.pdf | Pass |  |
| 10 | Biom\_univ.xls, PK\_param\_univ | Subject-level PKPD import data | PK-PD Forest plot | CD63+, % inhibition FlowCast FCERI vs Cmax, group by cohort |  | PK\_PD\_subjectlevel.pdf | Pass |  |
| 11 | Biom\_univ.xls, PK\_param\_univ | Subject-level PKPD import data | PK-PD 2D Forest plot | CD63+, % inhibition FlowCast FCERI vs Cmax, group by cohort |  | PK\_PD\_subjectlevel.pdf | Pass |  |
| 12 | Biom.xls | import data | data import | NA | NA | NA | Pass |  |
| 13 | Biom\_all.xls | Sample-level PKPD import data | summary | CT\_BASO\_FlowCastFCERI\_FcERI\_A and visit=1 | summary | Biom\_all\_summary.csv | Pass |  |
| 14 | Biom.xls | Sample-level PD analysis | Summary line plot | PD time profile: CD63+, % inhibition FlowCast FCERI by timepoint at Visit7 |  | PD\_Biom\_plot | Pass |  |
| 14.1 | Biom.xls | Sample-level PD analysis | Individual line plot | PD time profile: CD63+, % inhibition FlowCast FCERI by timepoint at Visit7 |  | PD\_Biom\_plot | Pass |  |
| 15 | Biom.xls | Sample-level PD analysis | Summary line plot | PD correlation: CD63+, % inhibition FlowCast FCERI (log) and % Baseline of CD63+ Cells FlowCast FMLP by timepoint at Visit7 |  | PD\_Biom\_plot | Pass |  |
| 16 | Biom.xls | Sample-level PD | Scatter plot | PD correlation: CD63+, % inhibition FlowCast FCERI and % Baseline of CD63+ Cells FlowCast FMLP by timepoint at Visit7 | Scatter plot | PD\_Biom\_plot | Pass |  |
| 17 | Biom.xls,PK\_param | Sample-level Import Data | Summary table | Merge by visit only | NA | NA | No | No text explanation for “merge by” |
| 18 | Biom.xls,PK\_param | Sample-level PKPD analysis | Summary line | CD63+, % inhibition FlowCast FCERI and Tmax vs visit |  | PK\_PD\_para\_byvisit.pdf | Pass |  |
| 19 | Biom.xls,PK\_param | Sample-level PKPD analysis | Scatter plot | CD63+, % inhibition FlowCast FCERI vs Tmax |  | PK\_PD\_para\_byvisit.pdf | Pass |  |
| 19.1 | Biom.xls,PK\_param | Sample-level PKPD analysis | Quartile plot | Merge by visit and timepoint: CD63+, % inhibition FlowCast FCERI vs Cmax |  |  | No | No text for “add line”. |
| 20 | Biom.xls,PK\_Conc.xls | Import Data |  | by visit and timepoint | NA | NA | No | No text explanation for “merge by” |
| 21 | Biom.xls,PK\_Conc.xls | Sample-level PKPD analysis | Scatter plot | Merge by visit and timepoint: CD63+, % inhibition FlowCast FCERI vs concentration |  | PK\_PD\_conc\_byVisitTimepoint.pdf | Pass |  |
| 22 | Biom.xls,PK\_Conc.xls | Sample-level PKPD analysis | Summary line | Merge by visit and timepoint: CD63+, % inhibition FlowCast FCERI vs concentration |  | PK\_PD\_conc\_byVisitTimepoint.pdf | Pass |  |
| 23 | Biom.xls,PK\_Conc.xls | Import Data |  | by visit only | NA | NA | Pass |  |
| 24 | Biom.xls,PK\_Conc.xls | Sample-level PKPD analysis | Scatter plot | Merge by visit only: CD63+, % inhibition FlowCast FCERI vs concentration |  | PK\_PD\_splevel\_byVisitonly.pdf | Pass |  |
| 25 | Biom.xls,PK\_Conc.xls | Sample-level PKPD analysis | Summary line | Merge by visit only: CD63+, % inhibition FlowCast FCERI vs concentration |  | PK\_PD\_splevel\_byVisitonly.pdf | Pass |  |
| 26 | PK\_Param\_Univ.xls | Subject-level PKPD analysis | Plot, estimates, and prediction | Dose proportionality, Cmax |  | Dose\_proportion.pdf | Pass |  |
| 27 | Lab\_1900.csv | Lab and AE safety analysis | Summary table | ALB |  |  |  |  |