

Normal Distribution Method vs Nonparametric/Poisson Method

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1. Traditional Stability and Capability JMP Outputs for DAR of Equipment A

Figure 1: XBar Control Chart for DAR with OOC at Cleaning Event 2 (Assume Normal Distribution for the Mean DAR)

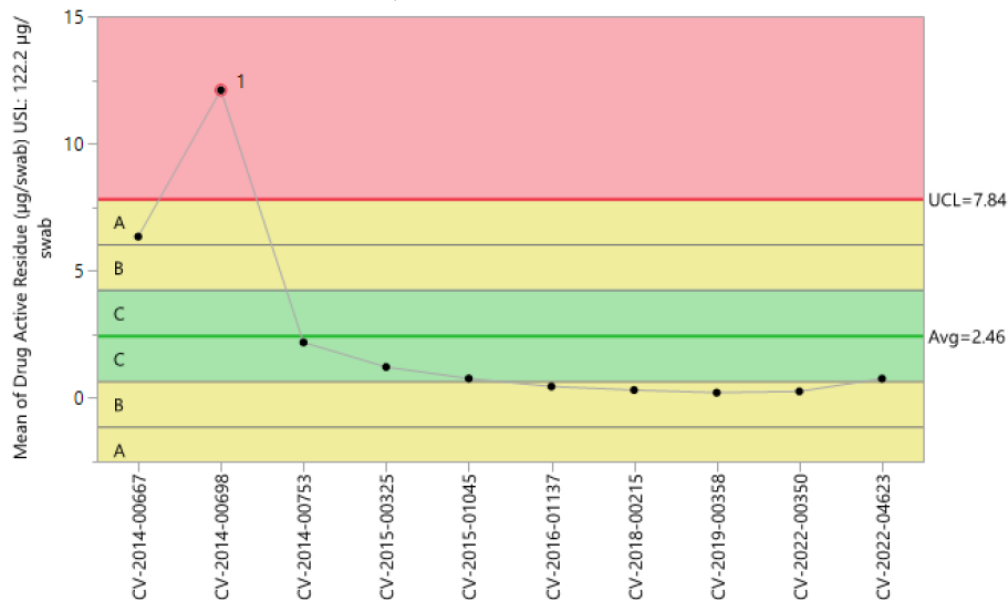
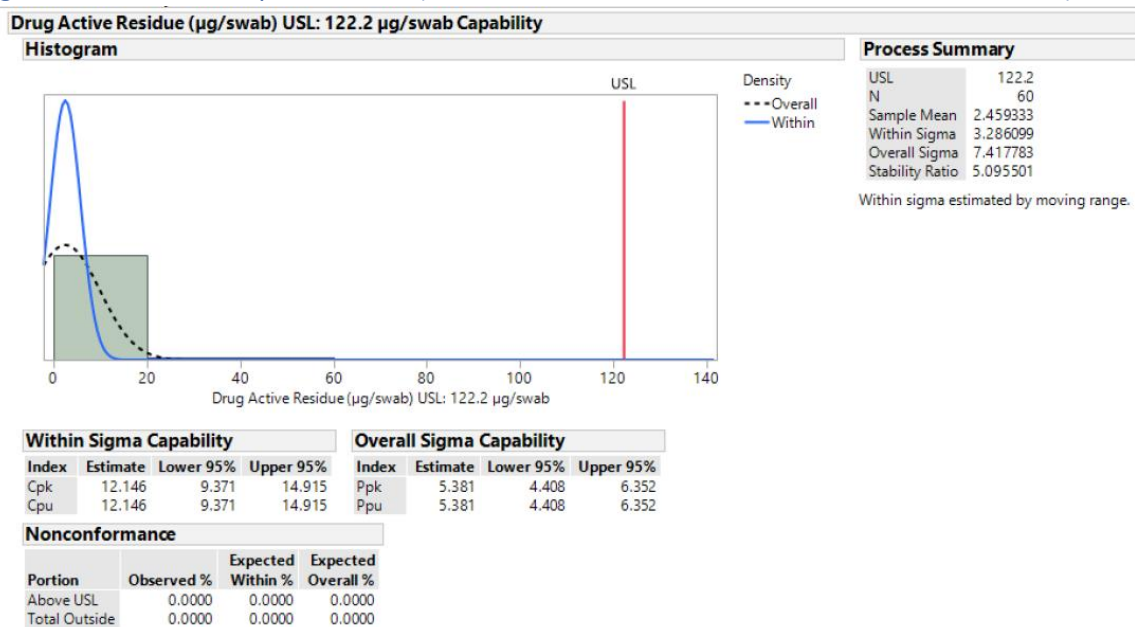


Figure 2: DAR with Cpu=12.146 (Assume Normal Distribution of individual DAR)



Comment: A very high Cpu=12.146 is contradict with mean OOC in XBar control Chart for Equipment A DAR.

2. Nonparametric Stability and Capability R Outputs for DAR of Equipment A

Figure 3: Nonparametric Method with KDE Determined UCL without OOC

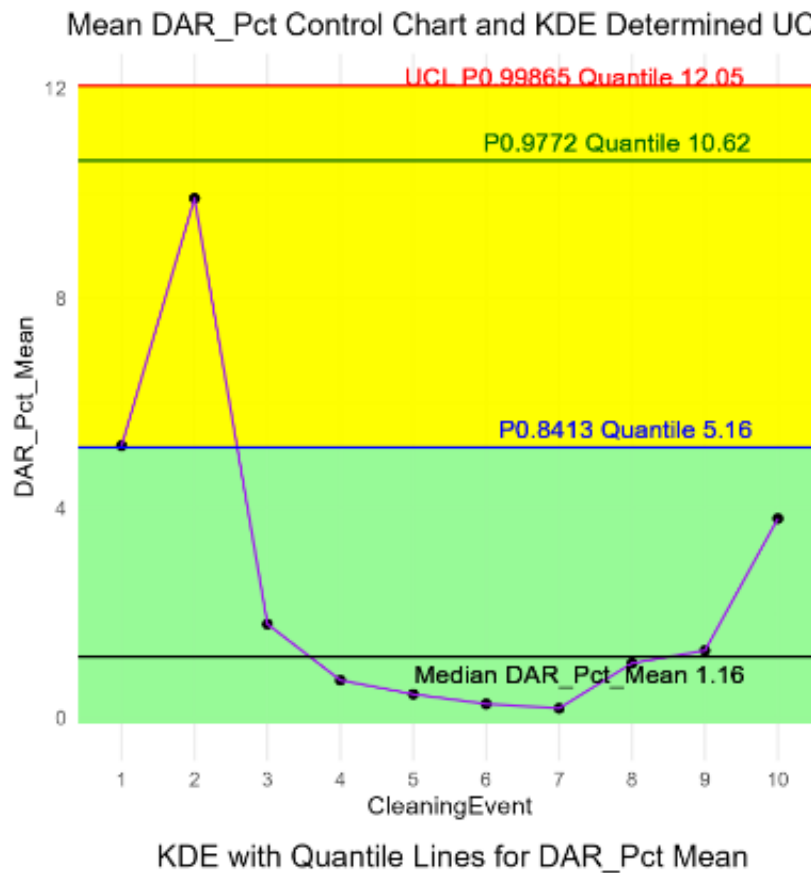


Figure 4: Nonparametric Capability Index Ppu by KDE and 1000 Bootstrap CI

Nonparametric Capability Index Ppu by KDE and Bootstrap Method

Estimate	Lower_CI	Upper_CI
2.783	2.709	21.42

Comment: A high Ppu=2.783 is consistent with mean control chart which has no mean OOC for Equipment A DAR.

3. Traditional Stability and Capability JMP Outputs for CAR of Equipment A

Figure 5: XBar Control Chart for CAR with OOC at Cleaning Event 2 (Assume Normal Distribution for the Mean CAR)

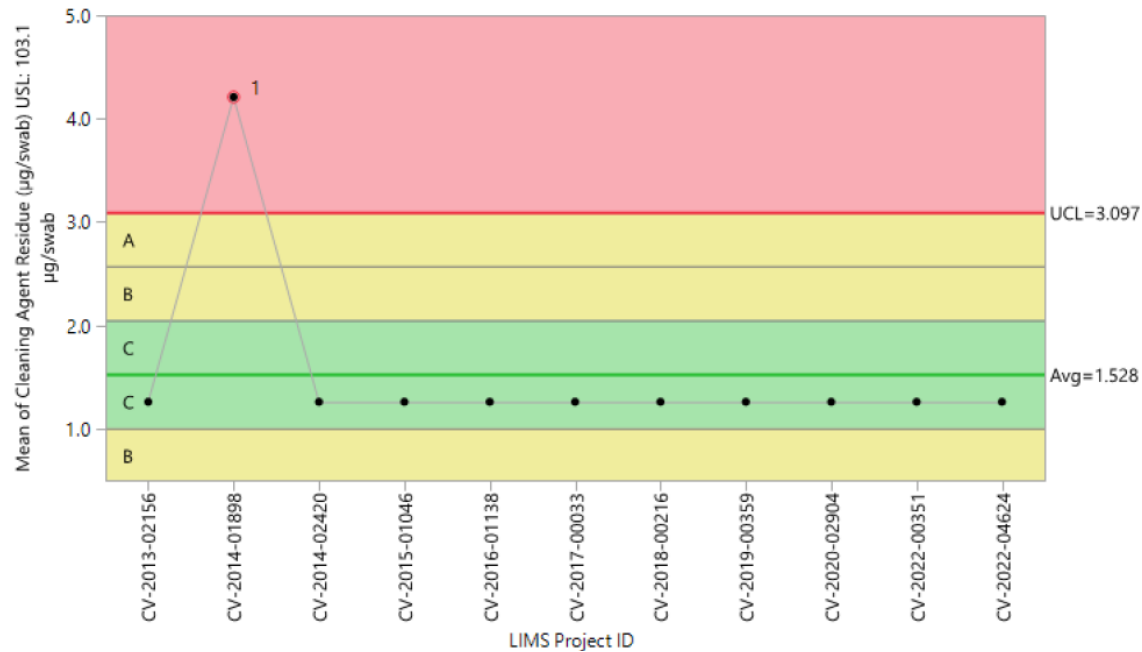
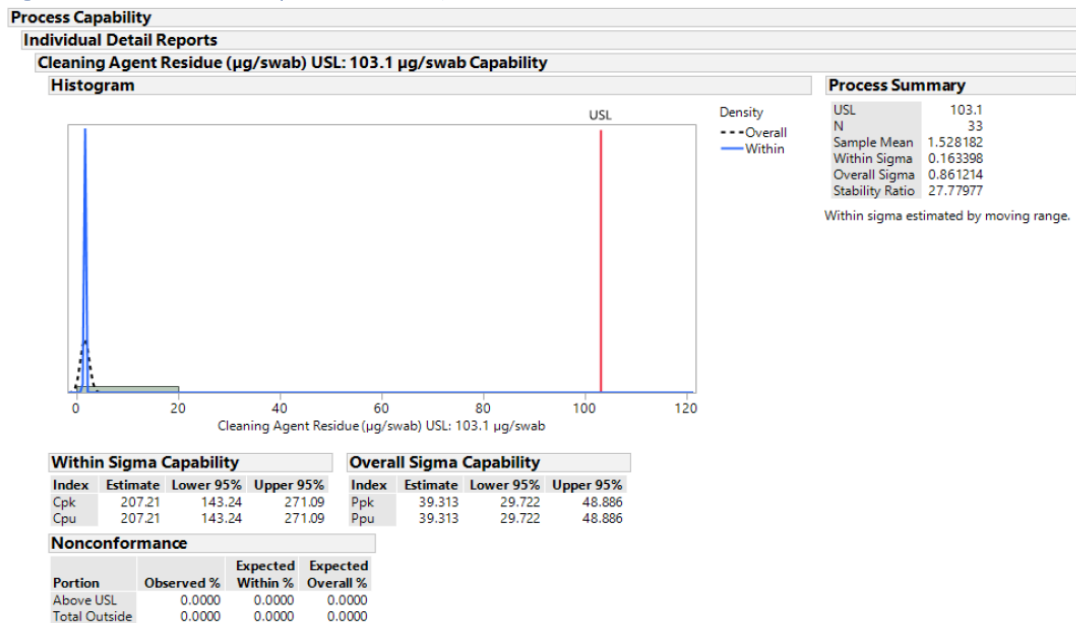


Figure 6: CAR with Cpu=20.721 (Assume Normal Distribution of individual CAR)



Comment: A very high Cpu=207.21 is contradict with mean OOC in XBar control Chart for Equipment A CAR.

4. Nonparametric Stability and Capability R Outputs for CAR of Equipment A

Figure 7: Nonparametric Method with KDE Determined UCL without OOC

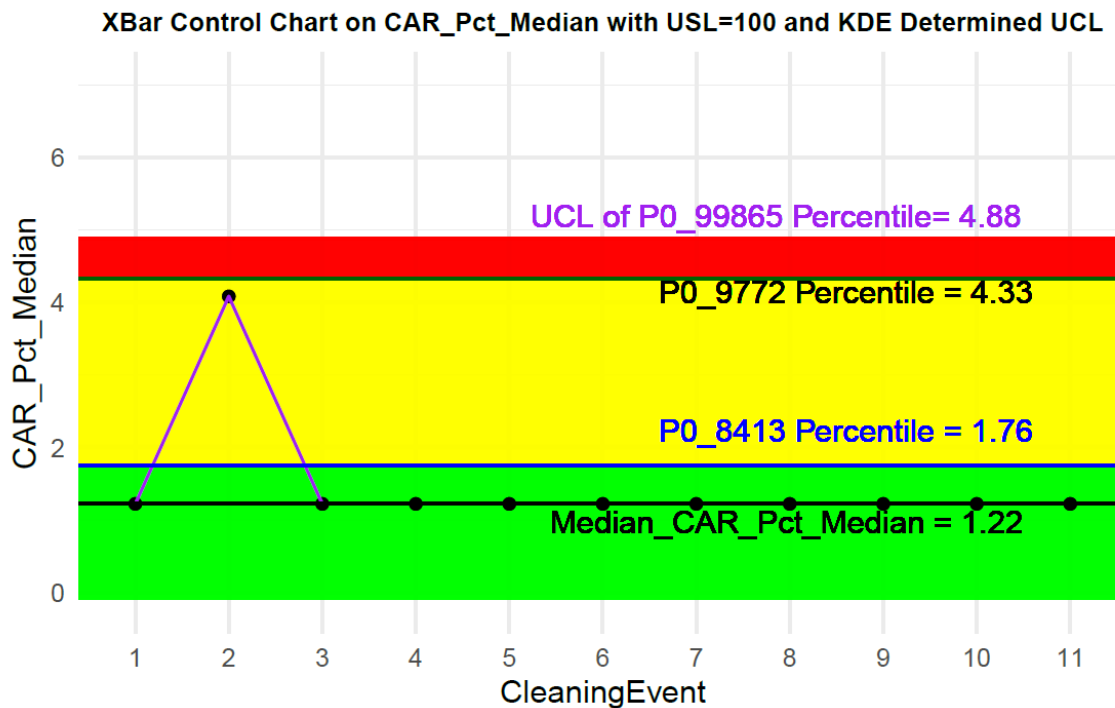


Figure 8: Nonparametric Capability Index Ppu by KDE and Bootstrap Method

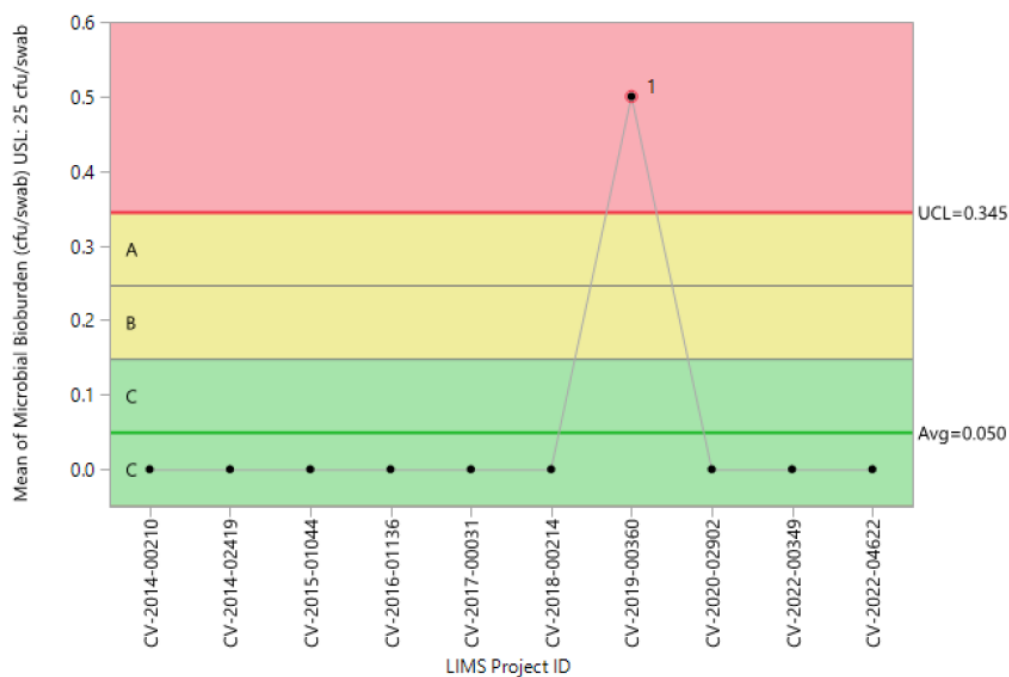
CAR_Pct Ppu with 95% CI by Bootstrap 1000 Times with KDE

Estimate	Lower_CI	Upper_CI
27.316	24.855	64.845

Comment: A high Cpu=27.316 consistent with nonparametric control chart without OOC.

5. Traditional Stability and Capability JMP Outputs for Mic of Equipment A

Figure 9: XBar Control Chart for Mic with OOC at Cleaning Event 7 (Assume Normal Distribution for the Mean Mic)



Comment: Mic data quality is good (only 1 cfu/swab for Event 7) but still has a mean OOC in the XBar Control Chart. Mic data does not have Cpu or Ppu since JMP does not provide it for count data.

6. Poisson Stability and Capability R Outputs for Mic of Equipment A

Figure 10: u Chart for Mic without OOC (Tested Poisson Distribution for Mic)

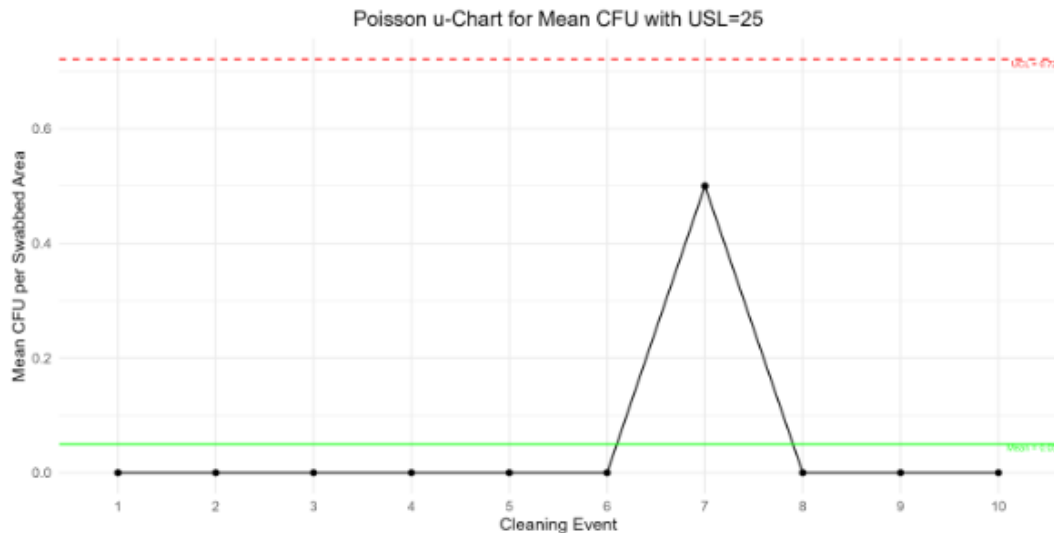


Figure 11: Mic Poisson Capability Index Ppu

Method	Ppu	CI_Lower	CI_Upper
Q-Binomial	100.000	NA	NA
Q-Poisson	100.000	3.044	100.000
Anscombe	4.590	2.980	4.590
Freeman	3.333	3.100	3.366
KDE	20.766	18.099	20.766
Min	3.333	3.100	3.366

Comment: A Ppu=3.333 is consistent with the stable u Chart.