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Supplemental Information

A Rapid and Sensitive Nucleic Acid Amplification Technique for *Mycoplasma* Screening of Cell Therapy Products

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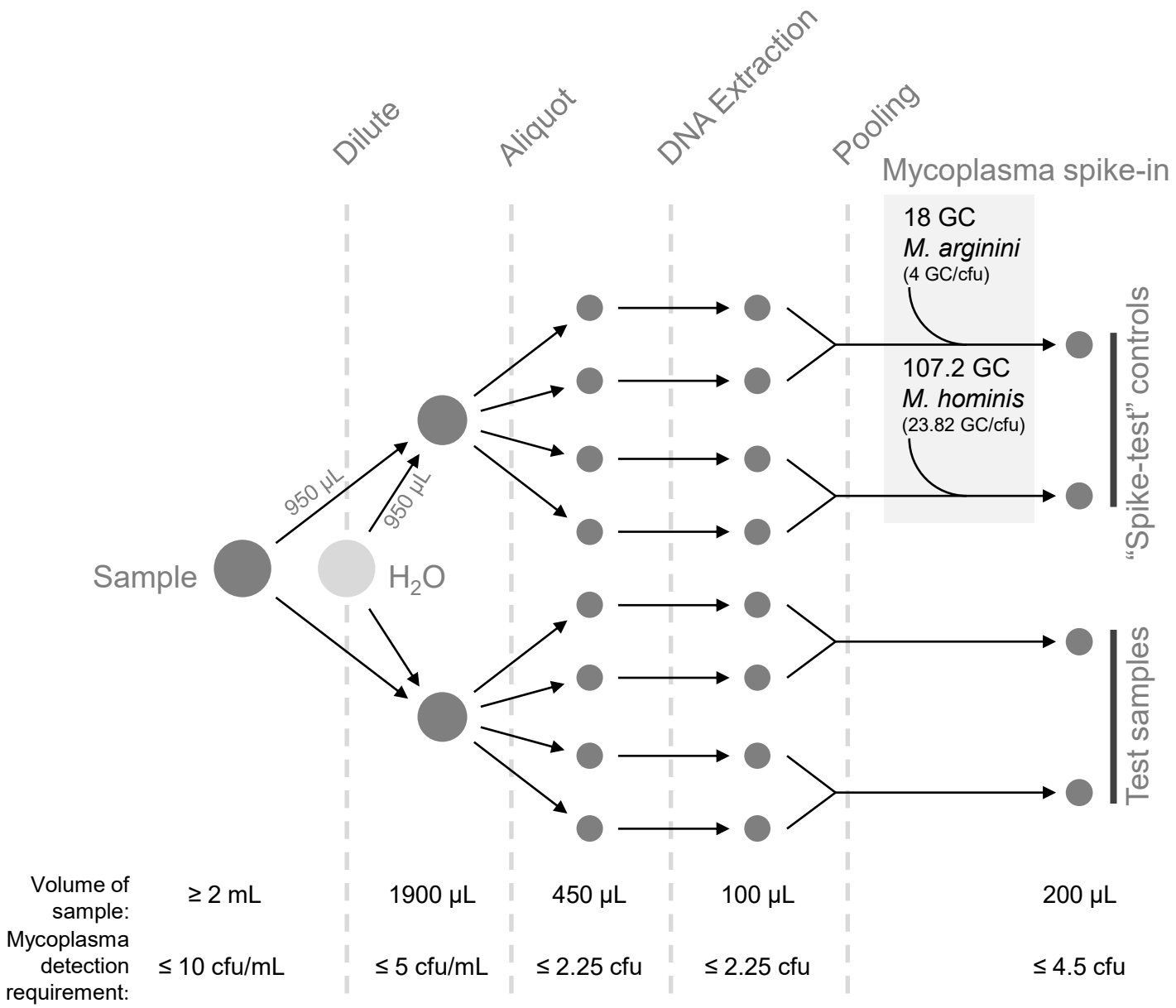

Figure S1: High cell density sample processing. This simplified schematic summarizes the steps involved in processing samples using the High cell Density DNA prep protocol (> 5 x 10^6 - 1 x 10^8 total cells/mL). Cell samples are diluted one half and split to eight 450 µL aliquots. Each of the aliquots is processed to generate DNA that is resuspended in 95 µL buffer. Samples are then pooled in pairs to generate four final samples in 190 µL volume. 10 µL EB (test samples) or 10 µL diluted gDNA ("spike-test" controls) is added to each vial to bring final volume to 200 µL. *M. arginini* (18 GC in 10 µL) or *M. hominis* (107.2 GC in 10 µL) gDNA is added to each of the "spike-test" control samples to test the 10 cfu/mL detection requirement.

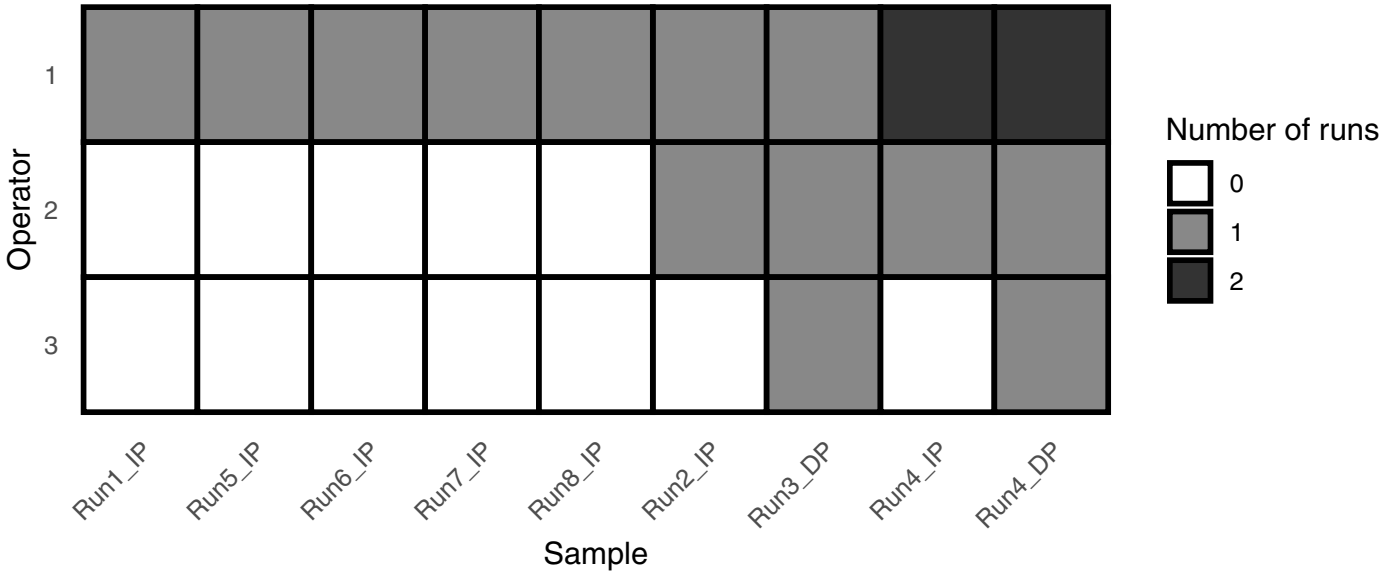

Figure S2: Manufacturing run samples tested during *Mycoplasma* Detection Assay qualification. Nine In Process (IP) and Drug Product (DP) samples from eight CAR-T production runs were tested between one and four times each for a total of seventeen rounds of testing.

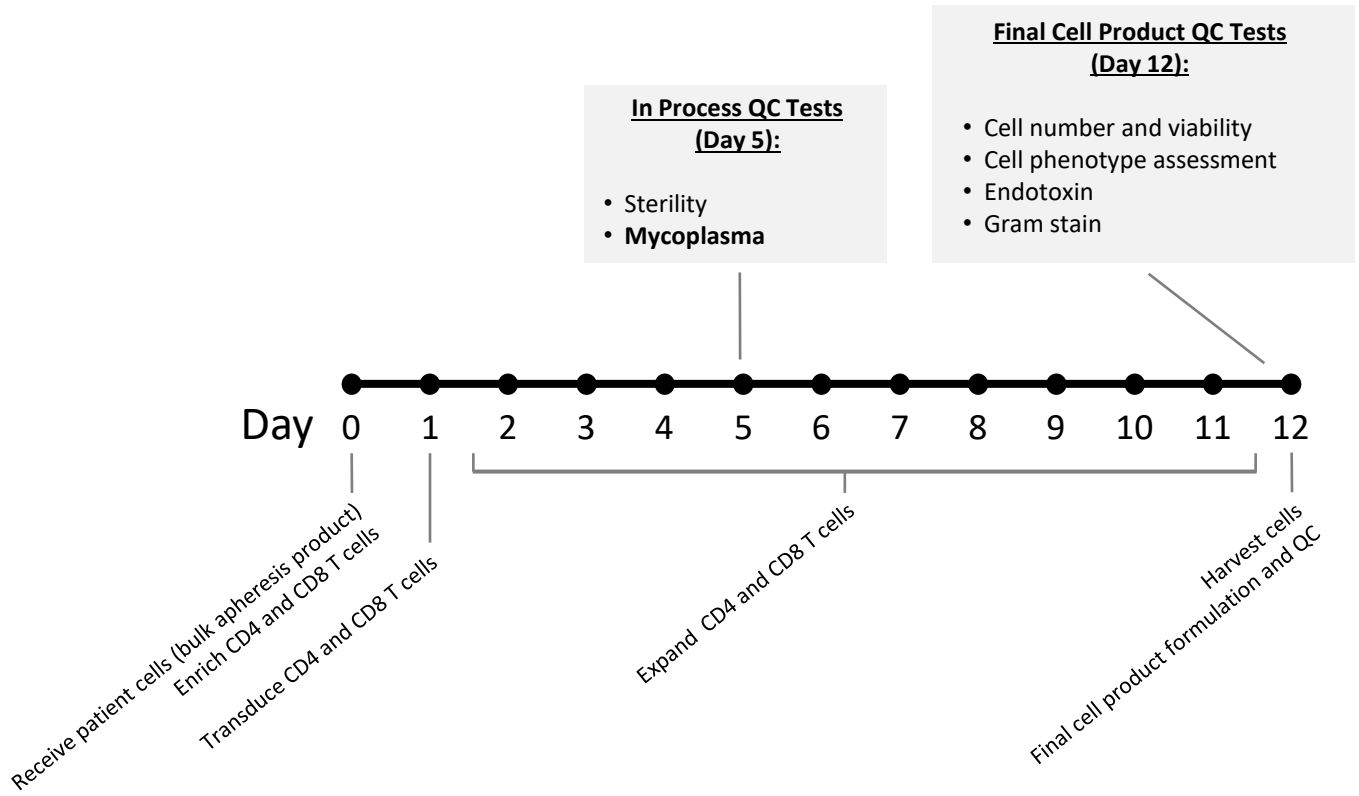

Figure S3: CAR-T manufacturing and QC process. Samples are removed from the culture at day 5 of the manufacturing process and assessed for Sterility (BacT Alert-in process test) and *Mycoplasma* (PCR). Samples from the final cell product are assessed for cell number and viability (Trypan Blue), phenotype (flow cytometry), endotoxin (Limulus amebocyte lysate) and Gram positive microorganisms (Gram stain).