ARMWG Titer Analysis

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Lab to lab variability not useful.

- The appropriateness of pooling: These data were not tested data point by data point for
  - Statistical sampling variability is not as great.
  - Pooled the raw data across dilutions then calculate
    - Locks in statistical sampling variability.
    - Calculated values across dilutions then take an
      - Average of averages

Statistical Analysis - taking the
What does infectious titer mean? • Infections Titer - Now What? Determined the ARMYC-50P
be demonstrated.

Scalability from one assay to another needs to

- L.U. From different assays are not the same.

C-Flow Cytometry Stability Study
B-ARMWG SOP 20% Confluence
A-ARMWG SOP 80% Confluence

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ARMWG 001503 Titer
The Material Is the Reference
C. For determining the absence of contamination of RCA.
   B. For measuring product-specific infectivity.
   A. For routine testing and for test method validation.

Guidance for sponsors on how to use the reference material:
A subgroup of ARMEG should be formed, including FDA, to draft
"Serotype 5:"
particle concentration 5.8 x 10^11 particles/ml of Infective Adenovirus
The "label concentration" for the ARM be solely based on the assigned
ARMEG.

any particular statistical method should be distributed or endorsed by the
No standardized spread sheet or other application for calculating tiers by
should be recommended as the best estimation method.
be provided using fan Callahan’s Pooled Estimaters. Maximum Likelihood
The infectious titer measured by Laboratories performing the ARMEG SOP