

Statistical committee - GMO task force  
**STA GMO TF**

# **Performance Data Evaluation (PDE)**

## **Reference Seed Purity Requirements**

ISTA GMO TF  
Kirk Remund

Presence of seeds with  
specified trait(s)

# Overview

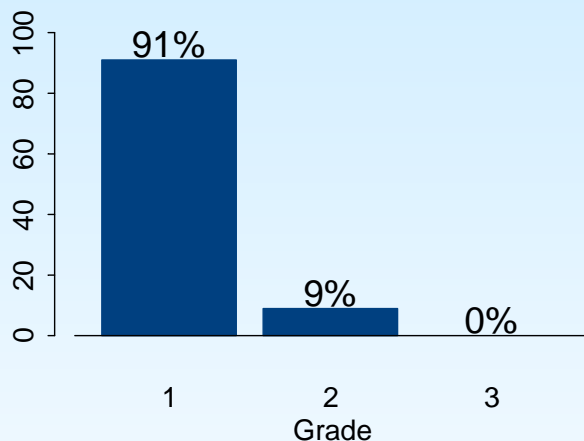
- PDE reference seed purity requirements for **presence of seed with specified trait(s) in seed lots** (i.e., unintended traits in seed lots)
  - ISTA Recommendation
  - Possible compromise based on lab comment
  - Impact of “low” reference seed purity on PDE results
- PDE reference seed purity requirements for **specified trait purity**

# ISTA Reference Seed Testing Recommendation for: PDE for the presence of seed with specified trait(s) in seed lots

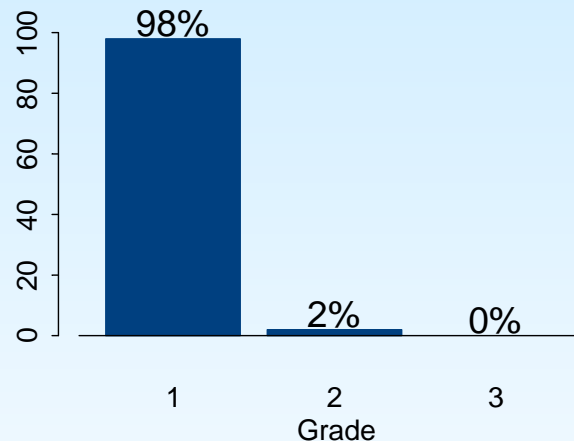
(Test 30,000 conventional seeds and 400 trait seeds) all true to type

(trait seed purity  $\geq 99.25\%$  and conventional seed impurity  $\geq 99.99\%$ )

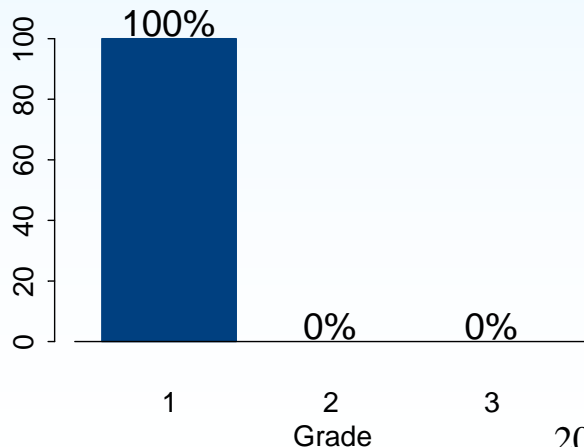
### Presence Evaluation



### Accuracy Evaluation



### Precision Evaluation



0% of time prepared kit will yield a “3” grade due to reference seed impurities

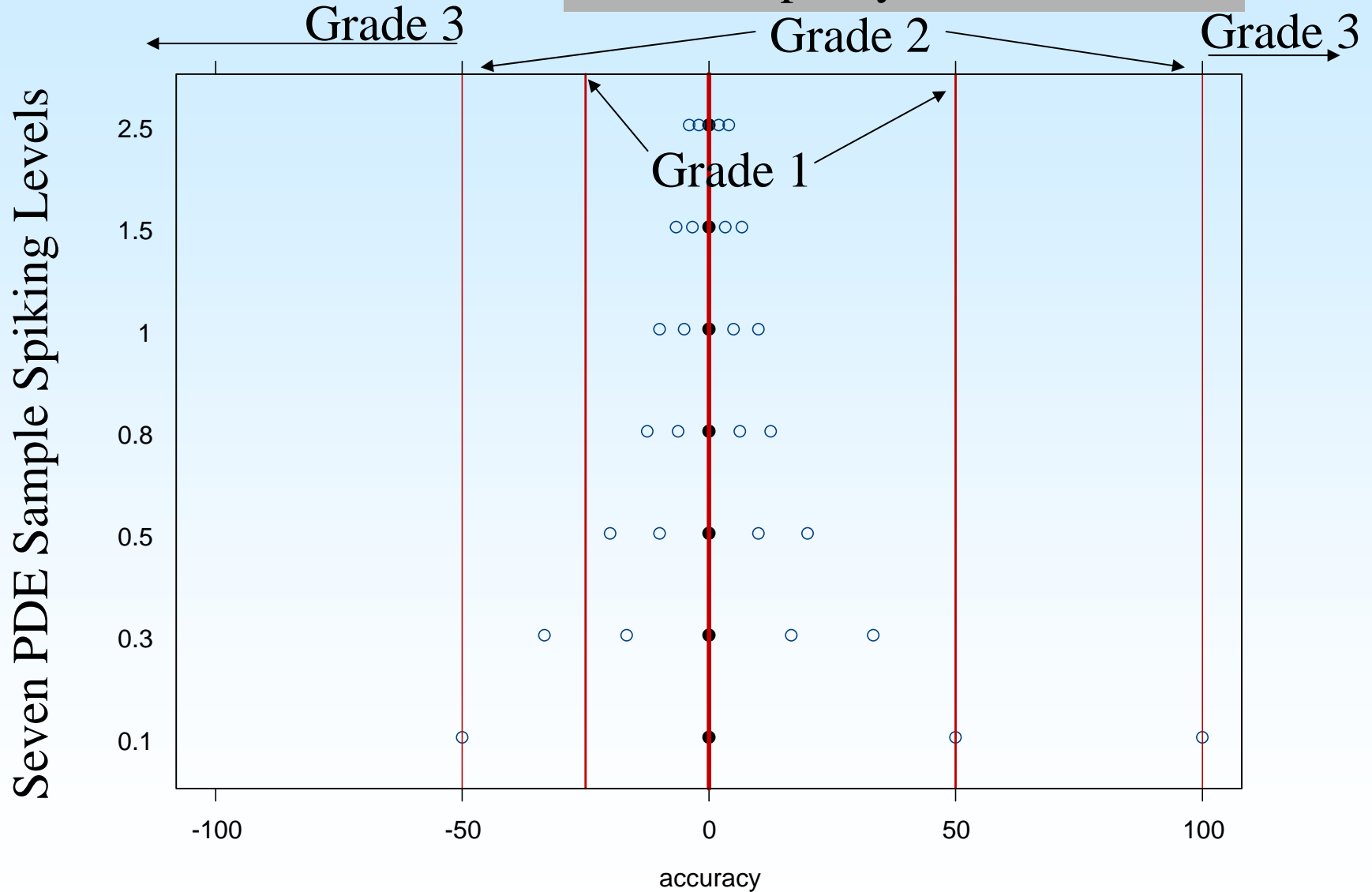
Practical purity estimate\*

\* Used 50% breakpoint on testing plan OC curve in Seedcalc

ISTA Recommendation

Conventional impurity < 0.01%

Trait purity  $\geq 99.25\%$

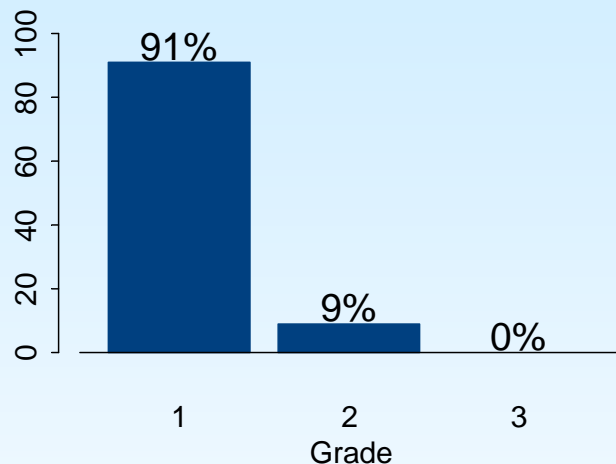


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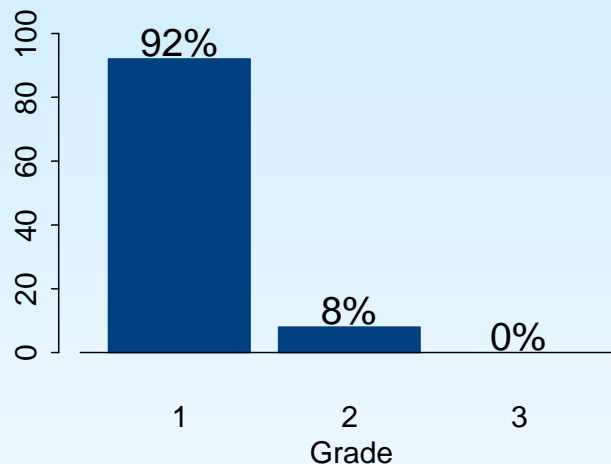
# Possible compromise from ISTA ref. seed testing recommendation for: PDE for the presence of seed with specified trait(s) in seed lots

(Test 30,000 conventional seeds and 100-300 trait seeds)

### Presence Evaluation

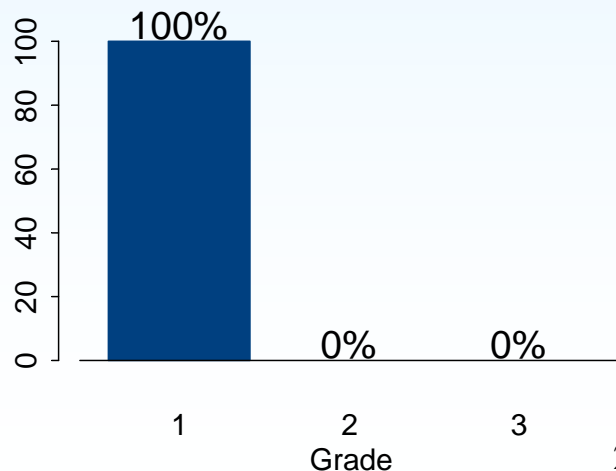


### Accuracy Evaluation



Response to a  
labs difficulty  
with PDE  
requirements

### Precision Evaluation



0% of time prepared kit will  
yield a “3” grade due to reference  
seed impurities

99% trait purity estimate

= test 100 trait seeds

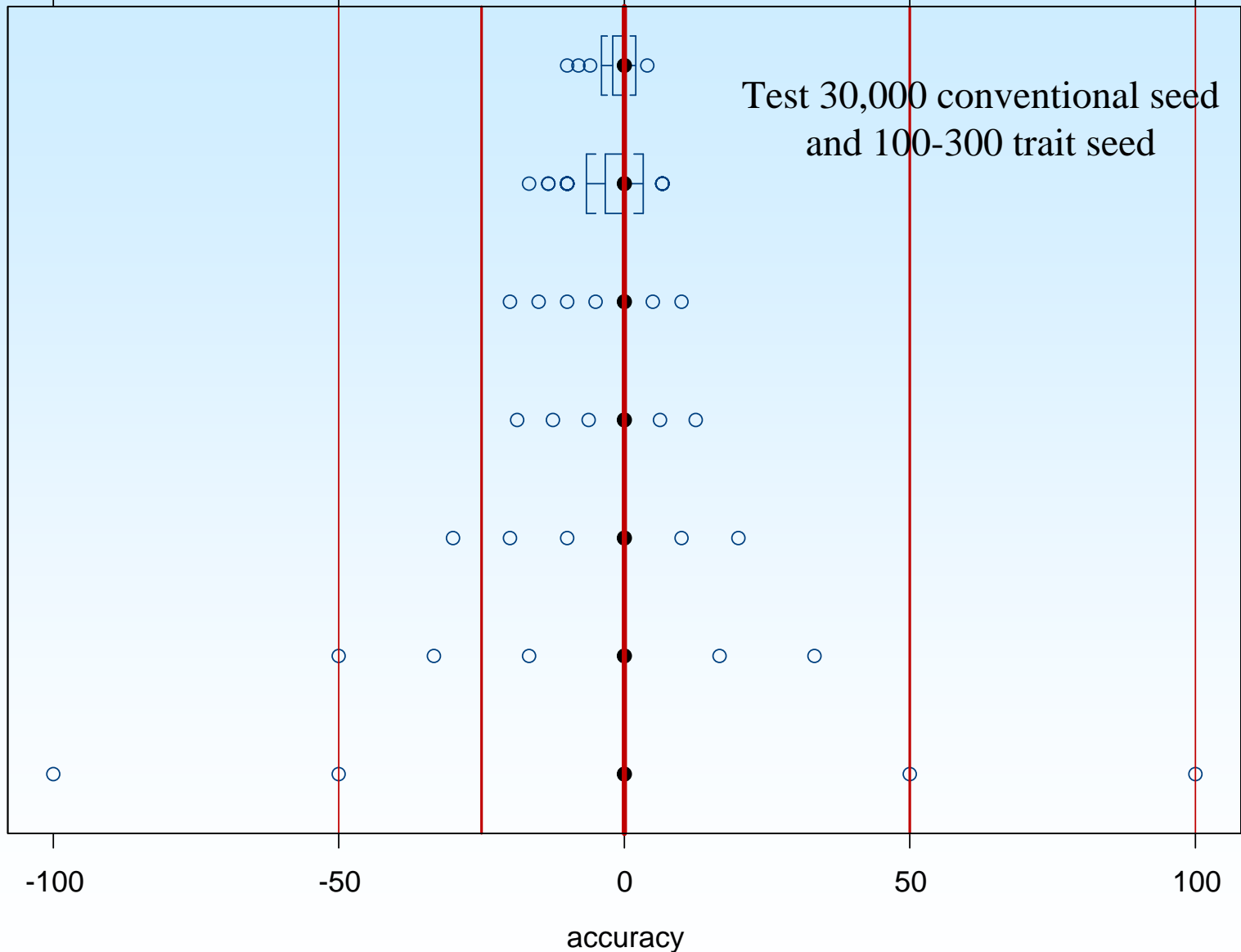
99% conservative trait purity estimate

= test 300 trait seeds

# Possible Compromise

Seven PDE Sample Spiking Levels

Test 30,000 conventional seed  
and 100-300 trait seed



Possible Situation: We have reference seed for a PDE for presence of seed with specified traits with **0.1% impurity in the conventional seed and 98% purity of trait seed.**

This seed does not meet the ISTA recommendation in the PDE documents, but is the purity of reference seed good enough for PDE purposes??

Grade 1: No problem is detected from the experiment

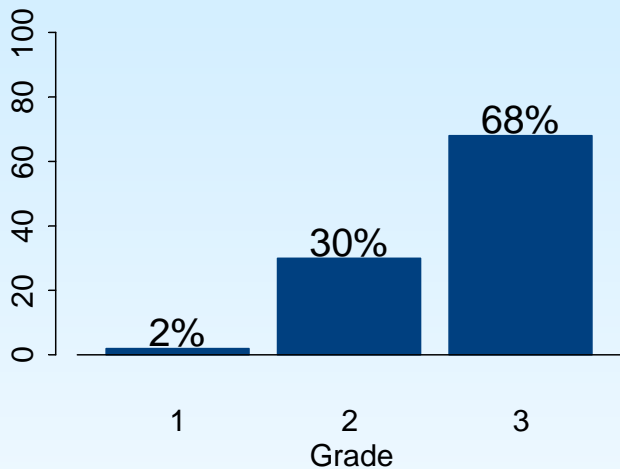
Grade 2: Improvement is possible

Grade 3: There is serious problem

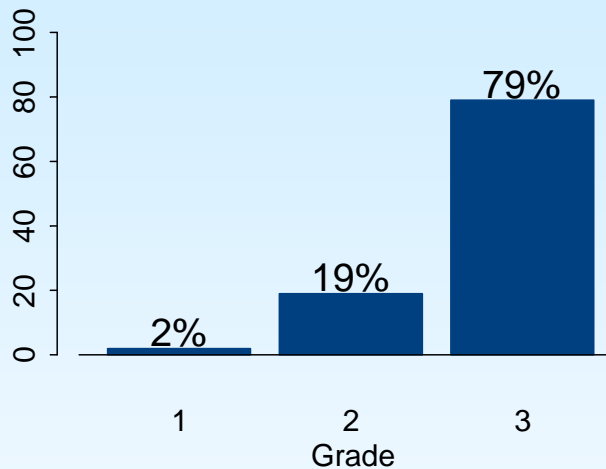
# Use of reference seed with **lower purity** for: PDE for the presence of seed with specified trait(s) in seed lots

(trait seed purity = 98% and conventional seed impurity = 0.1%)

### Presence Evaluation

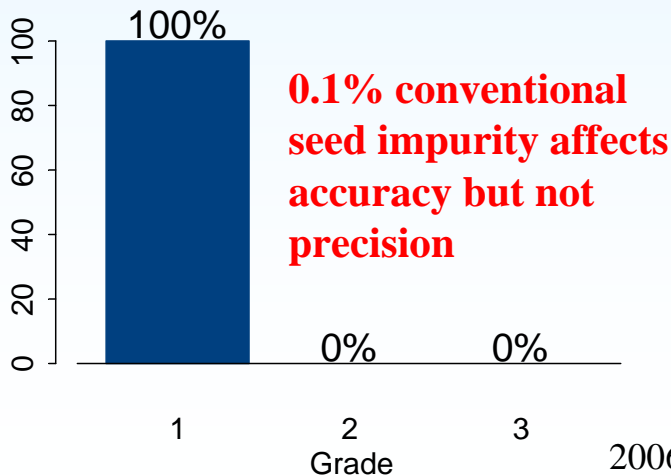


### Accuracy Evaluation



*Lab nearly fails before they begin because of impurity in reference seed*

### Precision Evaluation

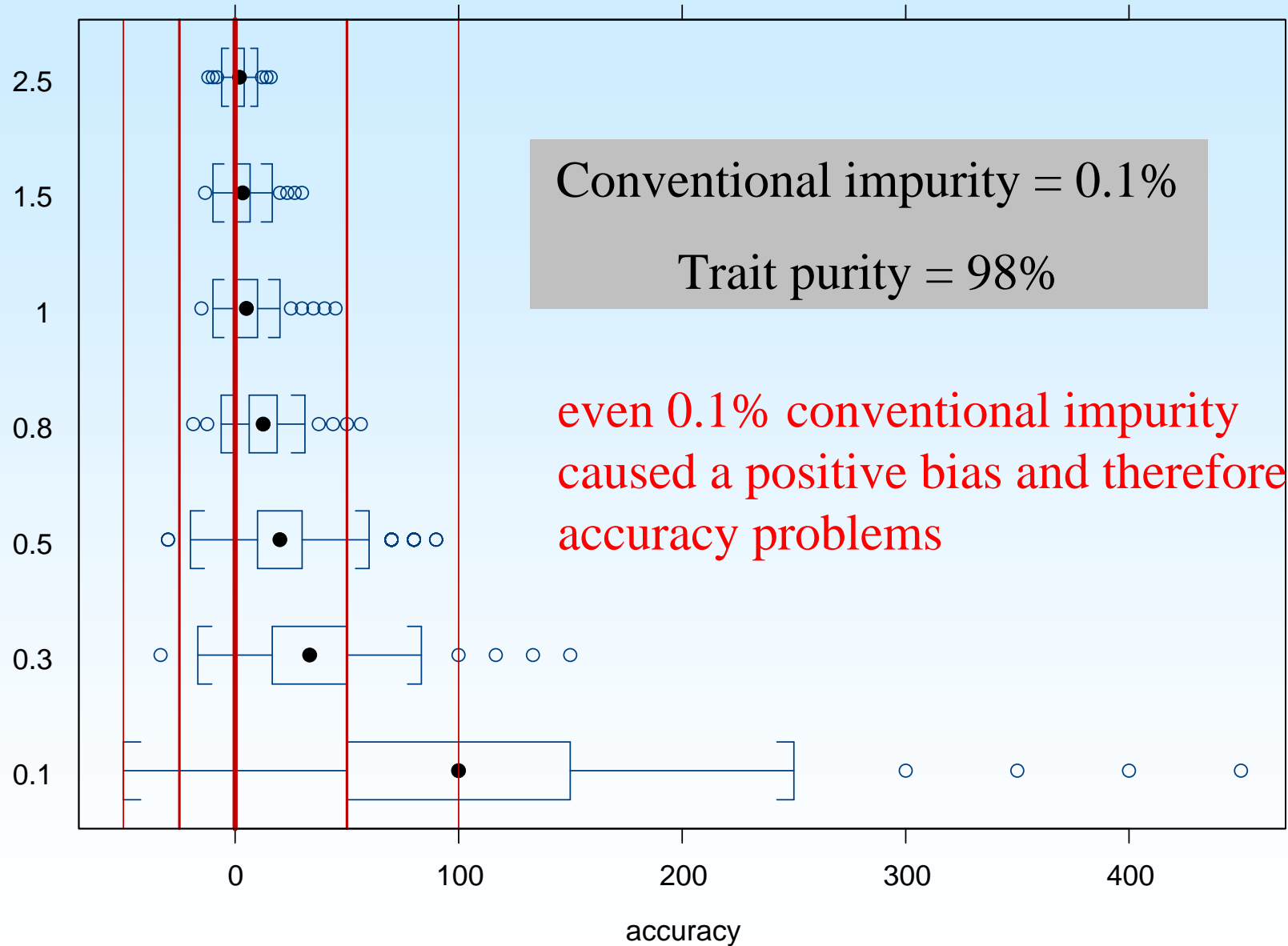


*The lab will have a grade 3 (or 2) even if assay is perfect the lab will have very poor PDE results!*

*Less than 1% of the time prepared kit will allow a possible "1" Grade for all three criteria*

# Low Purity of Reference Seed

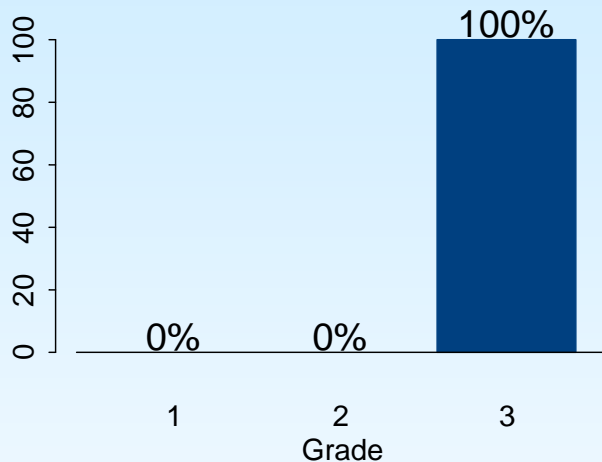
Seven PDE Sample Spiking Levels



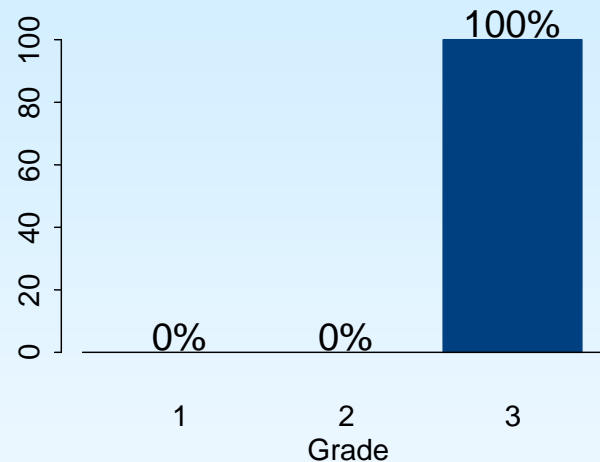
# Use of reference seed with “**very low**” purity for: PDE for the presence of seed with specified trait(s) in seed lots

(trait seed purity = 95% and conventional seed impurity = 2%)

### Presence Evaluation

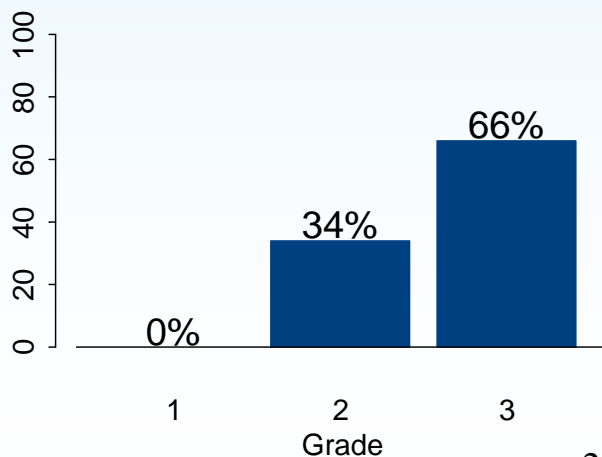


### Accuracy Evaluation



*Lab fails before they begin because of impurity in reference seed*

### Precision Evaluation

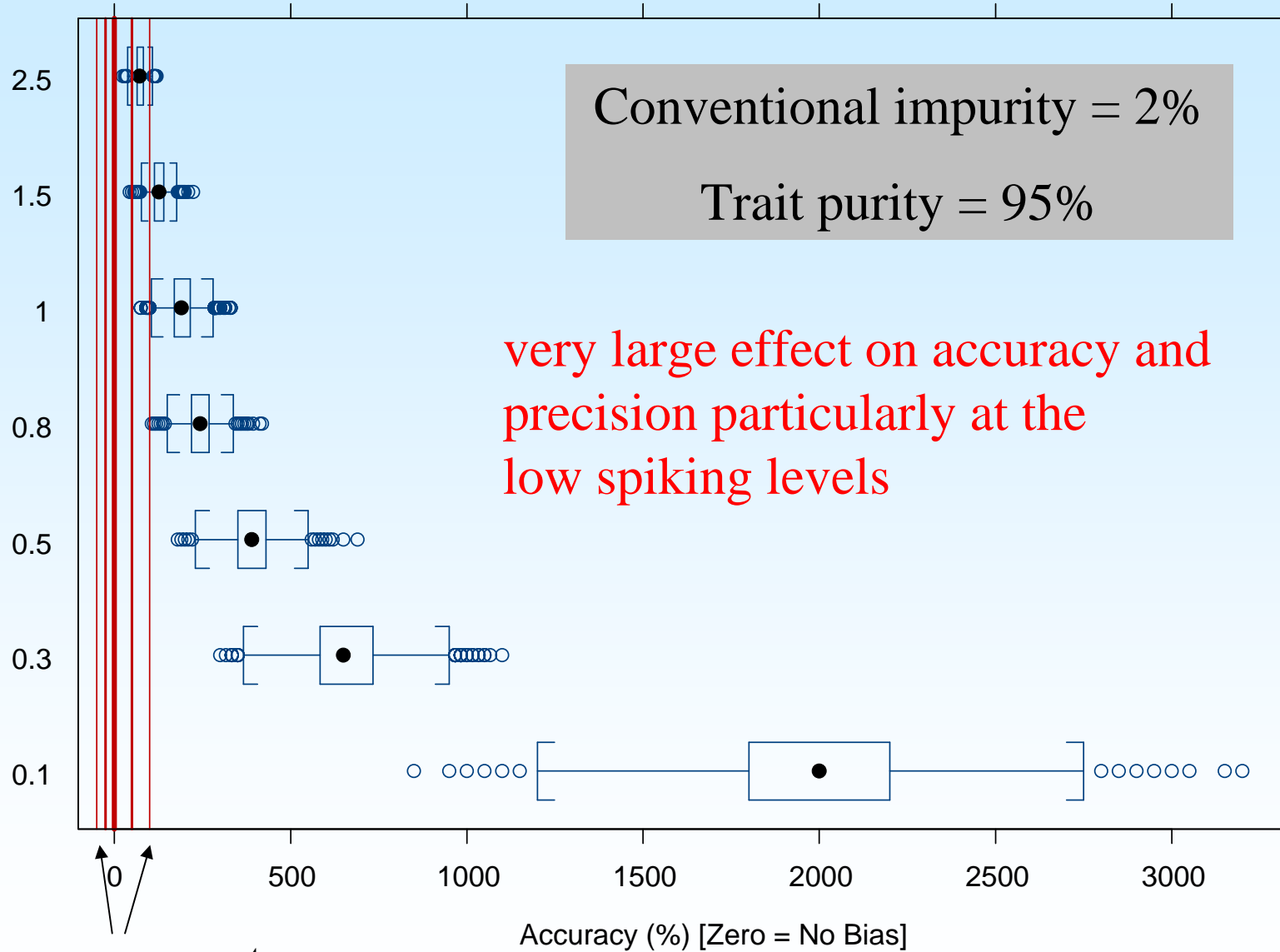


*The lab will have a grade 3 even if assay is perfect the lab will have very poor PDE results!*

*Less than 1% of the time prepared kit will allow a possible “1” Grade for all three criteria*

# Very Low Purity of Reference Seed

Seven PDE Sample Spiking Levels



accuracy range to get 1 or 2 Grade

# STA Recommendation for seed purity requirements for PDE for presence of seed with specified trait(s) in lots

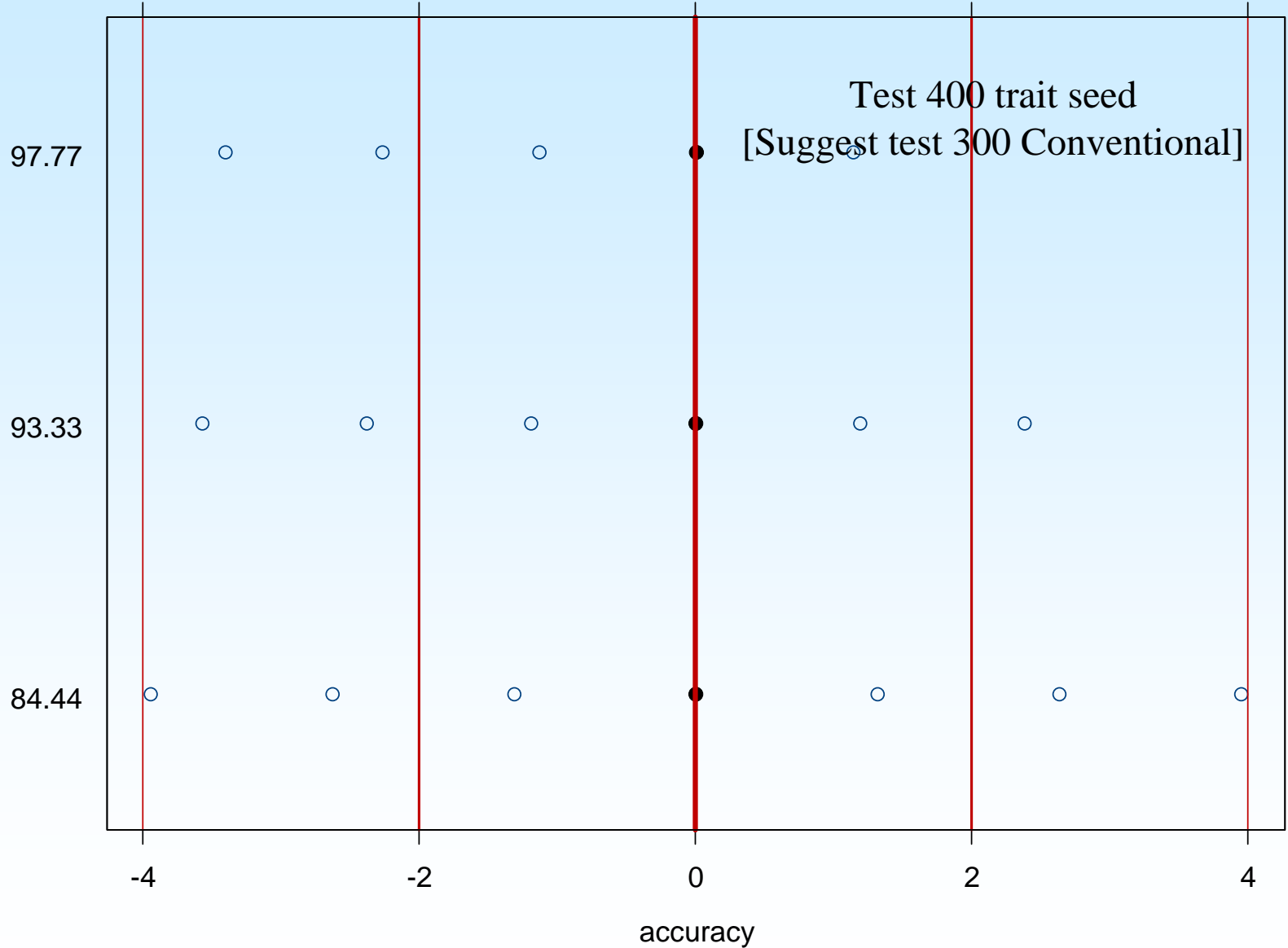
- Conclusion: Impurity in conventional seed has the largest impact in PDE
- Whenever possible follow ISTA Recommendation
- Possible Compromise:
  - 30,000 conventional seeds should be tested
  - 100-300 individual trait seeds need to be tested (instead of 400)
    - Conservative 1% upper limit: test 300 seeds, all negative
    - More liberal 1% estimate: test 100 seeds, all negative

## ISTA Recommendation for seed purity requirements for **PDE for Specified Trait Purity**

- Conclusion: Impurity in Trait seed has the largest impact in PDE
- Original ISTA Recommendation is OK
- Possible Compromise:
  - Test only 300 conventional seeds
  - 400 trait seeds need to be tested (original recommendation)

# ISTA Recommendation

Three PDE Sample Spiking Levels



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Thank you for your attention