BACKGROUND
- The WHO has developed a global laboratory network to support an HIV drug resistance prevention and assessment strategy at national, regional, and global levels.
- A QA program is being implemented to ensure the reliability of genotyping data generated by the various laboratories.

METHODS
- Two proficiency panels were developed in collaboration with VQA and NIH and sent to 58 network member laboratories in Europe, North America, Asia, Africa and the Caribbean during 2007-08.
- Appropriate and widely accepted evaluation criteria have not been described previously.

RESULTS
- Overall, 41 of 58 submissions passed (71%).
- Success rates were higher with panel 1 (80%) than panel 2 (64%).
- Specific reasons for failure included:
  - Editing errors leading to frame shifts.
  - Incorrect sequence (primer design, subtype issues).
  - Amplification failure (primer design, subtype issues).
  - Post-processing file naming errors.
- Samples and sites with naturally-occurring mixtures were more challenging than others (Tables 4-7).
- No lab obtained a nucleotide alignment score >99% for sample 4 in panel 1 (this sample's consensus sequence had the most mixtures) (Tables 2 and 7).
- For sample 4 in panel 2, only 18 out of 31 labs reported sequence with >99% concordance, compared to 26-30 out of 31 labs for the other 4 samples (Table 3).
- Based on comparison of chromatogram data from several labs (Figures 8 and 9).

CONCLUSIONS
- The use of a single stringent criterion for evaluation of sequence-based assays may be unrealistic when using clinical samples containing mixed bases.
- Acceptance criteria may need to be relaxed for such samples, or be flexible and based on the number of mixed positions in each sample.
- Proposed assessment criteria for 2009 proficiency panels:
  - Discrepancies must be counted in the DRMs site score:
    - Mixed WT+mutant in consensus, lab reports mutant.
  - Consensus not achieved in any single lab.
  - Consensus not achieved in any panel.
  - Consensus not achieved in any sample.
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