Update on Rapid HIV Tests

CLIAC
September 10, 2002

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Purpose of This Presentation

To inform CLIAC of progress made toward the approval of new rapid HIV tests since the last meeting.
Discussion of Submission Status

- FDA is prohibited from releasing any information related to submissions, as this is considered proprietary.
- Limited to discussion of public information only, or information authorized for release by the applicant.

In addition, MedMira has given FDA permission to disclose that they received an approvable letter for their PMA on May 24, 2002
On May 13, 2002, OraSure Technologies, Inc, announced, "it has received notification from the U.S. Food and Drug Administration (‘FDA’) that the OraQuick® Rapid HIV-1 Antibody Test is approvable… Final approval is subject to the Company submitting product labeling and resolving specific validation and design control issues identified during FDA’s recent pre-approval inspection of the Company’s manufacturing facilities…"