TO: CSTE National Office

From: Gus Birkhead, NY

Date: May 7, 2003

Subject: Follow up on 2002 Position Statement 02-ID-07: Surveillance for HIV Incidence.

Summary of statement: The statement 1) supported the goal of every state being able to measure HIV incidence, 2) recommended that CSTE work with FDA and the test kit manufacturers to obtain licensure of tests for recent HIV seroconversion (e.g. STARHS), 3) that CSTE convene a consultation on the best programmatic approaches to conduct HIV incidence surveillance and provide technical assistance to states, and 4) that funding for base HIV surveillance be increased.

CDC response: CDC 1) funded 24 areas to begin population-based STARHS testing, 2) held consultations in September, 2002, on policy and ethical issues, and in March 2003 on strategies and procedures for implementation, and 3) discussed licensure issues with FDA; at the March conference it was announced that the LS-EIA assay would continue to be classified as a research tool (the manufacturer is not pursuing FDA licensure). Thus, FDA IND rules and regs apply, and local IRB approval and patient consent will be necessary for any use of the test in which the patient identifying information will be maintained, 4) No additional base funds for surveillance were available.

Positive action: CDC is working with states collaboratively to determine the most effective ways to implement HIV incidence surveillance.

Recommendations: 1) The lack of a pathway for a test to be licensed for surveillance use even if it is not to be licensed for individual use makes undertaking population-based HIV incidence surveillance quite complicated; CDC should continue to pursue simplified means of obtaining such testing, 2) CDC should explore the impact of increasing use of oral fluid HIV tests which will decrease the number of blood samples available for STARHS testing. CDC should consider supporting development of a STARHS methodology for use with oral fluid tests. 3) CSTE should include the need for increased base funding for HIV surveillance in its annual federal budget recommendations.