Response to Item 1

To provide a written response to the points raised in the letter of the American Association of Blood Banks and the article on "一國兩檢" by 李鈞陶.

Letter from American Association of Blood Banks (AABB) dated 4 December 2000

1. On the question of single-lab testing, AABB does not specifically stipulate such practice as one of its standards. Single-lab testing, whilst being an example of a good process, is not the only reliable method. Indeed, a more important criterion which is required as a standard by AABB as stated in its letter is that the laboratory concerned should have a process to ensure that processes and procedures are followed and fully validated.

2. On the question of collaborative testing, it is stated in AABB's letter that recent advances in DNA molecular-based testing have produced less subjectivity and more control, so much so that "collaborative testing could be made technologically viable and sound". AABB points out that collaborative testing will require a close relationship between the laboratories concerned. We fully agree with AABB's view on the need for close coordination between the collaborating laboratories, and the need for clear and validated processes and procedures. As explained in our previous submissions, both Government Laboratory and the Mainland authorities will implement a comprehensive set of quality assurance measures to ensure reliability and accuracy of the test results. Such measures include, inter alia, those suggested in paragraph 4 of AABB's letter –

(a) "Use exactly the same genetic systems, DNA technologies and reagents" – the designated laboratory in the Mainland and Government Laboratory will adopt the same technology and procedures which meet international accreditation standard.

(b) "Cross-train their technologists" – officers from the designated laboratory in the Mainland paid a 5-day study visit to Government Laboratory in July 2000. Simulation tests have also been done for cross-training. The two sides will continue such exchanges as necessary.

(c) "Continually exchange specimens for proficiency testing" – the two laboratories will randomly select samples which have previously been analyzed as "blind tests" for their counterpart to analyze. The results will be cross-checked to ensure full compatibility. In addition, in all cases the two laboratories will conduct their tests independently and cross check the results and conclusions of the other party.

3. Paragraph 3 of AABB's letter refers to the practice that "the cells of all individuals in a parentage case be tested together in the same laboratory and/or tested with the same trays or tray sets". As stated in the letter, this only applies to Human Leucocyte Antigens (HLA) testing and is therefore irrelevant to DNA testing.

Article in Hong Kong Economic Journal dated 9 December 2000 by 李鈞陶

4. The article focused on Restriction Fragment Length Polymorphism (RFLP) technology of DNA analysis which, as described by the author, involves a lot of manual and complicated experimentation which takes a relatively longer time to complete. However, RFLP is <u>not</u> the technology that will be applied in our proposed procedures. Rather, we will be relying on Polymerase Chain

Reaction (PCR)-based DNA analysis the application of which in parentage testing has been made possible by technological advances. This PCR methodology is simple, quick and highly discriminatory. It is now being used in place of RFLP in many parentage testing laboratories around the world.

5. The article expressed concern on the possibility of cumulative error arising from human and experimental errors and variations. We wish to clarify two points –

(a) In terms of the limitation of the genetic test science, the chance of an unrelated person being included as a possible parent is about 1 in 500,000 and the chance of a true parent being excluded as to be unrelated is lower than 1 in 1 million.

(b) Human and experimental errors and variations may occur, regardless of whether the tests are conducted by one laboratory or collaboratively by two. The comprehensive quality assurance system we propose ensures that errors and variations are immediately detected, rectified and minimised to the extent that they do not affect the outcome of the analysis. Indeed the built-in cross-checking mechanism will help to detect and rectify errors.

Response to Item 2

To explain the steps that would be taken by the relevant authorities in Hong Kong and the Mainland should there be an error due to the genetic tests conducted in two places resulting in an adverse impact on the applicant, including the re-test arrangements.

1. A full set of comprehensive measures as set out in item 3 of our reply of 21 November 2000 will be put in place to ensure the integrity and accuracy of the genetic test procedure. Should any error be detected on either the Hong Kong or Mainland side through each side's respective internal checking system before the exchange of data for cross-checking, the sample concerned will be re-tested before proceeding further.

2. Government Laboratory and the Mainland authorities will exchange the test data and analytical results for comparison and verification before coming to a conclusion. If any incompatibility is detected in the cross-checking process, each side will examine the cause of the discrepancy through traceable records that are kept in accordance with the operating procedures. Particular attention will be paid to any discrepancy in cases where parentage cannot be established. A re-test will be done where necessary to ensure that the two sides arrive at a compatible and accurate test result. All efforts will be made to ensure that similar discrepancy will not recur in future.

3. Wherever discrepancy exists between the results of the two sides, a re-test will be conducted at no additional costs to the applicant.

Response to Item 3

To explain whether it is possible for a claimed parentage to be wrongly confirmed by the genetic test results due to an error in terms of science.

1. As stated in our submission dated 13 December 2000, at present the genetic science is unable to achieve an accuracy rate of 100%. There is still a margin of error, albeit a very small one: 1 in every 500,000 cases for an unrelated person claiming parentage to be wrongly confirmed and less than 1 in every 1 million cases for true parentage to be wrongly rejected. Our prescribed genetic test is subject to the same margin of error in terms of science.

Response to Item 4

To consider amending the Bill to the effect that the Director of Immigration cannot draw an adverse inference against an applicant on the ground that his claimed parents refuse to undergo a genetic test.

1. The Administration has an alternative wording of S.2AB(8) (see our reply to item (5)). This will enable the Director of Immigration to draw any inference from the failure of the applicant or his claimed parents to undergo the prescribed genetic test as he considers proper, according to the circumstances of individual cases. The wording is without prejudice to the nature of the inference so drawn, i.e. the inference may be positive, neutral or adverse as is proper in the circumstances of a case. It shall be based on the facts and the reasons for refusal to take the test pertaining to the case concerned.

2. We do not consider it appropriate to amend the Bill to impose a blanket restriction on the Director's discretion barring him, after having examined the circumstances of an individual case, from drawing any inference as he considers proper, including an adverse inference, in the event that the applicant's claimed parents refuse to undergo the prescribed test.

Response to Item 5

To provide the Administration's proposed amendments to the proposed section 2AB(8).

1. It is the common concern of the Bills Committee and the Administration that integrity of the genetic test procedure be ensured so as to prevent fraud or abuses. The Administration considers that the statutory prescription of a genetic test procedure is essential to achieving this objective. As requested by Members, we provide herewith our proposed alternative wording for s. 2AB(8) as follows –

" (8) The Director may draw any inference from the failure of –

(a) an applicant; or

(b) a person of whom an applicant claims to be born,

to undergo a genetic test referred in subsection 7(a) as he considers proper and determine the application accordingly."

2. The revised wording makes it clear that the Director may draw any inference as he considers proper based on the circumstances and facts of the individual case. Under s. 2AB(9), the Director is obligated to inform a person who is required to undergo the genetic test the provision in s. 2AB(8).

3. We are also proposing to amend Section 2AD of the Immigration Ordinance to explicitly provide for the Immigration Tribunal drawing any inference from the failure of an applicant or his or her claimed parents to undergo the prescribed genetic test. It is proposed that the following new subsection be added to Section 2AD –

" (6A) Where –

(a) an appeal is lodged by an applicant for a certificate of entitlement under subsection (1); and

(b) the applicant or the person of whom the applicant claimed to be born was required under section 2 AB(7) to undergo a genetic test and failed to undergo such test,

the Tribunal may draw any inference from such failure as it considers proper."

Security Bureau
January 2001