



TO : ASISA Risk Board  
ALL MEMBER COMPANIES

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CONVENOR: MUSC

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SUBJECT : **BUCCAL TRANSUDATE TEST (BTT) FOR HIV: ASISA POSITION PAPER**

The Medical and Underwriting Standing Committee (MUSC) is committed to keeping abreast of medical and scientific advances for underwriting purposes. At present the ASISA HIV protocol does not allow for saliva testing. As this is successfully used in foreign markets, the use of this test in South Africa continuously warrants re-evaluation. This paper sets out information about current developments and thinking on the BTT test and the recommendations of MUSC.

The BTT is better known as Saliva or Oral Fluid Testing. It is important to understand the difference between a buccal transudate and saliva:

1. Saliva (oral fluid) is a fluid secreted by salivary glands in the mouth and can be collected by spitting into a container. It contains low antibody titres and is easily manipulated by eating and drinking prior to sample collection. It yields unacceptable low sensitivity and specificity for HIV testing, and is at best indicated for screening population groups to determine estimated prevalence rates.
2. A buccal transudate is collected with a special device and through a special technique requiring training and skill. A cotton swab is held between the cheek and gum for 60 seconds, during which some of the intracellular fluid (a transudate) of the epithelial lining diffuses into the swab. This transudate has higher titres (approx 10-fold) of antibodies, is not as easily influenced by diet, and yields very accurate results (sensitivity and specificity) in international studies. It has, however, not been tested on the African continent where other local factors may influence the results e.g. exposure to other retroviral infections, malaria etc.

After scanning the international medical and scientific literature on BTT, and meeting with experts from the National Pathology Group (NPG), the following are the pertinent issues.

1. **Market-related issues**

1.1 **Orasure usage in USA vs S.A. markets**

The USA is often quoted as a market where saliva testing (Orasure) is successfully applied by the sales intermediary.

It is important to note the enormous difference in seroprevalence of the general population of the USA and South Africa. A test with low sensitivity could be accepted with prevalence rates below 3%, but is unacceptable in our country where this figure exceeds 13%.

BTT could be done in S.A. with proper training and control over sample taking procedures. The only practical way to manage this, would be to have only accredited NPG labs do BTT sampling. This would have a limited advantage of not being available in the rural countryside, but warrants further investigation and discussion with the NPG.

As the NPG has already stated categorically that they cannot police, nor take responsibility for any sample taken outside their depots, the possibility of having BTT sampling done by general practitioners increases the risk for fraud beyond any level of comfort.

### 1.2 Needle phobia

BTT unquestionably has a huge advantage over venesection in terms of the fairly widespread presence of needle phobia.

However, this has limited application in practice. At present only HIV and cotinine can be tested with BTT sampling. All other underwriting requirements, e.g. cholesterol-test, blood-sugar, liver function tests still require a blood sample, which negates this non-invasive advantage.

### 1.3 Fraud

The risk for increased fraud with the introduction of BTT, is significant. The main reasons are:

- Complete control over sample collection devices will be impossible.
- Once the collection device is in the wrong hands, it is much easier to collect and substitute an oral fluid sample than a blood sample. As these BTT samples will be incorrectly collected, their results will be non-reactive (due to low titres) and policies will be issued unbeknown to the insurer.

This could be managed, however, by limiting BTT sampling to NPG lab depots as mentioned, and by pricing an additional premium for fraud at product development stage.

## 2. Scientific issues

Providing the sample is taken correctly, international studies show similar sensitivity and specificity between blood- and BTT results for HIV. However, this needs to be tested in a practical set-up without the stringent control measures of scientific studies in a controlled environment.

Although the manufacturer claims accuracy of Orasure samples for type II HIV, subtype 0 and the C-strain, this has not been proven with any comparative study on African sera.

Of particular concern is the fact that the Orasure commercial kit information pack specifically states that an increase in false negative and false indetermined results may be expected when comparing Orasure results with blood specimen results.

Other technical concerns are:

- Saliva tests cannot be automated in the laboratory, which in turn will lead to slower turn-around times.
- The storage time of a saliva sample is 21 days under optimal conditions. The ASISA protocol requires storage of all positive serum samples for one year in case of any disputes.
- Further confirmatory tests required on samples testing positive, cannot be done on saliva and will require a serum sample.

## 3. Commercial issues

Although the cost of doing the HIV test in the lab are the same for BTT and blood samples, the difference lies in the sample taking.

Almost 80% of venesections done for insurance HIV testing, are done at no charge by NPG lab depots. The sample device for collecting BTT costs approximately 50% of the current HIV testing cost. We are told that with bulk discount, this could be reduced to 33%. This would still increase the total cost of a BTT to 33% above that of a blood test.

Furthermore, not all currently ASISA approved HIV testing kits are approved for use on saliva/buccal transudate. This may mean expensive upgrading of equipment and reagents for many NPG laboratories, the cost of which will be transferred onto HIV test pricing negotiations.

### **RECOMMENDATION**

MUSC recommends the following regarding BBT:

1. The increased cost and potential for increased fraud, are business issues beyond the mandate of our Committee, but need to be taken into account by pricing actuaries. The desirability of increased acquisition costs in an already difficult market, remains questionable if the only advantage is a non-invasive sample collection technique.
2. No study on the accuracy of the BTT test on sera of the African continent is available. The scientific merit of BTT needs to be evaluated in a South African study by the manufacturers in collaboration with ASISA and the NPG prior to approving this technique in the ASISA HIV protocol.
3. BTT can at best be allowed for purposes of anonymous screening of large groups of clients in order to estimate seroprevalence in the specific group. This could be of value to Employee Benefit Products for pricing purposes.

It should however be borne in mind that if saliva testing instead of BTT testing is used for this purpose, the results obtained will be no better than statistical extrapolation of available epidemiological data.

4. Any progress made in this arena will be closely monitored by MUSC.

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