**Molecular Diagnostic Services Australia Pty Ltd**

**OUTLINE FOR WTO PROPOSAL**

**Brief background.**

Molecular Diagnostic Services Australia Pty Ltd (MDSAustralia) is a small Australian based Company, that offers the services of molecular testing and sub-contractors the bulk of the molecular testing to Molecular Diagnostic Services (Pty) Ltd, South Africa.

Molecular Diagnostic Services (Pty) Ltd is a specialist Molecular Diagnostic Laboratory

(ISO 17025 accredited) that provides a diagnostic service to the human, veterinary and avian fields. MDS uses a simple collection device referred to as a – Sample Collection Kit, which contains a sterile needle, a plastic safelock tube with a small strip of special FTA (testing) paper. This paper serves to capture and inactivate a small spot of blood that is stable and non-infectious at room temperature. Blood spots would typically contain less than 5 ul of the bird’s blood. This dried blood sample is contained in a secure (safelock) plastic tube and sent to MDSAustralia, who weekly courier the samples to the laboratory in South Africa for analysis.

The dried blood spot on FTA paper is regarded as the safest way to transport a small blood sample. The sample is used mainly for the purposes of DNA sexing. However, it is also possible to test that sample for the presence of other pathogens such as PBFDV, APV and Chlamydia.

Immediately on receipt of the sample in the Laboratory it is heated and the DNA extracted from the sample for analysis. The sample is stored for 30 days after analysis and then is discarded as biological waste.

It is important to emphasise that the samples and used solely for diagnostic purposes and not for cloning or other genetic purposes or propagation of any sort. The genetic material is not sold on or given to a third party and is discarded.

**General comments.**

I firmly believe and support the good work that is being done by the authorities to legislate the protection of endangered animals and support their objectives where ever possible. However, it needs to be emphasised that the only purpose of the collected sample is for diagnostic purposes.

Please find below a formal application.

**Application to receive dried blood spots of all avian species for the sole purpose of DNA analysis.**

1. **Source of blood spots**

A small blood spot – collected on special FTA paper - from a pin prick on the claw of the avian species.

**1.1 Origin of samples**

The samples are sent from bird owners from all parts of Australia and are from captive breed birds solely.

* 1. **What is being sent?**

The technology is so sensitive that all that is required is a small blood sample immobilised on a special paper that is inserted into an inert labelled plastic tube. The sample can be collected from avian species at any age. In the molecular laboratory the DNA is extracted and analysed to determine the sex of the sample and/or to determine if there is any viral or bacterial DNA in that sample. Some of the viruses tested for include psittacine Beak and Feather Virus (PBFDV), Avian Polyoma virus (APV), Pacheco’s Disease virus and Chlamydophila psittaci. The most common request is to establish the sex of the sample.

* 1. **Cites List:**

The samples are used solely for diagnostic purposes and discarded as biological waste. There is no trading or manipulation of the samples other than for diagnostic purposes. We request that the proposed list of species be considered – Attachment 1, which excludes any CITES Appendix 1 and EPBC Listed species. We would, however, like to strongly motivate that the permission applies to all species as the purpose is solely for diagnostic applications

**Goals and Objectives:**

MDSAustralia is a company that offers molecular diagnostic services through MDS Pty Ltd, a specialised molecular diagnostic company/laboratory that performs molecular diagnostic work. Our sole objective is to request permission to receive a small spot of blood from privately owned captive bred birds so that it can be used for the DNA tests and return the results to the owner or veterinarian who submitted the samples.

1. **Harvesting details.**

Typically, the breeder, owner or veterinarian will carefully hold the bird and briefly prick the claw with a sterile needle. After a brief pause a piece of special FTA paper is removed from a sterile tube and touched against the bead of blood that appears at the prick site. Once collected the paper is returned to the tube and sent to the laboratory for analysis. This is a single procedure that takes a few minutes to perform. The timing of the procedure depends on whether the bird needs to be sexed or to be screened for the presence of a pathogen. Once collected the DNA is stable at room temperature for many months.

1. **Impact of harvest on the taxa and the relevant ecosystem**

The procedure is performed as an alternate to surgical sexing with many advantages. The sample harvesting procedure is less invasive for the bird than surgical sexing. In addition, to the DNA sexing, the same sample can be tested for the presence of pathogens this is an important tool to monitor and reduce the spread of pathogens ie testing at this level provides an effective management tool in reducing the spread of diseases in the aviary, as many birds can appear to be clinically asymptomatic, but they could be carriers of viruses and thereby spread the virus to virus free birds.

1. **Monitoring and assessment**

A direct spin off from this type of testing is that data is generated in terms of location and distribution of different species as well as the epidemiology and incidence of different pathogens as well as their locality. Whilst this data base is confidential there is no reason why the fields of location, species, numbers, pathogens etc should not be made available for surveillance and monitoring purposes. This could be most useful for statistics.

6. **Management strategies**

The objective of this application is to request permission to receive a small blood sample from the bird solely for analysis. The numbers and species that we receive will form part of a database. It is possible that information gained in this manner could be used as a reliable proxy to estimate the numbers of the different species that exist. It is not our intention to use this information to manage any process, however, it might turn out to be a useful tool to monitor the populations of the different species.

**7. Compliance**

We only do the testing of a small blood sample. We do not keep material, give it away or sell it on. We solely analyse it. Thirty days after it has been extracted it is then discarded safely as biological waste according to accredited procedures. In addition, Export and Import permits are in place and current.

**8. Reports:**

We report to the Department as per the requirements of the CITES’ multiple consignment permits**.**

**9. Background information**

The technology of DNA analysis has reached a stage where it is accurate and reliable. As DNA is the target material transportation of the samples can be at room temperature. The ability to determine the sex of a species from a small blood sample is well established in forensic, paternity and other applications. For sexing there are alternate procedures such as morphological identification and endoscopic visualisation, however, DNA sexing has many advantages and is fast becoming the preferred method of sexing. Our laboratory uses manydifferent DNA sexing methods. The tests are different for the different species. It is fairly difficult to morphologically determine the sex of certain species especially at a young age. DNA sexing is rapidly becoming the method of choice for avian sexing. We are a focused and specialised laboratory that offers this service as part of our livelihood. This application is to request permission to be able to receive samples so that we can offer our service. As the conservation and preservation of rare species is of international importance, we want to assure the authorities that we do not use the material for any use other than to analyse the sample, the most common analysis being to determine the sex of the sample.

**Additional personal details**

All the laboratory analysis of the samples takes place at Molecular Diagnostic Services (PTY) Ltd South Africa under the direction of Dr D.F. York (BScH., MSc., Ph.D), Managing Director, which has the relevant International Accreditation ie ISO/IEC17025; SANAS #V0023

All biological waste is discarded by a registered professional Company. A certificate is received from the company each time the waste is discarded.

We do not harvest or culture any material. The owner of the bird collects the pin prick drop of blood that is inactivated and denatured. The samples are submitted to MDSAustralia who then send the samples on to the laboratory for analysis.