

SOP 2.6 Saliva Collection

SOP Number: 2.6
Version Number 1.0

	Name	Title	Date
Author			
Authoriser			

Effective Date	
Version Number	

Purpose

This SOP describes the procedure for saliva collection from research participants.

Responsibility

It is the responsibility of the research personnel carrying out this procedure to ensure that all steps are completed both competently and safely.

Equipment

- Personal protective equipment: gloves (optional)
- Specimen container or saliva collection kit (for example Oragene DNA Emergo Europe)
- Sterile container with warm water

Procedure

1. Research personnel will greet the research participant, identify themselves, and then explain the saliva collection procedure to the research participant.
2. The research participant will be approached in a friendly calm manner and their co-operation will be gained prior to saliva collection.
3. The research participant will be correctly identified prior to saliva collection, by asking them to give their name and date of birth.
4. All sample containers and equipment needed to competently and efficiently carry out the saliva collection will be assembled prior to the procedure. For specific saliva

collection kits follow the manufacturer's instruction for sample collection as outlined in the information for use, for example Oragene DNA saliva collection kit (Emergo Europe).

5. The research participant will rinse mouth out with warm water. Avoid use of mouthwashes or fluoride rinses. In addition, the research participant should not drink, smoke or chew gum for 30 min before giving a saliva sample.
6. The research participant will be asked to fill the specimen container to a certain marked level with saliva.
7. The inside of the specimen container will not be touched and the outer surfaces of the container will not be contaminated with saliva.
8. A unique study identification number or bar code label will be applied to the sample immediately after saliva collection. Record the time of saliva collection in the study specific documentation or data management system.
9. Transport to the processing laboratory as soon as is practicable or within a maximum of 48 hours for immediate processing of DNA or for direct storage at -80°C. Saliva collection tubes should be transported at 4°C in a polystyrene container on ice. Alternatively when using commercial collection kits such as Oragene DNA the sample may be stored at RT for up to 18 months in the cell lysis buffer in the container prior to DNA processing. The saliva collection kit should be transported to the processing laboratory at RT. Follow the manufacturer's instructions for use in the information for use/package insert in all cases. Record date/time processing was initiated and date/time of storage in the study specific documentation or data management system.

Note: As a general rule samples should be processed and reach the appropriate storage conditions as soon as is practicable. The maximum time limits proposed are guidelines and should be read in association with a study specific protocol.

Change History

SOP Number	Effective Date	Significant Change	Previous SOP No.