UK Biobank

Saliva Sample Collection, Processing and Transport

Version 1.0

http://www.ukbiobank.ac.uk/

15th April 2011

This manual details the procedure for Saliva Sample Collection and Exit at an Assessment Centre of the UK Biobank. Also detailed are the methods for sample processing and transport prior to storage.

Contents

1. Introduction

1.1: This manual details the procedure for Saliva Sample Collection at an Assessment Centre of the UK Biobank. Also detailed are the methods for sample processing and transport prior to storage. This takes place at the 7th 'station' of the Assessment Centre visit, as listed in Table 1.

Table 1: Sequence of assessment visit

	Visit station	Assessments undertaken
1	Reception	• **Welcome & registration** • Generating a USB key for Participants
2	Touch screen Section	• **Consent** • **Touch screen questionnaire** • **Hearing Test** • Cognitive function tests (**Shape, Pairs, Fluid Intelligence, Snap**)
3	Interview & blood pressure	• **Interviewer questionnaire** • **Blood pressure measurement** • **Measurement of arterial stiffness (Pulse Wave Velocity)**
4	Eye measurements	• **Visual acuity** • **Auto-refraction** • **Intraocular pressure** • **Retinal image (OCT Scan)**
5	Physical measurements	• **Height (Standing and Sitting)** • **Hip & waist measurement** • **Weight and Bio-impedance (Body Composition) measurement** • **Hand-grip strength** • **Ultrasound bone densitometry** • **Spirometry (Lung function Test)**
6	Cardio (Physical fitness)	• **Exercise ECG (Cycling)**
7	Sample collection & exit	• **Blood samples collected** • **Urine sample sought**

		• **Saliva sample sought** • Consent & result summary printed • Travel expense claim provided
8	Web-based diet questionnaire	• **Dietary assessment**

1.2: Throughout this document, the term 'Participant' signifies a study participant who is taking part in the Assessment Centre process, regardless of whether they eventually give or withhold consent to take part in the UK Biobank study.

1.3: The collection of data from assessment visits uses the direct data entry system of the Assessment Centre Environment (ACE). This has five components (**Assessment Centre Environment**), of which Porto operates the Sample Collection and Exit station of the assessment visit.

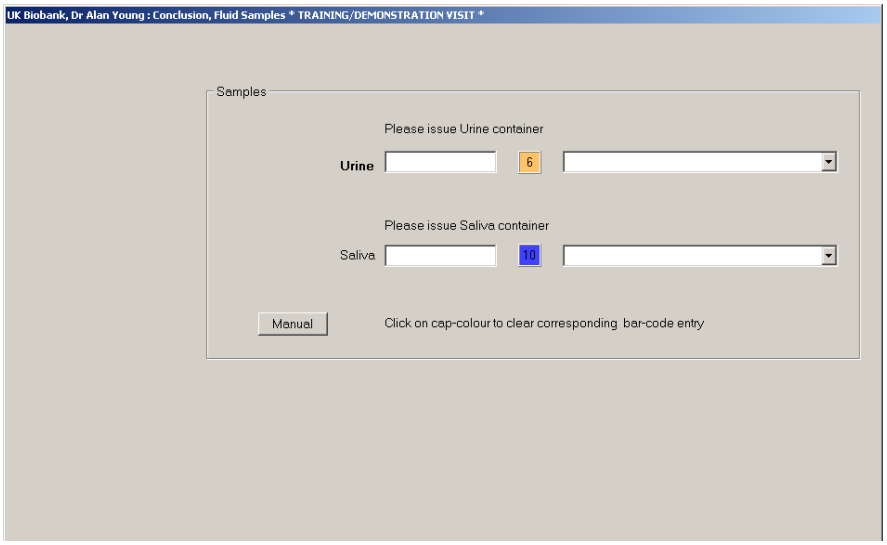
1.4: At the start of their visit, each participant is issued with a USB Key at the Reception station. This USB Key acts as a participant identifier (it contains Participant ID, name, date of birth and gender) and as a temporary storage device for the recorded data. As the participant progresses between stations, the USB key acts as an identifying token and also as a data transfer mechanism. At the Reception & Exit module, all data on the USB key is removed, after it has been backed up to the Assessment Centre head PC.

2. Staff

All operational clinical staff may perform sample processing tasks. It is the responsibility of the Assessment Centre manager to oversee and ensure that sample processing is carried out according to protocol and in a safe manner.

3. Saliva sample procedure

3.1: After completion of the blood sampling process, the participant is asked if they are able to provide a urine and saliva sample before they leave. If so, the barcode is scanned on urine and saliva collection tubes. If the participant does not wish to provide a sample, the reason why can be recorded using the drop-down menu. Participants do not receive urine or saliva tubes prior to the blood donation station. All scanned urine and saliva tubes are sent to the Coordinating Centre, whether a sample has been provided or not.



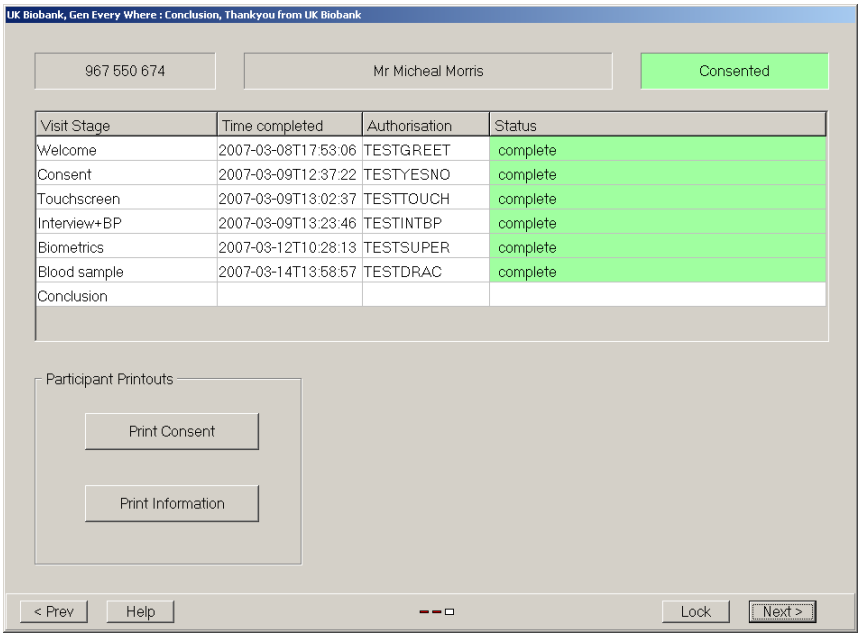
3.2: The participant is given the scanned Vacutainer tubes for the urine and saliva samples plus a urine collection pot in an opaque plastic 'privacy' bag (Appendix 1: Equipment for blood collection station).

3.3: The participant is shown the saliva collection tube (figure 1) and is asked to provide a 2.5ml sample. The saliva sample can be collected in the toilet cubicle. The participant is instructed to spit into the tube up to the red fill line marked on the tube (see below) but not measuring froth. Saliva production can be helped by placing the tip of the tongue behind the front teeth. They are not to drink anything immediately beforehand, but can have water after the **Spirometry** measurement, or after **Cardio** testing in later versions of UK Biobank.

Figure 1: Saliva sample tube

3.4: The screens below are used to print copies of the results provided and signed consent. Also to record any incidental findings (Appendix 2: Procedures for dealing with potentially serious results and incidental findings).

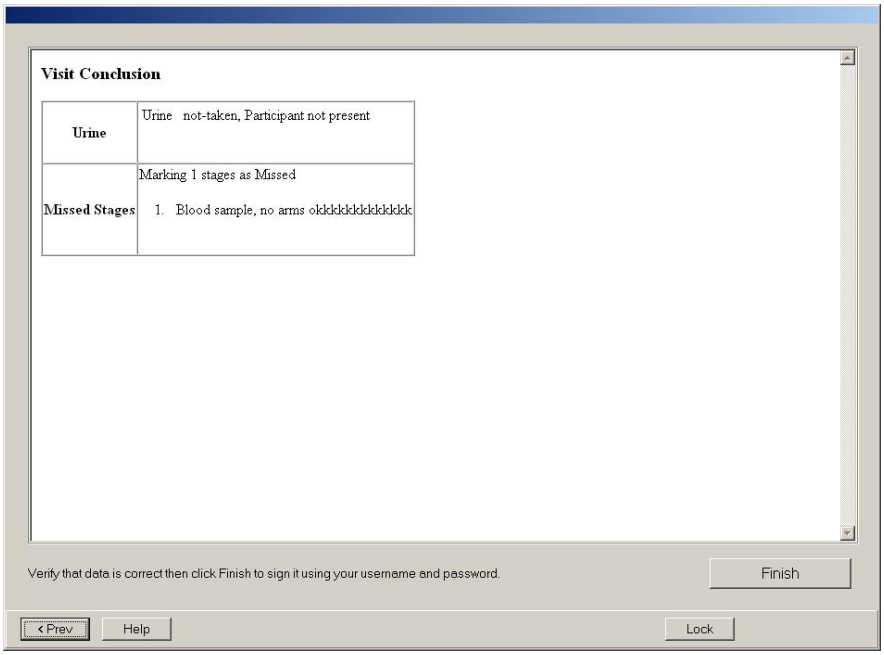
3.5: The results information sheet contains the Diet Questionnaire PIN and log-in details. The participant's attention is drawn to this and it is explained that on completion of the visit they have the option of completing a self administered Web Based Diet Questionnaire http://www.ukbiobank.ac.uk/docs/quaire_v3.pdf.



3.6: If the participant has any questions about their results, it is explained that UK Biobank are unable to provide any interpretation of these results and it is suggested they contact either NHS Direct (0845 4647 available 24 hours/ www.nhsdirect.nhs.uk) or their own GP.

3.7: On-screen it is checked that the participant has completed all of the stations. The status column shows successfully completed stations are indicated in green, whereas incomplete or missed stations are shown in red. If any stations are showing red on-screen, the participant is asked if they have visited that station. If not, and if the participant is willing, they and their USB key are taken to that station. If a participant was unable to complete a station, the reason for this is entered in the status column below.

3.8: On the screen below, once data is correct, 'finish' is selected and the staff member's user name and password are entered.



3.9: The participant is thanked and checked that they are feeling well and fit to leave the Assessment Centre. They are directed to the toilet and asked to return the urine and saliva samples to the sample specimen fridge before they leave. If required, the participant is given a travel expense claim form which is completed at home and returned in the pre-paid envelope. The participant is given a Comments Card, which, once completed can be placed in the Comments Box at Reception area.

3.10: The participant is directed to the Web Based Diet Questionnaire Area http://www.ukbiobank.ac.uk/docs/quaire_v3.pdf. They are reminded that the log-in details and PIN number are shown on the results information sheet and that log-in assistance can be provided by any member of staff supervising the Reception and Touchscreen areas.

3.11: The participant is invited to help themselves to a hot drink and biscuits before or after completion of Web Based Diet Questionnaire.

4. Sample processing and storage

4.1: This section details the methodology of processing saliva samples collected from participants in the Assessment Centre from the point after the samples have been logged into the centre's application system. This method is used by UK Biobank clinical staff to process the clinical samples taken from participants, safely and to required quality standards. The samples are packed according to protocol and are transported by a dedicated TNT courier, according to a schedule that ensures they remain at the correct temperature.

4.2: Operating the sample refrigeration.
Refrigerators used for storing the blood, urine and saliva samples are kept between 2 to 8°C. Frequent openings of the refrigerator door may require the temperature to be turned down during the clinic operating times. Temperature of the fridges and freezers are recorded each day before opening the doors.

4.3: Processing of saliva samples
The saliva sample is removed from the privacy bag and transferred to the lab refrigerator immediately. It is placed in the next available position in the corresponding sample rack in the fridge.

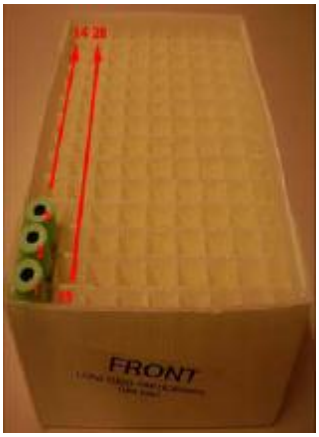
4.4: Fridges and freezers
Each fridge has its own digital thermometer with the display positioned outside the fridge. Temperature is recorded daily for all fridges and freezers are defrosted every three months. Only one freezer is defrosted at a time.

5. Transporting of samples

5.1: This section details the correct method of packing the saliva samples so they reach the UK Biobank laboratory undamaged and within acceptable temperature limits. Also detailed are the correct method for dealing with courier pick ups, any delays in pick up and the return of sample boxes from UK Biobank Coordinating Centre.

5.2: Preparing samples for transport
At the beginning of each day the lab processing staff member prepares 4 transport racks for the saliva tubes. These are stored in the Assessment Centre holding fridge. During the day the sample tubes are loaded into the specific transport rack from the first participant to the last participant (figure 2).

Figure 2: Transport rack



5.3: The saliva sample tube has a larger inner rack within the transport rack to ensure that the larger tubes are transported safely

5.4: 45 minutes prior to the courier arriving, lids are placed on the racks and each rack is individually placed inside a plastic bag. Three sheets of absorbent paper are placed inside the bag. The plastic bag is sealed with a cable tie (see figure 3).

Figure 3: Sealing racks for transport

5.5: On the two short sides of the transport box are placed a cool pack and a spacer (see figure 4). The cool packs are kept in the freezer for at least 24 hours before use and are taken out 30 minutes before being used each day.

Figure 4: Mediporter transport box with cool packs

5.6: The bagged racks are placed into the large transport box (figure 5).

Figure 5: Racks in Mediporter

5.7: A third spacer is placed on top once the sample racks are all loaded and the third cool pack is placed on top of the spacer (figure 6).

Figure 6: Mediporter with cool pack

5.8: The polystyrene lid is placed on top of the box. The lid of the plastic outer box is closed. Every Tuesday place a datalogger is placed in both the large transport box and the Mediporter (section 7)

5.9: The lids of both transport boxes are closed and sealed with plain cable ties (figure 7) and they are moved to the designated pick up area.

Figure 7: Sealing the transport boxes

6. Courier collection

6.1: All Assessment Centres use TNT to return the sample transport boxes to the Co-ordinating Centre Laboratory. Collections from all Assessment Centres occur at 8:30pm, Monday to Saturday (excluding Bank Holidays).

6.2: The sample transport boxes are packed (Section 5) and placed ready for collection in a designated area. TNT provide all UK Biobank Assessment Centres with pre-addressed consignment notes. Assessment Centre Staff complete a TNT Consignment note by inserting the date, and then attaching a barcode from the consignment note on to each individual transport box, prior to collection. Transport boxes are made ready for collection before 8:30pm.

6.3: The TNT courier signs the consignment note and leaves a copy as proof of collection, collects all transport boxes and delivers them to the UK Biobank Co-ordinating Centre for 07:30am the following morning.

6.4: Late Courier Pick Up

If the TNT courier has not arrived by 8:45pm the Assessment Centre Manager is informed. The Assessment Centre Manager telephones the TNT Emergency Contact telephone number immediately. Arrangements are then be made with TNT for a separate pick up that same evening, transporting the samples to UK Biobank Coordinating Centre for the following morning.

6.5: Return of sample boxes from UK Biobank coordinating centre.

Initially each Assessment Centre is provided with a supply of sample transport boxes. From the start of the centre the sample boxes are returned to the Assessment Centre via TNT on a daily basis. The boxes are emptied of the cool packs and stored in the freezers within the lab/storage area. The freezer packs are kept in the freezers provided so they are ready for use.

7. Temperature monitoring

7.1: On a weekly basis a temperature monitor (datalogger), TempTale 4 (figure 8), is placed inside both large transport boxes (blood /urine and saliva) and the Mediporter.

Figure 8: Temptale 4

7.2: The co-ordinating centre configures the dataloggers to automatically begin recording, this is done before they are sent out to the assessment centre. Therefore the assessment centre does not need to press the start button. A symbol of a sun will be present on the datalogger screen to indicate it is set to automatically begin recording (figure 9).

Figure 9: Temptale 4 set to record

7.3: The datalogger is placed on top of the rack within the plastic bag, with this rack at the top of the large transport boxes or mediporter. This will stop the datalogger being inadvertently switched off in transit.

8. Appendices

8.2 Appendix 1: Equipment for blood collection station

Equipment list
Furniture 1 desk 1 chair 1 adjustable desk lamp
Computing 1 desktop personal computer 1 monitor 1 bar code reader
Other Equipment 1 tourniquet 1 test tube rack

Consumables
21G green Vacutainer needle
21G Safety Lok butterfly needle
23G Safety Lok butterfly needle
Vacutainer barrel
Mediswab alcohol impregnated skin wipe
Pre labelled Becton-Dickinson vacutainer blood tubes
Micropore/hypoallergenic tape
Disposable materials tray
Disposable gloves
Disposable apron
Cotton wool balls or gauze squares
Plasters
Sharps bin
Clinical waste bag
Urine collection pots
Vacutainer urine tubes
Opaque plastic bags (for urine sample)
Printing paper
Travel expense claim forms
Pre- paid envelopes

8.2 Appendix 2: Procedures for dealing with potentially serious results and incidental findings

8.2.1: Background

8.2.1.1: The Information Leaflet advises participants that the baseline assessment visit is not a health check. With the exception of the feedback of a limited range of measures (e.g. blood pressure, weight, lung function and bone density) at the end of the assessment visit, participants will not receive any feedback of their individual results. (The overall findings from research based on UK Biobank will, however, be made available to participants.)

8.2.1.2: Staff do not have the same duty of care that they would have in a clinical setting. Rather, their legal duty of care is determined by the research context, and relates to safe and competent collection of consent, questionnaire data, physical measurements, and blood and urine samples.

8.2.1.3: Assessment centre staff are trained not to provide interpretation of results. There may, however, be occasions when it is appropriate to draw attention to results (e.g. very high blood pressure) or incidental findings (e.g. suspected melanoma) that may be potentially serious (i.e. life-threatening).

8.2.2 Dealing with potentially serious results

8.2.2.1: At the end of the assessment visit, participants receive a printed summary of the results of a limited number of physical measurements made during the visit. This summary indicates whether any of these results fall outside defined desirable ranges depending on age, sex and weight (as relevant).

8.2.2.2: Staff may draw these findings to the attention of the participant, but should not attempt to interpret them. Instead, the person should be directed for relevant advice (e.g. stopping smoking; reducing dietary fat and salt) to leaflets available in the Assessment Centre and to NHS Direct (telephone 0845-4647 or www.nhsdirect.nhs.uk).

8.2.2.3: Participants found to have high blood pressure levels at the assessment visit are to be asked whether this is already being managed by their own doctor. If not, the person should be advised to discuss the result with their GP at the earliest opportunity.

8.2.3 Dealing with potentially serious incidental findings

8.2.3.1: An incidental finding is defined as an unexpected finding which is not part of the research assessment and may have clinical significance. Incidental findings may be identified at any stage of the assessment visit.

8.2.3.2: Incidental findings can be divided into two main types:

- Observational findings: Staff may identify observational findings that range from physical evidence (e.g. skin discolouration suggestive of melanoma) through to comments made by participants (e.g. threatened suicide); and
- Disclosed findings: Participants may voluntarily raise health concerns with staff during the course of the assessment visit (e.g. severe chest pain on exercise).

8.2.3.2: Potentially serious incidental findings identified during the Assessment Centre visit by any member of staff should be reported immediately to the Assessment Centre manager or their deputy. This senior member of staff should use their professional judgement to decide what action to take.

8.2.3.3: This may involve discussing the finding with the participant in a neutral manner (e.g. “Are you aware of changes in this mole?”) and, if it remains a serious concern, enquiring about any action already taken (e.g. “Have you asked your GP to look at this mole?”). Where no action has been taken regarding a potentially serous incidental finding, the participant should be advised to discuss it with their GP at the earliest opportunity. [Note: In an emergency, it would be appropriate to call for an ambulance or other appropriate assistance.]

8.2.3.4: A record is to be made in the comments section of the ACE IT system of actions taken for potentially serious incidental findings that are identified. These records will be monitored by the Coordinating Centre on a regular basis.