Oral Fluid Laboratory Screen & Confirmation Test - SOPDRG007S

The following instructions must be completed for this test. A copy of this SOP can be found in your black reference file or online at https://crystal-health.co.uk/sample-collector-training/. If any of the below tasks cannot be completed, call Crystal Health immediately on 0161 707 4935.

The specific sample collection details will be emailed to you for each confirmed booking.

PREPARATION OF FACILITIES

YOU MUST PERFORM THE FOLLOWING TO MAINTAIN CHAIN OF CUSTODY

- Ensure the sample collection facility is private and includes adequate fixtures to perform the sample collection e.g. desk/table and chairs.
- Confirm that no other individuals with exception to the test participant, will have access to the sample collection facility while the work is on progress.
- You must comply with GDPR and confidentiality requirements, and not disclose any personal information or materials either purposefully or accidently.

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COLLECTION INSTRUCTIONS

- 1) Provide the donor with the DONOR ADVICE SHEET
- 2) Ensure all pre-sample collection details have been recorded on the COC form (refer to yellow boxes within the sample collection details sent via email)
- 3) Ensure all Pre-sample collection details have been recorded on the COC form (from yellow boxes previously indicated)
- 4) Complete Section 3 of the COC form (Donor Identification) Refer to troubleshooting and guidance for further instructions
- 5) Complete Section 5 (Declared Medication) of the COC form. If illegal drug use is declared then record in Section 10, continue with the collection and call Crystal Health Group ASAP.

BREATH ALCOHOL SCREEN ONLY (if ordered)- Refer to additional SOPDRG006S (Breathalyser instructions)

- 7) You put on a pair of gloves
- 8) Obtain the oral fluid samples (for both the A and B samples). Refer to troubleshooting and guidance for full visual instruction
- 9) Complete Section 6 of the COC form (Sample Collection Details). Sample temperature is not required
- 10) Complete and sign Section 7 of the COC form (Sample Collector Details)
- 11) Instruct the donor to initial and date (DD/MM/YY) both tamper seals. (be very careful when peeling the seals off).
- 12) Apply the tamper seals to the 2 collection tubes. Refer to troubleshooting and guidance for visual instruction
- 13) Place the tamper sealed collection tubes inside the transport tubes. Place red cap in first to ensure it fits into tube.
- 14) Apply a bar code label to the laboratory sample bag
- 15) Ask the donor to complete Section 11 (Consent of Donor), after reading the consent on the reverse. Please note, NI number is only required for Network Rail testing Refer to troubleshooting and guidance for further instructions
- 16) Review the COC form for accuracy. Detach the top (white) copy and place in the front pouch of the laboratory sample bag with the 2 samples and seal. Refer to troubleshooting and guidance for instruction
- 17) Provide all COC form copies to relevant parties. Refer to troubleshooting and guidance for instruction
- 18) Choose an appropriately sized postal return bag. Place the sealed laboratory bag(s) into the outer postal bag marked for Matrix, seal and post on the same day Refer to troubleshooting and guidance for instruction
- 19) Return all other documentation (including your invoice) to Crystal Health using the first class envelope provided

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TROUBLESHOOTING & GUIDANCE 4) Complete Section3 If the required ID is not available and no authorised person is available to verify the identity of the of the COC form individual, STOP the test and call Crystal Health immediately. (Donor Identification) This is a critical part of the collection process. Instruct the donor to pool saliva in the mouth prior to collection 1. Remove the swab from the pouch 2. Place the collection pad under the tongue like a thermometer. The swab should be oriented so that the round window in the handle is facing upwards. (see yellow arrow) Advise the donor to bow their head so gravity can facilitate 8) Obtain the oral fluid saliva collection. samples (for both the A and B samples). 3. Instruct the donor to keep the pad stationary (the pad should not be chewed or sucked). The collection process is complete when the blue colour appears **Ensure donor has** in the round (sample adequacy) window of the handle. If after 5 minutes the had nil by mouth adequacy indicator has not activated, ask the donor to take out of mouth and for 15 mins prior to try to collect another pool of saliva in the mouth before reattempting collection collection For any other device issues, stop and call Crystal Health immediately 4. Put the entire swab into the Collection Tube and firmly screw on the lid If the donor refuses to provide a sample: Complete Section 12 of the COC form (Non-Conformity) If you observe any unusual behaviour from the donor or you are concerned that the sample may have been adulterated, STOP the test and call Crystal Health fig.1 fig.2 Fig 1. Ensure tamper seals (A & B) are applied over both **Collection Tubes** 12, 13 & 14) Apply initialled tamper seals Fig 2. Place the Collection Tubes inside the Transport Tubes to the 2 Collection ensuring red cap is facing downwards Tubes. Fig 3. Ensure that a barcode is also applied to the laboratory sample bag, as indicated by the red arrow. If the donor refuses to provide consent: **Complete Section 12 (Non-Conformity)** 15) Donor must If the donor provides an admission of illegal drug use: ensure you report this to Crystal Health ASAP complete and SIGN Record the name of the drug and the date last taken in Section 10 (Comments) Section 11 (Consent of If applicable, inform the company representative of the admission and request that they call Crystal Donor) Health Group as soon as possible. Regardless of this, proceed with the sample collection and send the samples to the laboratory. Place the two Transporter Tubes into the back pouch of the bag. Fold the white copy of the COC form and 16) Package the place in the front pouch of the bag. sample ready to send Seal the laboratory sample bag by removing the red text leader tape, fold over (where indicated on the bag) to the laboratory. and seal so the black hatched area is covered and seals the bag. YELLOW COPY TO **GREEN COPY** 17) Provide all COC WHITE COPY **BLUE COPY TO** ORGANISATION TO CRYSTAL form copies to relevant OR CRYSTAL TO LAB **DONOR HEALTH** parties. **HEALTH** 18) Place the sealed Depending on whether your are performing a single collection or multiple laboratory bag into the donor collection, please choose a small or large return postal bag accordingly. postal bag marked for If you cannot dispatch the samples on the same day as the collection, you Matrix, seal and post on must inform Crystal Health immediately. The samples must be stored in a refrigerator overnight. the same day. Version Approval Date Review Date CRYSTAL

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