

# 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 accidentally.

THIS SPACE LEFT INTENTIONALLY BLANK

	Version	Approval Date	Review Date
	v12.07.23	July 2023	July 2024


# Oral Fluid Laboratory Screen & Confirmation Test - SOPDRG007S

## 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 2 of the COC form (Donor Identification) **Refer to troubleshooting and guidance for further instructions**
- 5) Complete Section 4 (Declared Medication) of the COC form. **If illegal drug use is declared then record in Section 9, continue with the collection and call Crystal Health Group ASAP.**

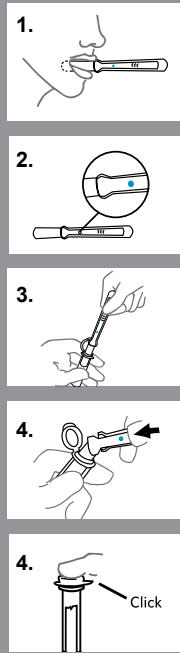



**BREATH ALCOHOL SCREEN ONLY** (if ordered)- Refer to additional SOPDRG006S (Breathalyser instructions)

- 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 5 of the COC form (Sample Collection Details). Sample temperature is not required.
- 10) Complete and sign Section 6 of the COC form (Sample Collector Details)
- 11) Instruct the donor to initial and date (DD/MM/YY) both tamper seals.
- 12) Apply the tamper seals to the 2 collection tubes then place in front pouch of laboratory sample bag. **Refer to troubleshooting and guidance for visual instruction**
- 13) Apply a bar code label to the laboratory sample bag
- 14) Ask the donor to complete Section 10 (Consent of Donor), after reading the consent on the reverse. **Refer to troubleshooting and guidance for further instructions**
- 15) Review the COC form for accuracy. Detach the top (white) copy and place in the back pouch of the laboratory sample bag with the samples and seal. **Refer to troubleshooting and guidance for instruction**
- 16) Provide all COC form copies to relevant parties. **Refer to troubleshooting and guidance for instruction**
- 17) Choose an appropriately sized postal return bag. Place the sealed laboratory bag(s) into the Laboratory postal bag, seal and post on the same day **Refer to troubleshooting and guidance for instruction**
- 18) Return all other documentation (including your invoice) to Crystal Health using the first class envelope provided

	Version	Approval Date	Review Date
	v12.07.23	July 2023	July 2024

# Oral Fluid Laboratory Screen & Confirmation Test - SOPDRG007S

## TROUBLESHOOTING & GUIDANCE

<p>4) Complete Section 2 of the COC form (Donor Identification)</p>	<p>If the required ID is not available and no authorised person is available to verify the identity of the individual, <b>STOP the test and call Crystal Health immediately.</b></p>			
<p>8) Obtain the oral fluid samples (for both the A and B samples).  <b>Ensure donor has had nil by mouth for 15 mins prior to collection</b></p>	<p><b>This is a critical part of the collection process.</b> Instruct the donor to pool saliva into the mouth for a brief period prior to collection</p> <ol style="list-style-type: none"> <li>1. Place the collection pad between the lower cheek and gum with the plastic shield facing the cheek. (The pad should be oriented so that the round window in the handle is facing towards the centre of the mouth). Advise the donor to bow their head so gravity can facilitate saliva collection.</li> <li>2. 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 in the round (sample adequacy) window of the handle. If after 10 minutes the adequacy indicator has not activated, then enough sample will have been collected anyway. <b>For any other device issues, stop and call Crystal Health immediately</b></li> <li>3. Put the pad into the Collection Tube</li> <li>4. Place your thumb on the ridges of the Oral Fluid Collector handle and push forward to eject the pad from the handle by lightly pressing the pad against the side of the Collection Tube until it drops. After ejection, replace the cap on the Collection Tube and seal tightly. The plastic handle may be discarded.</li> </ol> <p><b>If the donor refuses to provide a sample:</b> Complete Section 11 of the COC form (Non-Conformity)</p> <p>If you observe any unusual behaviour from the donor or you are concerned that the sample may have been adulterated, <b>STOP the test and call Crystal Health immediately.</b></p>			
<p>12, ) Apply initialled tamper seals to the 2 Collection Tubes.</p>	<p>Apply initialled and dated tamper seals over the sample tube to seal lid in place</p>			
<p>14) Donor must complete and SIGN Section 10 (Consent of Donor)</p>	<p><b>If the donor refuses to provide consent:</b> <b>Complete Section 11 (Non-Conformity)</b></p> <p><b>If the donor provides an admission of illegal drug use: ensure you report this to Crystal Health ASAP</b></p> <ul style="list-style-type: none"> <li>• Record the name of the drug and the date last taken in Section 9 (Comments)</li> <li>• If applicable, inform the company representative of the admission and request that they call Crystal Health Group as soon as possible. Regardless of this, proceed with the sample collection and send the samples to the laboratory.</li> </ul>			
<p>15) Package the sample ready to send to the laboratory.</p>	<p>Place the two sample tubes into the front pouch of the bag. Fold the white copy of the COC form and place in the back pouch of the bag.</p> <p>Seal the laboratory sample bag by removing the white leader tape, fold over (where indicated on the bag) and seal.</p>			
<p>16) Provide all COC form copies to relevant parties.</p>	<div style="border: 1px solid black; padding: 5px; text-align: center;">WHITE COPY TO LAB</div>	<div style="border: 1px solid black; padding: 5px; text-align: center;">GREEN COPY TO CRYSTAL HEALTH</div>	<div style="border: 1px solid black; padding: 5px; text-align: center;">BLUE COPY TO DONOR</div>	<div style="border: 1px solid black; padding: 5px; text-align: center;">YELLOW COPY TO ORGANISATION OR CRYSTAL HEALTH</div>
<p>17) Place the sealed sample bag into the laboratory postal bag, seal and post on the same day.</p>	<p>Depending on whether you are performing a single collection or multiple donor collection, please choose a small or large return postal bag accordingly. If requested please upgrade postage and retain receipt for tracking purposes. <b>If you cannot dispatch the samples on the same day as the collection, you must inform Crystal Health immediately. The samples must be stored in a refrigerator overnight.</b></p>			
	<p>Version</p>	<p>Approval Date</p>	<p>Review Date</p>	
	<p>v12.07.23</p>	<p>July 2023</p>	<p>July 2024</p>	