

Oral Fluid Collection – Healthcare

Collection Site Preparation

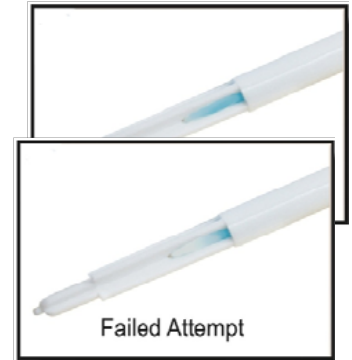
1. The collection site must have all the supplies needed to complete a specimen collection (e.g. collection kits, ink pens, Custody and Control Forms (CCFs), leak-resistant plastic bags, absorbent material, shipping containers, and disposable gloves).
2. Ensure that there is a means for washing hands, suitable clean surface for the collector to use as a work area, and a secure temporary storage area for maintaining specimens until they are transferred to the laboratory.
3. Ensure access to collection supplies is restricted only to the collector(s)/donor(s) and other authorized personnel.

Oral Fluid Collection

1. Obtain and complete the applicable Laboratory Request Form (instructions are included in Appendix 1). For electronic requisitions see Appendix 2.
 - a. Write the donor's name and date of birth on both the adhesive label and the Requisition Form
 - b. Enter remaining requisition data
 - c. Verify with the donor their name and date of birth
2. Check the Quantisal™ packaging to ensure the expiration date has not been exceeded.
 - a. Do not use expired devices
 - i. Ask the practitioner if an alternative specimen may be collected
 - ii. Discard expired devices
 - iii. Order more supplies
3. Ask the donor to “swish and spit” with water at least 10 minutes prior to the specimen collection.
 - a. The donor must then refrain from consumption of food (including gum, candy, etc.) or beverage (including water, coffee, soda, etc.) until after sample collection.
4. Instruct the donor to wash their hands thoroughly and not touch or handle anything prior to opening the collection kit.
5. Ask the donor to accumulate saliva in his/her mouth prior to starting collection.
6. Open Quantisal™ package. Ask the donor to remove the collection device components (transport tube and sealed collector pad) from its package. Set the transport tube aside for later use.
7. Ask the donor to peel open the sealed package and remove the collector pad. Keep the pointed end of the device pointed down once opened. **Do not handle the pad or set it on a counter.**
8. Instruct donor to position the pad under the tongue, close their mouth as they would with a thermometer, and keep their head down to allow gravity to help with saliva collection.

NOTE: Advise the donor to avoid chewing or sucking the pad

9. The collection device should remain under the tongue until the stem indicator turns **completely** blue (see successful collection photo). The collection technician must not remove the collection device at the first sign of blue in the indicator window, as illustrated in the failed attempt photo.
10. Prior to removing collection pad from the donor's mouth, the collection technician must put on clean medical gloves.
11. Remove collection device as soon as the indicator turns **completely** blue.
12. If the indicator has not turned blue in 10 minutes, remove the device and discard. The donor may try drinking water. After drinking water and waiting 10 minutes, try to recollect with another device.
13. If donor cannot provide an adequate oral fluid specimen, the physician may request an alternative specimen type (blood or urine). The alternative specimen should be collected and submitted for testing instead of the OF kit to ensure accuracy of test results. **DO NOT** send in the oral fluid specimen, as the blue color will continue to develop during transport and the laboratory will be unaware of the insufficient volume. Discard the specimen.
14. Hold the Quantisal™ transport tube in an upright position and uncap by pushing up the red cap.
15. It is critical not to spill or empty the proprietary blue buffer liquid (3mL) from the tube.
16. With clean gloved hands from step 10, the collection technician should insert the device into the uncapped transport tube and carefully replace the cap. Ensure you hear a definite "snap" when closing the transport tube.
NOTE: Do not ingest blue buffer solution or place device in mouth after it has made contact with the buffer solution
***In order to avoid contamination, the swab must only be handled with clean donor hands or clean gloved hands**
17. Remove the label from the top of the Laboratory Request Form and place the label length-wise on the side of the tube – **DO NOT** wrap the label around the tube otherwise the barcode cannot be read.
18. Place the closed transport tube into the specimen bag with the absorbent pad.
 - a. Fold and place the completed Laboratory Request Form along with a copy of the donor's insurance card in the back pouch of the Aegis specimen bag.
 - b. If the patient does not have an insurance card, you must obtain and verify their social security number and document it in the demographics section of the Laboratory Request Form.
19. It is important that the specimen be in one compartment and the paperwork in the other to avoid contamination of the requisition in the event of specimen leakage.
20. Seal the bag using the zip-top closure.
21. Immediately place the sealed specimen bag into the proper shipping container.
22. Oral Fluid specimens may be shipped in the same package as other specimens collected that day.



23. If no urine specimens are collected on the same day you collect an oral fluid sample, place the FedEx Billable Stamp on the Small Clinical Box and proceed with shipping. The Small Clinical Box may be shipped along with urine specimens in the FedEx Clinical Pak if space permits. If oral fluid specimens are being shipped along with urine in the Large Clinical Box, no other outer packaging is needed.
24. Remove gloves and discard into the Hazardous waste container.
25. Wash and dry your hands.
26. Ship to the laboratory within 24 hours of collection using the preprinted FedEx labels provided by Aegis.
NOTE: If the specimen(s) cannot be shipped within 24 hours of collection, refrigeration is recommended. If the specimen(s) cannot be shipped within 48 hours of collection, freezing is recommended.

Appendix 1

Laboratory Request Form Completion

Diagnosis Code(s)

NOTE: All requisitions must have a valid ICD-10 code provided by the physician to support the medical necessity of the order.

Diagnosis codes are 3-7 characters (e.g., M79.604). The first digit is alpha, 2nd and 3rd are numeric and 4-7 can be alpha and/or numeric.

1. Codes beginning with a numeric digit are not valid. All diagnosis codes must begin with a letter.
2. V58.69 is not a valid code

Billing/Insurance

Obtain insurance information and ALWAYS validate it with the patient.

Mark the appropriate check box on the Laboratory Request Form.

If Worker's Comp, Letter of Protection (LOP), or Auto:

Completely fill out the Aegis Insurance Information Form and make a copy of the applicable Letter of Protection (LOP), the front and back of the auto insurance card and the patient's health insurance card and send in with the specimen.

Patient Information

Fill in patients complete Social Security Number, First Name, Middle Initial, Last Name, Sex, Date of Birth, Address, City, State, Zip Code and Phone Number

Patient Signature

Ask the patient to verify their information and get their signature

Collector's Initials

Legibly write your initials in the box.

Date Collected

This is the Date of Service (DOS).

Requesting Provider

Select the appropriate requesting provider (Choose only one).

Sample Label

With the patient present and after completing the patient information, remove the label and place it on the top of the specimen device.

Test Selected

Select the test(s) requested by the provider.

Prescribed Medication(s)

Mark the drugs prescribed and the appropriate usage—either Daily or PRN.

Provider Signature

Obtain the ordering provider's signature.

Appendix 2

Contact Aegis Sciences Corporation at (800) 533-7052 for options to utilize an Electronic Laboratory Requisition

Appendix 3**Packaging and shipping samples**

At the end of the business day package all secured specimens for shipment. Select the appropriate container based on the number of specimens. Place the FedEx Express Paid Shipping label on the package for pickup. Schedule pickup by calling 1.800.GoFedEx (1.800.463.3339) or go to fedex.com.

Small white Aegis urine specimen box ("white box") up to 6 specimens

Small and Large Aegis Clinical Boxes (“Aegis box”) up to 20



Clinical pack bag

