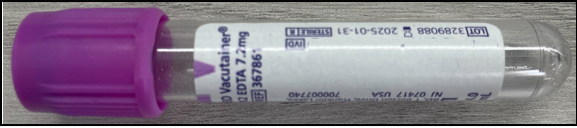
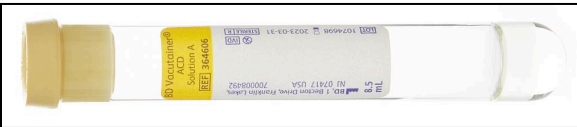
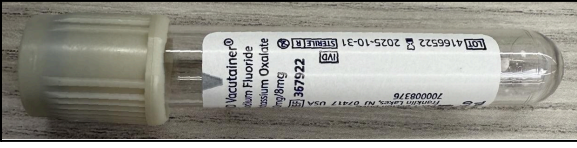


1. Whole Blood - Specimen Criteria
2. Saliva - Specimen Criteria
3. Buccal Swabs - Specimen Criteria
4. Shipping
5. Ordering & Supplies

## 1. Whole Blood - Specimen Criteria

| Blood Tube Info | Preferred |  |        |        |            |                  |
|-----------------|-----------|--|--------|--------|------------|------------------|
|                 | Type      | Product  | Part # | Volume | Dimensions | Preference       |
|                 | K2 EDTA   | <a href="#">BD Vacutainer Whole Blood K2 EDTA 7.2 mg</a>   | 367861 | 4mL    | 13x75 mm   | <b>Preferred</b> |
|                 | K2 EDTA   | <a href="#">BD Vacutainer Whole Blood K2 EDTA 5.4 mg</a>   | 367856 | 3mL    | 13x75 mm   | Acceptable       |
|                 | K2 EDTA   | <a href="#">BD Vacutainer Whole Blood K2 EDTA 10.8 mg</a>  | 367863 | 6mL    | 13x100 mm  | Acceptable       |
|                 | ACD       | <a href="#">BD Vacutainer® Acid citric dextrose (ACD) solution A - trisodium citrate, 22.0 g/L, citric acid, 8.0 g/L, and dextrose, 24.5 g/L</a> | 364606 | 8.5mL  | 16x100 mm  | Acceptable       |
|                 | Grey Top  | <a href="#">BD Hemogard™ Closure/gray - Sodium fluoride 15 mg, potassium oxalate 12 mg</a>   | 367925 | 6mL    | 13x100 mm  | Acceptable       |


### Specimen Tube Images

| Vendor        | Image  | Description                                      |
|---------------|--|--|
| BD Vacutainer |  | <b>Preferred</b><br>EDTA<br>Vacutainer Tube      |
| ACD           |  | Acceptable<br>ACD<br>Vacutainer Glass            |
| Grey Top      |  | Acceptable<br>Sodium Fluoride<br>Vacutainer Tube |

|                |   |
|----------------|---|
| <b>Volume</b>  | <p>Minimum: 3 mL</p> <p>Maximum: Do not exceed tube fill volume</p>   |
| <b>Storage</b> | <ul style="list-style-type: none"> <li>● <b>Ambient</b>, room temperature (15°C to 30°C).</li> <li>● Samples collected late Friday or over the weekend should be stored at room temperature and then shipped the following Monday.</li> </ul> |

| 1. Whole Blood - Specimen Criteria |   |  |  |
|------------------------------------|---|--|--|
|                                    | <ul style="list-style-type: none"> <li>See shipping notes below.</li> </ul>   |  |  |
| <b>Retention</b>                   | No more than 60 days (for blood, saliva, and buccal)  |  |  |
| <b>Specimen Labeling</b>           | Information must match the associated test requisition form. Each tube must be labeled with   |  |  |
|                                    | <ol style="list-style-type: none"> <li>Sample Specimen ID</li> <li>Two (2) patient-specific identifiers (PHI)</li> </ol>  |  |  |
|                                    |   |  |  |
|                                    | <b>#</b>  | <b>Identifiers</b>   | <b>Format</b>  |
|                                    | <b>1</b>  | <b>Sample Specimen ID</b>  | Human-readable & scannable barcode.<br><br>Accepted barcode formats:<br>Code 128 or PDF417 |
|                                    | <b>2</b>  | <b>Patient Specific Identifier (PSI)</b> <ul style="list-style-type: none"> <li>First and Last Name</li> <li>Date of Birth (DOB)</li> <li>Medical Record Number (MRN)</li> </ul> | Human-readable   |
|                                    |   |  | <b>Required</b>  |
|                                    |   |  | Yes.   |
|                                    |   |  | Yes.<br>At least two (2) PSI   |
| <b>Specimen Rejection</b>          | <b>Rejection Criteria</b>   |  | <b>Examples</b>  |
|                                    | Improper Labeling   |  | Hand written PHI, lack of barcodes, or illegible barcodes.                                 |
|                                    | Improper Collection   |  | Non purple, non yellow, non grey such as: red top or green top tubes.                      |
|                                    | Low Volume  |  | Below 3mL.   |
|                                    | Spilled, Leaked, or Damaged   |  | Spilled or damaged during transport.   |
|                                    | Unsuitable Collections: Hemolyzed or Clotted Blood  |  | Improper mixing of specimen tubes after collection.  |
|                                    | Unsuitable Collections: Cord blood  |  | N/A  |
|                                    | Blood from patients who have had an allogeneic bone marrow transplant or an allogeneic stem cell transplant.<br><br>Blood from patients who have had a packed cell/platelet transfusion less than 2 weeks prior to specimen collection.<br><br>Blood from patients who have had a whole blood transfusion less than 4 weeks prior to specimen collection. |  | N/A  |


## 2. Saliva - Specimen Criteria

|  |  |   |  |            |
|--|--|---|--|------------|
| <b>Saliva Tube Information</b>   | <b>Acceptable</b>  |   |  |            |
|  | Product  | Part Number   | Volume   | Dimensions |
|  | Oragene Dx Saliva Collection Kit   | OGD-610   | 5mL  | 16x71 mm   |
|  | Oragene Dx Saliva Collection Kit   | OGD-610.010   | 5mL  | 16x76 mm   |
| <b>Specimen Tube Images</b>  |  |   |  |            |
|  | Vendor   | Image   | Description  |            |
|  | Oragene DX   |       | OGD 610.xxx<br><br>*The OGD-610 kit does not include a hexagon plug at the bottom. |            |
| <b>Volume</b>  | Minimum: 2.0mL (saliva and preservative)<br>Maximum: 4.0mL (saliva and preservative)   |   |  |            |
| <b>Storage</b>   | <ul style="list-style-type: none"> <li>• <b>Ambient</b>, room temperature (15°C to 30°C).</li> <li>• Samples collected late Friday or over the weekend should be stored at room temperature and then shipped the following Monday.</li> <li>• See shipping notes below.</li> </ul>                             |   |  |            |
| <b>Retention</b>   | No more than 60 days (for blood, saliva, and buccal).  |   |  |            |
| <b>Labeling</b>  | Information must match the associated test requisition form. Each tube must be labeled with <ol style="list-style-type: none"> <li>1. Sample Specimen ID</li> <li>2. Two (2) patient-specific identifiers (PHI)</li> <li>3. Ensure the expiration date (collect by date) is visible, do not conceal</li> </ol> |   |  |            |
|  | Identifiers  | Format  | Required   |            |
|  | <b>Sample Specimen ID</b>  | Human-readable & scannable barcode.<br><br>Accepted barcode formats: Code 128 or PDF417 | Yes.   |            |
| <b>Patient Specific Identifier</b> <ul style="list-style-type: none"> <li>• First and Last Name</li> <li>• Date of Birth (DOB)</li> <li>• Medical Record Number (MRN)</li> </ul> | Human-readable   | Yes.<br>At least two (2) from the identifier list.                                      |  |            |

## 2. Saliva - Specimen Criteria

| Specimen Rejection | Rejection Criteria          | Examples  |
|--------------------|-----------------------------|---|
|                    | Volume (Low or High)        | Low: Saliva + Buffer below the indicated line.<br>High: Saliva + Buffer 4 times the indicated line. |
|                    | Color/Opacity               | If the specimen does not resemble saliva, it will be failed.  |
|                    | Particulates                | Solid matter that cannot be broken up after vigorous shaking.                                       |
|                    | Mucous                      | High levels of mucous, not suitable for testing.  |
|                    | Spilled, Leaked, or Damaged | Spilled or damaged during transport.  |
|                    | Improper Collection         | The blue cap was not attached and the funnel was sent.<br>A non-Helix approved saliva kit was sent. |

## 3. Buccal - Specimen Criteria

| Buccal Tube Information | Acceptable   |  |                              |            |
|-------------------------|--|--|------------------------------|------------|
|                         | Product  | Part Number  | Volume                       | Dimensions |
|                         | iSWAB®-DNA Collection Kit  | SD-T-1200XL  | 600µL                        | 16x65 mm   |
| Specimen Tube Images    | Vendor   | Image  | Description                  |            |
|                         | Mawi   |  | SD-T-1200XL requires 2 swabs |            |
|                         |  |  |                              |            |
| Buffer Volume           | Minimum: 700µL<br>Maximum: 800µL   |  |                              |            |
| Storage                 | <ul style="list-style-type: none"> <li>● <b>Ambient</b>, room temperature (15°C to 30°C).</li> <li>● Samples collected late Friday or over the weekend should be stored at room temperature and then shipped the following Monday.</li> <li>● See shipping notes below.</li> </ul>                             |  |                              |            |
| Retention               | No more than 60 days (for blood, saliva, and buccal).  |  |                              |            |
| Labeling                | Information must match the associated test requisition form. Each tube must be labeled with <ol style="list-style-type: none"> <li>1. Sample Specimen ID</li> <li>2. Two (2) patient-specific identifiers (PHI)</li> <li>3. Ensure the expiration date (collect by date) is visible, do not conceal</li> </ol> |  |                              |            |

| 3. Buccal - Specimen Criteria |  |   |  |
|-------------------------------|--|---|--|
|                               | Identifiers  | Format  | Required   |
|                               | <b>Sample Specimen ID</b>  | Human-readable & scannable barcode.<br>Accepted barcode formats: Code 128 or PDF417 | Yes.   |
|                               | <b>Patient Specific Identifier</b> <ul style="list-style-type: none"> <li>• First and Last Name</li> <li>• Date of Birth (DOB)</li> <li>• Medical Record Number (MRN)</li> </ul> | Human-readable  | Yes.<br>At least two (2) from the identifier list. |
| Specimen Rejection            | Rejection Criteria   | Examples  |  |
|                               | Volume (Low or High)   | Low: Less than 600 µL<br>High: Greater than 600 µL                                  |  |
|                               | Color/Opacity  | If the material is not the vendor's buffer  |  |
|                               | Unknown Particulates   | Solid matter that cannot be broken up after vigorous shaking.                       |  |
|                               | Spilled, Leaked, or Damaged  | Spilled or damaged during transport.  |  |
|                               | Improper Collection  | The cap was not attached appropriately.<br>A non-Helix approved kit was sent.       |  |

| 4. SHIPPING                              |   |
|--|---|
| <b>Helix Laboratory</b>                  | <b>Shipping Address</b><br>10170 Sorrento Valley Road, Suite 100, San Diego, CA 92121   |
| <b>General Details</b>                   | <ul style="list-style-type: none"> <li>• Ship samples at <b>ambient temperature</b> to arrive at Helix within <b>96 hours of collection</b>.</li> <li>• Samples must be shipped Monday through Friday, overnight.</li> <li>• Samples collected late Friday or over the weekend should be stored at room temperature and then shipped the following Monday.</li> <li>• Helix Laboratory accepts packages Monday through Saturday between 8AM-4PM PT.</li> <li>• Helix Laboratory is closed on Sunday.</li> </ul>   |
| <b>Packing and Shipping Requirements</b> | <ul style="list-style-type: none"> <li>• Specimen must be placed in a leak-proof biohazard specimen bag containing enough absorbent material to absorb the total volume within the sample.</li> <li>• Multiple specimens in a biohazard specimen bag is acceptable, use discretion when packing.</li> <li>• If shipping multiple samples, up to 40 samples can fit inside an insulated envelope.</li> <li>• Up to 2 insulated envelopes can be contained in the same UPS Laboratory Box (18" x 13" x 3").</li> <li>• A copy of the packing slip should be provided at time of shipment (not required, though</li> </ul> |

| 4. SHIPPING           |  |
|-----------------------|--|
|                       | <p>preferred for traceability).</p> <ul style="list-style-type: none"> <li>○ Please email the packing slip to <a href="mailto:packingslip@helix.com">packingslip@helix.com</a>.</li> </ul>   |
| <b>Shipping Label</b> | <ul style="list-style-type: none"> <li>● Return labels are pre-purchased UPS shipping labels.</li> <li>● Once the box is ready for shipping the site can either leave the box in a designated UPS courier pickup spot, drop off the return boxes directly at UPS, or schedule UPS pickups online.</li> <li>● Option to set up a Placard UPS Healthcare Pickup Point for more frequent pickups- please reach out to <a href="mailto:supply@helix.com">supply@helix.com</a> to get started. This can take up to 4 weeks to implement.</li> </ul> <p>Note: A Partner Site does not need to create a UPS account to schedule UPS pickups</p> |
| <b>Receipt</b>        | Helix Lab will confirm receipt of the shipment once the samples are accessioned.   |

| 5. ORDERING & SUPPLIES    |  |
|---------------------------|--|
| <b>General Details</b>    | <p>A purchase order (PO) is required for any product to be shipped out.</p> <ul style="list-style-type: none"> <li>● Order sufficient quantities to support collection workflows for the entirety of a 3-month supply.</li> <li>● Additional costs are associated with the expedited orders.</li> <li>● For shipment the following are required on the Purchase Order:               <ul style="list-style-type: none"> <li>○ Purchase Order Number</li> <li>○ Ship to location name</li> <li>○ Attention to name</li> <li>○ Address</li> <li>○ Items requested</li> <li>○ Quantity</li> </ul> </li> </ul>   |
| <b>Ordering Workflow</b>  | <p><b>General Information</b></p> <ul style="list-style-type: none"> <li>● Standard lead time for delivery from time of order is 2 weeks,</li> <li>● Helix ships supplies from Columbus, Georgia or San Diego, CA via UPS ground.</li> <li>● Please allow for 5-7 business days in-transit.</li> <li>● Helix encourages quarterly supply orders. This provides Helix with sufficient time to plan activities and the most efficient management of</li> </ul> <p><b>Email Workflow (workflow required for saliva kits)</b></p> <ul style="list-style-type: none"> <li>● Orders must be emailed to <a href="mailto:supply@helix.com">supply@helix.com</a></li> <li>● Orders will ship 3-5 business days after the PO has been approved by the Helix Finance team.</li> </ul> <p><b>Self Service (SpectraPath)</b></p> <ul style="list-style-type: none"> <li>● Contact the dedicated advisor for Spectrapath order guide.</li> </ul> |
| <b>Order Requirements</b> | Electronic health records (EHR) or electronic test requisition forms (TRF) orders are required.  |

## 5. ORDERING & SUPPLIES

### Orderable Supplies

- Oragene Dx Saliva Collection Kit
  - Item#: OGD-610.024+ACP094
  - Item Description: DNA Saliva Collection Kit
  - Minimum Order: 200 units
  - Unit of Measure: 1 Case (CS) =200
- Mawi Buccal Collection Kit
  - Item#: ISD-T-1200XL
  - Item Description: ISWAB DNA XL Collection Tube Bag 1mL
  - Minimum Order: TBD
  - Unit of Measure: TBD
- Biohazard Bags
  - Item #: 17208
  - Item Description: Bag, Biohazard, Reclosable, 6" x 9", Clear, 2mil, 3" x 5" Absorbent Pad, Three-Wall
  - Minimum Order: 1 pack / 100 individual bags
  - Unit of Measure: pack, bag
- Insulated Mailers
  - Item #: S-15217
  - Item Description: Mailer, Silver, Bubble, 11" x 15"
  - Minimum Order: 1 case / 50 individual mailers each
  - Unit of Measure: case, each
- UPS Return Boxes- Healthcare Exempt Human Specimen
  - Item #: 010196140
  - Item Description: 1 box, 16" x 11" x 3"
  - Minimum Order: 1 case / 20 individual boxes each
  - Unit of Measure: case, each
- Return Shipping Label UPS Next Day Air with Saturday Delivery
  - Item #: 17341
  - Minimum Order: 20 return shipping labels each
  - Unit of Measure: label, each

*Note: Insulated Mailers, UPS Return Boxes, and Return Shipping Labels should be ordered together.*