Customization and fulfillment workflow

This is a broad overview of the steps involved in producing a customized product with DNA Genotek, Inc.

1 Introductory sales discussion with client to understand broad requirements

- Preliminary discussion with client
- Project is queued with the customization team
- Customization/SOF team follows up with any questions

2 Customization team call(s) with client to define unique requirements

- Specifics are confirmed for quoting purposes (e.g. barcode format, box form, inserts, bio-specimen bags, workflows, artwork).
- Customization team members are involved as required (Design, SOF/CRM, Regulatory, Engineering)

Iterative process!

3 Quote drafted

- Drafts of quoted configuration(s) reviewed by internal stakeholders before sending to client

4 Single order fulfillment (SOF) quote drafted (if required)

- Request for quote (RFQ) sent to internal fulfillment for service pricing
- Kit and SOF quotes are provided separately

! Quote(s) signed by customer

5 Customization requirements document (CRD) drafted

- Drafts of document(s) reviewed by regulatory and engineering before sending to client
- **NOTE:** Most changes to the configuration post-quoting will require a requote

6 Artwork drafted (if required)

- Drafts of content reviewed by regulatory and design before sending to client
- DNA Genotek provides device-specific content; client provides workflow-specific content
- **NOTE:** Some changes to the material or artwork post-quoting may require a requote

DNA Genotek supplied

- No cost for up to 3 revision cycles
- Average 2 to 3 weeks for initial draft(s)

or

Customer supplied

- Dieline(s) supplied to client once the quote is signed
- Draft timeline is controlled by client

! CRD (+ artwork, if applicable) signed by customer

GO Production ready

- All documents signed by client (e.g. CRD, artwork)
- All documents published in document control system
- Production timeline begins, entered into schedule
- Raw materials sourced

7 Standard shipment

- Account manager provides ship date

or

Single order fulfillment (SOF)

- CRM provides expected launch date

8 Manufacturing

- Production begins
- Internal quality control conducted

Manufacturing

- Production begins
- Internal quality control conducted
- SOF project set up (fulfillment center documentation, customer API integration, forecasting)

9 Delivery

- Ship date provided excludes transit time

Fulfillment

- Components received and inspected
- Sample finished goods built, available to customer upon request
- Ready for client orders

Approximately 10-14 weeks*

+

2-3 weeks SOF

*Final timeline for shipping a customized product shall be defined based on complexity of the order, number of artwork pieces and volume of kits required and does not include any development time that may be needed for new components not currently available in our offerings.

DNAgenotek®

Key considerations for product customization or fulfillment

Regulatory

What is the intended use of your test offering (e.g., research use, clinical diagnostic or medical use, general wellness use, animal use)?

Is the kit being sold direct to consumer (DTC) without the involvement of a clinician?

What country(ies) are you selling your service in?

Does your company have a professional healthcare license or credential in order to purchase the professional-use only and prescription (Rx) medical devices?

Will you be working with infectious samples?

Is the test (assay, software or service) registered with a regulatory authority (e.g., U.S. FDA, Health Canada) within the region it is being sold?

Is the test (assay, software or service) CLIA certified or waived?
If yes, confirm which and specify the state jurisdiction where it is certified or waived.

Are there claims **related to the test (assay, software or service)** that you want to include on the kit packaging labeling?
Do you have data or regulatory clearance† to support the claims?

Is the testing laboratory based in the U.S.? If not, where?

Is the testing laboratory certified or licensed?
If yes, confirm the applicable type (e.g., State Laboratory, FDA, DEA, or EPA License; CLIA, CAP, A2LA, JCAHO, ISO 17025, or ISO 15189 certifications).

Single order fulfillment

Are you intending to ship to customers in **both** the U.S. and Canada?

Do you need **both** individual shipments to end users and bulk shipments to clinics/physicians?

Where will you be shipping kits after a sample has been provided by the donor/consumer? Lab, office, other location?

Which country will receive the kits for **processing**?

What is your 12-month order forecast? 2,500+, 5,000+, 10,000+?

Design

Are you providing designs, or will you use our design service?

Do you have branding assets you can provide (e.g., fonts, brand colors, vector logo)?

Will donors be required to register their kits online?

Do you require any translations?

Are there extra steps unique to your workflow that your end user will need to complete?

Sample identification

Are there unique identifiers that you would like to include for kit identification (e.g., name, date of birth)?‡
Consider any regional laws, privacy standards or regulatory rules that may apply.

Do you require a barcode on the tube?
If yes, consider what format you will need (e.g., Standard 128C, 128B, 2D, QR).

Do you require a barcode data file (list of barcodes per shipment)?

OraSure Technologies

† For diagnostic tests, the claims and related labeling must be approved by relevant regulatory authorities.
‡ DNA Genotek attempts to minimize personally identifiable information (PII) on the kits. Please collaborate with us to determine how we can support your requirements for recording information while maintaining privacy standards.