clonoSEQ®

Testing Service FAQ

Send all specimens to:
Adaptive Clinical Laboratories
1551 Eastlake Avenue East, Suite 200, Seattle, WA 98102

Questions?
Contact Adaptive Clinical Services
clinicalservices@adaptivebiotech.com | (888) 552-8988

A Guide to the clonoSEQ Service Experience

clonoSEQ® is available as an FDA-cleared *in vitro* diagnostic (IVD) test service provided by Adaptive Biotechnologies to detect measurable residual disease (MRD) in bone marrow from patients with multiple myeloma or B-cell acute lymphoblastic leukemia (B-ALL) and blood or bone marrow from patients with chronic lymphocytic leukemia (CLL). clonoSEQ is also available for use in other lymphoid cancers as a CLIA-validated laboratory developed test (LDT) service. For important information about the FDA-cleared uses of clonoSEQ including test limitations, please visit clonoSEQ.com/technical-summary.

PHYSICIAN REGISTRATION

This is my first time ordering the clonoSEQ Assay. How do I get started?

All clinicians who wish to order must first complete a Physician Registration Form. This form can be obtained from and returned to Adaptive Clinical Services. Because this form will be updated on occasion, clinicians who have ordered in the past may be contacted by Adaptive to re-confirm their registration details.

In addition to the Registration Form, Adaptive will need to work with hospital-based institutions or practices treating hospital-registered patients to put in place a **Laboratory Services Agreement** which establishes the features of our service offering and agreed-upon billing terms. We will work with you and/or a colleague you designate to establish a mutually-beneficial agreement. Please contact Clinical Services or your Diagnostic Key Account Manager with questions about this process.

ORDERING AND TEST REQUISITION FORM

How do I place a clonoSEQ order?

All Test Requisition Forms (TRFs) must be completed through our easy-to-use, secure online **Diagnostic Portal**. Please contact Clinical Services for information on how to set up an account.

SPECIMEN REQUIREMENTS AND SHIPPING

What are the requirements for shipping?

Once you have completed a TRF within the Diagnostic Portal, please **print, sign and date** the TRF.

- If you are shipping a specimen for testing, you must include the signed TRF inside the box containing the specimen.
- If you are requesting pathology retrieval assistance from Adaptive, please send the TRF by secure email or fax to Clinical Services.

If you indicate on the TRF that your test order should be billed to the patient's insurance, a **front/back copy of the patient's insurance card** must be included with the TRF.

If you are shipping a specimen, please be sure to:

- Follow the preparation and shipping instructions specified in the **clonoSEQ Test Specimen Requirements**, which are accessible at clonoSEQ.com.
- Label the specimen tube with **two unique patient identifiers** to ensure proper identification.

Adaptive can provide a clonoSEQ Fresh Collection Kit and a clonoSEQ Frozen Shipper. To order, please contact Clinical Services. You may also use your own packaging materials; ship to the address listed at the top of this guide.

PATHOLOGY RETRIEVAL PROCESS

How do I request pathology retrieval assistance?

If desired, Adaptive can assist with the retrieval of archived pathology specimens. Requests for this assistance must be indicated in the Specimen Information section of the TRF. To enable pathology specimen retrieval, the patient's complete pathology report must be included with the signed TRF.

TURNAROUND TIME

How long will it take to get patient results back?

Adaptive aims to provide accurate and timely patient results. You can expect to receive results in approximately **7 days** for fresh specimens and **14 days** for stored specimens, measured from the date that an appropriate sample is received and reconciled in Adaptive's Seattle laboratory. Samples that arrive without requisite information will require additional time to reconcile.

Adaptive must have a valid Clonality (ID) Test result in order to generate a Tracking (MRD) Test result for a given patient. **Delivery of clinical reports containing MRD results will be delayed until a corresponding Clonality (ID) result becomes available.**

If you are requesting Adaptive assistance with pathology specimen retrieval, please note that lab response times to our requests vary considerably. The turnaround times listed above are measured from the date Adaptive receives and reconciles an appropriate specimen. **Turnaround times do not include time required for specimen retrieval.** If specimen retrieval is urgent, Adaptive recommends that the clinician request and submit the specimen directly from the pathology lab.

REPORT DELIVERY

How will I receive the patient report?

You can easily access patient results through Adaptive's Diagnostic Portal—the same portal that you will use to complete clonoSEQ TRFs.

- The Diagnostic Portal enables you to filter and sort patient reports so that you can find specific reports quickly and easily.
- Upon release of new patient results, you will receive an **email notification** with a direct link to your patient's report. You can also choose to have patient results delivered via **secure fax**.
- You will only receive **one email or fax notification per order**, at the time when all results for the patient's order are available. Results of individual tests within an order will always be available in real-time in the Diagnostic Portal.

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