Clonality (ID) Test Specimen Requirements

The clonoSEQ® Clonality (ID) Test determines the clonal diversity of a sample and can also be used to identify the trackable immune receptor sequence(s) of a lymphoid clone. Diagnostic samples are typically used, but other samples with high disease load (e.g., relapse) are also acceptable.

clonoSEQ is available as an FDA-cleared *in vitro* diagnostic (IVD) test service provided by Adaptive Biotechnologies to detect minimal 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). Additionally, clonoSEQ is available for use in other lymphoid cancers and specimen types as a CLIA validated laboratory developed test (LDT). IGHV testing is available as a CLIA-validated LDT and has not been cleared or approved by the FDA. clonoSEQ is only available by prescription from a licensed healthcare professional.

For important information about the FDA-cleared uses of clonoSEQ including test limitations, please visit clonoSEQ.com/technical-summary.

Disease	Sample Sources
Leukemia (e.g., ALL, CLL)	Bone marrow or blood
Multiple myeloma	Bone marrow or plasmacytoma
Non-Hodgkin's Lymphoma (e.g., Mantle cell lymphoma, Diffuse large B-cell lymphoma)	Bone marrow, blood or lymph node
T-cell lymphoma (e.g., Cutaneous T-cell lymphoma, Peripheral T-cell lymphoma)	Skin, blood or lymph node
Sézary syndrome	Skin, blood or bone marrow
Other	Consult with Adaptive Biotechnologies prior to sample submission.

SPECIMEN REQUIREMENTS FOR CLONALITY (ID) TESTING—*Choose source material with the highest level of tumor burden*

The guidance below reflects **minimum input material recommended** for the clonoSEQ Clonality (ID) Test. Providing more material may increase assay success rates. Please provide twice the amount of sample volume specified below if ordering Clonality (ID) testing for both B-cell and T-cell processes.

Please ensure specimen is labeled with **two** patient identifiers. Any specimen processing after collection must occur in a CLIA certified laboratory or a laboratory meeting equivalent requirements.

Sample Source		Sample Preparation & Shipping Information
Fresh Peripheral Blood[1]	• >2 mL in EDTA tube	• Store specimen ambient for same day shipment for next day 10 AM PT delivery • If same day shipment is not an option, store specimen refrigerated until shipment for next day 10 AM PT delivery. Fresh specimens should be received at Adaptive within 5 days of collection.
Fresh Bone Marrow Aspirate[1]	• >200 µL in EDTA tube • Do **NOT** send syringes	• Store specimen ambient for same day shipment for next day 10 AM PT delivery • If same day shipment is not an option, store specimen refrigerated until shipment for next day 10 AM PT delivery. Fresh specimens should be received at Adaptive within 5 days of collection.
Bone Marrow Aspirate Slides[2]	• 3-5 slides	• Unstained slides without cover slips preferred • Ensure slide is labeled with a patient identifier • Ship in slide box labeled with 2 patient identifiers, one of which matches slide identifier • Ensure slides are packed to avoid breakage during shipping • Ship overnight at ambient temperature, 10 AM PT delivery
Genomic DNA[3]	• ≥1 µg (minimum concentration of 15ng/µL)	• Ship specimen ambient for next day 10 AM PT delivery • Genomic DNA must be from one of the primary sample sources listed in this document for Clonality (ID) testing
Cell Pellets	• >50,000 cells	• Ship overnight on dry ice Mon-Thurs only, for next day 10 AM PT delivery
Cell Suspensions	• >50,000 cells	• Ship overnight on dry ice Mon-Thurs only, for next day 10 AM PT delivery
FFPE Scrolls[4,5]	• 5-10 scrolls cut from block, ≥5 µm thickness	• Ship overnight at ambient temperature, 10 AM PT delivery • Place all scrolls from a single block into **one** 2.0 mL tube • We do **NOT** accept decalcified bone marrow core biopsies
FFPE Slides[2,4,5]	• 5-10 slides (FFPE tissue cut from block, ≥5 µm thickness)	• Unstained slides without cover slips preferred • Ensure slide is labeled with a patient identifier • Ship in slide box labeled with 2 patient identifiers, one of which matches slide identifier • Ensure slides are packed to avoid breakage during shipping • Ship overnight at ambient temperature, 10 AM PT delivery

[1] Ship frozen blood or bone marrow overnight on dry ice Mon-Thurs only, for next day 10 AM delivery; [2] Slides that include cover slips require additional processing time and may result in delayed reporting; [3] Adaptive Biotechnologies has assessed the performance of the clonoSEQ Assay based on in-house extraction methods. gDNA extracted by an outside laboratory may be suboptimal in quantity or quality, which could increase the risk of sample failure, reduce sample sensitivity and/or introduce bias in MRD measurement; [4] The dominant clone identification rate may be lower when using FFPE slides/scrolls vs. other ID sample types due to the DNA damage that occurs upon tissue fixation; [5] Clonality (ID) test reports for CLL/SLL patients that are generated based on processing of FFPE specimens will not include an IGHV mutation status result.

Shipping Address	Clinical Services Contact Information
Adaptive Biotechnologies **Attn: CLIA Clinical Laboratory** **1551 Eastlake Ave E, Ste 200, Seattle, Wa 98102**	**Clinical Services** **P: 888 552 8988 | F: 866 623 4408** **E: clinicalservices@adaptivebiotech.com**

Tracking (MRD) Test Specimen Requirements

The clonoSEQ® Tracking (MRD) Test uses **follow-up samples** for the purposes of following the immune receptor sequence(s) identified by the clonoSEQ Clonality (ID) Test.

Follow-up samples can be analyzed **only if results from a previously ordered clonoSEQ Clonality (ID) Test have been reported.**

clonoSEQ is available as an FDA-cleared *in vitro* diagnostic (IVD) test service provided by Adaptive Biotechnologies to detect minimal 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 and specimen types as a CLIA-validated laboratory developed test (LDT). clonoSEQ is only available by prescription from a licensed healthcare professional.

For important information about the FDA-cleared uses of clonoSEQ including test limitations, please visit clonoSEQ.com/technical-summary.

Disease	Sample Sources*
Leukemia (e.g., ALL, CLL)	Bone marrow or blood
Multiple myeloma	Bone marrow or blood
Diffuse Large B-Cell Lymphoma (DLBCL)	Bone marrow, blood or plasma
Other Non-Hodgkin's Lymphoma (e.g., Mantle cell lymphoma)	Bone marrow or blood
T-cell lymphoma (e.g., Cutaneous T-cell lymphoma, Peripheral T-cell lymphoma)	Blood or bone marrow
Sézary syndrome	Blood or bone marrow
Other	Consult with Adaptive Biotechnologies prior to sample submission.

*Inclusion of a sample source in this table does not imply it is preferred for the given indication.

SPECIMEN REQUIREMENTS FOR TRACKING (MRD) TESTING—*Only fresh or frozen specimens accepted*

The guidance below reflects **minimum input material recommended** for the clonoSEQ Tracking (MRD) Test. The amount of material received will impact assay sensitivity. In addition, sensitivity may vary by sample source submitted.

Please ensure specimen is labeled with **two** patient identifiers. Any specimen processing after collection must occur in a CLIA certified laboratory or a laboratory meeting equivalent requirements.

Sample Source		Sample Preparation & Shipping Information
Fresh Peripheral Blood[1]	• >2 mL in EDTA tube	• Store specimen ambient for same day shipment for next day 10 AM PT delivery • If same day shipment is not an option, store specimen refrigerated until shipment for next day 10 AM PT delivery. Fresh specimens should be received at Adaptive within 5 days of collection.
Fresh Bone Marrow Aspirate[1]	• ≥1 mL in EDTA tube[2] • Do **NOT** send syringes	• Store specimen ambient for same day shipment for next day 10 AM PT delivery • If same day shipment is not an option, store specimen refrigerated until shipment for next day 10 AM PT delivery. Fresh specimens should be received at Adaptive within 5 days of collection.
Frozen Plasma (DLBCL only)	• Original blood collection should be in EDTA tube • After plasma isolation, provide >2 mL in nuclease-free tube or cryovial	• Plasma should be isolated from blood within 2 hours of collection • Contact Clinical Services to obtain a copy of our Plasma Isolation Guidelines[3] • Store specimens at -80˚C or below prior to shipment • Ship overnight on dry ice Mon-Thurs only, for next day 10 AM PT delivery
Cell Pellets	• >1 million cells	• Ship overnight on dry ice Mon-Thurs only, for next day 10 AM PT delivery
Cell Suspensions	• >1 million cells	• Ship overnight on dry ice Mon-Thurs only, for next day 10 AM PT delivery

[1] Ship frozen blood or bone marrow overnight on dry ice Mon-Thurs only, for next day 10 AM delivery; [2] For pediatric patients, >200 µL in EDTA tube;
[3] Plasma Isolation Guidelines FORM-00535

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