

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 an FDA-cleared in vitro diagnostic (IVD) test service for use in B-cell acute lymphoblastic leukemia and multiple myeloma patients to detect and monitor measurable

residual disease (MRD) in bone marrow samples. clonoSEQ is also available for use in other lymphoid cancers and validated sample types as a CLIA-regulated laboratory developed test (LDT) service provided by Adaptive Biotechnologies. clonoSEQ is available by prescription only.

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

Disease	Sample Sources
Leukemia (e.g., ALL, CLL)	Bone marrow or blood
Multiple myeloma	Bone marrow
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

The guidance below reflects **minimum input material requirements** 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 <ul style="list-style-type: none"> >2 mL in EDTA tube 	<ul style="list-style-type: none"> 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 <ul style="list-style-type: none"> >200 µL in EDTA tube Do NOT send syringes 	<ul style="list-style-type: none"> 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 Slides¹ <ul style="list-style-type: none"> 3-5 slides 	<ul style="list-style-type: none"> 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 DNA² <ul style="list-style-type: none"> ≥1 µg (minimum concentration of 15ng/µL) 	<ul style="list-style-type: none"> Ship overnight on dry ice, 10 AM PT delivery³ Genomic DNA must be from one of the primary sample sources listed in this document for Clonality (ID) testing
Cell Pellets <ul style="list-style-type: none"> >50,000 cells 	<ul style="list-style-type: none"> Ship overnight on dry ice, 10 AM PT delivery³
Cell Suspensions <ul style="list-style-type: none"> >50,000 cells 	<ul style="list-style-type: none"> Ship overnight on dry ice, 10 AM PT delivery³
FFPE Scrolls⁴ <ul style="list-style-type: none"> 5-10 scrolls cut from block, ≥5 µm thickness 	<ul style="list-style-type: none"> 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^{1,4} <ul style="list-style-type: none"> 3-5 slides (FFPE tissue cut from block, ≥5 µm thickness) 	<ul style="list-style-type: none"> 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 Slides that include cover slips require additional processing time and may result in delayed reporting; ² 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; ³ Please ship specimen on dry ice for delivery Mon-Thurs; 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.

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.**

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monitor measurable residual disease (MRD) in bone marrow samples. clonoSEQ is also available for use in other lymphoid cancers and validated sample types as a CLIA-regulated laboratory developed test (LDT) service provided by Adaptive Biotechnologies. clonoSEQ is available by prescription only.

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

Disease	Sample Sources
Leukemia (e.g., ALL, CLL)	Bone marrow or blood
Multiple myeloma	Bone marrow
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.

SPECIMEN REQUIREMENTS

The guidance below reflects **minimum input material requirements** for the clonoSEQ Tracking (MRD) Test. The amount of material received will impact assay sensitivity.

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 <ul style="list-style-type: none"> >2 mL in EDTA tube 	<ul style="list-style-type: none"> 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 <ul style="list-style-type: none"> ≥1 mL in EDTA tube¹ Do NOT send syringes 	<ul style="list-style-type: none"> 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) <ul style="list-style-type: none"> Original blood collection should be in EDTA tube After plasma isolation, provide >2 mL in nuclease-free tube or cryovial 	<ul style="list-style-type: none"> Contact Clinical Services to obtain a copy of our Plasma Isolation Guidelines² Store specimens at -80°C or below prior to shipment Ship overnight on dry ice, 10 AM PT delivery³
Genomic DNA⁴ <ul style="list-style-type: none"> >7 µg (minimum concentration of 75 ng/µL) 	<ul style="list-style-type: none"> Ship overnight on dry ice, 10 AM PT delivery³ Genomic DNA must be from one of the primary sample sources listed in this document for Tracking (MRD) testing
Cell Pellets <ul style="list-style-type: none"> >1 million cells 	<ul style="list-style-type: none"> Ship overnight on dry ice, 10 AM PT delivery³
Cell Suspensions <ul style="list-style-type: none"> >1 million cells 	<ul style="list-style-type: none"> Ship overnight on dry ice, 10 AM PT delivery³

¹For pediatric patients, >200 µL in EDTA tube; ²Plasma Isolation Guidelines FORM-00535; ³Please ship specimen on dry ice for delivery Mon-Thurs;

⁴Adaptive 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.

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