

## 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](http://clonoSEQ.com/technical-summary).

Disease	Suggested 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
<b>Fresh Peripheral Blood</b> <ul style="list-style-type: none"> <li>&gt;2 mL in EDTA tube</li> </ul>	<ul style="list-style-type: none"> <li>Store fresh specimens at ambient temperature until same-day shipment</li> <li>Ship overnight at ambient temperature, 10 AM PT delivery</li> </ul>
<b>Fresh Bone Marrow Aspirate</b> <ul style="list-style-type: none"> <li>&gt;200 µL in EDTA tube</li> <li>Do <b>NOT</b> send syringes</li> </ul>	<ul style="list-style-type: none"> <li>Store fresh specimens at ambient temperature until same-day shipment</li> <li>Ship overnight at ambient temperature, 10 AM PT delivery</li> </ul>
<b>Bone Marrow Aspirate Slides<sup>1</sup></b> <ul style="list-style-type: none"> <li>3-5 slides</li> </ul>	<ul style="list-style-type: none"> <li>Unstained slides without cover slips preferred</li> <li>Ensure slide is labeled with a patient identifier</li> <li>Ship in slide box labeled with 2 patient identifiers, one of which matches slide identifier</li> <li>Ensure slides are packed to avoid breakage during shipping</li> <li>Ship overnight at ambient temperature, 10 AM PT delivery</li> </ul>
<b>Genomic DNA</b> <ul style="list-style-type: none"> <li>≥1 µg (minimum concentration of 15ng/µL)</li> </ul>	<ul style="list-style-type: none"> <li>Ship overnight on dry ice, 10 AM PT delivery<sup>2</sup></li> <li>Genomic DNA must be from one of the primary sample sources listed in this document for Clonality (ID) testing</li> </ul>
<b>Cell Pellets</b> <ul style="list-style-type: none"> <li>&gt;50,000 cells</li> </ul>	<ul style="list-style-type: none"> <li>Ship overnight on dry ice, 10 AM PT delivery<sup>2</sup></li> </ul>
<b>Cell Suspensions</b> <ul style="list-style-type: none"> <li>&gt;50,000 cells</li> </ul>	<ul style="list-style-type: none"> <li>Ship overnight on dry ice, 10 AM PT delivery<sup>2</sup></li> </ul>
<b>FFPE Scrolls<sup>3</sup></b> <ul style="list-style-type: none"> <li>5-10 scrolls cut from block, ≥5 µm thickness</li> </ul>	<ul style="list-style-type: none"> <li>Ship overnight at ambient temperature, 10 AM PT delivery</li> <li>Place all scrolls from a single block into <b>one</b> 2.0 mL tube</li> <li>We do <b>NOT</b> accept decalcified bone marrow core biopsies</li> </ul>
<b>FFPE Slides<sup>1,3</sup></b> <ul style="list-style-type: none"> <li>3-5 slides (FFPE tissue cut from block, ≥5 µm thickness)</li> </ul>	<ul style="list-style-type: none"> <li>Unstained slides without cover slips preferred</li> <li>Ensure slide is labeled with a patient identifier</li> <li>Ship in slide box labeled with 2 patient identifiers, one of which matches slide identifier</li> <li>Ensure slides are packed to avoid breakage during shipping</li> <li>Ship overnight at ambient temperature, 10 AM PT delivery</li> </ul>

<sup>1</sup> Slides that include cover slips require additional processing time and may result in delayed reporting.

<sup>2</sup> Please ship specimen on dry ice for delivery Mon-Thurs.

<sup>3</sup> 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: <a href="mailto:clinicalservices@adaptivebiotech.com">clinicalservices@adaptivebiotech.com</a>

## 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 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](http://clonoSEQ.com/technical-summary).

Disease	Suggested 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
<b>Fresh Peripheral Blood</b> <ul style="list-style-type: none"> <li>&gt;2 mL in EDTA tube</li> </ul>	<ul style="list-style-type: none"> <li>Store fresh specimens at ambient temperature until same-day shipment</li> <li>Ship overnight at ambient temperature, 10 AM PT delivery</li> </ul>
<b>Fresh Bone Marrow Aspirate</b> <ul style="list-style-type: none"> <li>≥1 mL in EDTA tube<sup>1</sup></li> <li>Do <b>NOT</b> send syringes</li> </ul>	<ul style="list-style-type: none"> <li>Store fresh specimens at ambient temperature until same-day shipment</li> <li>Ship overnight at ambient temperature, 10 AM PT delivery</li> </ul>
<b>Frozen Plasma (DLBCL only)</b> <ul style="list-style-type: none"> <li>Original blood collection should be in EDTA tube</li> <li>After plasma isolation, provide &gt;2 mL in nuclease-free tube or cryovial</li> </ul>	<ul style="list-style-type: none"> <li>Contact Clinical Services to obtain a copy of our Plasma Isolation Guidelines<sup>2</sup></li> <li>Store specimens at -80 °C or below prior to shipment</li> <li>Ship overnight on dry ice, 10 AM PT delivery<sup>3</sup></li> </ul>
<b>Genomic DNA</b> <ul style="list-style-type: none"> <li>&gt;7 µg (minimum concentration of 75 ng/µL)</li> </ul>	<ul style="list-style-type: none"> <li>Ship overnight on dry ice, 10 AM PT delivery<sup>3</sup></li> <li>Genomic DNA must be from one of the primary sample sources listed in this document for Tracking (MRD) testing</li> </ul>
<b>Cell Pellets</b> <ul style="list-style-type: none"> <li>&gt;1 million cells</li> </ul>	<ul style="list-style-type: none"> <li>Ship overnight on dry ice, 10 AM PT delivery<sup>3</sup></li> </ul>
<b>Cell Suspensions</b> <ul style="list-style-type: none"> <li>&gt;1 million cells</li> </ul>	<ul style="list-style-type: none"> <li>Ship overnight on dry ice, 10 AM PT delivery<sup>3</sup></li> </ul>

<sup>1</sup>For pediatric patients, >200 µL in EDTA tube.

<sup>2</sup>Plasma Isolation Guidelines FORM-00535.

<sup>3</sup>Please ship specimen on dry ice for delivery Mon-Thurs.

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