Adaptive

MEDICARE COVERED

clonoSEQ®

THE FIRST & ONLY FDA-CLEARED ASSAY FOR MRD DETECTION

In bone marrow from patients with multiple myeloma and B-cell acute lymphoblastic leukemia (ALL) and blood or bone marrow from patients with chronic lymphocytic leukemia (CLL)

MRD: A powerful way to assess response and predict patient outcomes

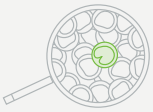
Measurable (or minimal) residual disease (MRD) refers to the small number of cancer cells that may remain in a patient's body during and after treatment. Clinical practice guidelines recognize that MRD status is a reliable indicator of clinical outcome and response to therapy in myeloma, ALL and CLL patients.[1,2,3]

The clonoSEQ® Assay is an MRD assessment tool powered by next-generation sequencing (NGS) technology and differentiated from other NGS assays by groundbreaking advances in chemistry and proprietary bioinformatics.[4,5]

Clinicians who leverage the latest advances in personalized medicine use clonoSEQ to:[4]

- ✓ **Predict** long-term outcomes
- ✓ **Assess** treatment response
- ✓ **Monitor** disease burden
- ✓ **Detect** potential relapse

Why choose clonoSEQ?[4,5]



Deep sensitivity: Able to detect one cancerous cell in 1 million normal cells*

Reliable results: First and only FDA-cleared MRD assay; demonstrates accuracy, precision, and reproducibility

Easy to order: Ordered through a central reference lab with 7-day MRD turnaround

Broad patient experience: >12,900 patients tested to date

Widely utilized by experts: 30 out of 30 NCCN institutions currently using in clinical trials and/or clinical practice

NCCN Guidelines: NGS MRD testing incorporated in NCCN guidelines for myeloma, ALL and CLL[1,2,3]

How clonoSEQ works[4]

Clonality (ID) Test

Identifies trackable malignant DNA sequence(s) in a high disease load sample collected at the time of diagnosis or relapse

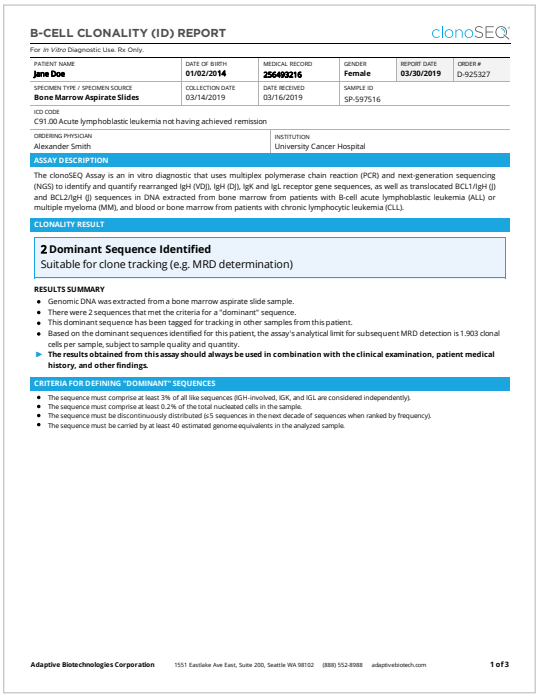
Tracking (MRD) Test

Quantifies and tracks MRD during or after treatment in a freshly-drawn bone marrow or blood sample

*With sufficient input material

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.

Clonality (ID) Report



B-CELL CLONALITY (ID) REPORT

clonoSEQ

For In Vitro Diagnostic Use. *Rx Only.*

PATIENT NAME	DATE OF BIRTH	MEDICAL RECORD	GENDER	REPORT DATE	ORDER #
Jane Doe	01/02/2014	256493216	Female	03/30/2019	D-925327

SPECIMEN TYPE / SPECIMEN SOURCE	COLLECTION DATE	DATE RECEIVED	SAMPLE ID
Bone Marrow Aspirate Slides	03/14/2019	03/16/2019	SP-597516

ICD CODE
C91.00 Acute lymphoblastic leukemia not having achieved remission

ORDERING PHYSICIAN	INSTITUTION
Alexander Smith	University Cancer Hospital

ASSAY DESCRIPTION

The clonoSEQ Assay is an in vitro diagnostic that uses multiplex polymerase chain reaction (PCR) and next-generation sequencing (NGS) to identify and quantify rearranged IgH (VDJ), IgH (DJ), IgK and IgL receptor gene sequences, as well as translocated BCL1/IgH (J) and BCL2/IgH (J) sequences in DNA extracted from bone marrow from patients with B-cell acute lymphoblastic leukemia (ALL) or multiple myeloma (MM), and blood or bone marrow from patients with chronic lymphocytic leukemia (CLL).

CLONALITY RESULT

2 Dominant Sequence Identified
Suitable for clone tracking (e.g. MRD determination)

RESULTS SUMMARY

- Genomic DNA was extracted from a bone marrow aspirate slide sample.
- There were 2 sequences that met the criteria for a "dominant" sequence.
- This dominant sequence has been tagged for tracking in other samples from this patient.
- Based on the dominant sequences identified for this patient, the assay's analytical limit for subsequent MRD detection is 1.903 clonal cells per sample, subject to sample quality and quantity.
- **The results obtained from this assay should always be used in combination with the clinical examination, patient medical history, and other findings.**

CRITERIA FOR DEFINING "DOMINANT" SEQUENCES

- The sequence must comprise at least 3% of all like sequences (IGH-involved, IGK, and IGL are considered independently).
- The sequence must comprise at least 0.2% of the total nucleated cells in the sample.
- The sequence must be discontinuously distributed (≤5 sequences in the next decade of sequences when ranked by frequency).
- The sequence must be carried by at least 40 estimated genome equivalents in the analyzed sample.

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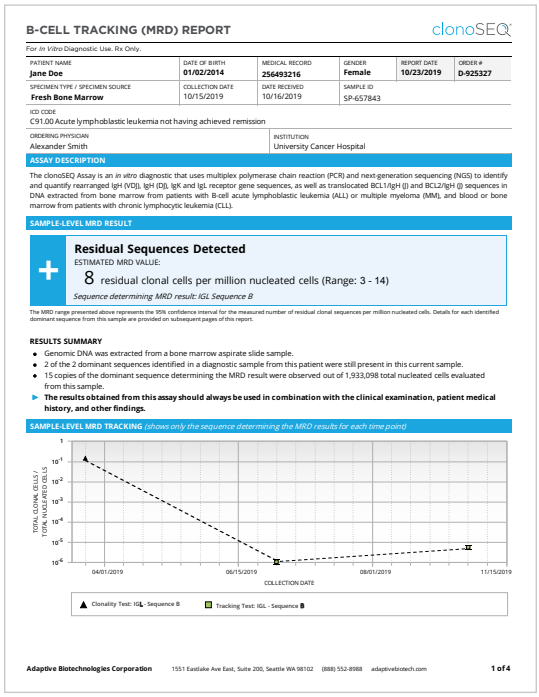
Tracking (MRD) Report



B-CELL TRACKING (MRD) REPORT

clonoSEQ

For In Vitro Diagnostic Use. Rx Only.

PATIENT NAME	DATE OF BIRTH	MEDICAL RECORD	GENDER	REPORT DATE	ORDER #
Jane Doe	01/02/2014	256493216	Female	10/23/2019	D-925327

SPECIMEN TYPE / SPECIMEN SOURCE	COLLECTION DATE	DATE RECEIVED	SAMPLE ID
Fresh Bone Marrow	10/15/2019	10/16/2019	SP-657843

ICD CODE
C91.00 Acute lymphoblastic leukemia not having achieved remission

ORDERING PHYSICIAN	INSTITUTION
Alexander Smith	University Cancer Hospital

ASSAY DESCRIPTION

The clonoSEQ Assay is an *in vitro* diagnostic that uses multiplex polymerase chain reaction (PCR) and next-generation sequencing (NGS) to identify and quantify rearranged IgH (VDJ), IgH (DJ), IgK and IgL receptor gene sequences, as well as translocated BCL1/IgH (J) and BCL2/IgH (J) sequences in DNA extracted from bone marrow from patients with B-cell acute lymphoblastic leukemia (ALL) or multiple myeloma (MM), and blood or bone marrow from patients with chronic lymphocytic leukemia (CLL).

SAMPLE-LEVEL MRD RESULT

Residual Sequences Detected
ESTIMATED MRD VALUE:
8 residual clonal cells per million nucleated cells (Range: 3 - 14)
Sequence determining MRD result: IGL Sequence B

The MRD range presented above represents the 95% confidence interval for the measured number of residual clonal sequences per million nucleated cells. Details for each identified dominant sequence from this sample are provided on subsequent pages of this report.

RESULTS SUMMARY

- Genomic DNA was extracted from a bone marrow aspirate slide sample.
- 2 of the 2 dominant sequences identified in a diagnostic sample from this patient were still present in this current sample.
- 15 copies of the dominant sequence determining the MRD result were observed out of 1,933,098 total nucleated cells evaluated from this sample.
- **The results obtained from this assay should always be used in combination with the clinical examination, patient medical history, and other findings.**

SAMPLE-LEVEL MRD TRACKING *(shows only the sequence determining the MRD results for each time point)*

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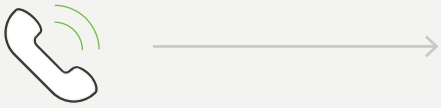
I want to order clonoSEQ. How do I get started?



Contact Clinical Services

Contact Adaptive's Clinical Services team at 1-888-552-8988 or clinicalservices@adaptivebiotech.com

Set up account

Obtain an account setup form for your practice

Fill out Physician Registration Form

Provide details on your practice and establish contact preferences

Order online

Our secure online Diagnostic Portal reduces data entry errors and makes repeat ordering easy

Samples processed

Turnaround time is approximately 7 days for fresh specimens and 14 days for stored/archived specimens

Access reports online

Patient reports are available through the Diagnostic Portal or secure fax

1. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Acute Lymphoblastic Leukemia V.1.2020. © National Comprehensive Cancer Network, Inc. 2020. All rights reserved. Accessed [February 19, 2020]. To view the most recent and complete version of the guideline, go online to NCCN.org.*
2. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Multiple Myeloma V.2.2020. © National Comprehensive Cancer Network, Inc. 2020. All rights reserved. Accessed [February 19, 2020]. To view the most recent and complete version of the guideline, go online to NCCN.org*.
3. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Chronic Lymphocytic Leukemia/Small Lymphocytic Leukemia V.4.2020. © National Comprehensive Cancer Network, Inc. 2020. All rights reserved. Accessed [February 19, 2020]. To view the most recent and complete version of the guideline, go online to NCCN.org.*
4. clonoSEQ®. [technical summary]. Seattle, WA: Adaptive Biotechnologies Corporation; 2020.
5. Ching T, et al. *BMC Cancer*. 2020;20:612.

* NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way.

PM-US-cSEQ-0145-3

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