

clonoSEQ®

THE FIRST & ONLY FDA-CLEARED ASSAY FOR MRD DETECTION

In bone marrow samples from multiple myeloma and B-cell acute lymphoblastic leukemia (ALL) patients

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 MM and ALL patients.^{1,2}

The clonoSEQ Assay detects and monitors MRD

in bone marrow samples from patients with multiple myeloma or B-ALL. Clinical outcomes are strongly associated with MRD levels as measured by clonoSEQ.³

Clinicians who leverage the latest advances in personalized medicine use clonoSEQ to:³

✓ **Help Predict**
clinical outcomes

✓ **Assess**
treatment response

✓ **Monitor**
remission status

✓ **Detect**
potential relapse

Why choose clonoSEQ?³



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



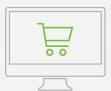
Broad patient experience:
>9,000 patients tested to date



Reliable results: First MRD assay to demonstrate accuracy, precision and reproducibility that meets FDA standards



Widely utilized by experts: 25 of 28 NCCN institutions currently using in clinical trials and/or clinical practice



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

How clonoSEQ works³

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

Remember: A successful ID test is required BEFORE an MRD test can be completed

*With sufficient input material; [†]Blood-based MRD testing is available as a CLIA-regulated laboratory developed test (LDT) service provided by Adaptive Biotechnologies. This use of clonoSEQ has not been approved or cleared by the FDA.

clonoSEQ is an FDA-cleared in vitro diagnostic (IVD) test service provided by Adaptive Biotechnologies 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 as a CLIA-regulated laboratory developed test (LDT) service provided by Adaptive Biotechnologies. clonoSEQ is available by prescription only. clonoSEQ results should always be used in combination with clinical examination, patient medical history, and other findings. For important information about the FDA-cleared uses of clonoSEQ, including test limitations, visit clonoSEQ.com/technical-summary.

clonoSEQ Clonality (ID) and Tracking (MRD) reports

B-CELL CLONALITY (ID) REPORT
clonoSEQ

For In Vitro Diagnostic Use. Rx Only.

PATIENT NAME Jane Doe	DATE OF BIRTH 01/02/2014	MEDICAL RECORD 256493216	GENDER Female	REPORT DATE 03/30/2018	ORDER # D-925327
SPECIMEN TYPE / SPECIMEN SOURCE Bone Marrow Aspirate Slides	COLLECTION DATE 03/14/2018	DATE RECEIVED 03/16/2018	SAMPLE ID SP-597516		

ID CODE
CSI.00 Acute lymphoblastic leukemia not having achieved remission

ORDERING PHYSICIAN
Alexander Smith INSTITUTION
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), IghD(J), IghK, and Igl receptor gene sequences, as well as translocated BCL1(IgH) and BCL2(IgH) sequences in DNA extracted from bone marrow from patients with B-cell acute lymphoblastic leukemia (ALL) or multiple myeloma (MM).

CLONALITY RESULT

1 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 was 1 sequence 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 1,933 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 file sequences (IGH involved, IGHK, 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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B-CELL TRACKING (MRD) REPORT
clonoSEQ

For In Vitro Diagnostic Use. Rx Only.

PATIENT NAME Jane Doe	DATE OF BIRTH 01/02/2014	MEDICAL RECORD 256493216	GENDER Female	REPORT DATE 10/23/2018	ORDER # D-925327
SPECIMEN TYPE / SPECIMEN SOURCE Fresh Bone Marrow	COLLECTION DATE 10/15/2018	DATE RECEIVED 10/16/2018	SAMPLE ID SP-657843		

ID CODE
CSI.00 Acute lymphoblastic leukemia not having achieved remission

ORDERING PHYSICIAN
Alexander Smith INSTITUTION
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), IghD(J), IghK, and Igl receptor gene sequences, as well as translocated BCL1(IgH) and BCL2(IgH) sequences in DNA extracted from bone marrow from patients with B-cell acute lymphoblastic leukemia (ALL) or multiple myeloma (MM).

SAMPLE-LEVEL MRD RESULT

Residual Sequences Detected
ESTIMATED MRD VALUE:

8 residual clonal cells per million nucleated cells (Range: 6 - 27)

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.

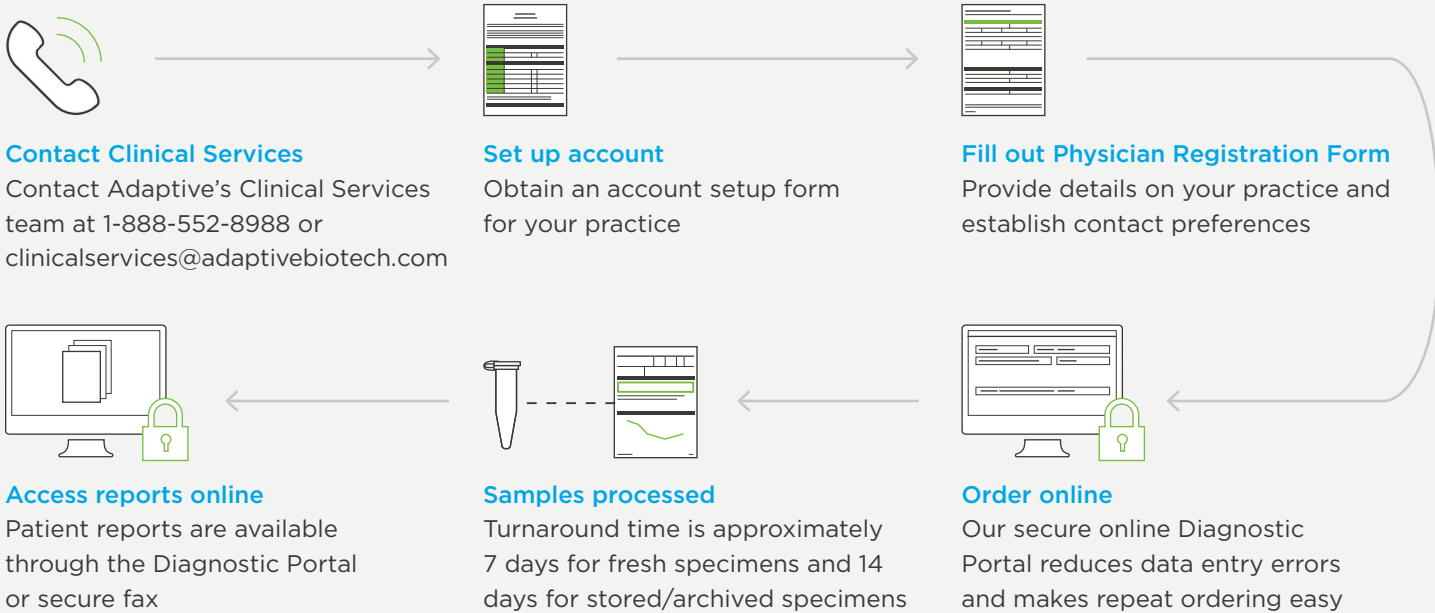
RESULTS SUMMARY

- 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?



1. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines[®]) for Multiple Myeloma V.1.2019. © National Comprehensive Cancer Network, Inc. 2018. All rights reserved. Accessed July 20, 2018. 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 Acute Lymphoblastic Leukemia V.1.2018. © National Comprehensive Cancer Network, Inc. 2018. All rights reserved. Accessed March 12, 2018. To view the most recent and complete version of the guideline, go online to NCCN.org.*

3. clonoSEQ[®]. [technical summary]. Seattle, WA: Adaptive Biotechnologies Corporation; 2018.

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