CatALLyst™: Considerations for Measurable Residual Disease (MRD) Pathology Report Template Creation, Reporting, and Interpretation of Results

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Program Information

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- This presentation is not a CME-accredited program

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About CatALLyst™

- Recognizing the need for a comprehensive resource on measurable residual disease (MRD) education, Amgen Oncology engaged with several opinion leaders in acute lymphoblastic leukemia (ALL) and MRD. CatALLyst™ is an initiative that gives treaters of ALL a reference for management considerations and other helpful content gathered and inspired by this engagement

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Disclosures

[Speaker Name, Degree]	[Speaker Name, Degree]

These speakers are two of the opinion leaders that Amgen brought together to help give treaters of acute lymphoblastic leukemia (ALL) a reference for management considerations and other helpful content.

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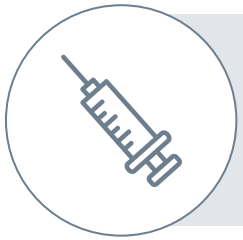
Educational Objectives

Review MRD testing methodologies in ALL and understand the differences in testing requirements



Discuss a sample MRD pathology report, highlighting information that the opinion leaders brought together by Amgen Oncology view as important to drive standardization of reporting and interpretation of MRD test results

Provide a brief overview of helpful considerations to interpret test results to potentially make MRD-based treatment decisions in ALL

ALL, acute lymphoblastic leukemia; MRD, measurable residual disease.

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Outline

- **Considerations Prior to MRD Testing**
  MRD Testing Methodologies, Baseline Sample Requirements for MRD Detection Methods, and Considerations for Submitting an MRD Test Requisition Form
- **Key Information Contained in a Sample MRD Pathology Report**
  Overview of a Sample MRD Pathology Report, the Perspective of Opinion Leaders Brought Together by Amgen Oncology on MRD Pathology Reports, and Summary
- **Considerations When Interpreting MRD Test Results**
  Considerations for the Interpretation of MRD Test Results
- **Summary**

MRD, measurable residual disease.

Considerations Prior to MRD Testing

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MRD in ALL Can Be Quantified Using Methodologies With Differences in Targets and Sensitivities

There are 3 common techniques to quantify MRD, with sensitivity thresholds ranging from < 0.01% to < 0.0001% [1]

	Flow Cytometry	Quantitative Polymerase Chain Reaction (Q-PCR)	Next-Generation Sequencing (NGS)
Description	Rapid and quantitative method of identifying cancer cells [2]	A method in which a section of DNA from cancer cells is replicated and amplified [2]	Extremely sensitive and accurate DNA sequencing method [3]
Target	Leukemia-associated immunophenotypes [4]	Ig and TCR gene rearrangements or gene fusions (eg, *BCR-ABL1*) [5]	Ig and TCR gene rearrangements [3]
Typical Sensitivity*	1 cancer cell in 10,000 normal cells (0.01%) [3]	1 cancer cell in 100,000 normal cells (0.001%) [3]	1 cancer cell in 1,000,000 normal cells (0.0001%) [3]
Turnaround Time	~ 1 day [4,5]	• ~ 1–2 weeks (eg, *BCR-ABL1*) [6] • 3–4 weeks for diagnostic sample and ~ 1 week for follow-up analyses (ASO-PCR) [7,†]	~ 1 week [4]

MRD testing can be performed in-house at some institutions, or the sample can be sent to an external CLIA-certified laboratory [8,9]

*Assays with < 0.01% sensitivity cannot be used to quantify MRD accurately. [5]
†Not widely available in the US. [10]
ALL, acute lymphoblastic leukemia; ASO, allele-specific oligonucleotide; BCR-ABL1, breakpoint cluster region protein-abelson murine leukemia viral oncogene homolog 1; CLIA, Clinical Laboratory Improvement Amendments; Ig, immunoglobulin; MRD, measurable residual disease; TCR, T-cell receptor.

1. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Acute Lymphoblastic Leukemia V.2.2021. © National Comprehensive Cancer Network, Inc. 2021. All rights reserved. Accessed December 1, 2021. To view the most recent and complete version of the guideline, go online to NCCN.org. 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. **2.** Brüggemann M, et al. *Semin Oncol.* 2012;39:47-57. **3.** Dalle IA, et al. *Ther Adv Hematol.* 2020;11. doi:2040620720910023. **4.** Kruse A, et al. *Int J Mol Sci.* 2020;21:1054. **5.** Correia RP, et al. *Int J Lab Hematol.* 2021;43:354-363. **6.** Paietta E. In: Wiernik PH, et al, eds. *Neoplastic Diseases of the Blood*. 6th ed. Springer; 2018:237-279. **7.** van Dongen JJM, et al. *Blood.* 2015;125:3996-4009. **8.** Ayala R, et al. *J Lab Precis Med.* 2018;11:105. **9.** Centers for Disease Control and Prevention. www.cdc.gov. Accessed December 1, 2021. **10.** Akabane H, et al. *Clin Adv Hematol Oncol*. 2020;18:413-422.

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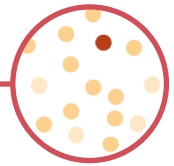
Baseline Characterization of Leukemic Clones May Be Required for Subsequent MRD Analysis in ALL

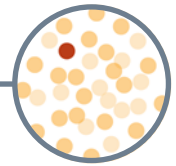
- A baseline sample can help characterize leukemic clones that can be monitored throughout therapy with subsequent MRD testing

Baseline Sample Requirements Based on MRD Detection Method



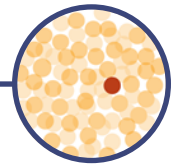
Flow Cytometry

Baseline sample preferred but not required *



Polymerase Chain Reaction (PCR)

Baseline or prior sample obtained at diagnosis with detectable disease is required to characterize leukemic clones



Next-Generation Sequencing (NGS)

Baseline or prior sample obtained at diagnosis with detectable disease is required to characterize leukemic clones

Consider the availability of a baseline or prior sample obtained at diagnosis when selecting the most appropriate MRD detection methodology

*For DfN method only.
ALL, acute lymphoblastic leukemia; DfN, different-from-normal; MRD, measurable residual disease.
Dalle IA, et al. *Ther Adv Hematol*. 2020;11. doi:2040620720910023.

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A Requisition Form Should Be Submitted to the Laboratory to Request MRD Testing

The opinion leaders brought together by Amgen Oncology suggest standardizing information documented within an MRD test requisition form to assist pathologists in assessing sample adequacy and analysis, in order to compile a pathology report for the hematologist/oncologist to interpret results

When ordering an MRD test, the opinion leaders brought together by Amgen Oncology suggest that the hematologist/oncologist include the following information within the requisition form:

- **Patient information** (eg, patient name, sex, date of birth, medical record number) [1,2]
- **Patient medical history** (eg, diagnosis, current treatment phase, current treatments [including the cycle and day of therapy], prior treatment history) [1-3]
- **Sample details** (eg, source/type, whether the sample was from the first or subsequent pull, sample volume, collection date and time, sample ID #) [1,2,4]
- **Testing methodology** requested, if requisition form is not assay specific (eg, flow cytometry, Q-PCR, NGS, other requests) [1,2]

Following submission of an MRD test requisition form, the pathologist should ensure that all relevant details of an MRD pathology report are compiled to assist the hematologist/oncologist in interpreting results [2]

MRD, measurable residual disease; NGS, next-generation sequencing; Q-PCR, quantitative polymerase chain reaction.

1. UW Medicine. https://testguide.labmed.uw.edu. Accessed December 1, 2021. **2.** Arber DA, et al. *Arch Pathol Lab Med*. 2017;141:1342-1393. **3.** Correia RP, et al. *Int J Lab Hematol.* 2021;43:354-363. **4.** Helgestad J, et al. *Pediatr Blood Cancer.* 2011;57:224-226.

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Key Information Contained in a Sample MRD Pathology Report

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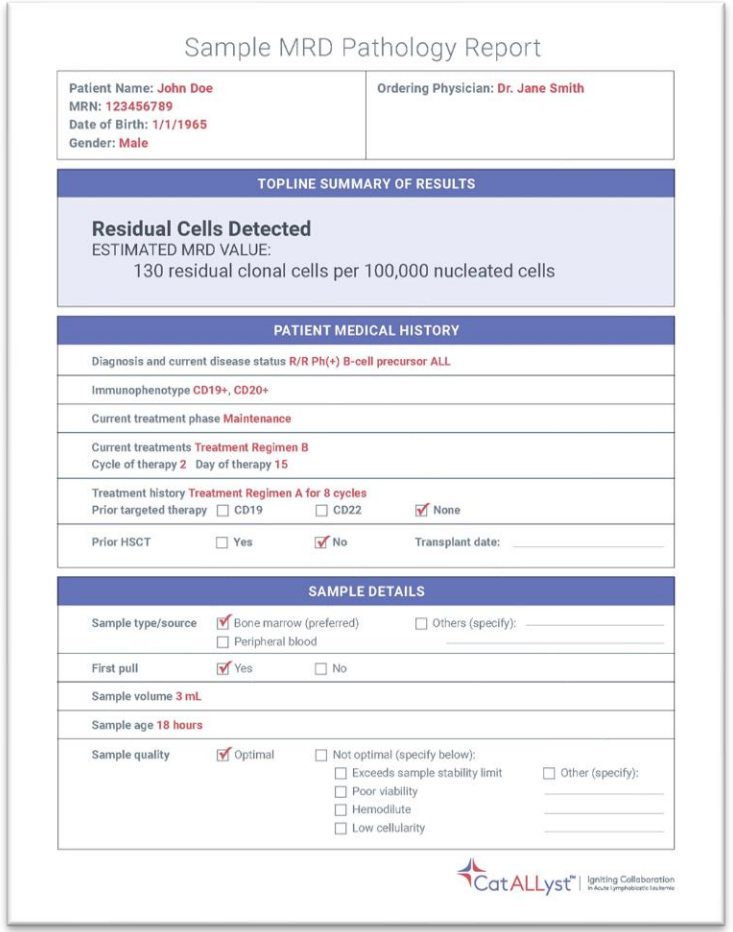
Overview of a Sample MRD Pathology Report *

The opinion leaders brought together by Amgen Oncology suggest standardizing information documented within an MRD pathology report, including:

1. **Patient information**
2. **Topline summary of results**
3. **Patient medical history**
4. **Sample details**
5. Methodology details
6. Detailed summary of results
7. Results over time



*The above MRD pathology report is a sample report that only highlights information that the opinion leaders brought together by Amgen Oncology view as important to document in reports. This sample report is for educational and informational purposes only.

ALL, acute lymphoblastic leukemia; CD, cluster of differentiation; HSCT, allogeneic hematopoietic stem cell transplantation; MRD, measurable residual disease; Ph(+), Philadelphia chromosome–positive; R/R, relapsed or refractory.

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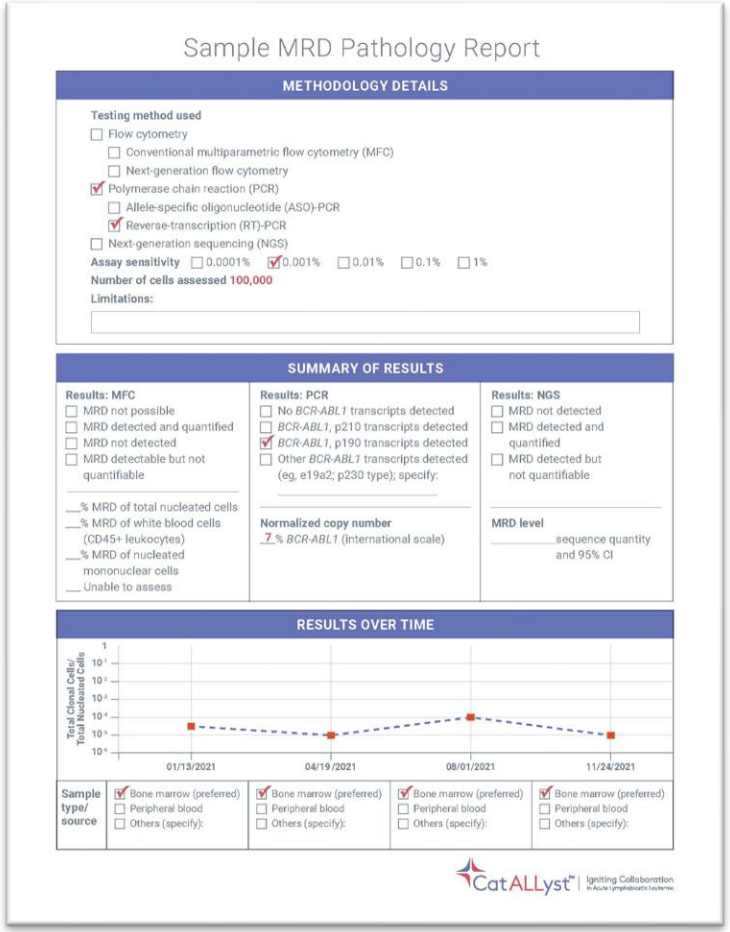
Overview of a Sample MRD Pathology Report * (cont'd)

The opinion leaders brought together by Amgen Oncology suggest standardizing information documented within an MRD pathology report, including:

1. Patient information
2. Topline summary of results
3. Patient medical history
4. Sample details
5. **Methodology details**
6. **Detailed summary of results**
7. **Results over time**



The information included within an MRD pathology report is key in determining the next steps in the treatment of ALL and to guide MRD-based treatment decisions [1-5]

*The above MRD pathology report is a sample report that only highlights information that the opinion leaders brought together by Amgen Oncology view as important to document in reports. This sample report is for educational and informational purposes only.

ALL, acute lymphoblastic leukemia; BCR-ABL1, breakpoint cluster region protein-abelson murine leukemia viral oncogene homolog; CD, cluster of differentiation; CI, confidence interval; HSCT, allogeneic hematopoietic stem cell transplantation; MRD, measurable residual disease.

1. Arber DA, et al. *Arch Pathol Lab Med*. 2017;141:1342-1393. **2.** Brüggemann M, et al. *Blood.* 2012;120:4470-4481. **3.** Paietta E. In: Wiernik PH, et al, eds. *Neoplastic Diseases of the Blood*. 6th ed. Springer; 2018:237-279. **4.** Correia RP, et al. *Int J Lab Hematol.* 2021;43:354-363. **5.** clonoSEQ®. https://adaptivebiotech.showpad.com/share/vENsMo9HgtZXfBdE0nd5x. Accessed December 1, 2021.

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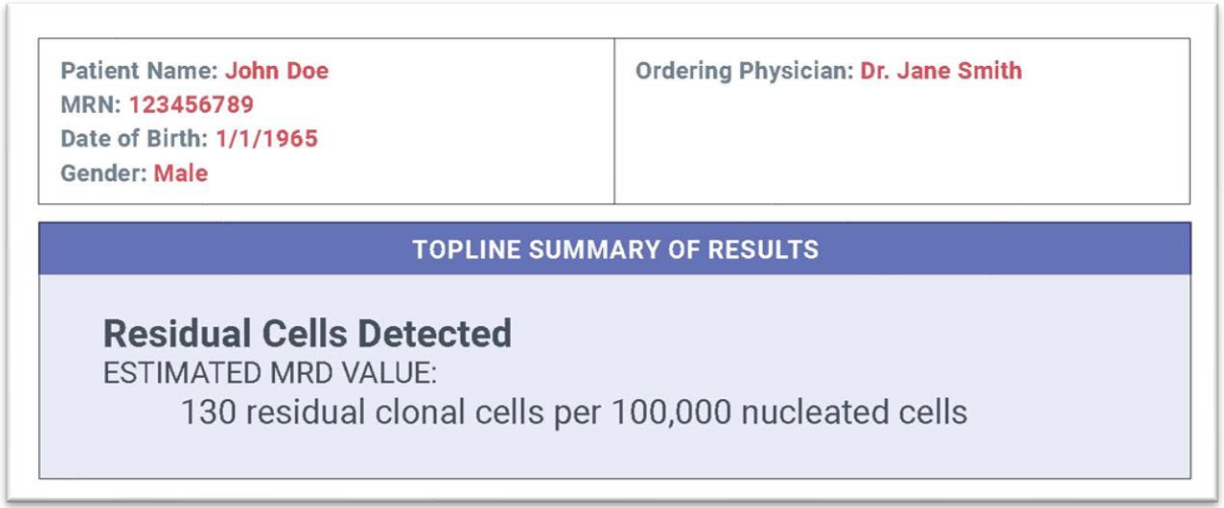
Patient Information and a Topline Summary Provide the Multidisciplinary Team With Easy Access to MRD Test Results *

Patient Information and Topline Summary of Results



Patient Name: John Doe MRN: 123456789 Date of Birth: 1/1/1965 Gender: Male	Ordering Physician: Dr. Jane Smith

TOPLINE SUMMARY OF RESULTS

Residual Cells Detected

ESTIMATED MRD VALUE:

130 residual clonal cells per 100,000 nucleated cells

- Reports should include patient information (eg, patient's name, date of birth, gender) to ensure that the multidisciplinary team is provided with relevant information on the patient
- The opinion leaders brought together by Amgen Oncology suggest including a topline summary of results (eg, number of residual leukemic cells detected) on the front page of the pathology report, so that the patient's MRD status is immediately available in order to help assist the hematologist/oncologist in determining a treatment plan

Consider including a topline summary of results that is easy to interpret on the front page of the pathology report

*The above MRD pathology report is a sample report that only highlights information that the opinion leaders brought together by Amgen Oncology view as important to document in reports. This sample report is for educational and informational purposes only.
MRD, measurable residual disease.

Arber DA, et al. *Arch Pathol Lab Med*. 2017;141:1342-1393.

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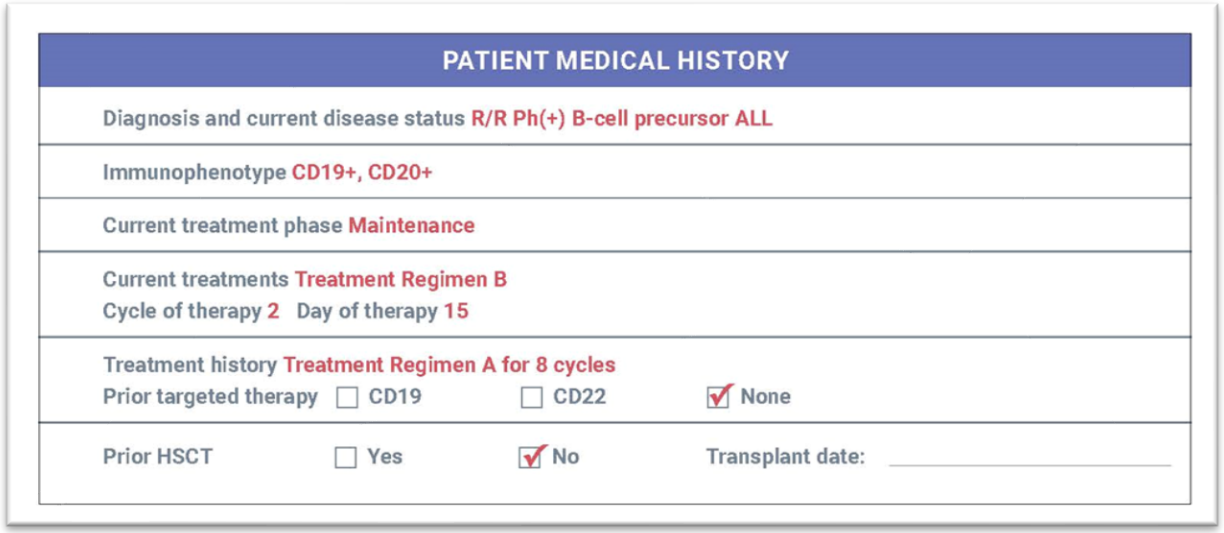
Patient Medical History May Provide Additional Context for the Interpretation of MRD Test Results *



PATIENT MEDICAL HISTORY

Diagnosis and current disease status R/R Ph(+) B-cell precursor ALL

Immunophenotype CD19+, CD20+

Current treatment phase Maintenance

Current treatments Treatment Regimen B
Cycle of therapy 2 Day of therapy 15

Treatment history Treatment Regimen A for 8 cycles
Prior targeted therapy ☐ CD19 ☐ CD22 ☑ None

Prior HSCT ☐ Yes ☑ No Transplant date: _____

- Relevant information on the patient's medical history (eg, diagnosis, current disease status, treatment history, transplant status) ensures that the multidisciplinary team is provided a detailed history on the patient's treatment journey [1]
- Details provided in this section may guide the multidisciplinary team in determining the need for additional testing and interpreting MRD test results [1]
  - Inclusion of a patient's treatment history (eg, prior CD19- or CD22-targeted therapy) may provide relevant information that may confound MRD test results [2]
  - Knowledge of current treatments, including the cycle and day of therapy, and prior treatment history can also help guide the hematologist/oncologist in choosing subsequent treatments [2]

Details, such as patient medical history, provide the multidisciplinary team with important information to guide next steps in the treatment journey

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ALL, acute lymphoblastic leukemia; CD, cluster of differentiation; HSCT, allogeneic hematopoietic stem cell transplantation; MRD, measurable residual disease; Ph(+), Philadelphia chromosome–positive; R/R, relapsed or refractory.

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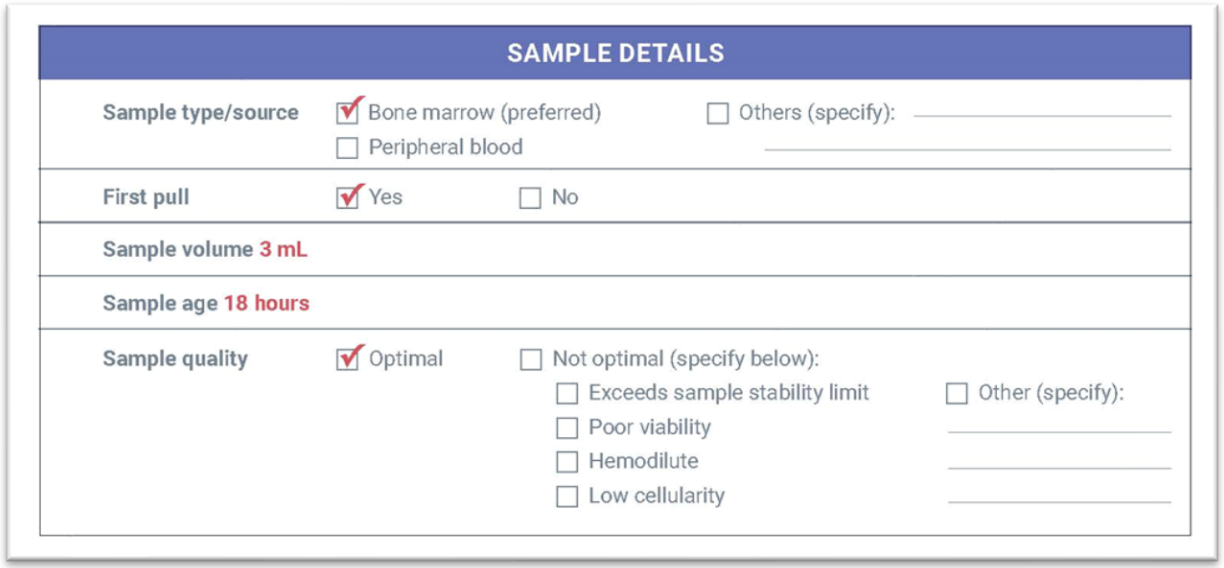
Sample Details Can Provide Key Information to Ensure Quality Data Analysis and Results *



SAMPLE DETAILS

Sample type/source	☑ Bone marrow (preferred) ☐ Peripheral blood	☐ Others (specify): _____
First pull	☑ Yes	☐ No
Sample volume 3 mL		
Sample age 18 hours		
Sample quality	☑ Optimal	☐ Not optimal (specify below): ☐ Exceeds sample stability limit ☐ Poor viability ☐ Hemodilute ☐ Low cellularity ☐ Other (specify): _____

- Bone marrow is the preferred sample source for MRD testing [1]
- It is important to document whether the sample was from the first small-volume (up to 3 mL) pull, as the highest-quality sample comes from the first pull to avoid hemodilution [1,2]
  - The second pull has been associated with a ~ 50% average reduction in leukemic cells [2]
- Sample quality is dependent on several factors:
  - A sample must be transported within the appropriate window of collection to maintain stability for optimal results [3-5]
  - Hemodilution and low cellularity can impact the accuracy of results [6,7]
- Knowledge of sample age and quality can also provide the oncologist with insights on sample requirements for subsequent MRD tests [2,3]

Sample details, such as type/source, age, and quality, can help determine whether the sample obtained is sufficient for MRD analysis and help inform treatment decisions based on MRD test results

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MRD, measurable residual disease.

1. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Acute Lymphoblastic Leukemia V.2.2021. © National Comprehensive Cancer Network, Inc. 2021. All rights reserved. Accessed December 1, 2021. To view the most recent and complete version of the guideline, go online to NCCN.org. 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. **2.** Helgestad J, et al. *Pediatr Blood Cancer.* 2011;57:224-226. **3.** Correia RP, et al. *Int J Lab Hematol.* 2021;43:354-363. **4.** Cellnetix. www.cellnetix.com. Accessed December 1, 2021. **5.** clonoSEQ®. https://adaptivebiotech.showpad.com/share/orMGe2KgT49rCt5j6RSBA. Accessed December 2, 2021. **6.** Paietta E. In: Wiernik PH, et al, eds. *Neoplastic Diseases of the Blood*. 6th ed. Springer; 2018:237-279. **7.** clonoSEQ®. https://adaptivebiotech.showpad.com/share/vENsMo9HgtZXfBdE0nd5x. Accessed December 1, 2021.

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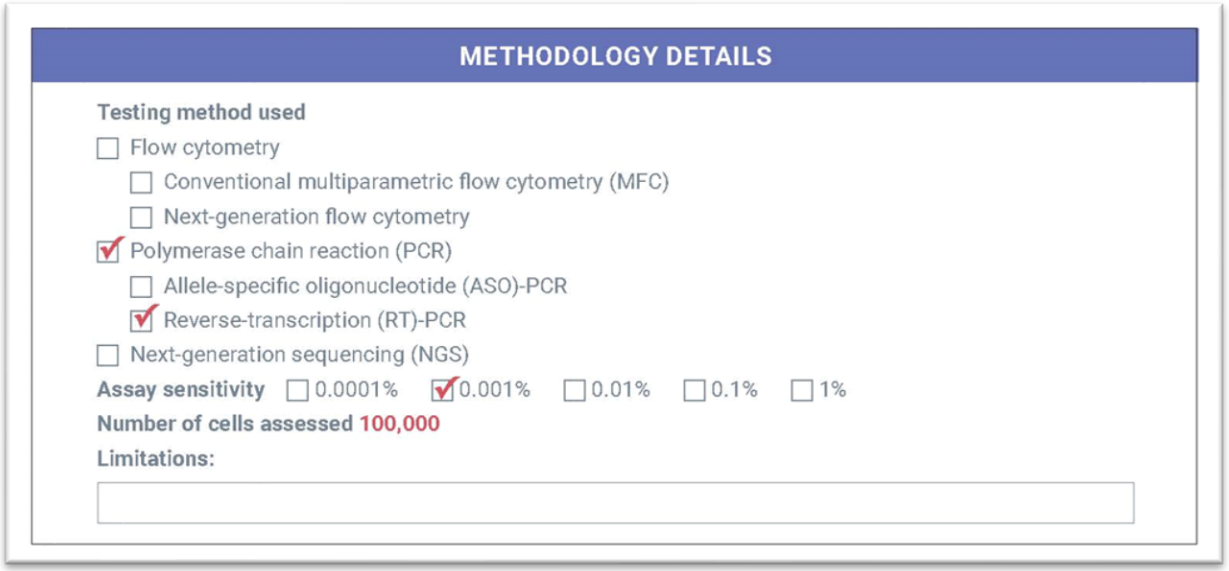
Assay Details Provide Information on Testing Technique, Sensitivity, and Limitations to Aid in Interpreting Results *



- Details on MRD testing methodology and associated limitations (eg, risk of false-positive or false-negative results) can be useful when interpreting results for determining the next steps in a patient's treatment journey [1]
  - For example, clonal evolution of Ig and TCR rearrangements throughout the disease course may result in false-negative results for MRD assessed via PCR [1]
- Documentation of the number of cells assessed provides context for residual disease observed when interpreting results [2]

Information regarding the MRD testing methodology, assay sensitivity, and limitations assist the treating oncologist in making informed treatment decisions based on MRD test results

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Ig, immunoglobulin; MRD, measurable residual disease; PCR, polymerase chain reaction; TCR, T-cell receptor.
1. Della Starza I, et al. *Front Oncol.* 2019;9:726. **2.** clonoSEQ®. https://adaptivebiotech.showpad.com/share/vENsMo9HgtZXfBdE0nd5x. Accessed December 1, 2021.

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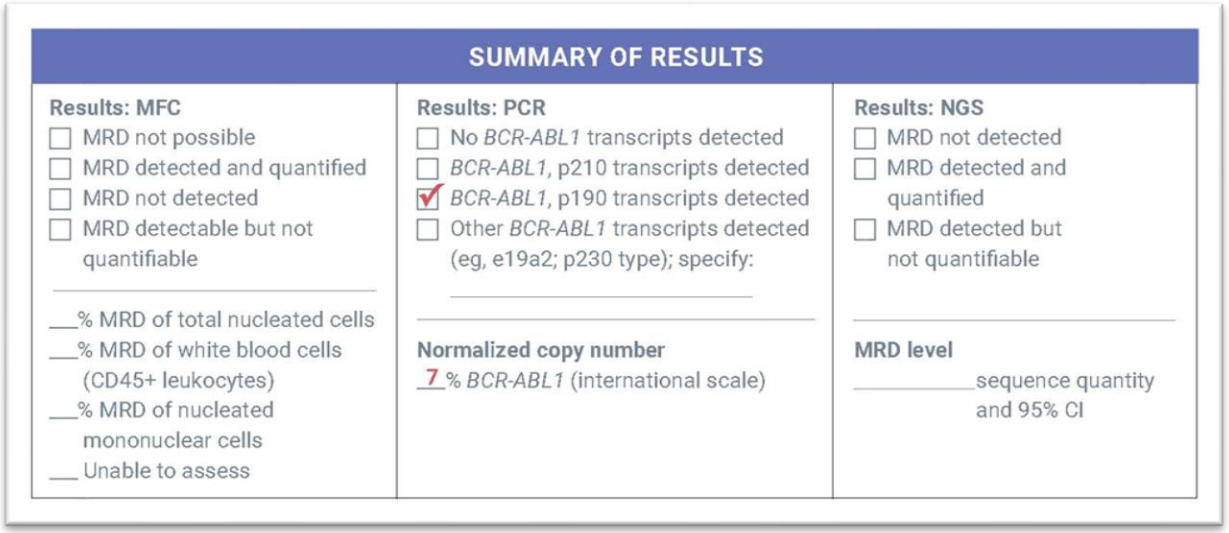
A Summary of Results Provides Data to Be Interpreted to Make MRD-Based Treatment Decisions *



SUMMARY OF RESULTS

Results: MFC

- ☐ MRD not possible
- ☐ MRD detected and quantified
- ☐ MRD not detected
- ☐ MRD detectable but not quantifiable

___% MRD of total nucleated cells
___% MRD of white blood cells (CD45+ leukocytes)
___% MRD of nucleated mononuclear cells
___ Unable to assess

Results: PCR

- ☐ No *BCR-ABL1* transcripts detected
- ☐ *BCR-ABL1*, p210 transcripts detected
- ☑ *BCR-ABL1*, p190 transcripts detected
- ☐ Other *BCR-ABL1* transcripts detected (eg, e19a2; p230 type); specify: _____

Normalized copy number

7 % *BCR-ABL1* (international scale)

Results: NGS

- ☐ MRD not detected
- ☐ MRD detected and quantified
- ☐ MRD detected but not quantifiable

MRD level

_____ sequence quantity and 95% CI

- A visible, concise, and easy-to-interpret summary of MRD test results may be useful for the oncologist to guide appropriate treatment decisions

A summary of key results that is easy to interpret provides the treating oncologist with a high-level overview of MRD test results to help guide next steps in the patient's treatment journey

*The above MRD pathology report is a sample report that only highlights information that the opinion leaders brought together by Amgen Oncology view as important to document in reports. This sample report is for educational and informational purposes only.

BCR-ABL1, breakpoint cluster region protein-abelson murine leukemia viral oncogene homolog; CD, cluster of differentiation; CI, confidence interval; MFC, multicolor flow cytometry; MRD, measurable residual disease; NGS, next-generation sequencing; PCR, polymerase chain reaction.

clonoSEQ®. https://adaptivebiotech.showpad.com/share/vENsMo9HgtZXfBdE0nd5x. Accessed December 1, 2021.

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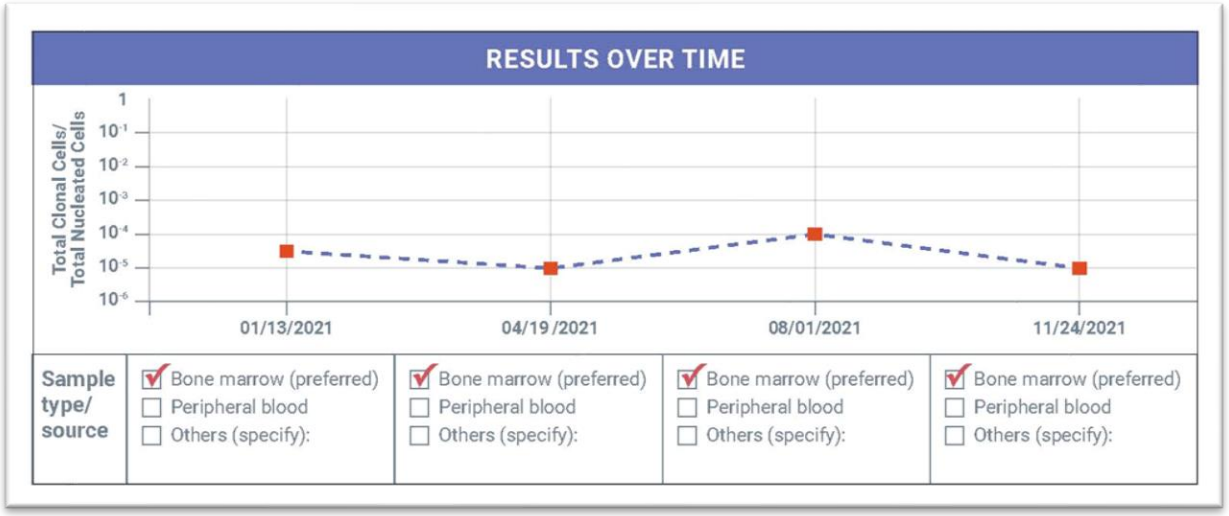
An Overview of Results Over Time Can Provide Additional Context on a Patient's MRD Status Throughout the Treatment Journey *



- Listing MRD results over time may be beneficial for providing a snapshot of the patient's MRD status over the course of treatment
  - The opinion leaders brought together by Amgen Oncology suggest indicating the sample type/source (eg, bone marrow versus peripheral blood versus other) for each MRD assessment performed at different time points in a patient's treatment journey

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MRD, measurable residual disease.

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Summary: Key Information Contained in a Sample MRD Pathology Report

The opinion leaders that Amgen Oncology brought together suggest standardizing information to be included in a sample MRD pathology report, including the template, to ensure consistency in reporting and interpretation of results [1]

Relevant patient information ensures communication of the patient's medical history among the multidisciplinary team [1]

Sample details, such as type, source, and quality, are important in determining whether the sample is of high quality to ensure optimal data analysis and results [2,3]

Details on MRD testing technique, sensitivity, and associated limitations can assist in interpreting test results [4]

A concise and easy to interpret summary of results and overview of results over time provide data that can be used to guide next steps in a patient's treatment journey [5]

MRD, measurable residual disease.

1. Arber DA, et al. *Arch Pathol Lab Med*. 2017;141:1342-1393. **2.** Brüggemann M, et al. *Blood Adv*. 2017;1:2456-2466. **3.** Paietta E. In: Wiernik PH, et al, eds. *Neoplastic Diseases of the Blood*. 6th ed. Springer; 2018:237-279. **4.** Della Starza I, et al. *Front Oncol*. 2019;9:726. **5.** clonoSEQ®. https://adaptivebiotech.showpad.com/share/vENsMo9HgtZXfBdE0nd5x. Accessed December 1, 2021.

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Considerations When Interpreting MRD Test Results

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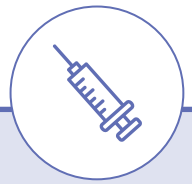
Considerations When Interpreting MRD Test Results for Proactive Treatment Planning



Consider the need for an additional sample for testing if the quality of the original sample is low [1,2]

Interpretation of MRD results may be influenced by the maximum sensitivity of the test being used [3]

Consider the possibility of false-negative or false-positive results based on the test being used [3]

The NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) Recommend the Following Next Steps in the Treatment Journey of a Patient With ALL:

- An MRD(+) test result may warrant additional intervention or a change in treatment [4,5]
- Continue to monitor the patient's MRD status following an MRD(–) test result as clinically applicable [4,5]
  - Continue to monitor every 3–6 months as clinically indicated for at least 5 years in adult/AYA patients and continue to monitor for suspected relapse in pediatric/AYA patients [4,5]

MRD status plays an important role in a patient's treatment journey and an MRD(+) test result may prompt additional intervention or a change in treatment approach [4,5]

ALL, acute lymphoblastic leukemia; AYA, adolescent and young adult; MRD, measurable residual disease; NCCN, National Comprehensive Cancer Network.

1. Brüggemann M, et al. *Blood.* 2012;120:4470-4481. **2.** Paietta E. In: Wiernik PH, et al, eds. *Neoplastic Diseases of the Blood*. 6th ed. Springer; 2018:237-279. **3.** Della Starza I, et al. *Front Oncol.* 2019;9:726. **4.** Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Acute Lymphoblastic Leukemia V.2.2021. © National Comprehensive Cancer Network, Inc. 2021. All rights reserved. Accessed December 1, 2021. To view the most recent and complete version of the guideline, go online to NCCN.org. 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. **5.** Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Pediatric Acute Lymphoblastic Leukemia V.1.2022. © National Comprehensive Cancer Network, Inc. 2021. All rights reserved. Accessed December 1, 2021. To view the most recent and complete version of the guideline, go online to NCCN.org. 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.

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Summary

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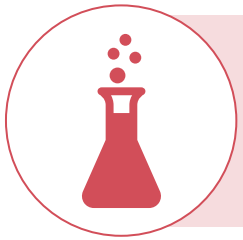
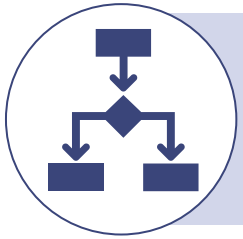


MRD in ALL can be quantified by various testing methodologies (eg, flow cytometry, PCR, NGS); depending on the methodology used, a baseline sample, or prior sample at diagnosis, may be required for subsequent MRD monitoring [1]

Documentation of information, such as patient information, a topline summary of results, patient medical history, sample details, methodology used, and a detailed summary of results, in an MRD pathology report can guide informed MRD-based treatment decision making [2-6]



An MRD(+) result may warrant additional intervention or change in treatment, whereas MRD should be monitored as clinically applicable following an MRD(–) result [7,8]

ALL, acute lymphoblastic leukemia; MRD, measurable residual disease; NGS, next-generation sequencing; PCR, polymerase chain reaction.

1. Dalle IA, et al. *Ther Adv Hematol*. 2020;11. doi:2040620720910023. **2.** Arber DA, et al. *Arch Pathol Lab Med*. 2017;141:1342-1393. **3.** Brüggemann M, et al. *Blood Adv*. 2017;1:2456-2466. **4.** Paietta E. In: Wiernik PH, et al, eds. *Neoplastic Diseases of the Blood*. 6th ed. Springer; 2018:237-279. **5.** clonoSEQ®. https://adaptivebiotech.showpad.com/share/vENsMo9HgtZXfBdE0nd5x. Accessed December 1, 2021. **6.** Della Starza I, et al. *Front Oncol*. 2019;9:726. **7.** Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Acute Lymphoblastic Leukemia V.2.2021. © National Comprehensive Cancer Network, Inc. 2021. All rights reserved. Accessed December 1, 2021. To view the most recent and complete version of the guideline, go online to NCCN.org. 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. **8.** Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Pediatric Acute Lymphoblastic Leukemia V.1.2022. © National Comprehensive Cancer Network, Inc. 2021. All rights reserved. Accessed December 1, 2021. To view the most recent and complete version of the guideline, go online to NCCN.org. 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.

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