GenPath® ONCOLOGY

Final Report

PHYSICIAN	PATIENT	SAMPLE
SAMPLE, PHYSICIAN ONCOLOGY HOSPITAL ACCT #: P: F:	**SAMPLE, PATIENT** **DOB:** **Age:** **Sex:** **Ethnicity:** **Surgical #:** **Patient ID:** **Address:**	**Specimen ID:** **Date Reported:** 07/14/2023 3:29 PM **Date Collected:** 07/06/2023 Time Unknown **Date Received:** 07/07/2023 6:27 AM **Source:** Peripheral blood Clinical Information: CLL/SLL

OnkoClone CLL MRD

RESULTS

ONKOCLONE CLL MRD: MRD DETECTED

Mutation Rate: 5.29%

IgVH Family: IgVH3-74_03

% total reads: 18.891%

Initial TM70% Total Reads: 33.52%

INTERPRETIVE INFORMATION

This test contains primers that amplify DNA in the conserved framework (FR1) and joining (J) regions within the immunoglobulin heavy chain (IgH) gene on chromosome 14. These regions are within the V-J region, where programmed genetic rearrangements occur during B-cell maturation. Each B-cell has a V-J rearrangement that is unique in both length and sequence. This assay is useful in monitoring for residual B-cell lymphoma following therapy. A small clonal B-cell population present in numbers below the lower limit of detection of this assay may also not be detected. Therefore, this result should be interpreted in the context of all other laboratory, histological, and clinical information. The lower limit of detection of this assay is 2.5%.

METHODOLOGY

Extracted genomic DNA from whole blood or bone marrow specimens is amplified by polymerase chain reaction (PCR) using indexed primers from the LymphoTrack® IGH Assay reagents from Invivoscribe (San Diego, CA). These primers target the conserved framework 1 (FR1) region within the VH segments of the IGH gene. IGH Amplicons are purified, pooled and subsequently sequenced on an Illumina MiSeq instrument (San Diego, CA). Sequencing data is then analyzed using the LymphoTrack® Software for MiSeq to identify clonal VH - JH rearrangements and the associated VH - JH region DNA sequences. The clonal sequences previously identified are compared to the current sample using the LymphoTrack® MRD Software. The clonal sequences previously identified are compared to the current sample using the LymphoTrack® MRD Software.

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This report was electronically signed.

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Final Report

PHYSICIAN
SAMPLE, PHYSICIAN
ONCOLOGY HOSPITAL

ACCT #:

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PATIENT
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DOB: **Age:** **Sex:**
Ethnicity:
Surgical #:
Patient ID:
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SAMPLE
Specimen ID:
Date Reported: 07/14/2023 3:29 PM
Date Collected: 07/06/2023 Time Unknown
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Source: Peripheral blood
Clinical Information: CLL/SLL

OnkoClone CLL MRD

This test was developed and its performance characteristics were determined by GenPath, a division of BioReference Health, LLC. It has not been cleared or approved by the U.S. Food and Drug Administration (FDA). The FDA has determined that such clearance or approval is not necessary. This lab has been approved by CLIA'88 and designated as a high complexity laboratory and is qualified to perform this test. Pursuant to the requirements of CLIA'88, this laboratory has established and verified the test's accuracy and precision. However, a false positive or false negative result incurred during any phase of the testing cannot be completely excluded. This assay does not detect all clonal cell populations. These results may be used for clinical or research purposesand therefore should be carefully considered within the context of other clinical and laboratory data. The information contained in this report reflects the current interpretation of the findings as of the date of the report, based on the available scientific information. This information, which comes from numerous sources, is subject to change over time in response to future scientific and medical findings and correlations. BioReference Health, LLC makes no representation or warranty of any kind regarding the accuracy of information provided or contained in these manuscripts, references or other sources of information. If any of the information provided by or contained in the referenced material is later deemed to be inaccurate, this may impact the accuracy of thisreport and interpretation of the findings. BioReference Health, LLC is not obligated to notify you of any impact that additional or modified information, or future scientific or medical research may have on this report. The laboratory is not responsible for reanalysis of the data or updated classification of this report or past reports' findings as the knowledge evolves. A medical provider can request a reassessment of clinical significance of variants and/or re-review of the clinical interpretation of the findings. Additional charges may apply for the updated report. This assay has been conditionally approved by the NYSDOH based on initial validation. Please contact the laboratory for more information if an update is requested.

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