IdentiClone® Dx *IGH* Assay

CE 2797 IVD

Confidently Detect Clonal *IGH* Gene Rearrangements

The only IVD assay in the EU which includes automated software to confirm diagnoses of B-cell lymphoproliferative diseases.

Clinical Significance

It is estimated that over 900,000 new cases of B-cell lymphoproliferative diseases are diagnosed worldwide each year.[1,2,3] These disorders, such as lymphomas and leukemias, often arise due to dysregulation of the normal processes of B-cell development, particularly in immunoglobulin heavy chain (*IGH*) gene rearrangements. In B-cell lymphoproliferative diseases, a single B-cell clone with a particular *IGH* rearrangement proliferates abnormally, leading to a population of B-cells with identical (or clonal) *IGH* gene rearrangements. The presence of clonal populations is a hallmark of B-cell malignancies.[1,4,5]

Key Benefits

- Simple, streamlined workflow
- Accurate, objective clonality results
- Intuitive & user-friendly software
- Easy-to-interpret reports

Concordance Analysis

The table on the right, demonstrates good concordance between the IdentiClone Dx *IGH* Assay clonality and clinical diagnosis (based on ICD-10 codes). A total of 278 retrospective and residual, de-identified DNA samples* extracted from peripheral blood (PB) of subjects diagnosed with lymphoproliferative disease (+), and DNA from normal, healthy PB (-) samples were evaluated in this study. The lower limit of the 95% CI for the negative percent agreement is 94.3% while the lower limit of the 95% CI for the positive agreement has been calculated to be 95.7%. The clinical evaluation confirmed that the IdentiClone Dx *IGH* Assay has a diagnostic sensitivity of 96.3% and specificity of 99.1%.

Concordance Between IdentiClone *IGH* Dx Assay and Clinical Diagnosis

Clinical Diagnosis	IdentiClone *IGH* Dx Assay		
	+	-	Total
+	132	6	138
-	8	132	140
Total	140	138	278

Ordering Information

Catalog #	Product Name	Quantity
91010101	IdentiClone® Dx *IGH* Assay	33 reactions
91010111	IdentiClone® Dx *IGH* Software	1 complementary software package

This is an *in vitro* diagnostic (IVD) product; not available for sale or use in North America.

* Four invalid samples were excluded from the concordance analysis

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IdentiClone® Dx
IGH Assay

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Principles of the Procedure

The IdentiClone Dx *IGH* Assay employs multiple consensus DNA primers that target the conserved frameworks (FR1, FR2 and FR3) of the variable (V_H) and joining (J_H) regions *IGH* gene, which lie on either side of an area where programmed genetic rearrangements occur during maturation of all B lymphocytes. PCR is used to amplify gene rearrangements and fluorescent dyes enable detection of the resulting amplicons by a capillary electrophoresis instrument. IdentiClone Dx *IGH* Software is designed to seamlessly complement the IdentiClone Dx *IGH* Assay and eliminate the subjectivity of manual electropherogram interpretation by evaluating the results of each FR to determine the presence or absence of clonality.

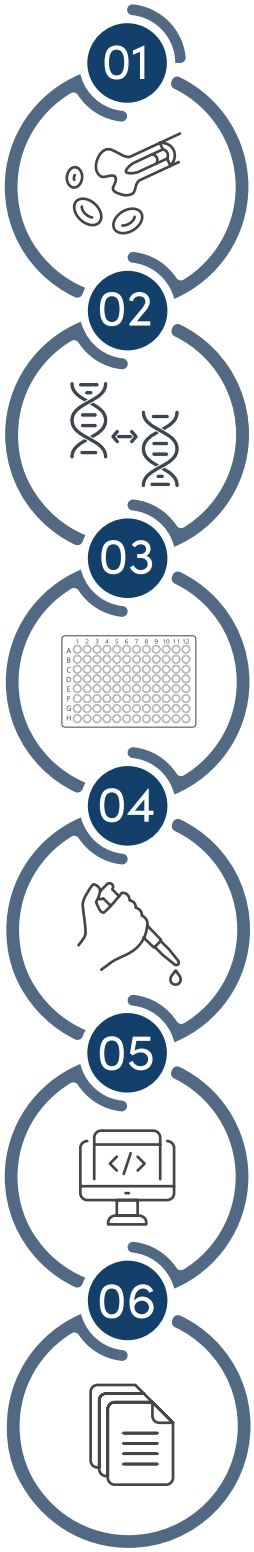
Intended Use

The IdentiClone Dx *IGH* Assay ("Assay") is an IVDR/CE 2797 IVD approved assay intended for capillary electrophoresis based-detection of clonality in immunoglobulin heavy chain (*IGH*) gene rearrangements in peripheral blood specimens as an adjunctive method for the diagnosis of patients suspected to have a B-cell lymphoproliferative disease.

Positive results (i.e., the detection of clonality) should not be the sole criterion for determining presence of disease. Negative results do not preclude lymphoproliferative disease. The use of additional laboratory testing (e.g., white blood cell [WBC] counts, morphology, immunohistochemistry, detection of driver mutations, flow cytometry, etc.) and clinical presentation must be taken into consideration in the final diagnosis of lymphoproliferative disease.

The qualitative, non-automated Assay is for use on the ABI 3500xL Dx and ABI 3500xL Genetic Analyzers.

Workflow



References

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2. Siegel RL, Miller KD, and Jemal A. *CA: A Cancer Journal for Clinicians*, 2020; 70:7-30.
3. Cowan AJ, et al. *Journal of American Medicine*, 2018 Sep; 4(9):1221-1227.
4. Miller JE, et al. *Journal of Molecular Diagnostics*, 1999; 4(2):101-117.
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M-0172 Rev01 September 2024