

INTRODUCING

IdentiClone[®] Dx

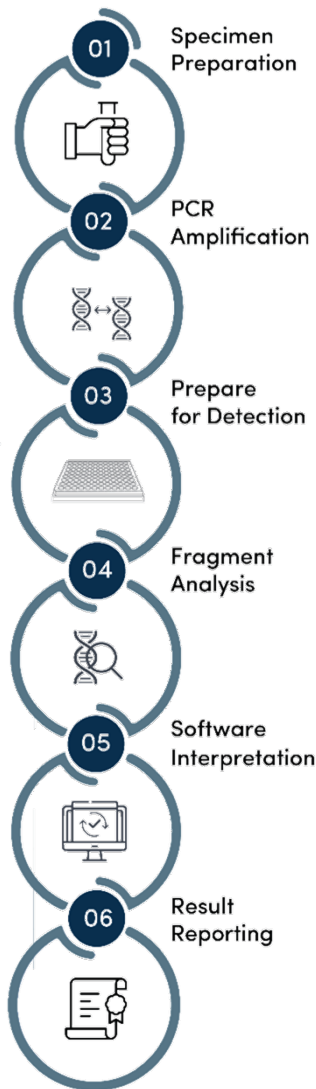
IGH Assay

The IVDR-approved IdentiClone Dx IGH Assay is a highly-characterized assay with a standardized, cost-effective workflow. Unlike in-house IVD assays, it is CE-2797 IVD certified and includes software to ensure objective data interpretation. This assay provides a comprehensive solution, including master mixes, enzymes, controls, and interpretation software.

IdentiClone[®] Dx

IGH Assay

WORKFLOW

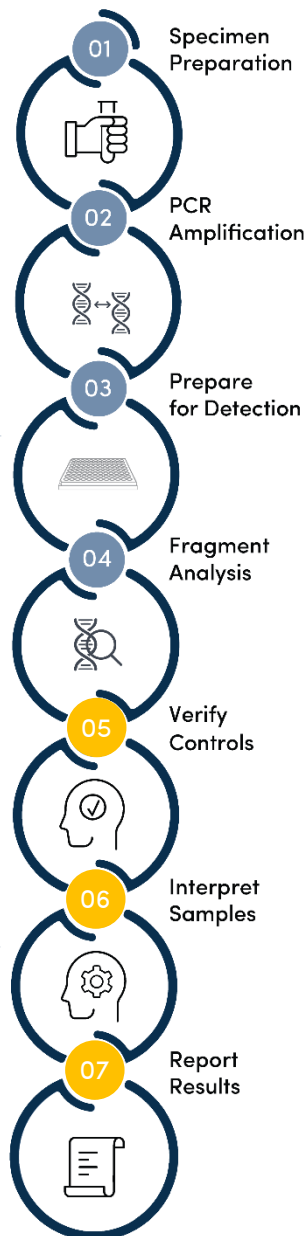


IdentiClone[®] IGH

Gene Clonality Assay

ABI Fluorescence Detection

WORKFLOW

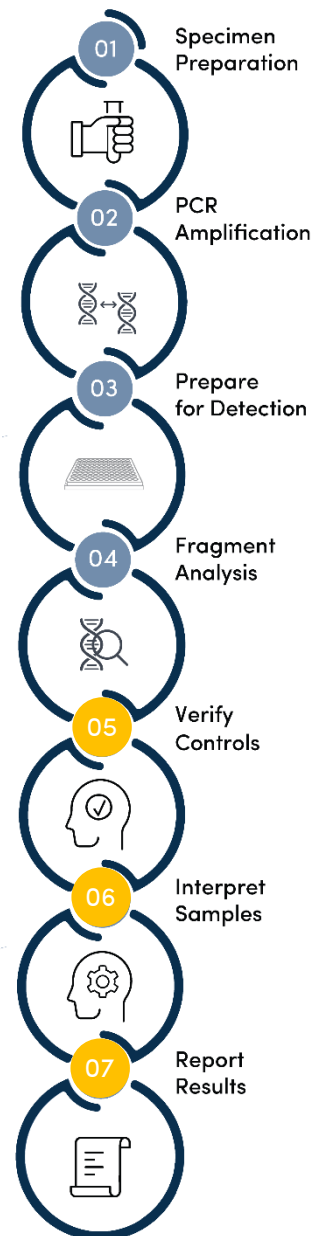


IdentiClone[®] IGH + IGK


















B-cell Clonality Assay

ABI Fluorescence Detection





















WORKFLOW






















 **NB-certified**
CE 2797 CE-IVDR

-  Available Spring 2026
-  Characterized controls verify assay sensitivity
-  Instrument parameters included
-  Software package
-  Automated interpretation
-  Automated control performance verification
-  Automated sample clonality
-  Run and Sample Reports
-  Data Output File (CSV)
-  33 reactions
-  Taq DNA Polymerase
-  MMA: $IGH V_H - FR1 > J_H$
-  MMB: $IGH V_H - FR2 > J_H$
-  MMC: $IGH V_H - FR3 > J_H$
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-
-
-  Polyclonal (-) Control
-  IGH Positive (+) Control
-  No Template Control
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The IdentiClone® Dx IGH Assay is a CE 2797 IVD product and for *in vitro* diagnostic use. Not available for sale or use in North America.

-  Self-certified CE-IVDD
-  Limited availability – to be discontinued mid-2026
-  User establishes control limits
-  User determines appropriate instrument parameters
-
-  Manual interpretation
-  User establishes cut-off
-  User determines clonality
-
-  Data Output File (CSV)
-  33 reactions
330 reactions
-
-  IGH Tube A: $V_H - FR1 > J_H$
-  IGH Tube B: $V_H - FR2 > J_H$
-  IGH Tube C: $V_H - FR3 > J_H$
-  IGH Tube D: $V_H - FR1 > J_H$
-  IGH Tube E: $V_H - FR1 > J_H$
-  Specimen Control Size Ladder
-  IVS-0000 Polyclonal Control DNA
-  IVS-0008 Clonal Control DNA
-  IVS-0019 Clonal Control DNA
-  IVS-0024 Clonal Control DNA
-  IVS-0030 Clonal Control DNA

The IdentiClone® IGH Gene Clonality Assays are for *in vitro* diagnostic use and are not available for sale or use in North America.

-  Self-certified CE-IVDD
-  Limited availability – to be discontinued mid-2026
-  User establishes control limits
-  User determines appropriate instrument parameters
-
-  Manual interpretation
-  User establishes cut-off
-  User determines clonality
-
-  Data Output File (CSV)
-  33 reactions
330 reactions
-
-  IGH Tube A: $V_H - FR1 > J_H$
-  IGH Tube B: $V_H - FR2 > J_H$
-  IGH Tube C: $V_H - FR3 > J_H$
-  IGK Tube A: $V_k - J_k > K_{de}$
-  IGK Tube B: $V_k - J_k - INTR > K_{de}$
-  Specimen Control Size Ladder
-  IVS-0000 Polyclonal Control DNA
-  IVS-0007 Clonal Control DNA
-  IVS-0019 Clonal Control DNA
-  IVS-0030 Clonal Control DNA
-

The IdentiClone® IGH + IGK B-Cell Clonality Assays are for *in vitro* diagnostic use and are not available for sale or use in North America.