CHAMPION YOUR CANCER DIAGNOSTICS

With the EasySep™ Human Bone Marrow Positive Selection IVD Kit for Plasma Cell Enrichment

Enrich Plasma Cells and Enhance Sensitivity for Downstream Multiple Myeloma Testing

Characterizing genetic abnormalities with diagnostic tests is essential for patient risk stratification, treatment selection, and disease monitoring of multiple myeloma. However, variable frequencies of plasma cells in patient bone marrow samples can impact assay readouts and reliability. Clinical laboratories performing diagnostic tests for multiple myeloma need solutions that provide reliable results, ensure quality performance, and reduce the validation burden of their diagnostic workflow. The EasySep™ Human Bone Marrow CD138 Positive Selection Kit (IVD) enables reliable CD138+ plasma cell enrichment of bone marrow samples from patients diagnosed with multiple myeloma, enhancing the sensitivity of validated downstream assays, and better informing patient care.

Because the CD138 antigen is expressed on all plasma cells, this antigen is a suitable target to enrich samples for cytogenetic analysis and increase the proportion of malignant myeloma cells. Plasma cell enrichment by CD138 selection is, therefore, a beneficial step before downstream analysis to enhance sensitivity and obtain more reliable diagnostic readouts (Figures 1 & 2).

Did You Know?

The National Comprehensive Cancer Network® (NCCN Guidelines Version 2.2020 Multiple Myeloma) and the American College of Medical Genetics and Genomics (ACMG) Technical Standards for Clinical Genetics Laboratories (2021) recommend using enriched plasma cells from bone marrow samples when performing fluorescence in situ hybridization (FISH) analysis for multiple myeloma testing.

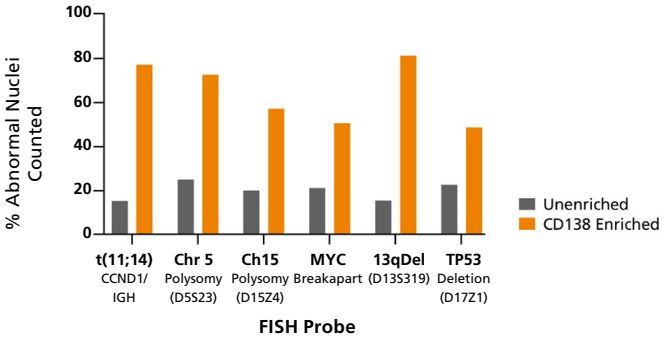

Figure 1. Percentage of Abnormal Nuclei Detected by FISH Is Higher Following CD138+ Cell Enrichment Compared to Unenriched Clinical Specimens

Clinical bone marrow specimens were evaluated using a panel of five common FISH probes detecting six genomic abnormalities: t(11;14) translocation (Vysis IntelliFISH CCND1/IGH XT Probe Kit), chromosome 5 (D5S23) or chromosome 15 polysomy (D15Z4), MYC Breakapart, 13q deletion (D13S319), and TP53 deletion (D17Z1). The percentage of abnormal nuclei detected for each probe was higher following CD138+ cell enrichment with the EasySep™ Human Bone Marrow CD138 Positive Selection Kit. Note: Only specimens with an abnormal FISH signal pattern for each probe were included in the analysis.

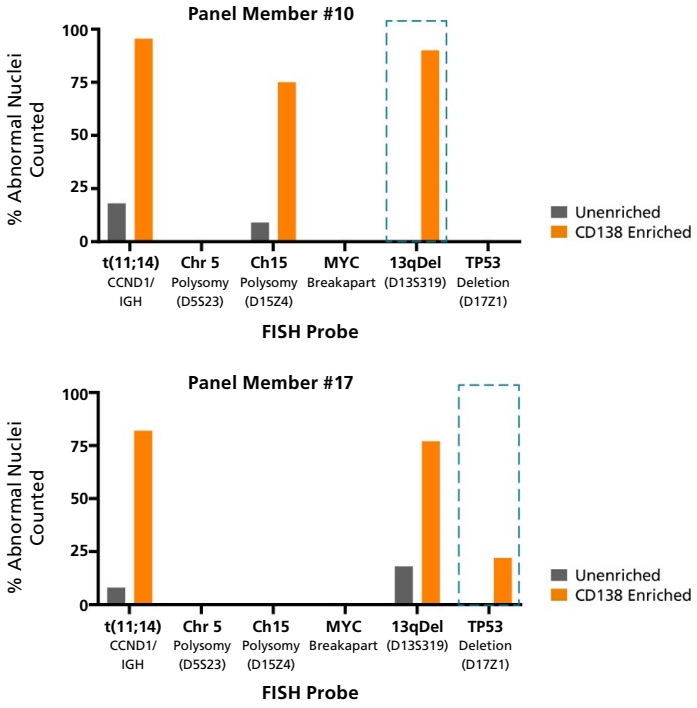

Figure 2. EasySep™ Human Bone Marrow CD138 Positive Selection Kit Increases the Sensitivity of Chromosomal Abnormality Detection by FISH Through CD138+ Cell Enrichment of Bone Marrow Specimens

In 14 out of 33 clinical bone marrow specimens analyzed by FISH, at least one genomic abnormality probed went undetected in unenriched specimens but was detected in CD138+ cell enriched specimens, demonstrating that plasma cell enrichment using the EasySep™ Human Bone Marrow CD138 Positive Selection Kit improves the sensitivity of FISH testing and can reduce the risk of false negative results. In the two representative patient bone marrow specimens analyzed above, CD138+ cell enrichment enabled the detection of chromosomal abnormalities that were not identified in unenriched specimens (blue boxes) and increased the frequency of abnormal nuclei detected when chromosomal abnormalities were detected in unenriched specimens.

Reduce the Validation Burden in Your Laboratory with the EasySep™ Human Bone Marrow CD138 Positive Selection Kit

The EasySep™ Human Bone Marrow CD138 Positive Selection Kit (IVD) has been classified by the US Food and Drug Administration (FDA) as a first-of-its-kind in vitro diagnostic (IVD) medical device for hematopoietic cell enrichment, and is also available as an IVD medical device in Canada, the EU, and the United Kingdom. The FDA identifies this new product type as a hematopoietic cell enrichment kit: a Class II IVD device for selecting specific cells from human whole blood or bone marrow, intended for use with diagnostic assays as part of the pre-analytical workflow. This kit is indicated for in vitro diagnostic use by laboratory professionals; the end user is responsible for determining whether the product is suitable for their specific application(s).

Designed for use with the "The Big Easy" EasySep™ Magnet and EasySep™ Buffer (IVD) (Figure 3) to isolate cells without the use of columns, the kit includes antibodies and magnetic particles to label CD138+ cells for separation, resulting in labeled CD138+ cells that remain in the tube after unlabeled cells are poured off.

Figure 3. Required Accessory Products for Use

(A) The EasySep™ Buffer (IVD) (Catalog #100-0780) and (B) "The Big Easy" EasySep™ Magnet (Catalog #18001) are both designed and validated for use with the EasySep™ Human Bone Marrow CD138 Positive Selection Kit..

Why Use the EasySep™ Human Bone Marrow CD138 Positive Selection Kit (IVD)?

- Follow an easy-to-use and column-free protocol by using EasySep™ immunomagnetic cell isolation technology
- Achieve high plasma cell purity for reliable results
- Reduce the burden required to implement and validate pre-analytical plasma cell enrichment for your laboratory
- Enhance the sensitivity of downstream FISH analysis

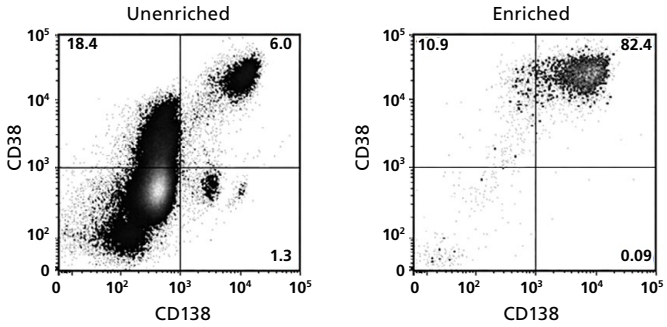

Figure 4. EasySep™ Human Bone Marrow CD138 Positive Selection Kit Enriches CD138+ Cells in Bone Marrow Specimens from Multiple Myeloma Patients

A clinical study was conducted on 33 clinical bone marrow specimens from multiple myeloma patients at various stages of the disease. The mean CD138+ cell purity, as measured by flow cytometry by gating on CD38+/CD138+ cells, was 12.9% (range 0.2% - 82.7%) in unenriched specimens and increased to 79.6% (range 18.5% - 98.6%) in the EasySep™-enriched specimens. In the representative patient bone marrow specimen above, the purities of the unenriched and final enriched plasma cell fractions were 6.0% and 82.4%, respectively.

Products Required for Use

Product	Catalog #
EasySep™ Human Bone Marrow CD138 Positive Selection Kit (IVD)	100-1133
EasySep™ Buffer (IVD)	100-0780
"The Big Easy" EasySep™ Magnet	18001

Product Information

For additional data and specifications, visit
www.stemcell.com/EasySep-CD138-IVD-Kit

Learn More

For more details and FAQs, visit
www.stemcell.com/EasySep-CD138-IVD-FAQs