



For hematopoietic progenitor cell engraftment assays, internal controls are used to determine appropriate genotypes or at least to distinguish patient from donor(s) with each run.

NOTE: There must be criteria for the acceptance and rejection of the amplification of a particular genetic locus or individual sample.

HSC.38180 Preferential Amplification Phase II



Reactions are optimized to avoid preferential amplification. The minimum amount of DNA is determined to obtain optimal sensitivity.

NOTE: Method validation must include a dilution study to evaluate the concentration of DNA to determine minimum sensitivity of the assay.

HSC.38190 Cell Subset Purity Phase II

If cell subset enrichment is performed, the patient report includes the actual or approximate purity of the cell subset.

NOTE: The determination of the actual or approximate purity of the cell subset does not imply that the purity determined in validation studies can be used without further evaluation. An actual measurement may be performed at the time of sample testing. Some isolation methods and cell subpopulations (eg, CD56) may not produce enough cells to test purity and run the monitoring engraftment test. At a minimum, the purity can be determined for each lot of reagent used to isolate the cell subset and then be reported as an approximate purity for that specific lot.

HSC.38200 Hematopoietic Progenitor Cell Engraftment Testing Phase II



For hematopoietic progenitor cell engraftment, samples from pre-transplant patient (recipient), pre-transplant donor(s), post-transplant patient, and an appropriate control are analyzed concurrently.

NOTE: Previously generated data from pre-transplant specimens may be used to compare to post-transplant results if a validated system is used to identify and link the appropriate data files for concurrent analysis.

Evidence of Compliance:

- ✓ Records of HPC testing

HSC.38205 Engraftment Analysis Phase II



Prior to evaluating post engraftment specimens, the laboratory evaluates a specimen from the donor(s) and a pre-transplant specimen from the patient to determine the number of informative loci to test in order to meet the minimum number of loci needed for calculations.

Evidence of Compliance:

- ✓ Records of hematopoietic progenitor cell engraftment testing

HSC.38208 Preferential Allele Amplification Phase II



Preferential allele amplification is considered in the interpretation of hematopoietic progenitor cell engraftment tests.

HSC.38220 Minimal Number of Informative Loci Phase II