

Technical Specification for Release Testing of “Master Cell Banks” and Retroviral Vectors

The Bambino Gesù Pediatric Hospital (OPBG) requests the activation of analytical services necessary for the development of assays to detect replication-competent retrovirus in two Master Cell Banks and their respective viral vectors. Tables 1 and 2 list the names of the analyses required for the two MCBs and the two retroviral vectors to be tested, respectively.

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Table 1. Assay development for the detection of replication-competent retrovirus in MCB.

Assay		#
Biocompatibility assessment of the MCB – preliminary to the test for evaluating RCR in the MCB	Non-regulatory tests for the evaluation of cell-mediated cytotoxicity in detector cells	x2

Table 2. Assay development for the detection of replication-competent retrovirus in retroviral vectors.

Assay		#
Biocompatibility assessment of the viral vector – preliminary to the test for evaluating RCR in the viral vector	Non-regulatory tests for the evaluation of cell-mediated cytotoxicity in detector cells	x2

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