

Rome, 10/06/2025

Esteemed

BioReliance Ltd.

*Glasgow, Scotland, at Unit 5, Todd Campus,
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It is hereby communicated that, with reference to **the Procedure for the activation of Analytical Services for the release of n. 2 “Master Cell Banks” (Mcb) and n. 3 Retroviral Vectors to be used as “Starting Materials” in the production of Car-T drugs. – CUP E83C22003170001**” at the Pharmaceutical Factory of the Bambino Gesù Pediatric Hospital, and in particular with regard to the official offer of 03/25/2025 **“R-10455064.P.1”** presented by your esteemed Company, we kindly request that it be reformulated, with the indication of the **CUP Code (Unique Project Code) E83C22003170001**, no later than 06/20/2025, following the discussions with the competent internal technical function and the consequent modification of the initial Technical Specifications, also in English, sent as an attachment to this letter of clarification.

Please note that within the updated initial Technical Specifications, the tests that will have to be eliminated will be highlighted in **grey with a strikethrough**, only the clarifications describing the test already present in the initial Technical Specifications and what was offered on 03/25/2025 by Your Dear Company will be highlighted in **yellow**, while some additional tests, not requested in the initial technical specifications and now reported in “Table 3”, will be highlighted in **green**.

In particular, the following most significant changes are highlighted:

- the test “009820GMP.BUK” is no longer required for both MCBs and three PPCBs;
- the test “005071GMP.BUK” test is no longer required for the three viral vectors.

In this regard, we also attach, in both Italian and English, the justification for the changes made to the initial Technical Specifications and, via Excel file, in accordance with the updated Technical Specifications, a list of the Bioreliance tests requested by the Pharmaceutical Factory of the Bambino Gesù Children's Hospital, which we invite you to include in the new official offer.

Best Regards,

The Sole Project Manager

Dott.ssa Monica Gunetti

