

Solvias NL Quote 2025 - 5374

CUP E83C22006230001

Quote Type: Cell Line Characterization

Modality: Viral Gene Therapies

Customer shipping address

Pediatric Hospital Bambino
 Viale San Paolo, 15
 Rome, 00146
 IT

QUOTE

Customer contact person
Customer e-mail

Rossana Bugianesi
 rossana.bugianesi@opbg.net

Quote date

24-10-2025

Quote number

Solvias NL Quote 2025 - 5374

Turnaround time

10 weeks

Created by

Juan Jose

Application (Solvias NL internal use only)

CGT

Project goals

- To determine transgene integration patterns and vector integrity in sample(s).

Project outline

- Customer will prepare and ship samples according to Solvias NL instructions;
- Customer will provide sequence information and other relevant information using the customer portal;
- Solvias NL will perform TLA prep and -amplification;
- Solvias NL will perform NGS prep and -sequencing;
- Solvias NL will perform data analysis;
- Solvias NL will compose and share .pdf report.

Deliverables

Genetic stability report:

A single report specifying:

- List of abbreviations;
- Extended explanation of the protocol;
- Characterization using TLA, includes:
 - Integration site analysis,
 - Fidelity of integrated transgene and vector sequences following genomic integration sequence variants (>5% filtering), structural variants (>1% filtering),
 - Identified structural variations in the host genome,
- Quality matrix for sequencing run;
- Extended coverage profile across vector sequence (figure);
- Extended explanation vector-vector fusions;
- Sequence of fusions inclusion in report;
- Copy number determination by TLA;
- Comparison of all samples.

Deliverables TLA Analysis

Standard Deliverables

- Genetic coordinates of integration site(s)
- Determination of small indels and/or sequence variations in the transgene and vector sequence (5% filtering)
- (OR) Limited reporting of sequence variants to GOI
- Determination of structural variations in the integrated transgene and vector sequences (1% filtering)
- (OR) Limited reporting of structural variants to GOI
- Assessment of structural variants surrounding the vector integration site(s)

Optional Deliverables

Additional costs apply

- Estimation of vector copy number by TLA
- Determination of exact vector copy number by ddPCR
- 1% sequence variant calling in a specific region-of-interest. Additional control samples are required
- Comparison between samples within the same project (applicable to projects with > related samples. Please indicate the relationship between samples in the section for additional comments below)
- Comparison between samples to samples in other projects. Please indicate the name of the related projects the relationship between samples in the section for additional comments below
- Evaluation of co-integration of E.coli genomic sequences at the integration site(s)
- Vector component identification, by which a list with all identified common vector elements will be provided. Applicable if the provided vector sequence is incomplete or no vector sequence is provided
- Report meeting regulatory requirements:
 - List of abbreviations;
 - Extended explanation of the TLA protocol;
 - Quality matrix for sequencing run;
 - Extended coverage profile across vector sequence (figure);
 - Extended explanation on vector-vector fusions;
 - Sequences of fusions inclusion in the report (in our basic report this is listed in a separate file);
 - An opportunity to review the report before finalization.
 - Review by a regulatory consultant

- Review and signature by our Director of Quality Assurance & Regulatory Affairs

Please indicate previous related projects or samples and any additional relevant details for the project (e.g. relationship between samples, related previous projects, etc)

n-a.

Additional comments (to be filled by Solvias NL representative)

Please specify:

Project items

Description	QTY	Price	Total
Project start-up costs (per assay)	1	€280,00	€280,00
Genetic Stability Package Project B7H3 (2025 - 5353) TLA analysis of up to 2 timepoints (e.g. MCB and EOP)Including 4 primer sets with extended sequencing per sample	1	€18.000,00	€18.000,00
Estimation of vector copy number by TLA Project B7H3 (2025 - 5353)	1	€115,00	€115,00
Genetic Characterization of Engineered Cell Lines Project B7H3 (2025 - 5356) Heterogeneous Sample	1	€5.040,00	€5.040,00
Genetic Stability Package Project CLEC2A (2025 - 5354) TLA analysis of up to 2 timepoints (e.g. MCB and EOP)Including 4 primer sets with extended sequencing per sample	1	€18.000,00	€18.000,00
Estimation of vector copy number by TLA Project CLEC2A (2025 - 5354)	1	€115,00	€115,00
Genetic Characterization of Engineered Cell Lines Project CLEC2A (2025 - 5357) Heterogeneous Sample	1	€5.040,00	€5.040,00
Genetic Stability Package Project GD2(2025 - 5355) TLA analysis of up to 2 timepoints (e.g. MCB and EOP)Including 4 primer sets with extended sequencing per sample	1	€18.000,00	€18.000,00
Estimation of vector copy number by TLA Project GD2 (2025 - 5355)	1	€115,00	€115,00
Genetic Characterization of Engineered Cell Lines Project GD2 (2025 - 5358) Heterogeneous Sample	1	€5.040,00	€5.040,00
Sample pick-up (Europe) For all samples if sent together. Including the box, dry ice (with refill if necessary), temperature monitoring, and import documentation.	1	€1.590,00	€1.590,00
Crosslinking kit (for 24 samples) Use of Products: Customer hereby agrees and confirms that Customer is the end-user of the Products supplied by Cergentis and that Customer will use the Products strictly according to the accompanying instructions and for use in scientific research and development (as defined in article 56 (3) REACH Regulation (EC) No 1907 / 2006) only	1	€370,00	€370,00

Total costs (EUR): €71.705,00

Estimated shipment date:	30-01-2025
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Signatures

By: Juan Jose Fernandez Business Developer	By: Monica Gunetti GMP facility Head
Solvias NL	OPBG
<i>JUANJO FERNANDEZ</i>	<i>Monica Gunetti</i>
Date: 10 / 24 / 2025	Date: 12 / 23 / 2025
Process & complete:	<input type="checkbox"/>

- Solvias NL's [General Sales and Supply Conditions](#) dated July 2, 2024 shall apply.
- Quote is valid for 60 days starting from Quote Date.
- Samples shall be delivered to Solvias NL within sixty (60) days from the date of the last signature in this Quote. In case the samples are not delivered to Solvias NL within sixty (60) days from the date of the last signature in this Quote, Solvias NL reserves the right to adjust the prices and fees in relation to this Quote and invoice the Customer based on the adjusted prices and fees.
- Solvias NL defines turnaround time of the project with the initiation of laboratory work.
- Sequencing data can be transferred upon request, which involves an additional charge.
- Gaps in coverage across the region of interest can occur due to biases in TLA, NGS library preparation, NGS and/or used mapping strategies.
- Price includes above a one hour discussion on the results. Additional reporting or consulting can be performed at an hourly rate.
- Prices are in Euro's (€) and exclusive of VAT. Prices in US Dollars (\$) include a 5% add-on for FX fluctuations.
- Payments through checks are not accepted.
- In the event of any inconsistency, conflict, or ambiguity between the provisions in the Solvias NL's General Sales and Supply Conditions dated July 2, 2024 and/or this quote on the one hand, and the provisions in the Specifications and/or Technical Specifications provided by Bambino Gesù Children's Hospital on the other hand, the provisions in the documents provided by Bambino Gesù Children's Hospital prevail .
- We informed you by e-mail of December 11th that services by Solvias NL are not performed in accordance with GMP regulations. Solvias NL does not accept liability for non-compliance with the Specifications and/or Technical Specifications provided by Bambino Gesù Children's Hospital by performance of its services not in accordance with GMP regulations.
- If due to the biology of the sample, additional sample processing steps are required or need to be repeated, the turnaround time specified above will be extended by 2 weeks.
- Should this Quote include delivery of either the biological material (samples) and/or the products organized through either QuickSTAT or any other courier service provider ("Courier"), that Courier shall be commissioned by Solvias NL for the Customer and Solvias NL shall pass on to Customer the limitations of liability as specified in the agreement between Solvias NL and the Courier. Solvias NL shall assign its rights and enforceable claims to Customer to the extent these are granted under the agreement between Solvias NL and Courier. Other than this Customer shall not have the right to enforce any claim against Solvias NL regarding the transport and delivery of



the biological material (samples) and/or the products and Customer shall be responsible for the timely delivery of the biological material (samples) to Solvias NL.

CERTIFICATE *of* SIGNATURE

REF. NUMBER
KYADD-WFJT4-FDYSU-RG7KM

DOCUMENT COMPLETED BY ALL PARTIES ON
23 DEC 2025 11:35:32
UTC

SIGNER

TIMESTAMP

SIGNATURE

EMAIL
JUANJOSE.FERNANDEZ@SOLVIAS.COM

SENT
15 DEC 2025 15:46:19
SIGNED
15 DEC 2025 15:46:20

JUANJO FERNANDEZ

IP ADDRESS
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SHARED VIA
LINK

SENT
15 DEC 2025 15:46:19
VIEWED
16 DEC 2025 08:21:30
SIGNED
23 DEC 2025 11:35:32

Monica Gunetti

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LOCATION
ROME, ITALY

