Instructions for Use

General Purpose Reagents: Controls

For use as qualitative PCR controls.

Catalog Number	Product Name	Quantity
REF 40880008	*IGH* SHM Pos (+)	1 Tube - 45 µL
REF 40880010	IVS-0001 Clonal Control DNA	1 Tube - 100 µL
REF 40880190	IVS-0004 Clonal Control DNA	1 Tube - 100 µL
REF 40880370	IVS-0007 Clonal Control DNA	1 Tube - 100 µL
REF 40880430	IVS-0008 Clonal Control DNA	1 Tube - 100 µL
REF 40880490	IVS-0009 Clonal Control DNA	1 Tube - 100 µL
REF 40880550	IVS-0010 Clonal Control DNA	1 Tube - 100 µL
REF 40880730	IVS-0013 Clonal Control DNA	1 Tube - 100 µL
REF 40881090	IVS-0019 Clonal Control DNA	1 Tube - 100 µL
REF 40881210	IVS-0021 Clonal Control DNA	1 Tube - 100 µL
REF 40881390	IVS-0024 Clonal Control DNA	1 Tube - 100 µL
REF 40881690	IVS-0029 Clonal Control DNA	1 Tube - 100 µL
REF 40881750	IVS-0030 Clonal Control DNA	1 Tube - 100 µL
REF 40881810	IVS-0031 Clonal Control DNA	1 Tube - 100 µL
REF 40883320	5% *TCRG* Positive Control DNA	1 Tube - 50 µL
REF 40920020	*TCRG* Negative Control DNA	1 Tube - 50 µL
REF 40920010	IVS-0000 Polyclonal Control DNA	1 Tube - 100 µL
REF R0880230	*FLT3* ITD Positive DNA	1 Tube - 100 µL
REF R0880240	*FLT3* TKD Positive DNA	1 Tube - 100 µL
REF R0880250	*FLT3* Extraction Control	1 Tube - 1800 µL
REF 40890100	IVS-0002 Clonal Control RNA	1 Tube - 100 µL
REF 40890190	IVS-0003 Clonal Control RNA	1 Tube - 100 µL
REF 40890910	IVS-0011 Clonal Control RNA	1 Tube - 100 µL
REF 40891270	IVS-0015 Clonal Control RNA	1 Tube - 100 µL
REF 40891720	IVS-0020 Clonal Control RNA	1 Tube - 100 µL
REF 40892800	IVS-0032 Clonal Control RNA	1 Tube - 100 µL
REF 40893070	IVS-0035 Clonal Control RNA	1 Tube - 100 µL

Table of Contents

1. Proprietary Name

Table 1. Proprietary Product Names and Unique Device Identification (UDI)

Catalog Number	Product Name	UDI	Volume
REF 40880008	*IGH* SHM Pos (+)	810022731642	45 µL
REF 40880010	IVS-0001 Clonal Control DNA	810022731666	100 µL
REF 40880190	IVS-0004 Clonal Control DNA	810022731710	100 µL
REF 40880370	IVS-0007 Clonal Control DNA	810022731727	100 µL
REF 40880430	IVS-0008 Clonal Control DNA	810022731734	100 µL
REF 40880490	IVS-0009 Clonal Control DNA	810022731741	100 µL
REF 40880550	IVS-0010 Clonal Control DNA	810022731758	100 µL
REF 40880730	IVS-0013 Clonal Control DNA	810022731765	100 µL
REF 40881090	IVS-0019 Clonal Control DNA	810022731789	100 µL
REF 40881210	IVS-0021 Clonal Control DNA	810022731796	100 µL
REF 40881390	IVS-0024 Clonal Control DNA	810022731802	100 µL
REF 40881690	IVS-0029 Clonal Control DNA	810022731819	100 µL
REF 40881750	IVS-0030 Clonal Control DNA	810022731826	100 µL
REF 40881810	IVS-0031 Clonal Control DNA	810022731833	100 µL
REF 40883320	5% *TCRG* Positive Control DNA	810022731857	50 µL
REF 40920020	*TCRG* Negative Control DNA	810022732076	50 µL
REF 40920010	IVS-0000 Polyclonal Control DNA	810022732052	100 µL
REF R0880230	*FLT3* ITD Positive DNA	810022732373	100 µL
REF R0880240	*FLT3* TKD Positive DNA	810022732380	100 µL
REF R0880250	*FLT3* Extraction Control	810022732472	1800 µL
REF 40890100	IVS-0002 Clonal Control RNA	810022731949	100 µL
REF 40890190	IVS-0003 Clonal Control RNA	810022731956	100 µL
REF 40890910	IVS-0011 Clonal Control RNA	810022731963	100 µL
REF 40891270	IVS-0015 Clonal Control RNA	810022731970	100 µL
REF 40891720	IVS-0020 Clonal Control RNA	810022731987	100 µL
REF 40892800	IVS-0032 Clonal Control RNA	810022731994	100 µL
REF 40893070	IVS-0035 Clonal Control RNA	810022731642	100 µL

2. Intended Use

Invivoscribe's General Purpose Reagents (GPR) are intended for validation by the end user for use in molecular assays. These controls are specific to gene rearrangements, mutations, and/or translocations from human DNA or RNA indicated in section 3: *Reagents*.

These products are General Purpose Reagents and are for Laboratory Use.

3. Reagents

3.1. Tissue DNA Controls

Tissue DNA controls are extracted from normal, disease-free tissue and are tested extensively to ensure quality and reproducibility of your test results.

- Tissue DNA Controls are adjusted to the final concentration specified in Table 2 with 1/10 TE (1 mM Tris-HCl (pH 8.0), 0.1 mM EDTA), which provides sufficient buffering capacity and EDTA to protect the DNA controls without interfering with the Mg^{2+} concentrations required for robust amplification reactions.

Table 2. Tissue DNA Controls

Catalog Number	Description	Concentration	Characteristics	Storage Conditions
REF 40920010	IVS-0000 Polyclonal Control DNA	200 µg/mL	▪ genomic DNA isolated from the tissue of normal human tonsils ▪ negative control for gene rearrangements, chromosome translocations, and mutation tests	8°C *

*Minimize the number of freeze-thaw cycles.

3.2. Cell Line DNA Controls

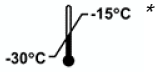
Cell Line DNA Controls are extracted from established cell lines grown under standard cell culture conditions and extensively tested to ensure quality and reproducibility.

- DNA Clonal Controls are adjusted to the final concentration specified in Table 3 with 1/10th TE (1 mM Tris-HCl (pH 8.0), 0.1 mM EDTA), which provides sufficient buffering capacity and EDTA to protect the DNA controls without interfering with the Mg^{2+} concentrations required for robust amplification reactions.

Table 3. Cell Line DNA Controls

Catalog Number	Description	Concentration	Characteristics			Storage Conditions
			Gene Rearrangement	Chromosome Translocation	Gene Mutation	
REF 40880008	*IGH* SHM Pos (+)‡	15 µg/mL	*IGH, IGK*	*IGH-BCL2* t(14;18) Mbr	n/c	8°C
REF 40880010	IVS-0001 Clonal Control DNA	200 µg/mL	n/c	*IGH-BCL2* t(14;18) mcr	n/c	
REF 40880190	IVS-0004 Clonal Control DNA	200 µg/mL	*TRB, TRG*	n/c	n/c	
REF 40880370	IVS-0007 Clonal Control DNA	200 µg/mL	*IGH, IGK, IGL*	*IGH-BCL2* t(14;18) Mbr	n/c	
REF 40880430	IVS-0008 Clonal Control DNA†	200 µg/mL	*IGH* D_H-J_H, *TRB, TRG*	n/c	n/c	
REF 40880490	IVS-0009 Clonal Control DNA	200 µg/mL	*TRB, TRG*	n/c	n/c	
REF 40880550	IVS-0010 Clonal Control DNA	200 µg/mL	*IGH, IGK, IGL*	*IGH-BCL1* t(11;14)§	n/c	
REF 40880730	IVS-0013 Clonal Control DNA	200 µg/mL	*IGH, IGK, IGL*	n/c	n/c	
REF 40881090	IVS-0019 Clonal Control DNA	200 µg/mL	*IGH, IGK*	n/c	n/c	
REF 40881210	IVS-0021 Clonal Control DNA	200 µg/mL	*TRG, TRB, TRD*	n/c	n/c	
REF 40881390	IVS-0024 Clonal Control DNA	200 µg/mL	*IGH, IGK*	n/c	n/c	
REF 40881690	IVS-0029 Clonal Control DNA	200 µg/mL	*IGH, IGK, IGL*	n/c	n/c	

Table 3. Cell Line DNA Controls

Catalog Number	Description	Concentration	Characteristics			Storage Conditions
			Gene Rearrangement	Chromosome Translocation	Gene Mutation	
REF 40881750	IVS-0030 Clonal Control DNA‡	200 µg/mL	*IGH, IGK*	*IGH-BCL2* t(14;18) Mbr	n/c	
REF 40881810	IVS-0031 Clonal Control DNA	200 µg/mL	*IGH, IGK*	*IGH-BCL2* t(14;18) mcr	n/c	
REF 40883320	5% *TCRG* Positive Control DNA	50 µg/mL	*TRG*	n/c	n/c	
REF 40920020	*TCRG* Negative Control DNA	50 µg/mL	negative control for *TRG* gene rearrangements	n/c	n/c	
REF R0880230	*FLT3* ITD Positive DNA	10 µg/mL	n/c	n/c	*FLT3* ITD	
REF R0880240	*FLT3* TKD Positive DNA	10 µg/mL	n/c	n/c	*FLT3* TKD	
REF R0880250	*FLT3* Extraction Control	50 µg/mL	n/c	n/c	*FLT3* negative	

Note: n/c is used to indicate that the control has not been fully characterized; there may be additional rearrangements, translocations or mutations associated with the control.

*Minimize the number of freeze-thaw cycles.

†This control does not contain a complete *IGH* V_H-J_H rearrangement and may only be suitable for *IGH* D_H-J_H rearrangements.

§*IGH-BCL1* was previously referred to as *BCL1*/J_H

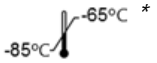
‡These controls can be used as SHM positive controls with ≥2% mutational rates compared to the germline sequence.

3.3. RNA Controls

Invivoscribe RNA Controls are extracted from established cell lines grown under standard cell culture conditions and extensively tested to ensure quality and reproducibility.RNA

- Controls are adjusted to the final concentration specified in Table 4. with molecular grade water.

Table 4. RNA Controls

Catalog Number	Description	Concentration	Target	Storage Conditions
REF 40890100	IVS-0002 Clonal Control RNA	400 µg/mL	*E2A-PBX1* t(1;19)(q23;p13)	
REF 40890190	IVS-0003 Clonal Control RNA	400 µg/mL	*BCR-ABL1* t(9;22) p210 e13a2 (b2a2)	
REF 40890910	IVS-0011 Clonal Control RNA	400 µg/mL	*BCR-ABL1* t(9;22) p210 e14a2 (b3a2)	
REF 40891270	IVS-0015 Clonal Control RNA	400 µg/mL	*CBFB-MYH11* inv(16)	
REF 40891720	IVS-0020 Clonal Control RNA	400 µg/mL	*PML-RARα* t(15;17)(q22;q11)	
REF 40892800	IVS-0032 Clonal Control RNA	400 µg/mL	*BCR-ABL1* t(9;22) p190 e1a2	
REF 40893070	IVS-0035 Clonal Control RNA	400 µg/mL	negative for *BCR-ABL* and *PML-RARα* chromosome translocations	

*Minimize the number of freeze-thaw cycles.

3.4. Warnings and Precautions

- Invivoscribe's GPRs are for Laboratory Use.
- Invivoscribe's GPR Controls are not intended for use as a substitute for the internal controls provided by *in vitro* diagnostic kit manufacturers.
- Establish standard operating procedures and instructions for using the Invivoscribe GPR DNA and RNA controls in molecular assays.
- Reagents are stable until the labeled expiration date when stored and handled as directed. Do not use reagents beyond their expiration date.
- Perform all quality control requirements in conformance with local, state and/or federal regulations or accreditation requirements.
- Wear appropriate personal protective equipment and follow good laboratory practices and universal precautions when working with specimens.
- Handle specimens in approved biological safety containment facilities and open only in certified biological safety cabinets.
- Use extreme care to avoid the contamination of reagents with samples, controls or amplified materials. Closely monitor all reagents for signs of contamination (*e.g.,* negative controls giving positive signals). Discard reagents suspected of contamination.
- To minimize contamination, wear clean gloves when handling samples and reagents and routinely clean work areas and pipettes prior to doing PCR.
- Autoclaving does not eliminate DNA contamination.
- Follow uni-directional workflow in the PCR laboratory; begin with master mix preparation, move to specimen preparation, then to amplification, and finally to detection. Do not bring amplified DNA into the areas designated for master mix or specimen preparation.
- Dedicate all pipettes, pipette tips, and any equipment used in a particular area to that area of the laboratory.
- Use sterile, disposable plastic ware whenever possible to avoid RNase, DNase, or cross-contamination.

3.5. Storage and Stability

- When stored at the intended storage conditions, Invivoscribe's GPR controls are stable until the expiration date indicated on the vial label.

4. Procedure

4.1. Allow the GPR control to equilibrate to room temperature.

4.2. Vortex gently, then pulse-spin in a centrifuge (4 to 6 seconds) to collect the contents at the bottom of the tube.

4.3. Introduce the GPR control as an independent sample at the template addition step in the workflow.

4.4. Handle the GPR control similarly to nucleic acids extracted from routine samples and run in parallel with routine samples.

5. Interpretation of Results

5.1. Results generated by Invivoscribe's GPR controls may differ according to the molecular test method.

5.2. To establish a baseline performance, incorporate results from multiple runs under different conditions (*e.g.*, operator, run, day) to determine a valid size range specific to the assay used.

5.3. Once the validated size range is ascertained, the expected size range can be used to verify each subsequent run result of the GPR control.

6. Symbols

The following symbols are used in labeling for Invivoscribe products.

	Storage Conditions		Expiration Date
	Catalog Number		Authorized Representative in the European Community
	Reagent Volume		Manufacturer
	Lot Number		Consult Instructions for Use

7. Technical and Customer Service

Technical and Customer Service Representatives are available Monday through Friday to answer phone, e-mail or website inquiries. Please do not hesitate to contact sales@invivoscribe.com for assistance evaluating controls to suit your testing needs.

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8. Legal Notice

Invivoscribe, Inc. (Invivoscribe®) is committed to providing the highest quality products. Invivoscribe® warrants that the products meet or exceed the performance standards described in the Instructions For Use, as to products with such an insert. If a product is covered by product specifications and does not perform as specified, our policy is to replace the product or credit the full purchase price. No other warranties of any kind, expressed or implied, are provided by Invivoscribe®. Invivoscribe® liability shall not exceed the purchase price of the product.Invivoscribe shall have no liability for direct, indirect, consequential or incidental damages arising from the use, results of use, or inability to use its products; product efficacy under purchaser controlled conditions in purchaser's laboratory must be established and continually monitored through purchaser defined and controlled processes including but not limited to testing of internally validated positive, negative, and blank controls every time a sample is tested. Ordering, acceptance and use of product constitutes purchaser acceptance of sole responsibility for assuring product efficacy and purchaser agreement to the limitation of liability set forth in this paragraph.

This product is a General Purpose Reagent (GPR).