

Controls, Reagents, and Enzymes

Invivoscribe® offers an extensive range of General Purpose Reagents (GPRs) and Research Use Only (RUO) nucleic acid controls.

LEARN MORE:

invivoscribe.com/products/controls

Warranty and Liability

Invivoscribe is committed to providing the highest quality products. Invivoscribe warrants that for products which are provided with Instructions for Use, these products meet or exceed the performance standards described in the Instructions For Use. 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 [lability 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 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 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.

Introduction

Controls are available in DNA extracted from tissue or cell lines, or RNA extracted from cell lines. These controls can be purchased in various dilutions or as complete dilution sets and panels for several purposes, such as to help with assay validation, sensitivity or proficiency testing, or troubleshooting.

The following pages will provide an overview of available controls, along with a number of tables and reference guides, to help you decide which Invivoscribe control(s) will be suitable for your application.

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DNA Controls

Every laboratory needs suitable controls (positive and negative) for sensitivity and proficiency testing, as well as for troubleshooting. Since patient samples cannot serve as true controls (due to a lack of characterization and inter-sample variability), Invivoscribe offers a multitude of high quality, reliable DNA controls manufactured under cGMP conditions.

These controls can be used for most assays targeting B- and T-cell antigen receptor loci, FLT3 ITD and TKD loci, or IGH-BCL2, BCR-ABL1, and PML-RARa chromosome translocations.

Quick Reference for DNA Controls

The vast majority of our high-quality DNA controls, including sensitivity controls and panels, are supplied in aliquots of 100 µL and are adjusted to a final concentration of 200 μ g/mL in 1/10 TE (1 mM Tris- HCl (pH 8.0), 0.1 mM EDTA).

Positive for	Immunoglobulin Rearrangements		Mutations		Translocations		T-Cell Receptor Gene Rearrangements				
	IGH	IGK	IGL	IGHV SHM	FLT3 ITD	FLT3 TKD	IGH-CCND1**	IGH-BCL2	TRB	TRG	TRD
VS-0001								•			
VS-0004									•	•	
VS-0007	•	•	•					•			
VS-0008 [€]	0								•	•	
VS-0009									•	•	
VS-0010	•	•					•				
VS-0013	•	•									
VS-0019	•	•									
VS-0021		•							•	•	•
VS-0024	•	•									
VS-0029	•	•									
VS-0030 ‡	•	•		•							
VS-0031	•	•									
ymphoQuant B-cell Internal Control	*	*									
ymphoQuant T-cell Internal Control									*	*	
ymphoTrack B-cell Low Positive Control	*	*									
ymphoTrack T-cell Low Positive Control									*	*	
FLT3 ITD Positive Control					•						
FLT3 TKD Positive Control						•					
These controls can be used as SHM positive co This control does not contain a complete IGH **IGH-CCND1 was previously referred to as B	V _H -J _H rearrang						5.	◆ Gene rearran ○ Partial IGH DH ★ Recommende	I-JH rearran	ngement	

Tissue DNA

Standard Concentrations

Our high-quality DNA controls are supplied in aliquots of 100 µL and are adjusted to a final concentration of 200 μ g/mL in 1/10 TE (1 mM Tris- HCI (pH 8.0), 0.1 mM EDTA). This diluent provides sufficient buffering capacity and EDTA to protect the DNA without interfering with the Mg²⁺ concentrations required for robust amplification reactions.

IVS-0000 Polyclonal Control DNA

Tissue DNA controls are extracted from normal, disease-free tissue and are tested extensively to ensure quality and reproducibility of your test results. IVS-0000 Polyclonal Control DNA consists of genomic DNA isolated from the tissue of normal human tonsils. This control represents an excellent negative control for gene rearrangements, chromosome translocations, and mutation tests and is included in all of our PCR DNA-based assay kits. This DNA is supplied at a volume of 100 μL and at a concentration of 200 µg/mL.

Catalog #	Description
4-092-0010	IVS-0000 Polyclonal Control DNA

*These controls are general purpose reagents (GPRs).

Cell Line DNA

Reliable Positive Controls

Cell Line DNA controls are extracted from established cell lines grown under cell culture conditions recommended by the supplier. Our controls are tested extensively to ensure quality and reproducibility of your test results. Please note, these controls are for qualitative use only.

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.

Standard Concentrations

Our high-quality DNA controls are supplied in aliquots of 100 μ L and are provided at a final concentration of 200 μ g/mL in 1/10 TE (1 mM Tris-HCl (pH 8.0), 0.1 mM EDTA). This diluent provides sufficient buffering capacity and EDTA to protect the DNA controls without interfering with the Mg²⁺ concentrations required for robust amplification reactions.

IVS-0001 Clonal Control DNA

IVS-0001 Clonal Control DNA can be used as a positive control for:

Gene Rearrangements: n/c

Chromosome Translocations: IGH-BCL2 t(14;18) mcr

Mutations: n/c

Catalog # Description

4-088-0010 IVS-0001 Clonal Control DNA

IVS-0008 Clonal Control DNA[‡]

IVS-0008 Clonal Control DNA can be used as a positive control for:

Gene Rearrangements: IGH DH-|H[‡], TRB, TRG

Chromosome Translocations: n/c Mutations: n/c

Catalog # Description

4-088-0430 IVS-0008 Clonal Control DNA

IVS-0004 Clonal Control DNA

IVS-0004 Clonal Control DNA can be used as a positive control for:

Gene Rearrangements: TRB, TRG
Chromosome Translocations: n/c
Mutations: n/c

Catalog # Description

4-088-0190 IVS-0004 Clonal Control DNA

IVS-0009 Clonal Control DNA

IVS-0009 Clonal Control DNA can be used as a positive control for:

Gene Rearrangements: TRB, TRG
Chromosome Translocations: n/c
Mutations: n/c

Catalog # Description

4-088-0490 IVS-0009 Clonal Control DNA

IVS-0007 Clonal Control DNA

IVS-0007 Clonal Control DNA can be used as a positive control for:

Gene Rearrangements: IGH, IGK, IGL
Chromosome Translocations: IGH-BCL2 t(14;18) Mbr

Mutations:

Catalog # Description

4-088-0370 IVS-0007 Clonal Control DNA

These controls are general purpose reagents (GPRs). 1 This control does not contain a complete 1 GH 1 V $_{H}$ - 1 J $_{H}$ rearrangement and may only be suitable for 1 GH 1 D $_{H}$ - 1 J $_{H}$ rearrangements.

Cell Line DNA

IVS-0010 Clonal Control DNA

IVS-0010 Clonal Control DNA can be used as a positive control for:

Gene Rearrangements: IGH, IGK, IGL
Chromosome Translocations: IGH-BCL1 t(11;14)

Mutations: n/c

Catalog # Description

4-088-0550 IVS-0010 Clonal Control DNA

IVS-0013 Clonal Control DNA

IVS-0013 Clonal Control DNA can be used as a positive control for:

Gene Rearrangements: IGH, IGK, IGL

Chromosome Translocations: n/c Mutations: n/c

Catalog # Description

4-088-0730 IVS-0013 Clonal Control DNA

IVS-0019 Clonal Control DNA

IVS-0019 Clonal Control DNA can be used as a positive control for:

Gene Rearrangements: IGH, IGK
Chromosome Translocations: n/c
Mutations: n/c

Catalog # Description

4-088-1090 IVS-0019 Clonal Control DNA

IVS-0021 Clonal Control DNA

IVS-0021 Clonal Control DNA can be used as a positive control for:

Gene Rearrangements: TRB, TRD, TRG

Chromosome Translocations: n/c Mutations: n/c

Catalog # Description

4-088-1210 IVS-0021 Clonal Control DNA

IVS-0024 Clonal Control DNA

IVS-0024 Clonal Control DNA can be used as a positive control for:

Gene Rearrangements: IGH, IGK
Chromosome Translocations: n/c
Mutations: n/c

Catalog # Description

4-088-1390 IVS-0024 Clonal Control DNA

IVS-0029 Clonal Control DNA

IVS-0029 Clonal Control DNA can be used as a positive control for:

Gene Rearrangements: IGH, IGK, IGL

Chromosome Translocations: n/c
Mutations: n/c

Catalog Description

4-088-1690 IVS-0029 Clonal Control DNA

IGH SHM Positive Control DNA

IGH SHM Postive Control can be used as a positive control for:

Gene Rearrangements: IGH
Chromosome Translocations: n/c
Mutations: IGH SHM

Catalog Description

4-088-0008 IGH SHM Positive Control DNA

IVS-0030 Clonal Control DNA

IVS-0030 Clonal Control DNA can be used as a positive control for:

Gene Rearrangements: IGH, IGK

Chromosome Translocations: IGH-BCL2 t(14;18) Mbr

Mutations: n/c

Catalog Description

4-088-1750 IVS-0030 Clonal Control DNA

IVS-0031 Clonal Control DNA

IVS-0031 Clonal Control DNA can be used as a positive control for:

Gene Rearrangements: IGH, IGK

Chromosome Translocations: IGH-BCL2 t(14;18) mcr

Mutations: n/c

Catalog Description

4-088-1810 IVS-0031 Clonal Control DNA

These controls are general purpose reagents (GPRs).

LymphoTrack® Low Positive Controls

Measurable Residual Disease (MRD) testing is a valuable tool that allows investigators to study and monitor multiple myeloma (MM), chronic lymphocytic leukemia (CLL), acute lymphoblastic leukemia (ALL), acute myelogenous leukemia (AML) and other hematologic diseases. Recent treatment advances have led to significantly increased clinical response and overall survival, but ultimately most subjects will relapse, driving the need for sensitive MRD monitoring. Sensitive and standardized testing such as NGS-based MRD may one day enable identification of those cases that will eventually relapse versus those who are potentially cured. In addition to the need for more sensitive tracking, it is clear that standardized methods are needed. Currently, MRD methods are highly subjective and recommendations are often based on consensus expert-shared knowledge and experience, not on a validated, objective method. Once specific rearrangements have been identified, LymphoTrack assays can be used with LymphoQuant and LymphoTrack Low Positive Controls to track these clonotype populations to a sensitivity as low as 10⁻⁴.

LymphoTrack® B-cell Low Positive Control

LymphoTrack B-cell Low Positive Control can be used as a control for:

Gene Rearrangements: IGH
Chromosome Translocations: n/c
Mutations: n/c

Catalog #

Description

4-088-0098

LymphoTrack® B-cell Low Positive Control*

LymphoTrack® T-cell Low Positive Control

LymphoTrack T-cell Low Positive Control can be used as a control for:

Gene Rearrangements: TRB, TRG
Chromosome Translocations: n/c
Mutations: n/c

Catalog # 4-088-0108

Description

LymphoTrack® T-cell Low Positive Control*

LymphoQuant® Internal Controls

LymphoQuant T-cell or B-cell Internal Controls may be spiked into specimens to estimate the respective number of clonotype T-cell or *IGH* equivalents present. Addition of the LymphoQuant Internal Control to the specimen PCR facilitates clonotype tracking over time without any additional sequencing cost. Consistent use of a LymphoQuant Internal Control enables investigators to objectively monitor the disease over time with a highly standardized, sensitive method. The LymphoTrack MRD software helps researchers that use the LymphoQuant Internal Control, calculate and report an estimated number of clonotype cell equivalents and the percent clonotype in the sample, enabling researchers and pharmaceutical companies to accurately monitor hematologic disease in longitudinal studies.

LymphoQuant® B-cell Internal Control

LymphoQuant B-cell Internal Control can be used to objectively track Ig clonotypes.

Gene Rearrangements: IGH.
Chromosome Translocations: n/c
Mutations: n/c

Catalog # Description

4-088-0118 LymphoQuant® B-cell Internal Control*

LymphoQuant® T-cell Internal Control

LymphoQuant T-cell Internal Control can be used to objectively track TCR clonotypes.

Gene Rearrangements: TRB, TRG
Chromosome Translocations: n/c
Mutations: n/c

Catalog # Description

4-088-0128 LymphoQuant® T-cell Internal Control*

^{*}LymphoTrack® Low Positive Controls and LymphoQuant® Internal Controls are research use only (RUO), not for diagnostic procedures.

RNA Controls

Quick Reference for RNA Controls

Reliable Assay Controls

Our RNA controls are extracted from well characterized cell lines grown under standard and carefully controlled culture conditions. The general purpose reagent (GPR) controls are tested to ensure linearity and reproducible results. Since this RNA is extracted from cell lines, these controls can be used with any of the standard housekeeping genes.

Standard Concentrations

Each RNA single control tube (as separate control tube, RNA sensitivity panel and proficiency panel) is supplied in aliquots of 100 μ L at a final concentration of 400 μ g/mL in water. Each *BCR/ABL* RNA dilution set member is supplied in aliquots of 50 μ L at a final concentration of 400 μ g/mL in water. To ensure maximum stability, store the dilutions at -85 °C to -65 °C and minimize the number of freeze-thaw cycles .

RNAs positive for chromosome translocations

Chromosome Translocation	Clonal Control RNA	Chromosome Translocation	Clonal Control RNA
BCR-ABL1 t(9;22) p210 e13a2 (b2a2)	IVS-0003	CBFB-MYH11 inv(16)	IVS-0015
BCR-ABL1 t(9;22) p210 e14a2 (b3a2)	IVS-0011	E2A-PBX1 t(1;19)(q23;p13)	IVS-0002
BCR-ABL1 t(9;22) p190 e1a2	IVS-0032	PML-RARA t(15;17)(q22;q11)	IVS-0020

RNAs negative for chromosome translocations

IVS-0035 Clonal Control RNA is negative for BCR-ABL t(9;22) and PML-RARa t(15;17) chromosome translocations.

IVS-0035 may be used as a negative control for other chromosome translocations or diluents for other chromosome translocation positive controls. Please do not hesitate to contact us at support@invivoscribe.com so we can evaluate whether this control may work for your testing needs.

Cell Line RNA

Reliable Positive and Negative Controls

Cell Line RNA controls are extracted from established cell lines grown under cell culture conditions recommended by the supplier. Our GPR controls are tested extensively to ensure quality and reproducibility of your test results. Please note, these controls are for qualitative use only.

Standard Concentrations

Our GMP-manufactured high-quality RNA controls, including sensitivity controls and proficiency panel samples, are supplied in aliquots of 100 μ L and are adjusted to a final concentration of 400 μ g/mL in RNase-free glass-distilled water. The pH of distilled water is slightly acidic; this protects the RNA from hydrolysis. RNA dilutions are diluted volume to volume in our negative control RNA, IVS-0035 Clonal Control RNA.

IVS-0002 Clonal Control RNA

IVS-0002 Clonal Control RNA can be used as a positive control for the chromosome translocation: *E2A-PBX1* t(1;19) (q23;p13).

Catalog #

Description

4-089-0100

IVS-0002 Clonal Control RNA*

IVS-0003 Clonal Control RNA

IVS-0003 Clonal Control RNA can be used as a positive control for the chromosome translocation: *BCR-ABL1* (9;22) p210 e13a2 (b2a2).

This control is also available as several ready-to-use dilutions into a standard negative control as listed in the table below.

Catalog #	Description
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4-089-0190	IVS-0003 Clonal Control RNA*
4-089-0200	10 ⁻¹ IVS-0003 Clonal Control RNA
4-089-0210	10 ⁻² IVS-0003 Clonal Control RNA
4-089-0220	10 ⁻³ IVS-0003 Clonal Control RNA
4-089-0230	10 ⁻⁴ IVS-0003 Clonal Control RNA
4-089-0240	10 ⁻⁵ IVS-0003 Clonal Control RNA

IVS-0011 Clonal Control RNA

IVS-0011 Clonal Control RNA can be used as a positive control for the chromosome translocation: *BCR-ABL1* (9;22) p210 e14a2 (b3a2).

This control is also available as several ready-to-use dilutions into a standard negative control as listed in the table below.

Cata	log #	Description
Culu	104 #	Description

^{*}These controls are general purpose reagents (GPRs). All others are research use only (RUO).

IVS-0015 Clonal Control RNA

IVS-0015 Clonal Control RNA can be used as a positive control for the chromosome translocation: CBFB-MYH11 inv(16)

Catalog #

Description

4-089-1270

IVS-0015 Clonal Control RNA*

IVS-0020 Clonal Control RNA

IVS-0020 Clonal Control RNA can be used as a positive control for the chromosome translocation: *PML-RARA* t(15;17) L-Form.

Catalog #

Description

4-089-1720

IVS-0020 Clonal Control RNA*

IVS-0032 Clonal Control RNA

IVS-0032 Clonal Control RNA can be used as a positive control for the chromosome translocation: *BCR-ABL1* t(9;22) p190 e1a2.

This control is also available as several ready-to-use dilutions into a standard negative control as listed in the table below.

Catalog # Description

4-089-2800	IVS-0032 Clonal Control RNA*
4-089-2810	10 ⁻¹ IVS-0032 Clonal Control RNA
4-089-2820	10 ⁻² IVS-0032 Clonal Control RNA
4-089-2830	10 ⁻³ IVS-0032 Clonal Control RNA
4-089-2840	10 ⁻⁴ IVS-0032 Clonal Control RNA
4-089-2850	10 ⁻⁵ IVS-0032 Clonal Control RNA

IVS-0035 Clonal Control RNA

IVS-0035 Clonal Control RNA can be used as a negative control for BCR-ABL1 t(9;22) and PML-RARa t(15; 17) chromosome translocations.

Catalog #

Description

4-089-3070

IVS-0035 Clonal Control RNA*

BCR/ABL RNA Dilution Sets

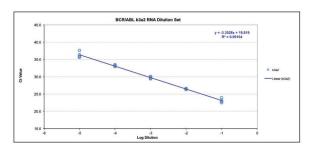
Our *BCR/ABL* b2a2, b3a2, and e1a2 RNA Dilution Sets consist of RNA that has been extracted from *BCR-ABL1* expressing and *BCR-ABL1* negative cell lines. Each set is composed of several dilutions (10^{-1} , 10^{-2} , 10^{-3} , 10^{-4} , 10^{-5}) of the *BCR-ABL1* positive RNA diluted (v/v) into RNA purified from a cell line that does not contain a *BCR-ABL1* translocation. Also included in these sets is a 100% *BCR-ABL1* negative RNA.

The individual BCR/ABL b2a2, b3a2, and e1a2 RNA Dilution Sets can be used as reference and validation materials with assays that target the main transcripts of BCR-ABL1 t(9;22) translocations: p210 (e13a2 (b2a2), e14a2 (b3a2), and p190 (e1a2). These products may be used as the following:

- 1. Routine testing controls for cDNA synthesis, amplification and detection
- 2. Controls to establish a standard reference curve
- 3. Proficiency controls
- 4. Sensitivity controls for specific target assays

Data

Plot of Ct values (5 replicates) for the 10^{-1} , 10^{-2} , 10^{-3} , 10^{-4} , and 10^{-5} dilutions.



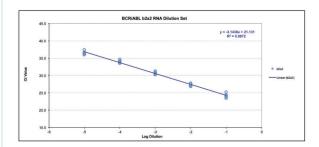
Ordering Information - e14a2 (b3a2)

Catalog

Description

4-085-0210

BCR/ABL b3a2 RNA Dilution Set (10-1, 10-2, 10-3, 10-4, 10-5 dilutions and negative)



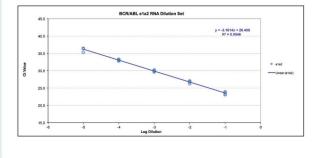
Ordering Information - e13a2 (b2a2)

Catalog

Description

4-085-0310

BCR/ABL b2a2 RNA Dilution Set (10⁻¹, 10⁻², 10⁻³, 10⁻⁴, 10⁻⁵ dilutions and negative)



Ordering Information – e1a2

Catalog

Description

4-085-0110

BCR/ABL e1a2 RNA Dilution Set (10⁻¹, 10⁻², 10⁻³, 10⁻⁴, 10⁻⁵ dilutions and negative)

These products are for Research Use Only (RUO).

Not intended for diagnostic purposes.

RNA Control Panels

RNA Sensitivity Panels

RNA sensitivity panels are 7 member panels that consist of 100% clonal RNA extracted from a positive control cell line and 10⁻¹, 10⁻², 10⁻³, 10⁻⁴, 10⁻⁵, and 10-6 (1:10 - 1:1 000 000) dilutions of the positive clonal RNA diluted (v/v) into our standard negative control RNA, IVS-0035 Clonal Control RNA. Each tube contains 100 μ L of RNA at 400 μ g/mL in RNase-free glass-distilled water. The pH of distilled water is slightly acidic thereby protecting the RNA from hydrolysis. Please note, these controls are for qualitative use only.

RNA Sensitivity Panels

Catalog #	Description	Can be used as a positive control for:
4-087-0030	Sensitivity Panel for IVS-0003 Clonal Control RNA	BCR-ABL1 t(9;22) p210 e13a2 (b2a2)
4-087-0110	Sensitivity Panel for IVS-0011 Clonal Control RNA	BCR-ABL1 t(9;22) p210 e14a2 (b3a2)
4-087-0150	Sensitivity Panel for IVS-0015 Clonal Control RNA	CBFB/MYH11 inv16
4-087-0200	Sensitivity Panel for IVS-0020 Clonal Control RNA	PML-RARA t(15;17) L-form
4-087-0320	Sensitivity Panel for IVS-0032 Clonal Control RNA	BCR-ABL1 t(9;22) p190 e1a2

These products are for Research Use Only (RUO). Not intended for diagnostic purposes

Master Mix Controls

These master mixes serve as control for many of our DNA assays to ensure that sample DNA is of sufficient quality and integrity to generate a valid result.

Specimen Control Size Ladder

Our Specimen Control Size Ladder master mix targets four different housekeeping genes producing products of approximately 100, 200, 300, 400, and 600 base pair in size to ensure that the quality and quantity of the sample DNA is adequate to yield a valid result with the specific assay(s). This master mix is based on the BIOMED-2 Concerted Action BMH4-CT98-3936 from the EuroClonality Group and is available for Gel Detection (unlabeled) or ABI detection (labeled with 6FAM).

Catalog # **Description**

Specimen Control Size Ladder - Unlabeled 2-096-0020

2-096-0021 Specimen Control Size Ladder - 6FAM

These master mixes are general purpose reagents (GPRs).

Reagents

ABI Detection Reagents

Invivoscribe also offers highly deionized (Hi-Di) Formamide with ROX size standards for ABI fluorescence detection with the ABI 310 or 3100 series. Hi-Di Formamide is used to stabilize single strands of denatured PCR amplicons. The ROX size standards are fluorescent labeled DNA standards which cover the 50 to 400 base pair size range. Sizes of the individual standards are: 50, 60, 90, 100, 120, 150, 160, 180, 190, 200, 220, 240, 260, 280, 290, 300, 320, 340, 360, 380, and 400 base pair.

For samples tested on an ABI 3100 series, we recommend using 10 µL of the Hi-Deionized Formamide with ROX Size Standards mixture for each microliter of PCR product. Please note that the ABI 3100 series require different concentrations of ROX size standards and the different Hi-Deionized Formamide with ROX Size Standards cannot be used interchangeably.

For samples tested on an ABI 3500 series, GeneScan™ 600® LIZ dye Size Standard v2.0 can be purchased from Thermo Fisher Scientific.

Catalog #

Description

6-098-0061

Hi-Deionized Formamide with ROX Size | Standard (ABI 3100), 1 mL

Available through Thermo Fisher Scientific®: 4408399

GeneScan™ 600 LIZ® dye v2.0 | Standard (ABI 3500), 800 reactions

Enzyme

FalconTaq[™] DNA Polymerase

FalconTaq™ DNA Polymerase can be used for amplification using PCR to obtain high specificity, sensitivity, and yield. This enzyme has been proven to minimize extension of non-specifically bound primers. Generate reliable results by using FalconTaq™ DNA Polymerase for robust performance.

Catalog #

Description

6-097-0130

FalconTag™ DNA Polymerase 250 U, 5 U/µL

FalconTaq[™] DNA Polymerase is replacing EagleTaq DNA Polymerase, please contact support@invivoscribe.com if you have questions.

> These products are for Research Use Only (RUO). Not intended for diagnostic purpos

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