# Instructions for Use BCR/ABL b3a2 RNA Dilution Set



For use as reference or validation material to target BCR-ABL1 t(9;22) b3a2 transcripts.

This product is for Research Use Only; not intended for diagnostic procedures.

Manufactured in U.S.A.





Storage Conditions: -85°C to -65°C

Catalog # **Description** Quantity

## **Table of Contents**

1.	Produc	CT USE	3			
2.	REAGENTS					
	2.1. 2.2. 2.3.	Dilution Set Components	3 3			
3.	PROCE	4				
4.	INTERPRETATION OF RESULTS					
5.	Symbols4					
6.	TECHNI	CAL AND CUSTOMER SERVICE	5			
7.	LEGAL NOTICE					

## 1. Product Use

The *BCR/ABL* b3a2 RNA Dilution Set can be used as reference and validation material within RUO assays that target *BCR-ABL1* t(9;22) translocations: p210 e14a2 (b3a2) and may be used for the following:

- Routine testing controls for cDNA synthesis, amplification and detection
- Establishing a standard reference curve
- Sensitivity controls for specific target assays

## 2. Reagents

#### 2.1. Dilution Set Components

Invivoscribe's *BCR/ABL* b3a2 RNA Dilution Set consists of RNA that has been extracted from established *BCR/ABL* b3a2 positive and *BCR/ABL* negative cell lines grown under standard cell culture conditions. Controls are adjusted to the final concentration specified in Table 1 with molecular grade water.

Table 1. BCR/ABL b3a2 RNA Dilution Set components

Description	Dilution	Concentration	Quantity	Volume	Target	Storage Conditions*
10 <sup>-1</sup> b3a2 RNA	1:10	400 μg/mL	1	50 μL		
10 <sup>-2</sup> b3a2 RNA	1:100	400 μg/mL	1	50 μL		
10 <sup>-3</sup> b3a2 RNA	1:1,000	400 μg/mL	1	50 μL	BCR-ABL1 p210 e14a2 (b3a2)	<b></b>
10 <sup>-4</sup> b3a2 RNA	1:10,000	400 μg/mL	1	50 μL	(0302)	-85°C *
10 <sup>-5</sup> b3a2 RNA	1:100,000	400 μg/mL	1	50 μL		
b3a2 Negative RNA	n/a	400 μg/mL	1	50 μL	negative for <i>BCR/ABL</i> b3a2 transcript	

<sup>\*</sup>Minimize the number of freeze-thaw cycles.

#### 2.2. Warnings and Precautions

- Ruo Invivoscribe's BCR/ABL b3a2 RNA Dilution Set is for Research Use Only. Not intended for diagnostic purposes.
- Establish standard operating procedures and instructions for using the Invivoscribe BCR/ABL b3a2 RNA Dilution Set in molecular assays.
- 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 nucleic acid 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 nucleic acid 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 plasticware whenever possible to avoid RNase, DNase, and cross-contamination.

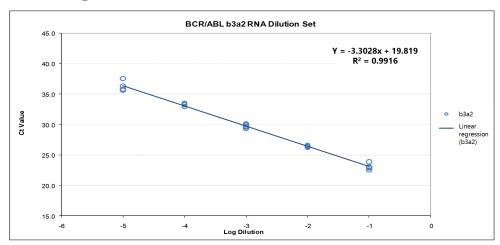
#### 2.3. Storage and Stability

- Store all RNA material at -85°C to -65°C to maintain product integrity.
- The material contains date of manufacture on the label. Conduct appropriate stability testing to ensure the integrity of the material after aliquoting into single-use volumes.

### 3. Procedure

- 3.1. Allow the BCR/ABL b3a2 RNA Dilution Set to equilibrate to room temperature.
- 3.2. Vortex gently, then pulse-spin in a centrifuge (4 to 6 seconds) to collect the contents at the bottom of the tube.
- 3.3. Introduce each component of the *BCR/ABL* b3a2 RNA Dilution Set as an independent sample at the template addition step in the workflow.
- 3.4. Handle each component of the *BCR/ABL* b3a2 RNA Dilution Set similarly to nucleic acids extracted from routine samples and run in parallel with routine samples.

# 4. Interpretation of Results

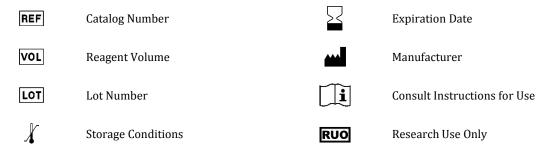


This plot indicates the Ct values versus 10<sup>-1</sup>, 10<sup>-2</sup>, 10<sup>-3</sup>, 10<sup>-4</sup> and 10<sup>-5</sup> dilutions of BCR/ABL b3a2 RNA Dilution Set (5 replicates).

- 4.1. Results generated by Invivoscribe's BCR/ABL b3a2 RNA Dilution Set may differ according to the molecular test method.
- 4.2. 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.
- 4.3. Once the validated size range is ascertained, the expected size range can be used to verify each subsequent run result of the *BCR/ABL* b3a2 RNA Dilution Set.

## 5. Symbols

The following symbols are used in labeling for Invivoscribe products.



#### 6. 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.

#### **Contact Information**

Invivoscribe, Inc

10222 Barnes Canyon Road | Building 1 | San Diego | California 92121-2711 | USA

Phone: +1 858 224-6600 | Fax: +1 858 224-6601 | Business Hours: 7:00AM - 5:00 PM PST/PDT

Technical Service: <a href="mailto:support@invivoscribe.com">support@invivoscribe.com</a> | Customer Service: <a href="mailto:sales@invivoscribe.com">sales@invivoscribe.com</a> | Website: <a href="https://www.invivoscribe.com">www.invivoscribe.com</a> | Customer Service: <a href="mailto:sales@invivoscribe.com">sales@invivoscribe.com</a> | Website: <a href="mailto:www.invivoscribe.com">www.invivoscribe.com</a> | Customer Service: <a href="mailto:sales@invivoscribe.com">sales@invivoscribe.com</a> | Website: <a href="mailto:www.invivoscribe.com">www.invivoscribe.com</a> | Website: <a href="mailto:www.invivoscribe.com">www.invivoscribe.

## 7. 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 product 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 for Research Use Only; not for use in diagnostic procedures.

©2023 Invivoscribe, Inc. All rights reserved. The trademarks mentioned herein are the property of Invivoscribe, Inc. and/or its affiliates or (as to the trademarks of others used herein) their respective owners.