& invivoscribe

IdentiClone[®] RUO TCRG 2.0 Software for Capillary-Based Detection of T-Cell Receptor Gamma Gene Rearrangements



Chris Conner, Junmei Liu, Griffin Charles, Emma L. Roberts, Christina Y. Howard, Tiger Anne Wing-Lawrence, Tony Galuhn, Sunghae Joo, Ying Huang, and Jeffrey E. Miller Invivoscribe, Inc.; San Diego, United States

Introduction

The IdentiClone Research Use Only (RUO) TCRG 2.0 desktop software is intended for the automated analysis of capillary electrophoresis (CE) data obtained from running Invivoscribe's RUO T-Cell Receptor Gamma Gene (TCRG) Rearrangement Assay 2.0. The software provides objective interpretation of raw data files (FSA) generated by ABI 3500 and ABI 3500xL instruments to identify clonal gene rearrangements in unknown samples.

The software employs automated analysis algorithms to determine T-Cell clonality based on electropherogram information such as peak distribution, individual peak size, and peak height to calculate a Regression Based Predictor (RBP) value. The software generates an assay call for each sample: Clonal, Non-Clonal, or Invalid.

IdentiClone RUO TCRG 2.0 Software



Methods

Using 176 CE-results as the training data set, the IdentiClone RUO TCRG 2.0 software was developed to automatically identify TCRG rearrangements from samples tested with the RUO T-Cell Receptor Gamma Gene Rearrangement Assay 2.0.

The performance of the software was validated using 92 unique Formalin-Fixed Paraffin-Embedded (FFPE) clinical specimens. This data set included 55% positive and 45% negative clinical specimens by diagnosis. A variety of common T-cell lymphoproliferative diseases such as angioimmunoblastic T-cell lymphoma (AITL), cutaneous T-cell lymphoma (CTCL), and peripheral T-cell lymphoma (PTCL) were included. The software generated results were then compared with those from two different reference methods, clinical diagnosis and the next-generation sequencing (NGS)-based LymphoTrack[®] TRG Assay.

Concordance to Medical Diagnosis and NGS

	Medical Diagnosis	
IdentiClone RUO TCRG 2.0 Software	Positive	Negative
Clonal	37	0
Non-Clonal	5	26
Total	42	26
Positive Percent Agreement (PPA)	88.1% (95% CI: 74.4% – 96.0%)	
Negative Percent Agreement (NPA)	100.0% (95% CI: 86.8% - 100.0%)	

	LymphoTrack TRG (NGS)	
IdentiClone RUO TCRG 2.0 Software	Clonal	Non-Clonal
Clonal	36	1
Non-Clonal	4	27
Total	40	28
Positive Percent Agreement (PPA)	90.0% (95% CI: 76.3% - 97.2%)	
Negative Percent Agreement (NPA)	96.4% (95% CI: 81.7% - 99.9%)	

Home	e Page		e Setup	
M IdentiClone RUO TCRG 2.0 Software v1.0.0.RUO	- C X	Home Tools Report Help	- ⊔ ∧ Admin ⊚	
Plate Setup	Indivision of the second secon	Import Configure Runs Plate Name * Results Group * Sample_Plate C.RUO_TORG_RG 1 2 3 4 5 6 7 Sample_Plate A02 A03 A04 A05 A06 A07 Sample A02 A03 A04 A05 A06 A07 Sample B02 B03 B04 B05 B06 B07 Sample C02 C03 C04 C05 C06 C07 Sample D02 D03 D04 D05 D06 D07 E01 E02 E03 E04 E05 E06 E07 NC G02 G03 G04 G05 G06 G07 NC G02 G03 G04 G05 G06 G07 NC H02 H03 H04 H05 H06 H07 Save Plate Clear Plate Pintet	File Name Convention* Pate Barcode 1C_RUO_TCRG_FNC 123456789 3 9 10 11 12 A08 A09 A10 A11 A12 B08 B09 B10 B11 B12 C08 C09 C10 C11 C12 D08 D09 D10 D11 D12 E08 E09 E10 E11 E12 E08 F09 F10 F11 F12 E08 G09 G10 G11 G12 E08 F09 F10 F11 F12 E08 G09 G10 G11 G12 E08 F09 F10 H11 H12 Save Delete Delete Delete	
Run R	leport	Sample Reports		
() IdentiClone® RUO TCRG 2.0 Software	Run Summary	() IdentiClone® RUO <i>TCRG</i> 2.0 Software	Sample Report	
Run Information		Sample Name Sample_3		
Run ID 1179d074-15fe-49e5-ba63-0f1f494b6e9c	Run Status Valid	Run Status Valid		
Plate Name Sample_Plate	Run Number 1			
Plate Barcode 123456789		RBP 1.9	RBP 1.9	
		Sample Notes		
Assav Reagents	ABI Detection Run			
Part Number 22070091	ABI Instrument 3500			
Lot Number 012345	ABI Serial Number 33873-040	L	L	
Expiration 1/1/2026	Run Start Date 2023-01-31 10:05:27	Run Information		
		Sample ID SIDfe3bd3623707		
Run Controls		Plate Barcode 123456789		
Type Sample Name	Sample ID Result Error Code(s)	Run ID 1179d074-15fe-49e5-ba63-0f1f494b6e9c	Run Number 1	
Positive PC	SIDa7f5e80ddd2c Valid	Sample ID – Unique ID generated by the software for sample tracking purposes		
Negative NC	SID9d4bab4e3b66 Valid	Assay Reagents	ABI Detection Run	
NTC NTC		Part Number 22070091	ABI Instrument 3500	
	SID217356ae2ca1 Valid			
Sample ID - Unique ID generated by the software for sample tracking purpor	SID217356ae2ca1 Valid Uses NTC - No template control	Lot Number 012345	ABI Serial Number 33873-040 Run Start Date 2023-01-31 10:05:27	

Conclusions

The software achieved a positive percent agreement (PPA) of 88.1% and 90.0% to medical diagnosis and NGS, respectively. The software achieved a negative percent agreement (NPA) of 100.0% and 96.4% to medical diagnosis and NGS, respectively.

The IdentiClone RUO TCRG 2.0 Software provides laboratories objective, fast, accurate, and automated analyses of CE-data generated by the RUO T-Cell Receptor Gamma Gene Rearrangement Assay 2.0.



AMP Europe 2024, June 24 - 26, Madrid, Spain

