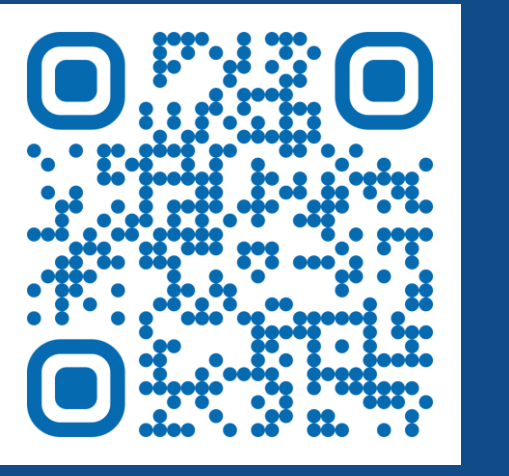


IdentiClone® RUO TCRG 2.0 Software for Capillary-Based Detection of T-Cell Receptor Gamma Gene Rearrangements



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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.

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

IdentiClone RUO TCRG 2.0 Software	Medical Diagnosis	
	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%)	

IdentiClone RUO TCRG 2.0 Software	LymphoTrack TRG (NGS)	
	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%)	

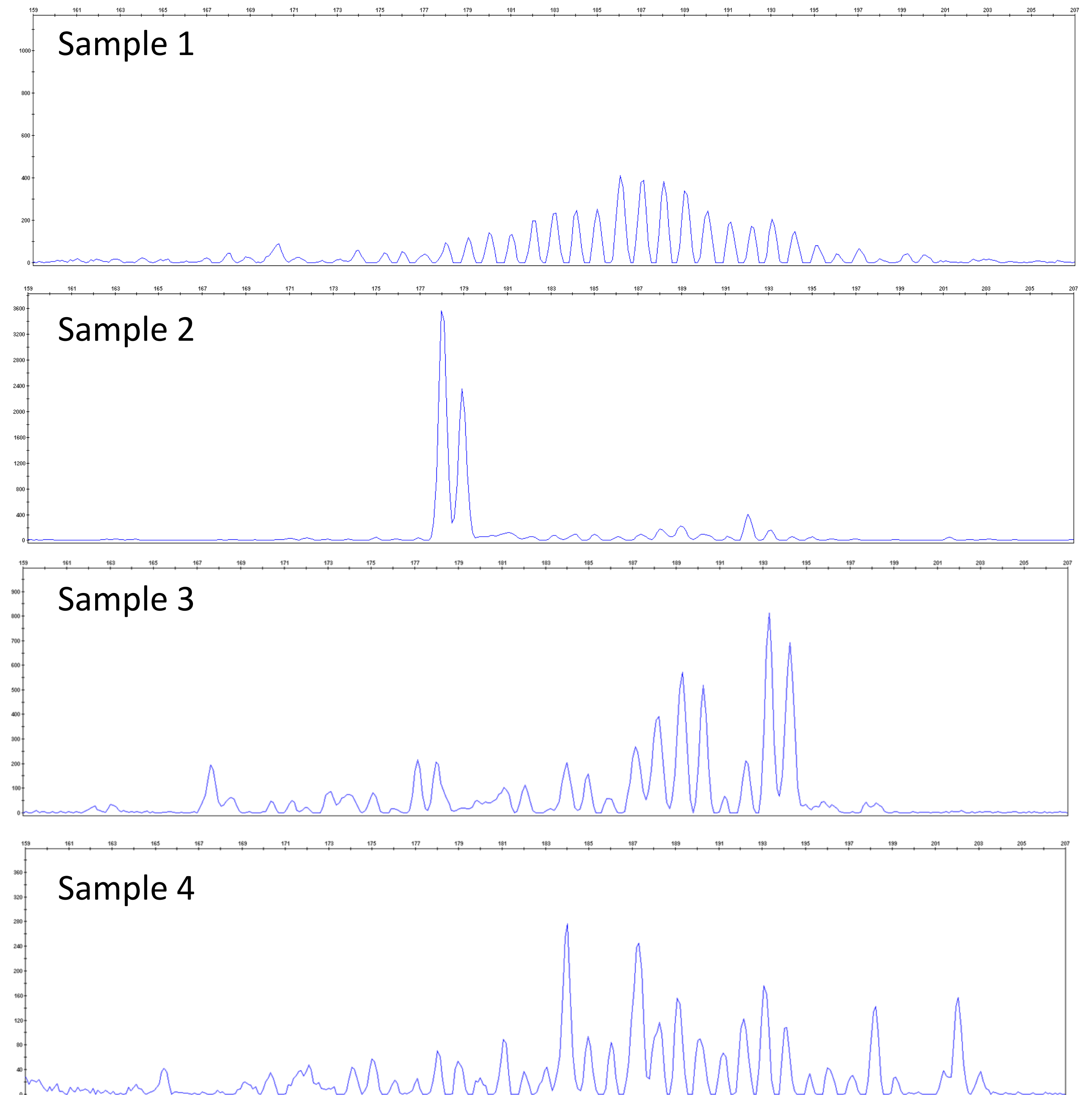
Conclusions

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.

IdentiClone RUO TCRG 2.0 Software

Software does **NOT** require visual identification of significant peaks



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