

## IdentiClone® RUO TCRG 2.0 Software

For automated analysis of TCRG capillary electrophoresis data obtained from ABI 3500 instruments.



For RESEARCH USE ONLY. Not for use in diagnostic procedures.

Manufactured in U.S.A.



### Product Compatibility

IdentiClone RUO TCRG 2.0 Software ([REF](#) S100001) was developed specifically for and is compatible with only the following Invivoscribe assays:

Catalog Number	Products	Quantity
<a href="#">REF</a> 12070101	T-Cell Receptor Gamma Gene Rearrangement Assay 2.0 - ABI Fluorescence Detection	33 reactions
<a href="#">REF</a> 12070111	T-Cell Receptor Gamma Gene Rearrangement Assay 2.0 MegaKit - ABI Fluorescence Detection	330 reactions



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## 1. Assay Use

This Research Use Only (RUO) software is intended for the analysis of raw FSA files obtained from ABI 3500 and ABI 3500xL instruments in conjunction with the T-Cell Receptor Gamma Gene Rearrangement Assay 2.0 to identify T-cell receptor gamma (*TCRG*) chain gene rearrangements and is useful for the identification of clonal T-cell populations and evaluation of new research and methods in malignancy studies.

## 2. Glossary and Abbreviations

### 2.1. Glossary

Table 1. Glossary Terms

Term	Definition
<b>Amplicon</b>	A DNA fragment created during the replication of genetic material.
<b>Assay</b>	T-cell Receptor Gamma Gene Rearrangement Assay 2.0
<b>Clonal</b>	The aggregate of genetically identical cells or organisms produced from a single progenitor cell. <ul style="list-style-type: none"> <li>A <i>Sample Name</i> result (final call) in which Clonality is detected.</li> </ul>
<b>Final call / Final Clonality call</b>	The final <i>Sample Name</i> clonality result
<b>Injection</b>	Set of up to 24 samples simultaneously analyzed on the ABI 3500xL instrument. These may include run controls from one or more PCR runs.
<b>Invalid</b>	A sample result which does not meet the validity criteria.
<b>Master Mix</b>	Amplification reagent with primers to amplify specifically targeted regions.
<b>Negative Control</b>	A buffer solution containing polyclonal DNA; this control is expected to generate a Non-Clonal result.
<b>No Template Control</b>	A buffer solution (or water) containing no template; this control is intended to detect the presence of contamination during PCR setup.
<b>Non-Clonal</b>	A <i>Sample Name</i> result in which clonality is not detected.
<b>Platemap / Plate Map</b>	Visual representation of a detection plate which gets imported to the ABI Genetic Analyzer. It provides a 96-well plate layout containing associated run information, including <i>Run number</i> , <i>Sample Name</i> , and <i>Sample Type</i> for each well location.
<b>Positive Control</b>	A buffer solution containing DNA used to assess assay validity; this control is expected to generate a Clonal result.
<b>Run</b>	At least one sample processed together with a set of run controls (Positive Control, Negative Control, NTC) through amplification and detection, using same MM.
<b>Sample ID</b>	Unique identification associated with a subject sample assigned by the software.
<b>Sample Name</b>	Unique identification associated with a subject sample assigned by the user.
<b>Software</b>	IdentiClone RUO <i>TCRG</i> 2.0 Software
<b>System</b>	The whole package of software, hardware and assay (as applicable) that make up the medical device.

### 2.2. Abbreviations

Table 2. Abbreviations defined

Abbreviation	Definitions
<b>ABI</b>	Applied Biosystems Instruments, a Life Technologies brand of Thermo Fisher Scientific
<b>CE</b>	Capillary electrophoresis; an electrokinetic method used to separate amplicons by size.
<b>RUO</b>	Research Use Only
<b>DNA</b>	Deoxyribonucleic Acid
<b>EULA</b>	End User License Agreement
<b>FNC</b>	File naming convention

Table 2. Abbreviations defined

Abbreviation	Definitions
FSA	Fragment analysis data file created by the capillary electrophoresis instrument.
IFU	Instructions for use
LIVS	A file format that gets generated while annotating a plate. Also known as an annotated plate map file.
MM	Master mix
PC	Positive control
NC	Negative control
NTC	No template control
OS	Operating system
PCR	Polymerase chain reaction
PDF	Portable document format
QC	Quality Control
UI	User Interface

### 3. Principles of the Procedure

#### 3.1. Gene Rearrangement Assay

Invivoscribe's T-Cell Receptor Gamma (*TCRG*) Gene Rearrangement Assay 2.0 contains a single multiplex master mix that targets all conserved regions within the variable (V) and the joining (J) region genes described in lymphoid malignancies. This is critical for more comprehensive analysis of samples, as some T-cell lymphoproliferative disorders involve V and J segments that would not be identified with a single V $\gamma$  (1-8) and J $\gamma$ 1/2 primer set. Amplification with all primers in a single tube has several additional important advantages over existing methods. The polyclonal background that results from the combination of all primers in a single tube produces a more robust and easily interpreted signal with capillary electrophoresis, which aids in the interpretation of small peaks. The average size of the *TCRG* gene rearrangement PCR product is 190 bp, with a normal distribution of product sizes between 159 and 207 bp. This protocol leads to improved PCR product formation from paraffin-embedded samples when compared to other protocols that yield products of 260 bp or longer. Positive and negative DNA controls, as well as a Specimen Control Size Ladder master mix are included. Clonality is indicated if a dominant amplicon is detected.

#### 3.2. Differential Fluorescence Detection

Differential fluorescence detection is commonly used to resolve the different-sized amplicon products using a capillary electrophoresis instrument. Primers can be conjugated with several different fluorescent dyes (fluorophores) so that they can produce different emission spectra upon excitation by a laser in the capillary electrophoresis instrument. In this manner, different fluorescent dyes can correspond to different targeted regions. This detection system results in unsurpassed sensitivity, single nucleotide resolution, differential product detection and relative quantification. In addition, the use of agarose and polyacrylamide gels, as well as the use of carcinogens such as ethidium bromide, can virtually be eliminated. Further, differential detection allows accurate, reproducible and objective interpretation of primer-specific products and automatic archiving of data. Inter-assay and intra-assay reproducibility in size determination using capillary electrophoresis is approximately one to two nucleotides.

#### 3.3. Software Interpretation

The IdentiClone RUO *TCRG* 2.0 Software provides an 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 allows the user to upload a plate map for sample traceability in addition to configuring multiple ABI instrument injections for high-throughput laboratories.

## 4. Minimum System Requirements

- **Processor:** Intel® X64 compatible CPU (Core 2 Duo or newer) with a clock speed of at least 1GHz
- **Hard Drive:** At least 50 GB of free disk space is required; 250 GB recommended.
- **RAM:** 4 GB required; 8 GB or more recommended.
- **Operating System:** Windows (64-bit) 10 Pro or 11 Pro is required.
- A PDF reader to visualize data reports generated by the IdentiClone RUO *TCRG 2.0* Software.

## 5. Warnings and Precautions

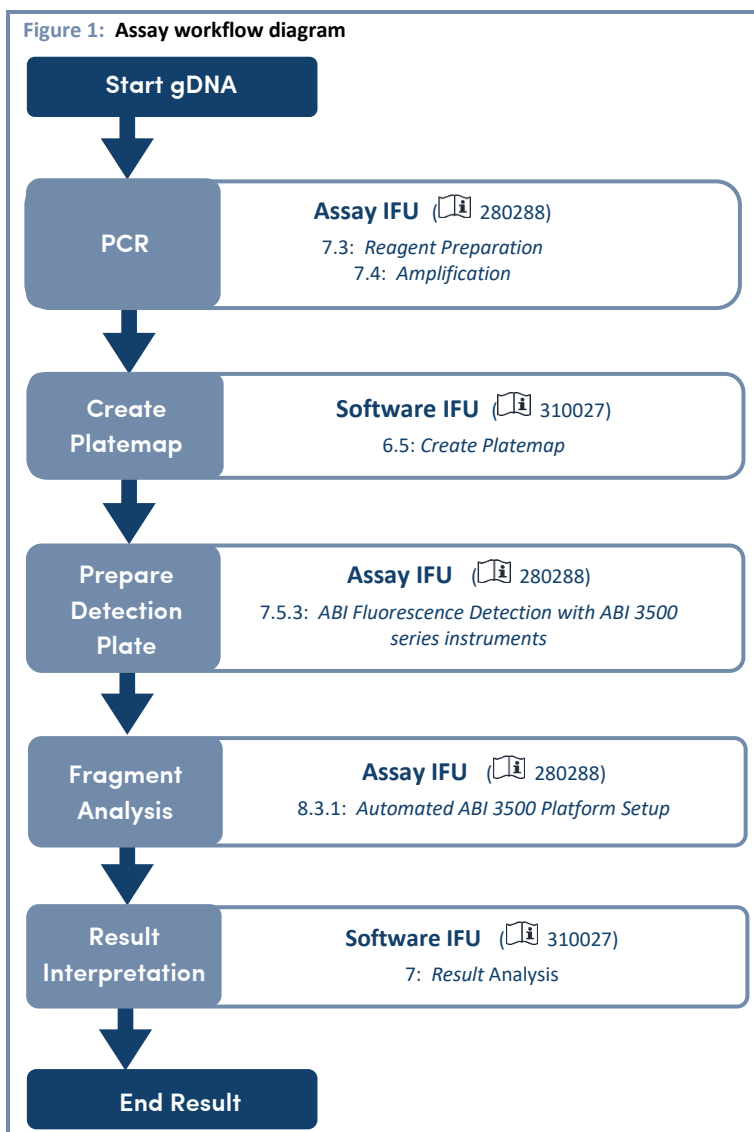
- **System font.** User interface is designed to use the default system font settings on a Windows computer.
- **Compatible files.** IdentiClone RUO *TCRG 2.0* Software is compatible with FSA files generated by the ABI 3500xL and ABI 3500xL Dx Genetic Analyzers.
- **Characters in pathname and file name.** It is important that the filenames only contain the following characters (A-Z, a-z, 0-9, ., \_ (underscore), - (hyphen)). If the Software encounters a character not within this set, it may fail.
- **End-user and in-use environment.** The Software is for Research use only (RUO) in a clinical laboratory setting. Use of this product must be limited to trained personnel.
- **Security.** Use of endpoint protection software is highly recommended to protect the computer running the Software.
  - Ensure no unauthorized devices are plugged into the workstation on which the Software is running, physically block all USB and other communication ports when not in use.
  - Endpoint protection software installed on the workstation containing the Software should be monitored for alerts so that action can be taken when the endpoint is compromised.
- **Network settings.** This software does not communicate over a network and no software specific firewall settings are needed.
  - Ensure the operating system firewall is turned on and that any network ports not needed for the functioning of the workstation are closed.
  - If the workstation containing the software is connected to a network, ensure all appropriate network security safeguards are in place, e.g., ensuring the workstation cannot be reached directly from the internet.
- **Access controls.** This Software supports account-based access controls. Passwords and account information must not be shared amongst users. If more users need to use the software, new accounts can be created.
  - Do not provide regular Software users administrator rights on the workstation, following the principle of least privilege. This Software does not require administrator rights to run.
  - Each Software user on the workstation must have the minimal access rights needed to perform their assigned tasks following the principle of least privilege.
  - When a new user account is created in the Windows OS, the password associated with the account must be changed before the account is used.
- **Software updates.** Updated Software will be provided via Invivoscribe Software Portal for download; only install software updates downloaded from the Invivoscribe Software Portal.
  - Customers will be notified when Invivoscribe issues any update, and updates will be available via the Invivoscribe Software Portal download portal and is installed just like the initial software installation. Double-click the installer executable file, verify the software was created by "Invivoscribe, Inc." by reading prompt shown by Microsoft Windows and follow the instructions on screen.
- **License Key.** A license key is required for the software to function and will be provided at the time of purchase of software.
- **Backup precautions.** The software has functionality to save a backup of the generated results to a pre-specified directory (see Section 0). It is recommended that this directory be itself backed-up as part of the normal backup procedure as used by the implementing organization. Ensure the workstation is backed up in its entirety so it can be quickly restored in case of an emergency.

### **IMPORTANT!** Do NOT change or alter any files generated by the Software.

- Editing the Platemap files generated by the Software using ABI Genetic Analyzer software will lead to file corruption and an inability to perform analysis.

## 6. Software Procedure

**Note:** The Software requires utilizing this document in conjunction with the T-Cell Gamma Gene Rearrangement Assay 2.0 IFU (IFU: 280288).



### 6.1. Download the software from Invivoscribe Software Portal

- 6.1.1. Using any web browser, navigate to <https://catalog.invivoscribe.com/softwareportal/>
- 6.1.2. Complete the following text fields:
  - 6.1.2.1. **Email:** Enter a valid email address. A link to the software download will be sent to this address.
  - 6.1.2.2. **Customer Account Number:** Enter your unique ID used when placing orders with Invivoscribe.
  - 6.1.2.3. **Software Code:** Enter the software code found on your sales order.
- 6.1.3. Check the *Terms and Conditions* box to proceed.
- 6.1.4. Click the Request Software icon.
- 6.1.5. Following valid input text into the above fields, a link to the software download will be sent to the provided email address.
- 6.1.6. Click the link or copy+paste into a web browser; the software will automatically download.

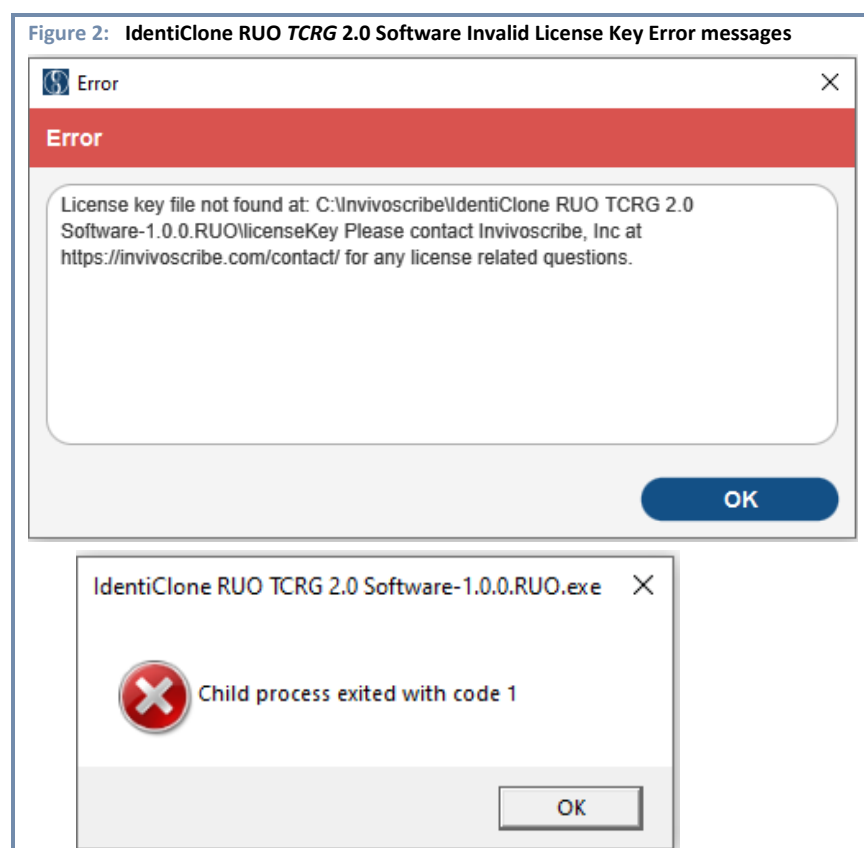
## 6.2. Install the IdentiClone RUO TCRG 2.0 Software

- 6.2.1. Double-click the IdentiClone RUO TCRG 2.0 Software-1.0.0.RUO.msi file.
  - 6.2.1.1. Follow the on-screen steps in the Windows setup wizard; click **Next**.
  - 6.2.1.2. Follow the Windows setup Wizard installation prompts, select the directory filepath to save the software in the desired location and click **Install**.
- 6.2.2. Once installation is complete, click **Finish**.

## 6.3. Enter the Software License Key Information

**Note:** License keys are customer and product-specific, and must be current in order for the software to function. The license keys are checked at software startup, after successful login, and before every analysis.

- 6.3.1. The license keys will be provided at the time of software purchase in a file called “licenseKey.”
- 6.3.2. Copy the “licenseKey” file and paste this file in the directory where the software was installed.
  - The software is now ready to use and can be accessed by navigating to the directory file path selected in step 6.2.1.2 and opening the executable. Alternatively, the software can also be accessed via the *Start Menu* shortcut under an *Invivoscribe* folder or via the Desktop shortcut.
- 6.3.3. Invalid license keys will cause an error message as shown. In the event that you experience such error, please contact <https://invivoscribe.com/contact/> for assistance with license related queries. (Figure 2)



## 6.4. Administrative Configuration

### 6.4.1. Create the Admin user account.

- If using the IdentiClone RUO TCRG 2.0 Software for the first time, a prompt will appear to create the first Admin user. (Figure 3)
- The first Admin user is required to create subsequent users.

**Figure 3: IdentiClone RUO TCRG 2.0 Admin User Setup**

IdentiClone® RUO  
TCRG 2.0 Software

Enter username and password for first admin user

User Name:

Password:

Confirm Password:

Create Cancel

### 6.4.2. During the first successful login, the Software End User License Agreement (EULA) will be displayed. (Figure 4)

- The software EULA must be accepted in order to continue on to the main application.

**Figure 4: End User License Agreement (EULA) window**

Terms of Service

IdentiClone® RUO  
TCRG 2.0 Software v1.0.0.RUO

TERMS AND CONDITIONS

These Terms and Conditions are part of the IDENTICLONE Software Agreement by and between Invivoscribe, Inc., a California corporation ("Company") and the company or entity (the "Customer") described on the IDENTICLONE Software License Agreement to which these Terms and Conditions are attached.

PLEASE READ THE BELOW TERMS AND CONDITIONS OF THIS AGREEMENT BEFORE USING THE COMPANY'S SOFTWARE PRODUCTS. BY ACCESSING OR USING COMPANY SOFTWARE PRODUCTS, YOU ("CUSTOMER") SIGNIFY ACCEPTANCE OF AND AGREE TO THE TERMS AND CONDITIONS OF THIS AGREEMENT. IF YOU DO NOT AGREE TO THE TERMS AND CONDITIONS OF THIS AGREEMENT, DO NOT ACCESS OR USE THE PRODUCTS OR THE SERVICES.

1. Background of this Agreement

IVS has developed and owns all rights in the proprietary computer program generally known as IdentiClone RUO TCRG 2.0 Software (the "IDENTICLONE Software"). These Terms and Conditions are part of the Agreement under which Customer will be entitled to install and use IDENTICLONE Software, including certain restrictions and limitations that apply to Customer's use of such software.

2. Definitions

2.1 "Annual Licensing Fee" has the meaning ascribed to it in Section 6 below.

2.2 "Documentation" means, with respect to IDENTICLONE SOFTWARE, any and all related specifications documents, user manuals and other related written materials, some of which may be made available online or otherwise in an electronic format.

2.3 "IDENTICLONE SOFTWARE" means version 1.0.0 of IVS's proprietary computer program generally known as IdentiClone RUO TCRG 2.0 Software.

2.4 "IDENTICLONE SOFTWARE Major Problem" means any error or problem with IDENTICLONE SOFTWARE that causes a complete operational failure of IDENTICLONE SOFTWARE, prevents Customer from accessing any material functionality of IDENTICLONE SOFTWARE, or causes IDENTICLONE SOFTWARE to return incorrect or inconsistent results.

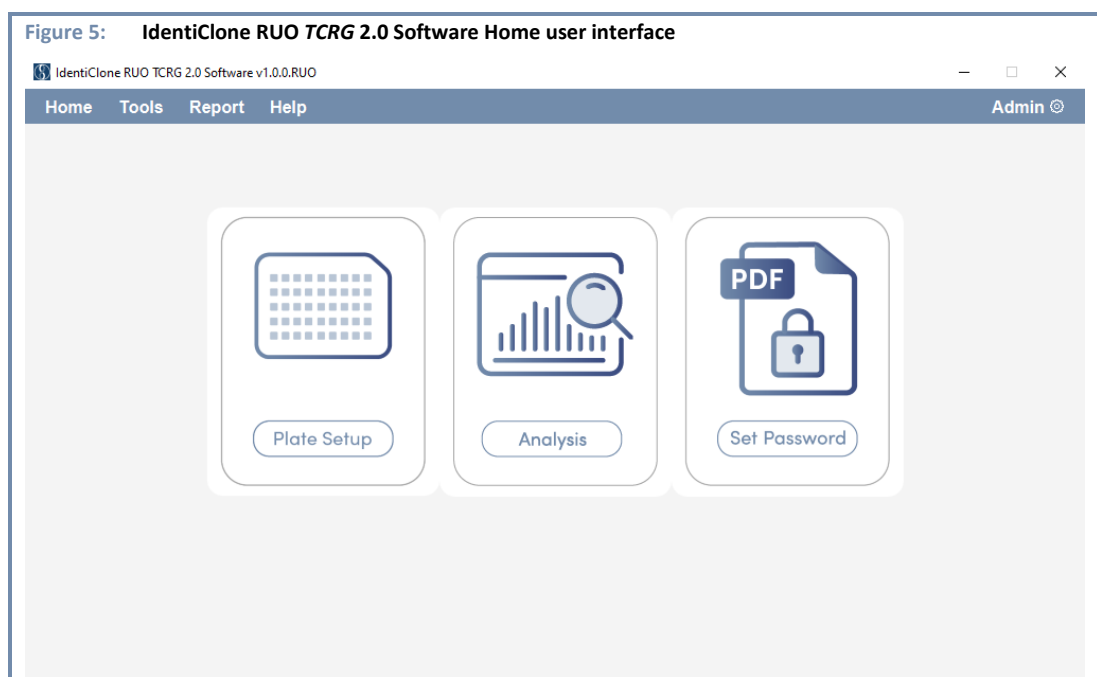
For Research use only (RUO). Not intended for Diagnostic purposes.

This software product is licensed to John Doe and is valid through 2024-12-30.  
Please contact Invivoscribe, Inc at <https://invivoscribe.com/contact/> for any license related questions.

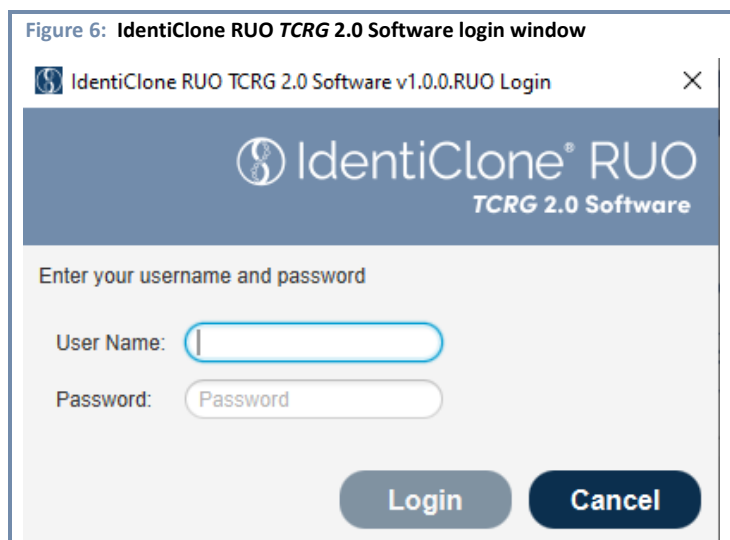
Accept Decline



- 6.4.2.1. The IdentiClone RUO TCRG 2.0 Software will always open to the home page after the EULA is accepted. (Figure 5)
- The home page is used to navigate to the main features of the applications like *Plate Setup*, *Analysis*, and *Set PDF Password* (available only for administrator).



- 6.4.2.2. Enter login credentials and click **Login**. (Figure 6)
- Click **Log Out** to logout from the application; the Software will automatically logout any user after 5 minutes of inactivity.



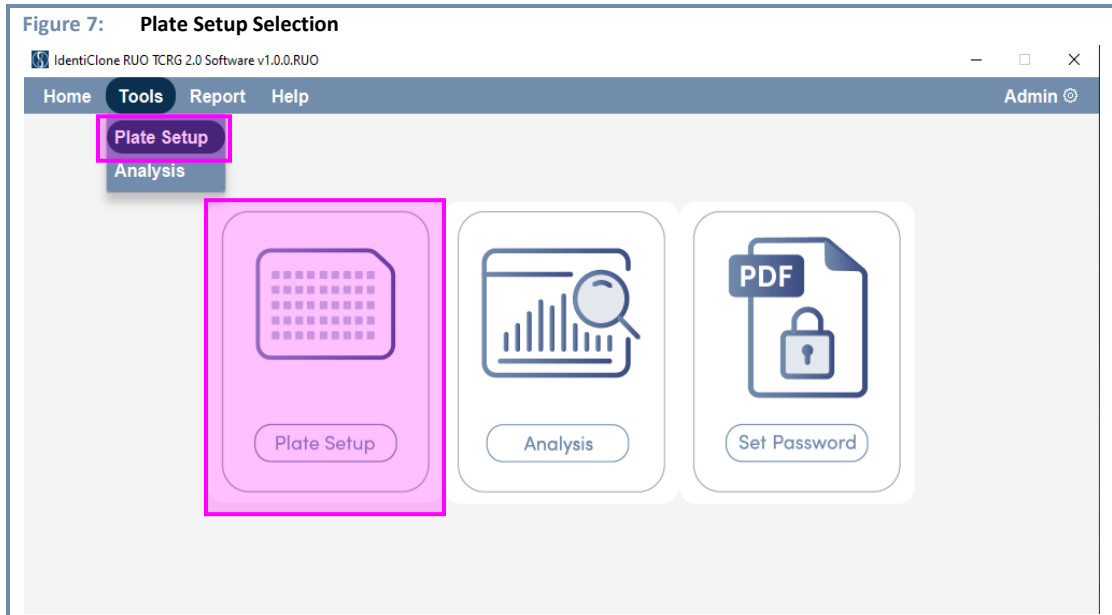
## 6.5. Create Platemap

**Note:** To create a new platemap with the Software, go to section 6.5.1. To create a platemap using a previously saved platemap (and make modifications), follow section 0.

### 6.5.1. Create a platemap using the *Plate Setup* function

6.5.1.1. Click **Plate Setup** from the home user interface. (Figure 7)

6.5.1.1.1. Alternatively, *Plate Setup* can also be accessed by navigating to **Tools** → **Plate Setup**.



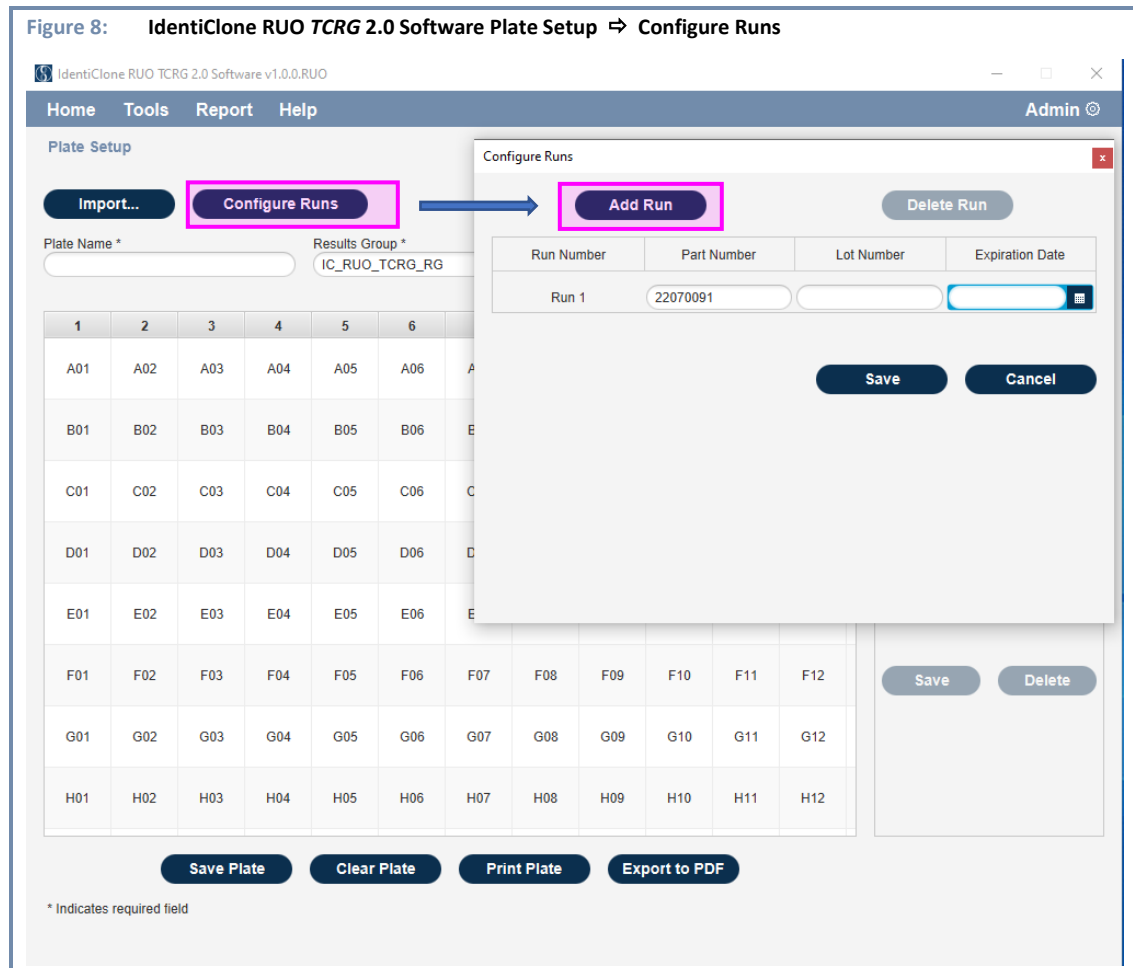
6.5.1.2. The IdentiClone RUO *TCRG* 2.0 Software defaults to **one** run. To add additional runs, click **Configure Runs**, then click **Add Run**. (Figure 8)

**Note:** Each Run must include a Positive, Negative and No Template Control; these controls will be indicated on the platemap as PC (Positive Control), NC (Negative Control), and NTC (No Template Control).

- Runs must be configured before annotating the plate.
- Up to 24 runs can be configured per plate (A run represents a set of controls and corresponding samples).

6.5.1.2.1. (Optional) Manually enter the associated master mix information, then click **Save**.

- The Part Number must contain 6-12 alphanumeric characters.
- The Lot Number must contain 6-10 alphanumeric characters.
- The Expiration Date can be selected from a calendar dropdown view.



6.5.1.3. To remove a run, navigate to **Configure Runs**, then click **Delete Run**.

- By default, the most recent run created will be deleted first; a run can be deleted only if there are no wells assigned to the run.

## 6.5.2. Configure and save a new plate

6.5.2.1. Navigate to *Plate Setup* and enter information into the 4 fields located above the plate map: *Plate Name*, *Results Group*, *File Name Convention*, and *Barcode (Optional)*. (Figure 9)

- These fields are limited to 50 characters or less and may only include letters (A-Z, a-z), numbers (0-9), hyphen (-) and underscore (\_). No spaces or special characters (other than specified) will be accepted.
- File Name Convention and Results Group will be automatically populated with default settings.

6.5.2.1.1. *Plate Name* refers to the user designated plate name and must be populated before proceeding to the next step.

6.5.2.1.2. *Results Group* indicates the FSA file save location and must be populated before proceeding to the next step.

6.5.2.1.3. *File Name Convention* defines the FSA file naming convention and must be populated before proceeding to the next step.

6.5.2.1.4. *Plate Barcode* is optional but, is displayed on analysis run reports.

6.5.2.1.5. *Results Group* and *File Name Convention* entries must match the names of the corresponding entries on the ABI 3500/3500xL instrument.

- Refer to the Assay IFU for the correct naming convention for the *Results Group* and *File Name Convention* (IFU: 280288, section 8.3).

**Figure 9: IdentiClone RUO TCRG 2.0 Software Plate Setup interface**

IdentiClone RUO TCRG 2.0 Software v1.0.0.RUO

Home Tools Report Help Admin

Plate Setup

Import... Configure Runs

Plate Name \* Example Results Group \* IC\_RUO\_TCRG\_RG File Name Convention \* IC\_RUO\_TCRG\_FNC Plate Barcode

1	2	3	4	5	6	7	8	9	10	11	12
A01	A02	A03	A04	A05	A06	A07	A08	A09	A10	A11	A12
B01	B02	B03	B04	B05	B06	B07	B08	B09	B10	B11	B12
C01	C02	C03	C04	C05	C06	C07	C08	C09	C10	C11	C12
D01	D02	D03	D04	D05	D06	D07	D08	D09	D10	D11	D12
E01	E02	E03	E04	E05	E06	E07	E08	E09	E10	E11	E12
F01	F02	F03	F04	F05	F06	F07	F08	F09	F10	F11	F12
G01	G02	G03	G04	G05	G06	G07	G08	G09	G10	G11	G12
H01	H02	H03	H04	H05	H06	H07	H08	H09	H10	H11	H12

Well:

Sample Type \*

Sample Name \*

Run \*

Notes

Save Delete

Save Plate Clear Plate Print Plate Export to PDF

\* Indicates required field

6.5.2.2. Select the well(s) to be used (i.e., to be loaded with diluted amplicon).

- **Shift + RightClick:** selection of multiple adjacent cells;
- **Ctrl + RightClick:** selection of multiple individual cells.

6.5.2.2.1. **Right-click** over the well selection to prompt the run assignment window, then assign a run. (Figure 10)

- The run can be assigned by individual wells or by selecting a group of wells.

**Figure 10: IdentiClone RUO TCRG 2.0 Software Plate Setup ⇒ Assign Run to associated plate wells**

IdentiClone RUO TCRG 2.0 Software v1.0.0.RUO

Home Tools Report Help Admin

Plate Setup

Import... Configure Runs

Plate Name \* Example Results Group \* IC\_RUO\_TCRG\_RG File Name Convention \* IC\_RUO\_TCRG\_FNC Plate Barcode

	1	2	3	4	5	6	7	8	9	10	11	12
Sample 1	Sample 1	Sample 2	A03	A04	A05	A06	A07	A08	A09	A10	A11	A12
PC	PC	PC	B03	B04	B05	B06	B07	B08	B09	B10	B11	B12
NC	NC	NC	C03	C04	C05	C06	C07	C08	C09	C10	C11	C12
NTC	NTC	NTC	D03	D04	D05	D06	D07	D08	D09	D10	D11	D12
E01	E02	E03	E04	E05	E06	E07	E08	E09	E10	E11	E12	
F01	F02	F03	F04	F05	F06	F07	F08	F09	F10	F11	F12	
G01	G02	G03	G04	G05	G06	G07	G08	G09	G10	G11	G12	
H01	H02	H03	H04	H05	H06	H07	H08	H09	H10	H11	H12	

Well: D02

Sample Type \* NTC

Sample Name \* NTC

Run \* Run 2

Notes

Save Delete

Save Plate Clear Plate Print Plate Export to PDF

\* Indicates required field

6.5.2.3. Select each well assigned to a run and enter required information on the right side of the window. (Figure 11)

- 6.5.2.3.1. Select the appropriate *Sample Type* from the designated dropdown box: PC, NC, NTC or Sample.
- 6.5.2.3.2. Enter *Sample Name*, a unique identification associated with a patient sample.

**Note:** **Sample Name can also be populated by using an external barcode scanner.**

- 6.5.2.3.3. Confirm that the correct *Run* is assigned to the sample.
- 6.5.2.3.4. (Optional) Enter *Notes*, if any.

**Figure 11: IdentiClone RUO TCRG 2.0 Software Plate Setup → configure samples and controls**

IdentiClone RUO TCRG 2.0 Software v1.0.0.RUO

Home Tools Report Help Admin

Plate Setup

Import... Configure Runs

Plate Name \* Example Results Group \* IC\_RUO\_TCRG\_RG File Name Convention \* IC\_RUO\_TCRG\_FNC Plate Barcode

1	2	3	4	5	6	7	8	9	10	11	12
A01	A02	A03	A04	A05	A06	A07	A08	A09	A10	A11	A12
B01	B02	B03	B04	B05	B06	B07	B08	B09	B10	B11	B12
C01	C02	C03	C04	C05	C06	C07	C08	C09	C10	C11	C12
D01	D02	D03	D04	D05	D06	D07	D08	D09	D10	D11	D12
E01	E02	E03	E04	E05	E06	E07	E08	E09	E10	E11	E12
F01	F02	F03	F04	F05	F06	F07	F08	F09	F10	F11	F12
G01	G02	G03	G04	G05	G06	G07	G08	G09	G10	G11	G12
H01	H02	H03	H04	H05	H06	H07	H08	H09	H10	H11	H12

Well: A01

Sample Type \*  
PC  
NC  
NTC  
SAMPLE

Notes

Save Delete

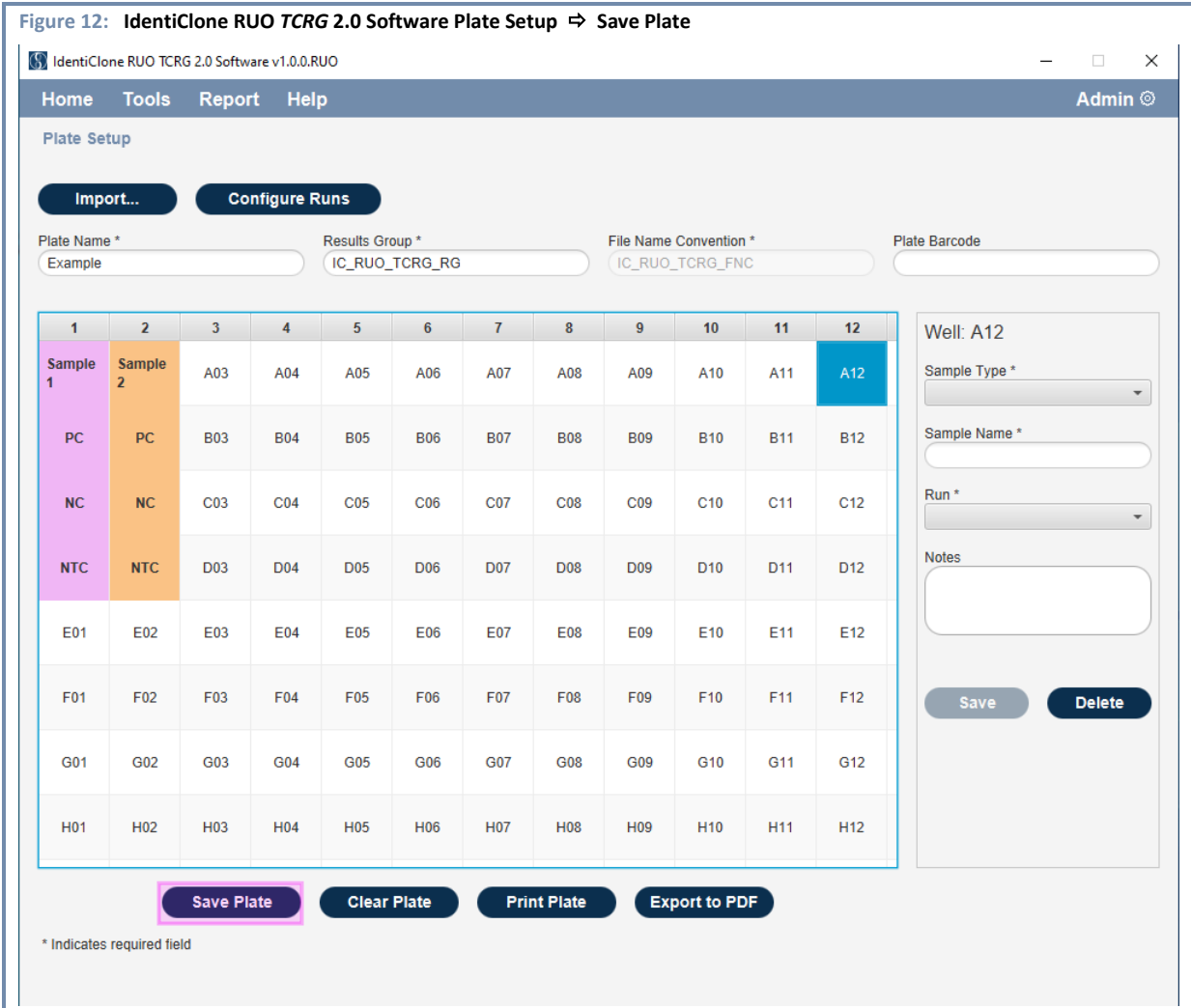
Save Plate Clear Plate Print Plate Export to PDF

\* Indicates required field

#### Platemap rules:

- Each run must include a Positive, Negative and No Template Control; these controls will be indicated on the platemap as *PC* (positive control), *NC* (negative control), and *NTC* (no template control)
- Fields marked with asterisk (\*) are required to save a well.
- The fields *Sample Name* and *Notes* may only contain 50 characters or less.
- *Sample Name* can only include letters (A-Z, a-z), numbers (0-9), hyphens (-) and underscores (\_). No spaces or special characters (other than specified) are allowed.
- The highlighted well position in the *Plate Setup* will become bold once all parameters are defined and saved for a particular sample or control.

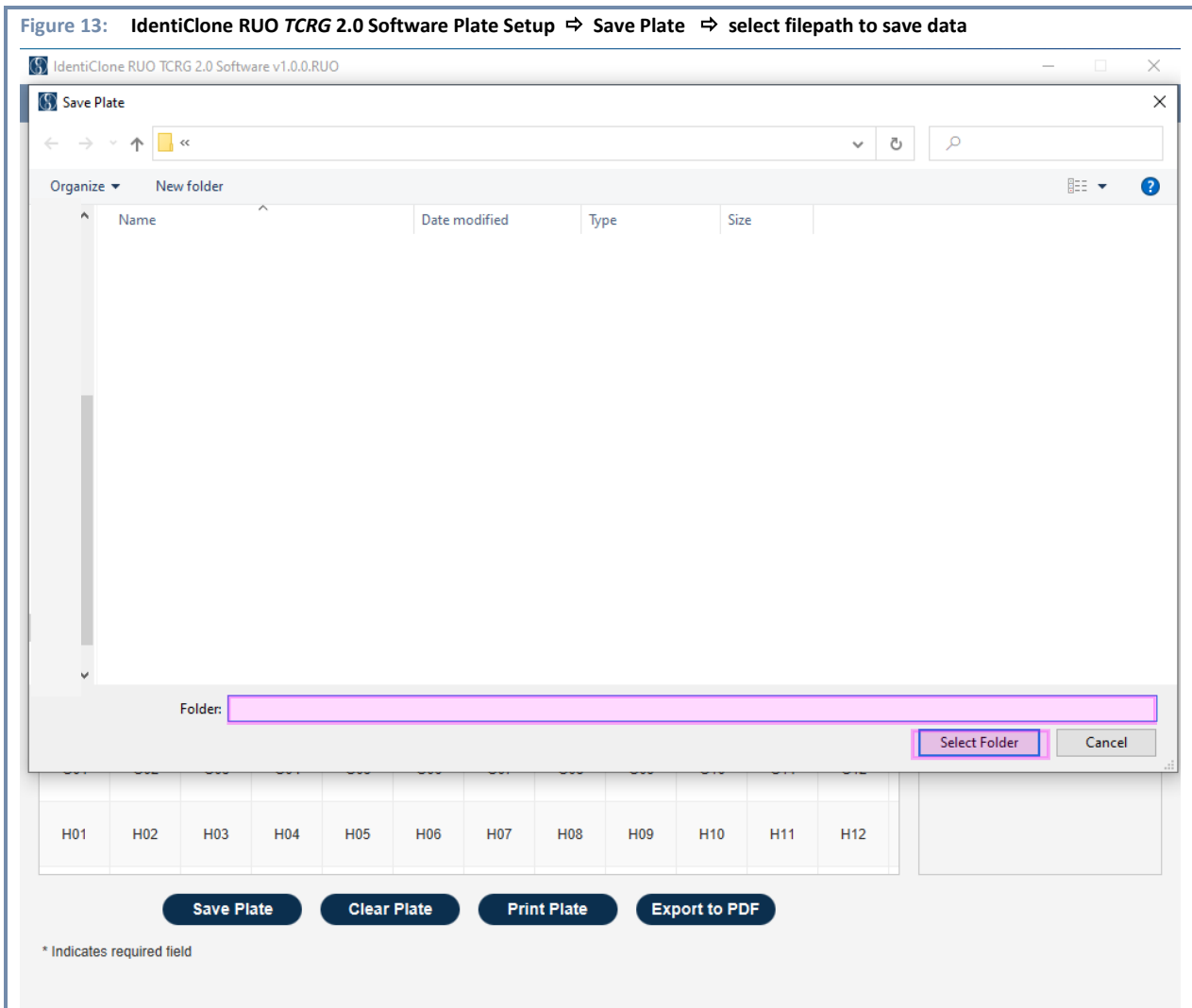
- 6.5.2.4. Click **Save** to complete configuration of the well; repeat step 6.5.2.3.3 for each assigned well on the plate.
- 6.5.2.5. Upon defining and saving all samples and controls for every run in the plate, click **Save Plate**.
  - Different runs will be highlighted and displayed in various colors on the plate map. (Figure 12)



6.5.2.6. Select the directory filepath for the output files. (Figure 13)

- 6.5.2.6.1. Once the platemap is saved, a paired set of output files will be generated, as CSV and LIVS file formats.
- The CSV file contains platemap information and will be imported to the ABI 3500xL or ABI 3500xL Dx Genetic Analyzer.
  - The LIVS file contains platemap specific data required for the analysis and will be used in conjunction with the respective ABI 3500xL or ABI 3500xL Dx result files (i.e., FSA file).

**Important:** Once generated, do NOT alter CSV and LIVS. If any further modifications are needed, refer back to Section 0 and generate a new platemap to obtain a new set of paired CSV and LIVS output files.





6.5.3. Alternatively, a user may create a platemap using a previously saved platemap file through excel.

- Using a previously used platemap will not replace existing results; every saved platemap possesses a unique identifier and is paired with unique LIVS file.

**IMPORTANT!** Import Feature only permits the use of previously configured platemap to be used as a template for creating the new plate. Previously configured platemap cannot be modified using this feature.

6.5.3.1. Manually set up the plate using a spreadsheet application, then import the resulting CSV file using the **Import** button (Figure 14).

6.5.3.1.1. Follow the CSV format (Figure 14) and platemap rules defined above; the CSV format and columns mapping includes:

- User Defined Field 1 => *Sample Type*, which can include SAMPLE, PC, NC or NTC
- User Defined Field 2 => *Run Number* requires a value from Run 1 to Run 24

**Figure 14: Example CSV file layout**

- Template CSV File** indicates the template file prior to any modifications. This file can be used as a template for generating a new platemap. Once the file is updated and saved, a unique SID number will be assigned at the end of the **Sample Name** (column B) in the newly generated CSV file.
- New CSV File** indicates the file after modification and saving.

**Template CSV File (Before Save)**

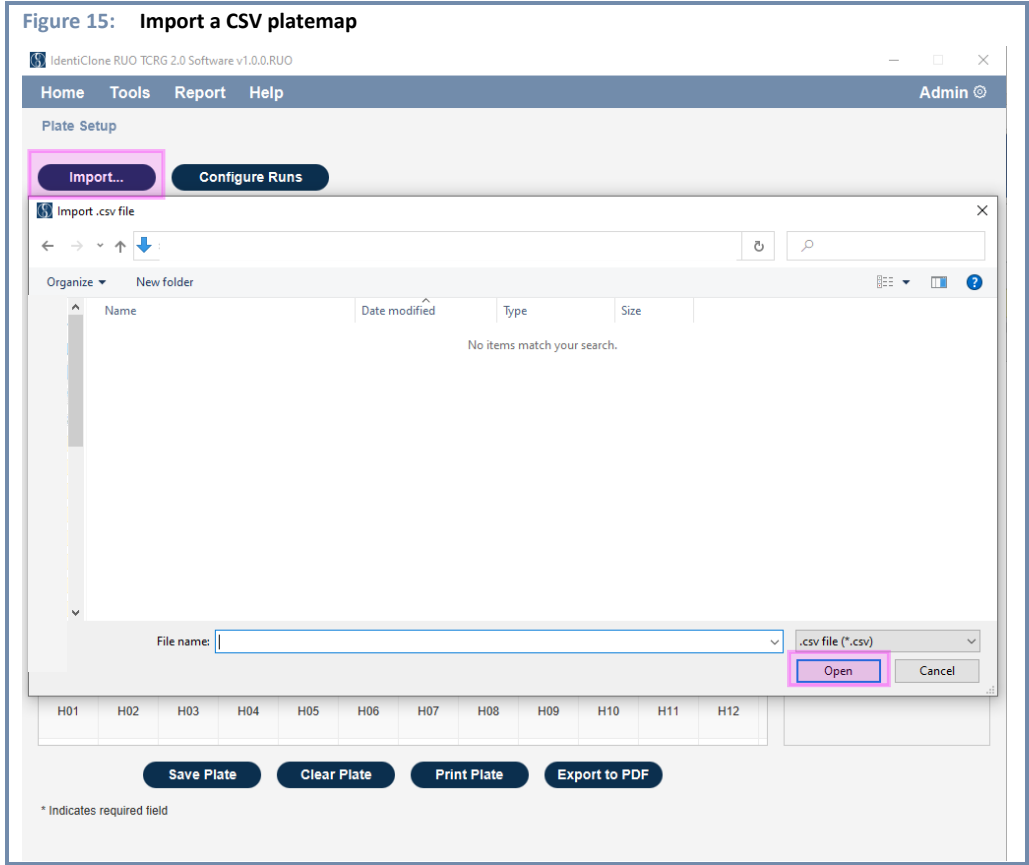
	A	B	C	D	E	F	G	H
1	3500 Plate Layout File Version 1.0							
2								
3	Plate Name	Application Type	Capillary Length (cm)	Polymer	Number of Wells	Owner Name	Barcode Number	Comments
4	Example	Fragment	50	POP7	96			
5								
6	Well	Sample Name	Assay	Results Group	File Name Convent	Sample Type	User Defined Field 1	User Defined Field 2
7	A01	Sample1	TCRG Instrument Parameters	IC_RUO_TCRG_RG	IC_RUO_TCRG_FNC	Sample	SAMPLE	Run 1
8	A02	Sample2	TCRG Instrument Parameters	IC_RUO_TCRG_RG	IC_RUO_TCRG_FNC	Sample	SAMPLE	Run 2

**New CSV File (After Save)**

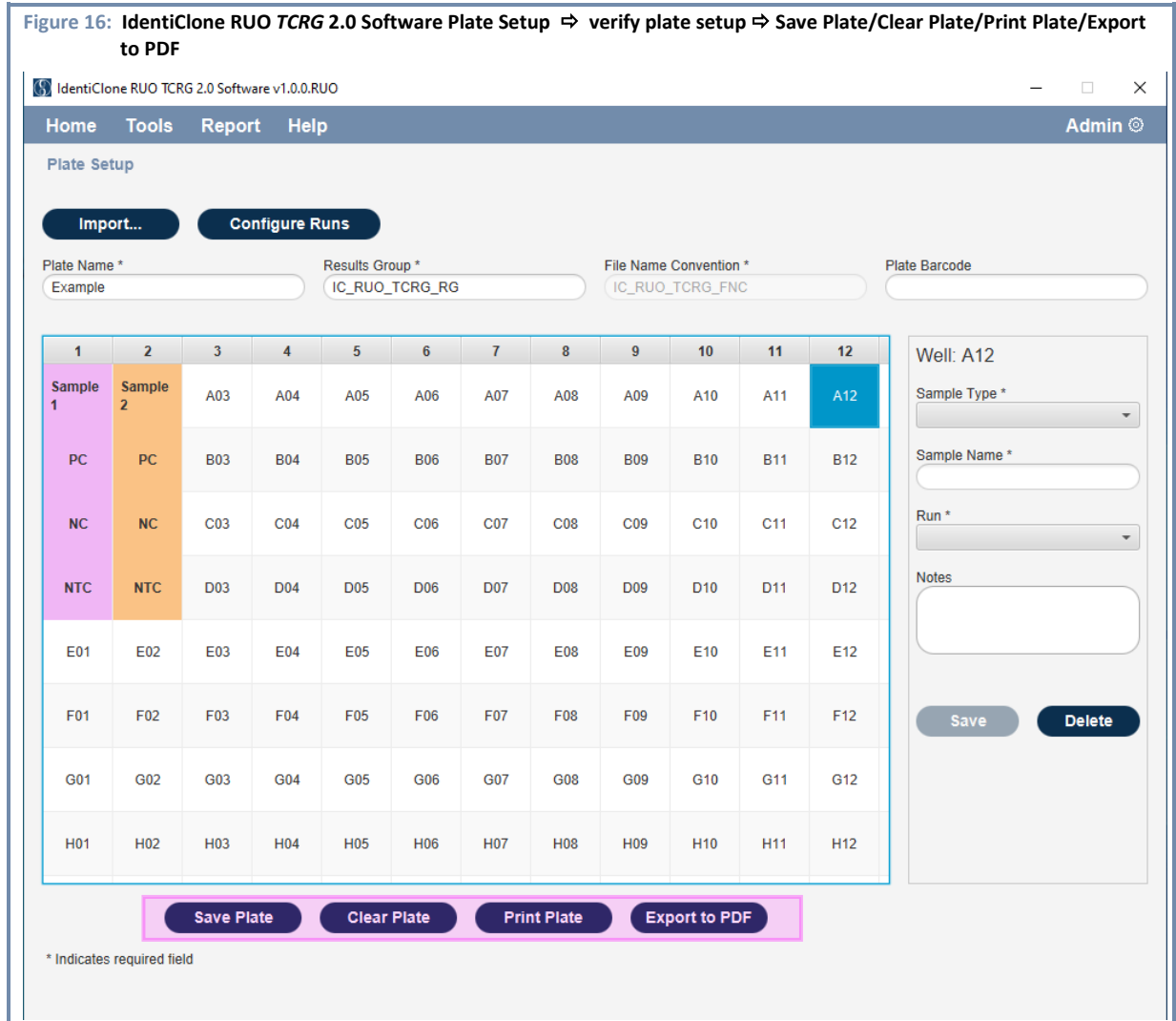
	A	B	C	D	E	F	G	H
1	3500 Plate Layout File Version 1.0							
2								
3	Plate Name	Application Type	Capillary Length (cm)	Polymer	Number of Wells	Owner Name	Barcode Number	Comments
4	Example	Fragment	50	POP7	96			
5								
6	Well	Sample Name	Assay	Results Group	File Name Convent	Sample Type	User Defined Field 1	User Defined Field 2
7	A01	Sample1_SIDd195682ca608	TCRG Instrument Parameters	IC_RUO_TCRG_RG	IC_RUO_TCRG_FNC	Sample	SAMPLE	Run 1
8	A02	Sample2_SIDc029313bc1d5	TCRG Instrument Parameters	IC_RUO_TCRG_RG	IC_RUO_TCRG_FNC	Sample	SAMPLE	Run 2

Note: SID Tag Added

- 6.5.3.1.2. Click **Import**, then select the corresponding CSV file. (Figure 15)
- 6.5.3.1.3. Verify the correct CSV file populates the *File name* box and click **Open**.



## 6.5.3.2. Confirm that each data field for the plate and each sample is populated correctly. (Figure 16)

6.5.3.3. After confirming that all samples and controls are populated correctly, click **Save**.

- Refer to section 6.5.2.6 and Figure 13 to save the newly generated CSV and LIVS files.
- To clear all information stored on the plate map, click **Clear Plate**.

## 6.5.4. Save/Print PDF template of plate map.

## 6.5.4.1. Print plate map to local printer.

- 6.5.4.1.1. To generate a hard copy of the plate map displaying Sample Name, well information, and assay information click **Print Plate**.
- 6.5.4.1.2. Select the appropriate printer to print. Adjust the printing properties/settings as needed, and click **OK** to print.

## 6.5.4.2. Save plate map as PDF. (Figure 17)


6.5.4.2.1. To save a PDF version of the plate map displaying Sample Name, well information, and assay information click **Export to PDF**.

6.5.4.2.2. Select desired file directory to save PDF file, click **Select Folder**.

**Figure 17: IdentiClone RUO TCRG 2.0 Software Printable Plate Map**

	1	2	3	4	5	6	7	8	9	10	11	12
A	Sample1	Sample2										
	Run 1	Run 2										
B	PC	PC										
	Run 1	Run 2										
C	NC	NC										
	Run 1	Run 2										
D	NTC	NTC										
	Run 1	Run 2										
E												
F												
G												
H												

Example IdentiClone RUO TCRG 2.0 Software v1.0.0.RUO 2024-01-05 09:22

6.5.5. Proceed to fragment analysis by capillary electrophoresis (refer to the TCRG 2.0 Assay IFU, : 280288, sections 7.5.3: *Detection Plate Setup* and 8.3: *ABI Parameter Setup*).

**IMPORTANT!** Do not edit the platemap on the ABI 3500xL instrument following importing of the CSV file onto the device. If additional changes are required, recreate the platemap in the IdentiClone RUO TCRG 2.0 Software and save as a new plate. Use the CSV file generated from the new plate to import onto the device. If the software platemap and ABI platemap do not match, software analysis cannot proceed.

## 7. Result Analysis

### 7.1. Select Data for Analysis

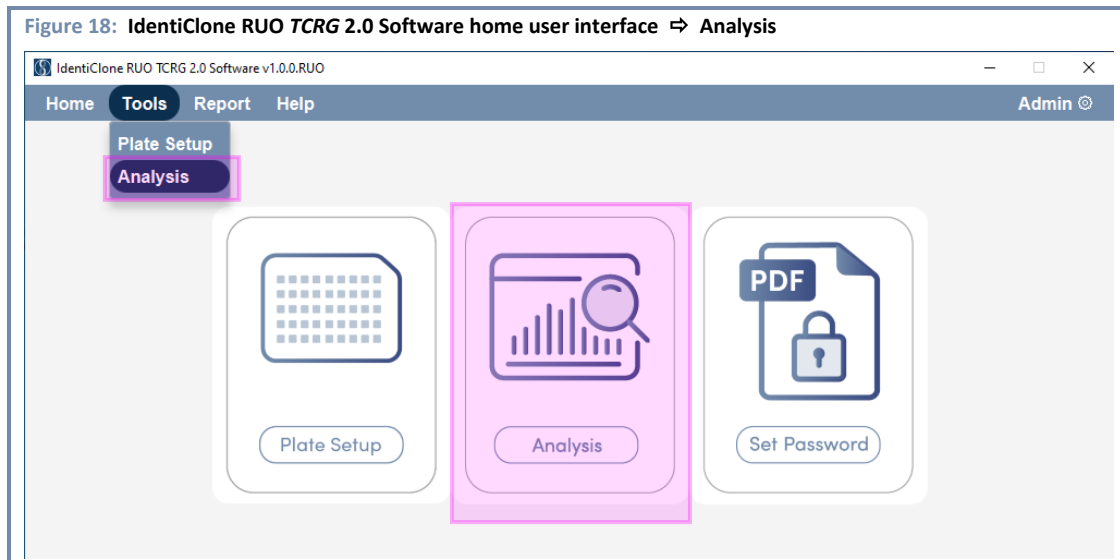
7.1.1. Select the *Analysis* tool from the home user Interface.

- Alternatively, *Analysis* can be accessed by navigating to **Tools → Analysis**. (Figure 18)

7.1.1.1. Verify that both FSA and LIVS files for the associated run(s) and plate(s) are located in the same directory filepath.

- Upon selecting the analysis module for the first time, the admin user will be prompted to set a password to protect analysis PDF reports.

7.1.1.2. Enter and confirm password, then click **Submit**.

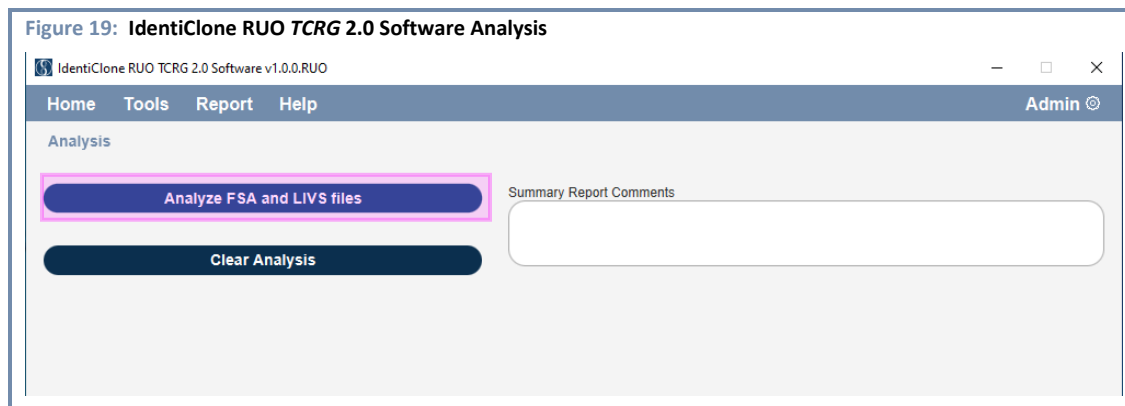


7.1.2. Click Analyze FSA and LIVS files. (Figure 19)

7.1.2.1. Navigate to the directory filepath containing the FSA and LIVS files, select the folder, and confirm the selection.

- Multiple plates can be processed simultaneously, provided all corresponding LIVS and FSA files are present within the selected folder, including those in nested folders.

**Note:** Do not edit FSA files generated by the ABI 3500xL platform. These FSA files are validated with LIVS files from the software. Uploading files incorrectly will halt analysis process. An error message window will pop-up with a corresponding error code. (Table 3)



**Important:** Sample results are generated at this time. These results are for Research Use Only purposes and should not be used for any determination of medical diagnosis.

## 7.2. Select Samples for Analysis

7.2.1. Select samples for report generation () (Figure 20)

- By default, all runs and samples from valid runs are preselected to generate corresponding PDF reports.

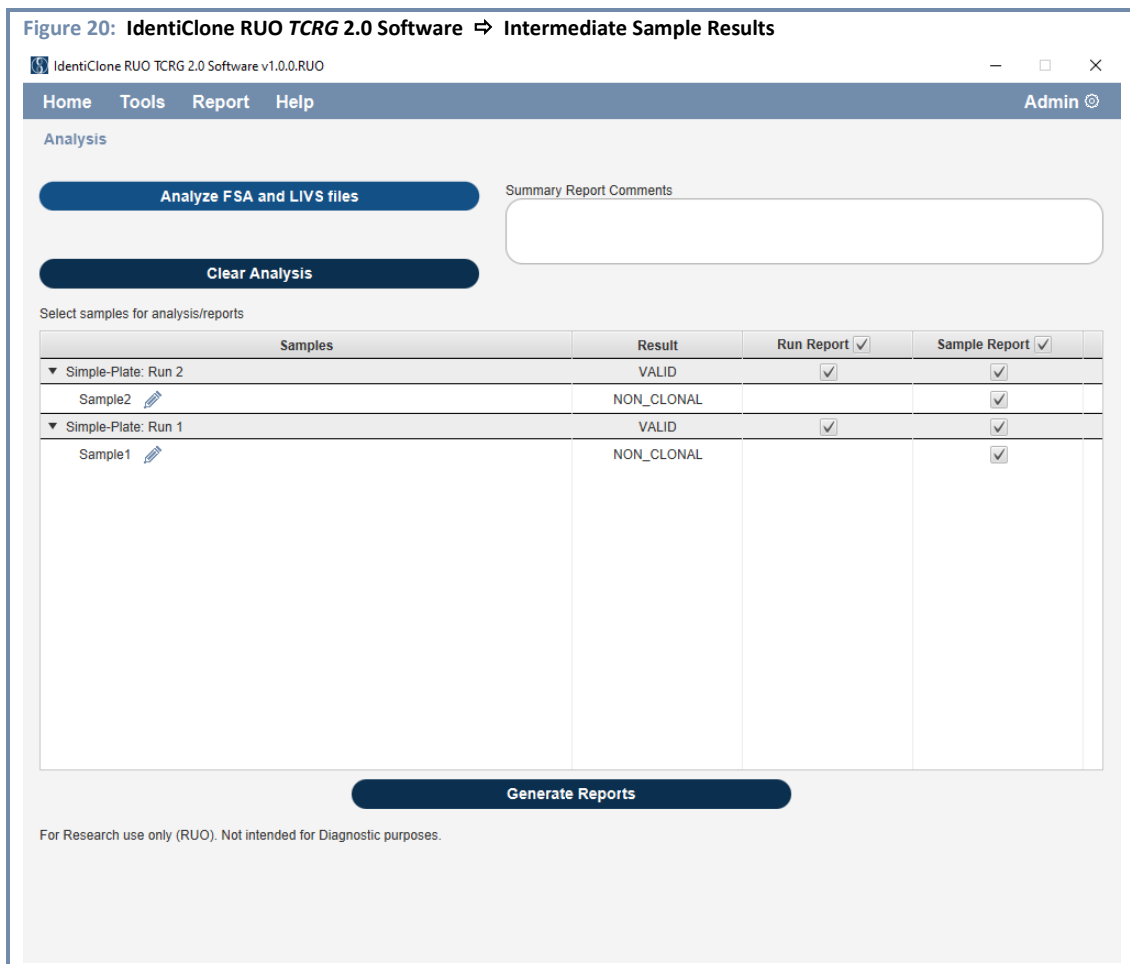
7.2.1.1. Click checkbox () to toggle the selection of any *Run Report* or *Sample Report*.

7.2.1.1.1. Click the checkbox by **Run Report**  to toggle the selection of all run reports.

7.2.1.1.2. Click the checkbox by **Sample Report**  to toggle the selection of all selectable sample reports.

7.2.1.1.3. Click the checkbox () under the *Sample Report* column, within a row corresponding to a run to select all samples included in that run. (Figure 21)

**Figure 20: IdentiClone RUO TCRG 2.0 Software ⇒ Intermediate Sample Results**



IdentiClone RUO TCRG 2.0 Software v1.0.0.RUO

Home Tools Report Help Admin

Analysis

Analyze FSA and LIVS files Summary Report Comments

Clear Analysis

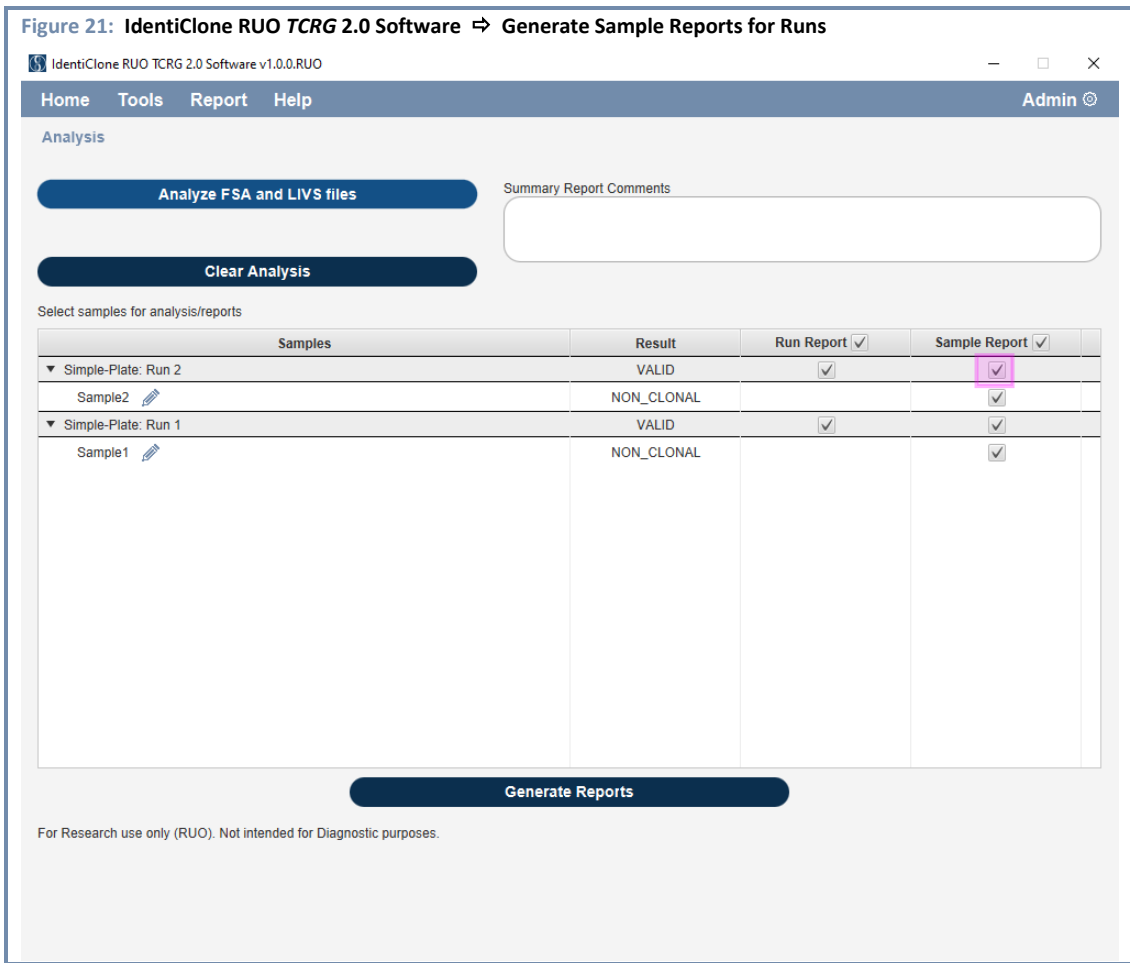
Select samples for analysis/reports

Samples	Result	Run Report <input checked="" type="checkbox"/>	Sample Report <input checked="" type="checkbox"/>
Simple-Plate: Run 2	VALID	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Sample2	NON_CLONAL		<input checked="" type="checkbox"/>
Simple-Plate: Run 1	VALID	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Sample1	NON_CLONAL		<input checked="" type="checkbox"/>

Generate Reports

For Research use only (RUO). Not intended for Diagnostic purposes.

**Figure 21: IdentiClone RUO TCRG 2.0 Software ⇒ Generate Sample Reports for Runs**



IdentiClone RUO TCRG 2.0 Software v1.0.0.RUO

Home Tools Report Help Admin

Analysis

Analyze FSA and LIVS files

Clear Analysis

Summary Report Comments

Select samples for analysis/reports

Samples	Result	Run Report <input checked="" type="checkbox"/>	Sample Report <input checked="" type="checkbox"/>
▼ Simple-Plate: Run 2	VALID	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Sample2	NON_CLONAL	<input type="checkbox"/>	<input checked="" type="checkbox"/>
▼ Simple-Plate: Run 1	VALID	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Sample1	NON_CLONAL	<input type="checkbox"/>	<input checked="" type="checkbox"/>

Generate Reports

For Research use only (RUO). Not intended for Diagnostic purposes.

**Note:** If a run is invalid, associated sample reports cannot be selected from that run.

## 7.3. Generate Reports

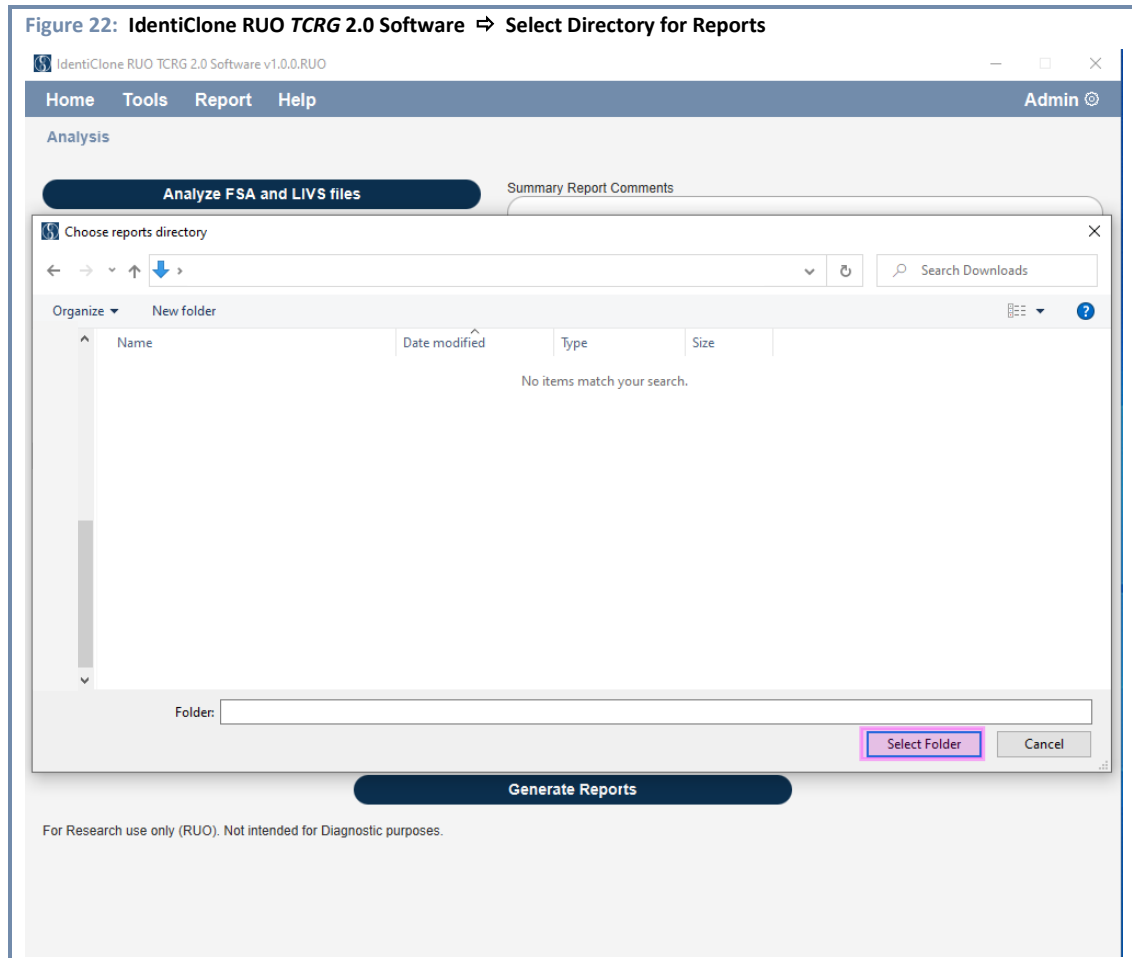
### 7.3.1.1. Click Generate Reports

#### 7.3.1.1.1. Select the directory location for the reports to be saved; click **Select Folder**. (Figure 22)

- An *Analysis Completed* pop-up window will appear if analysis was successful. Click **Open Folder** to open the designated file directory. Click **Close** to dismiss window.

### 7.3.1.2. After the reports are generated, a prompt will appear, providing the option to open the folder containing the reports.

- A password is set by the Admin user (see Appendix, section 13.8) and is required to view the PDF reports.
- Results are grouped by *Sample Name*.





7.3.2. Software Report Interpretation

7.3.2.1. A Run Report is generated by the software for every run selected following analysis.

- Traceable run information and control validity is recorded on Page 1 of the Run Report generated by the software. (Figure 23)
- A summary of samples included in a run is included starting on Page 2 of the Run Report generated by the software. (Figure 24)

Figure 23: Run Report Page 1

The screenshot shows the 'Run Summary' page of the IdentiClone RUO TCRG 2.0 Assay Run Report. The page is divided into several sections:

- Run Information:** Contains fields for Run ID, Run Number, Plate Name, Run Status, and Plate Barcode.
- Assay Reagents:** A table with columns for Part Number, Lot Number, and Expiration.
- ABI Detection Run:** A table with columns for ABI Instrument, ABI Serial Number, and Run Start Date.
- Run Controls:** A table with columns for Type, Sample ID, Result, and Error Code(s). The rows include Positive, Negative, and No Template Control.

Below the Run Controls table, there is a note: "Sample ID - Unique ID generated by the software for sample tracking purposes".

Figure 24: Run Report Page 2

The screenshot shows the 'Sample Summary' page of the IdentiClone RUO TCRG 2.0 Assay Run Report. The page features:

- A large field for the Run ID.
- A table titled 'Sample Results' with columns for Sample Name, Sample ID, Well, Result, Error Code, and Note(s).

- 7.3.3. A *Sample Report* is generated by the software for every sample selected following analysis (Figure 25); information in the report includes:
- Sample information, such as the sample result, unique identifiers (e.g., Sample Name, Sample ID) and associated notes; and
  - Run information contains traceability records, e.g., Run ID and Run Number, as well as optional fields such as Assay Reagent and ABI instrument data.

Figure 25: Sample Report

**IdentiClone® RUO**  
TCRG 2.0 Assay Sample Report

## Sample Report

**Sample Name**

**Sample Result**

**Sample Notes**

**Run Information**

Sample ID  Run ID

Plate Name  Run Number

Plate Barcode

Assay Reagents	ABI Detection Run
Part Number <input type="text"/>	ABI Instrument <input type="text"/>
Lot Number <input type="text"/>	ABI Serial Number <input type="text"/>
Expiration <input type="text"/>	Run Start Date <input type="text"/>

Sample ID - Unique ID generated by the software for sample tracking purposes

## 8. Software Error Messages and Corrective Action(s)

**Table 3: Error Messages, Potential Causes and Corrective Actions**

Error Code	Error Message	Potential Cause(s)	Corrective Action(s)
[AN01.01]	NTC Invalid; SQ error	Size Quality error from ABI 3500	Re-test entire run starting from capillary electrophoresis
[AN01.02]	NTC Invalid; Peak detected	Presence of peak in No Template Control	Re-test entire run starting from PCR
[AN02.01]	PC Invalid; SQ error	Size Quality error from ABI 3500	Re-test entire run starting from capillary electrophoresis
[AN02.02]	PC Invalid; Artifact detected	Presence of false peak that impacts analysis	Re-test entire run starting from capillary electrophoresis
[AN02.03]	PC Invalid; Saturation	Peak RFU above saturation cutoff	Re-test entire run starting from capillary electrophoresis
[AN02.04]	PC Invalid; Less than required number of peaks detected	Insufficient amplification during PCR	Re-test entire run starting from PCR
[AN02.05]	PC Invalid, No peak detected	Insufficient amplification during PCR.	Re-test entire run starting from PCR.
[AN02.06]	PC Invalid; Did not meet the result requirement	PC did not meet expected performance criteria.	Re-test entire run starting from PCR. If problem persists contact IVS Customer Support.
[AN03.01]	NC Invalid; SQ error	Size Quality error from ABI 3500.	Re-test entire run starting from capillary electrophoresis.
[AN03.02]	NC Invalid; Artifact detected	Presence of false peak that impacts analysis.	Re-test entire run starting from capillary electrophoresis.
[AN03.03]	NC Invalid; Saturation	Peak RFU above saturation cutoff.	Re-test entire run starting from capillary electrophoresis.
[AN03.04]	NC Invalid; Less than required number of peaks detected	Insufficient amplification during PCR.	Re-test entire run starting from PCR.
[AN03.05]	NC Invalid; No peak detected	Insufficient amplification during PCR.	Re-test entire run starting from PCR.
[AN03.06]	NC Invalid; Did not meet the result requirement	NC did not meet expected performance criteria	Re-test entire run starting from PCR. If problem persists contact IVS Customer Support.
[AN04.01]	Sample Invalid, SQ error	Size Quality error from ABI 3500	Re-test sample starting from capillary electrophoresis
[AN04.02]	Sample Invalid; Artifact detected	Presence of false peak that impacts analysis	Re-test sample starting from capillary electrophoresis
[AN04.03]	Sample Invalid; Saturation	Peak RFU above saturation cutoff	Re-test sample starting from capillary electrophoresis
[AN04.04]	Sample Invalid; Less than required number of peaks detected.	Insufficient amplification during PCR	Re-test sample starting from PCR
[AN04.05]	Sample Invalid; No peak detected.	Insufficient amplification during PCR	Re-test sample starting from PCR
[AN04.08]	Sample Invalid; Run Invalid	Run failed one of the validity criteria	Refer to run report to check for run failure error code

Table 3: Error Messages, Potential Causes and Corrective Actions

Error Code	Error Message	Potential Cause(s)	Corrective Action(s)
[FV03.5]	Invalid FSA file.	Not following IFU warnings regarding the files used by the software.	FSA files generated by the ABI instrument cannot be altered or used by other software.
[FV04.1]	The format of the LIVS file is invalid	Not following IFU warnings regarding the files used by the software.	LIVS files cannot be edited after generation by saving a plate. Regenerate a new LIVS file corresponding to the plate.
[FV06.1]	FSA files and LIVS file do not have matching samples. Ensure the ABI platemap is not manually edited.	Not following IFU warnings regarding the files used by the software.	<ul style="list-style-type: none"> <li>Do not edit the CSV or LIVS files after saving the plate</li> <li>Do not edit FSA file output from ABI 3500</li> </ul>
[FV06.2]	LIVS file cannot be located.	Not following IFU procedure for Analysis.	Upload the corresponding LIVS file generated by the Software (containing the annotated plate information) in conjunction with the FSA files for analysis.
[FV06.3]	Path provided is not a directory.	Incorrect selection of directory for sample analysis.	Ensure the correct directory is selected containing FSA and LIVS files.
[FV06.4]	Multiple LIVS files representing the same plate found.	Not following IFU warnings about the files used or generated by the software.	Only use LIVS file generated by the Software; do NOT duplicate any LIVS files – they include annotated plate information that allows traceability of samples to a plate.
[FV07.1]	The format of the import file is invalid OR There was a problem importing the plate.	Not following IFU warnings about the files used or generated by the software.	Verify the correct CSV file was selected for importing into the plate map setup.
[OT01]	Not enough disk space available in chosen result output location.	Not enough disk space.	Verify the output file location selected for file export has enough space (at least 10MB).
[OT02]	Output location for results file is not writable.	Lack of permission to the directory.	Verify the directory filepath selected has write permissions.
[OT03]	Input location is not readable.	Lack of permission to the directory.	Verify the selected directory filepath has read permissions.
[OT05]	Comments cannot exceed 300 characters.	Comments exceed 300 characters.	Shorten comments to less than 300 characters.
[PM04]	Plate name cannot be blank.	Not following IFU procedure for naming a plate or importing a plate.	Verify plate name field is populated.
[PM05]	Plate name contains illegal characters.	Not following IFU procedure for <i>Plate Name</i> .	Verify <i>Plate Name</i> contains only letters (A-Z, a-z) numbers (0-9), underscores and hyphens. No spaces are permitted.
[PM11]	Plate contains no samples.	Not following IFU procedure for setting up a plate.	Ensure each plate has at least one run containing one set of controls and at least one sample.
[PM12]	Sample name contains illegal characters.	Not following IFU procedure for <i>Sample Name</i> .	Verify <i>Sample Name</i> contains no more than 50 characters, only including letters (A-Z, a-z) numbers (0-9), underscores and hyphens. No spaces are permitted.
[PM14]	Sample Name cannot exceed 50 characters.	Sample Name exceeds 50 characters.	Shorten Sample Name to be less than or equal to 50 characters.

Table 3: Error Messages, Potential Causes and Corrective Actions

Error Code	Error Message	Potential Cause(s)	Corrective Action(s)
[PM15]	Invalid sample type detected.	Not following IFU procedure for manual plate setup or importing a CSV file for plate setup.	Ensure the rules below are followed before importing a CSV file representing platemap (this is created using a CSV file from a previous run): <ul style="list-style-type: none"> <li>The <i>Sample Type</i> column can only include values SAMPLE, PC, NC or NTC.</li> <li>The <i>Sample Name</i> and <i>User Defined Fields 1 and 2</i> in the CSV file must be empty or all the fields must be entered following the platemap rules.</li> <li><i>User Defined Field 1</i> =&gt; Sample Type with values SAMPLE, PC, NTC, NC</li> </ul> <i>User Defined Field 2</i> => Run numbers from Run 1 up to Run 24.
[PM16]	Sample name cannot be blank OR Run number cannot be blank OR Sample must have a sample type assigned.	Sample Name OR Run Number OR Sample Type were not assigned correctly.	Verify each well contains the necessary fields of information prior to saving.
[PM22]	Run is missing a positive/negative/no template control. Run has too many positive/negative/no template controls.	Not following IFU procedure for plate setup.	If a run is added, it must contain exactly one set of controls, i.e., one NC, one PC and one NTC.
[PM24]	Import file contains no samples.	Not following IFU procedure for importing.	Verify the import file is properly formatted with the appropriate Sample Name field.
[PM28]	Plate name cannot exceed 50 characters.	Plate Name exceeds 50 characters.	Shorten Plate Name to be less than or equal to 50 characters.
[PM29]	Sample notes contains illegal characters.	Not following IFU procedure for importing a CSV file to setup the plate.	<i>Sample Notes</i> can only include up to 50 characters and cannot use special characters; spaces are allowed.
[PM30]	Barcode contains illegal characters.	Not following IFU procedure for naming a <i>Barcode</i> on the plate.	The <i>Barcode</i> is defined on the ABI instrument.
[PM33]	Sample must have run assigned.	Not following IFU procedure for assigning runs to well information.	A well with a Sample Name must have a run assigned.
[PM34]	Well is assigned a run, but is missing a sample information.	Not following IFU procedure for setting up a plate.	Wells assigned to a run must be saved with the associated sample or control information.
[PM35]	Sample notes cannot exceed 50 characters.	Not following IFU procedure for importing a CSV file to setup the plate.	<i>Sample Notes</i> can only include up to 50 characters and cannot use special characters; spaces are allowed.
[PM36]	Invalid run number detected.	An invalid run number was included in an import sheet.	Run number can only be a numeric character from 1-24.
N/A	Part Number must be between 6-10 characters.	Not following IFU procedure for entering <i>Part Number</i> when configuring a run.	Verify <i>Part Number</i> is 6-10 characters in length.
N/A	Part Number contains illegal characters.	Not following IFU procedure for entering <i>Part Number</i> when configuring a run.	Verify <i>Part Number</i> contains only letters (A-Z, a-z) numbers (0-9), underscores and hyphens. No spaces are permitted.

**Table 3: Error Messages, Potential Causes and Corrective Actions**

Error Code	Error Message	Potential Cause(s)	Corrective Action(s)
N/A	Lot Number must be between 6-10 characters.	Not following IFU procedure for entering <i>Lot Number</i> when configuring a run.	Verify <i>Lot Number</i> is 6-12 characters in length.
N/A	Lot Number contains illegal characters.	Not following IFU procedure for entering <i>Lot Number</i> when configuring a run.	Verify <i>Lot Number</i> contains only letters (A-Z, a-z) numbers (0-9), underscores and hyphens. No spaces are permitted.
N/A	Comments cannot exceed 300 characters.	Not following IFU directions for Analysis.	<i>Comments</i> must be 300 characters or less.

## 9. References

- van Dongen, J, et al. (2003) "Design and standardization of PCR primers and protocols for detection of clonal immunoglobulin and T-cell receptor gene recombinations in suspect lymphoproliferations: Report of the BIOMED-2 Concerted Action BMH4-CT98-3936." *Leukemia*, 17:2257–2317.
  - Langerak, AW, et al. (2012) "EuroClonality/BIOMED-2 guidelines for interpretation and reporting of Ig/TCR clonality testing in suspected lymphoproliferations." *Leukemia*, 26:2159-2171.
  - Miller, JE, et al. (1999) "An automated semiquantitative B- and T-cell clonality assay." *Molecular Diagnostics*, 4(2):101-117.
- T-cell Receptor Gamma Gene Rearrangement Assay 2.0 Instructions for Use (📖): 280288)
  - ABI 3500xL Dx Genetic Analyzer User Manual (Thermo Fisher document # 100079380 Revision D)

## 10. Technical and Customer Service

We appreciate your business. We are happy to assist you with understanding this software, and will provide ongoing technical assistance Monday through Friday to ensure our assays are performing efficiently in your laboratory.

### 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: [support@invivoscribe.com](mailto:support@invivoscribe.com) | Customer Service: [sales@invivoscribe.com](mailto:sales@invivoscribe.com) | Website: [www.invivoscribe.com](http://www.invivoscribe.com)

## 11. Symbols

The following symbols are used in Invivoscribe RUO product labeling.



Catalog Number



Expiration Date



Storage Conditions



Research Use Only



Manufacturer



Expiration Date



Reagent Volume

## 12. Legal Notice

### 12.1. Warranty and Liability

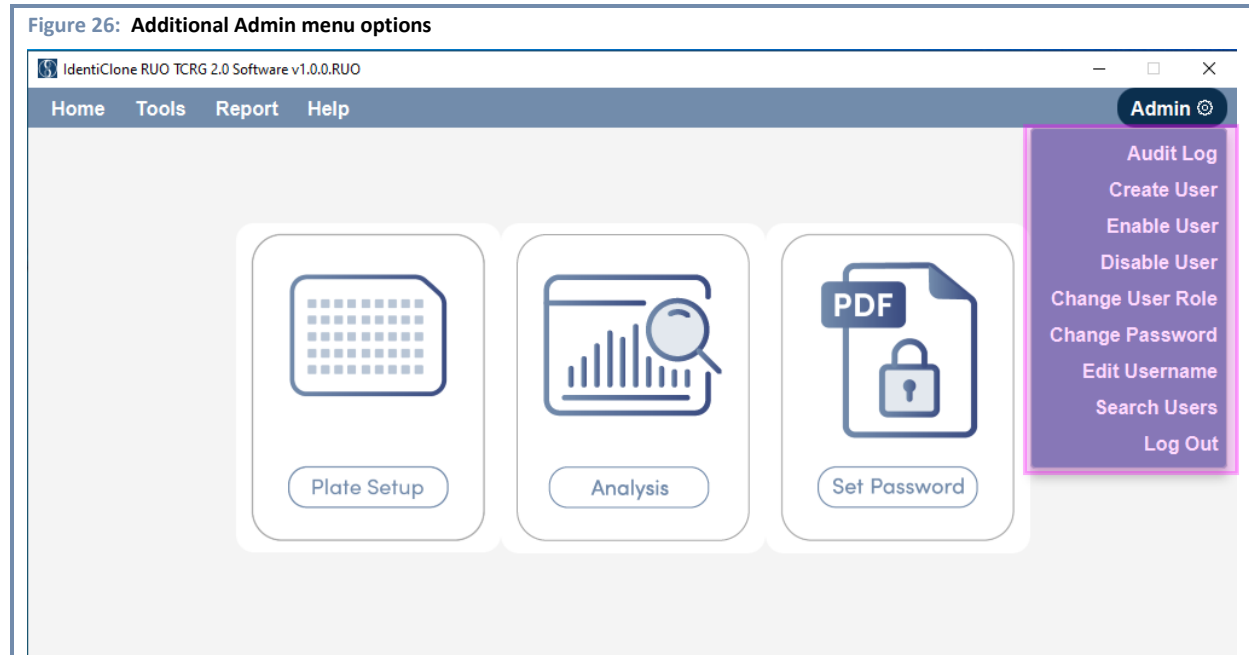
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This product is for Research Use Only; not for use in diagnostic procedures.

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### 13. Appendix A : Admin User Access

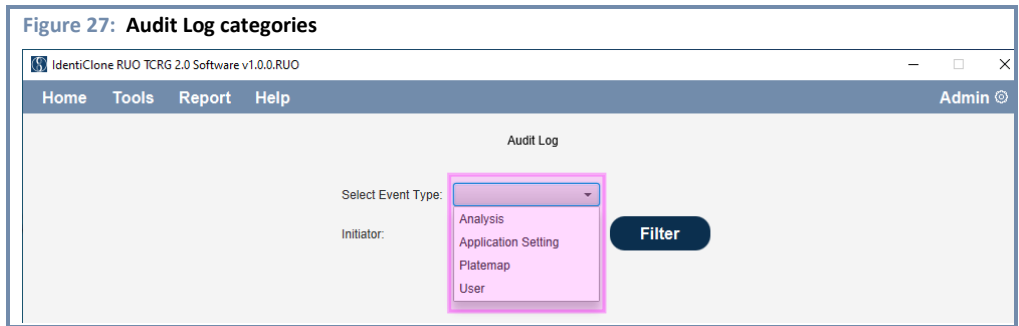
The Admin user has additional privileges as compared to a basic user, including additional menu options (Figure 26) to allow multiple user management features to be accessed.



#### 13.1. Audit log

Only users with Admin privileges have access to view the Audit logs, which allows all activities performed with the Software to be viewed by category based on the event type and corresponding action(s). (Figure 27)

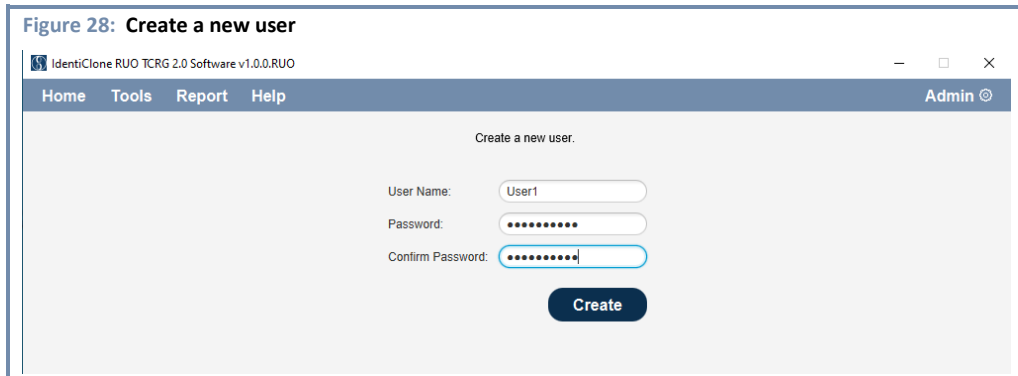
- 13.1.1. **Analysis Event Type:** All analysis activity is logged from start of analysis to the report generation activities.
- 13.1.2. **Application Setting:** The setting activity that applied throughout the application; e.g., setting PDF password and backup location activities are logged.
- 13.1.3. **PlateMap:** All plate setup activities, e.g., saving a platemap or importing a CSV file for plate setup.
- 13.1.4. **User:** All user activities, such as editing username, change role, login, logout etc., are logged.





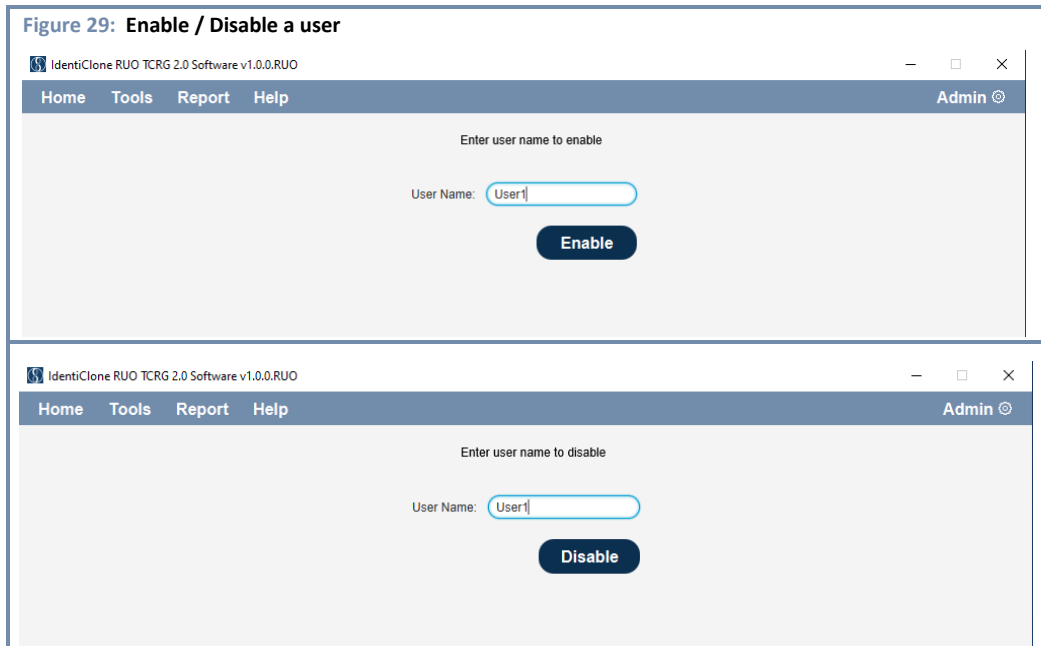
### 13.2. Create User

Only users with Admin privileges have the ability to create other users with basic role privileges; this requires a username and password. (Figure 28)



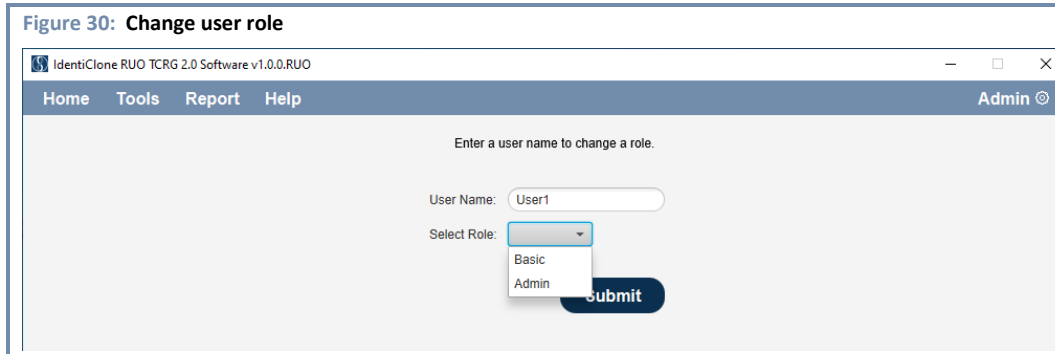
### 13.3. Enable and disable a User

Only users with Admin privileges have the ability to enable and disable users assigned a basic role. Admin level users cannot be disabled. If a user is disabled or deactivated, they cannot login to the Software until the user is enabled and activated. (Figure 29)



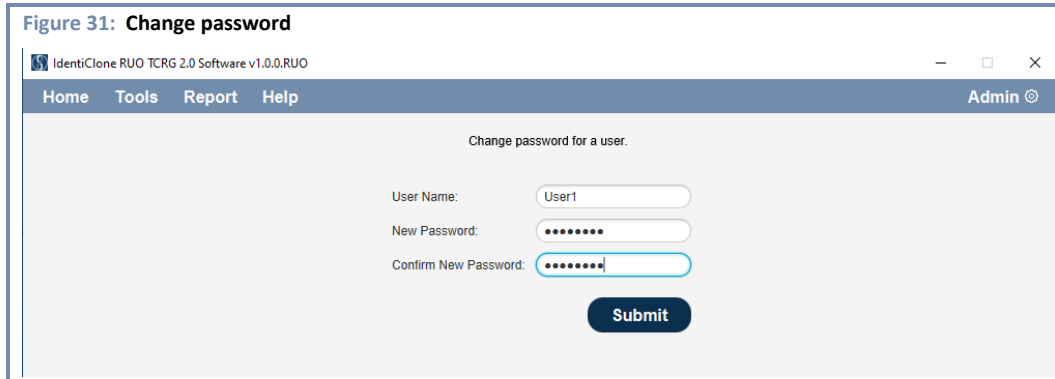
### 13.4. Change User Role

Only users with Admin privileges have the ability to change a user role from *Basic* to *Admin* or vice versa. (Figure 30)



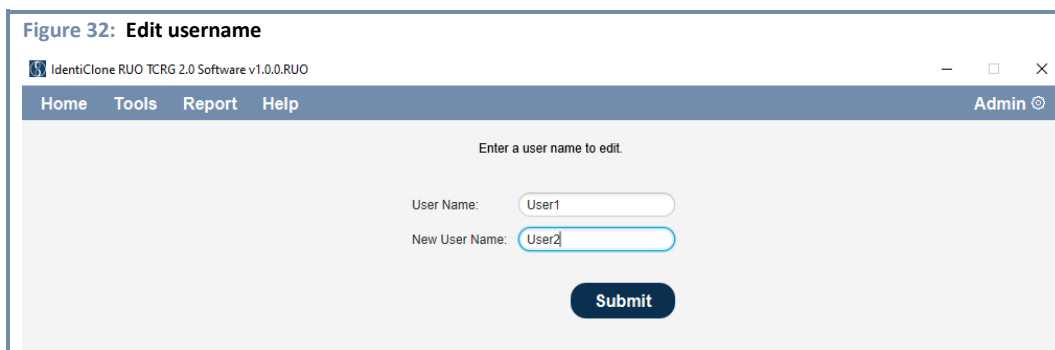
### 13.5. Change User Password

Only users with Admin privileges have the ability to change their own and other user passwords by providing a username and a new password. (Figure 31)



### 13.6. Edit Username

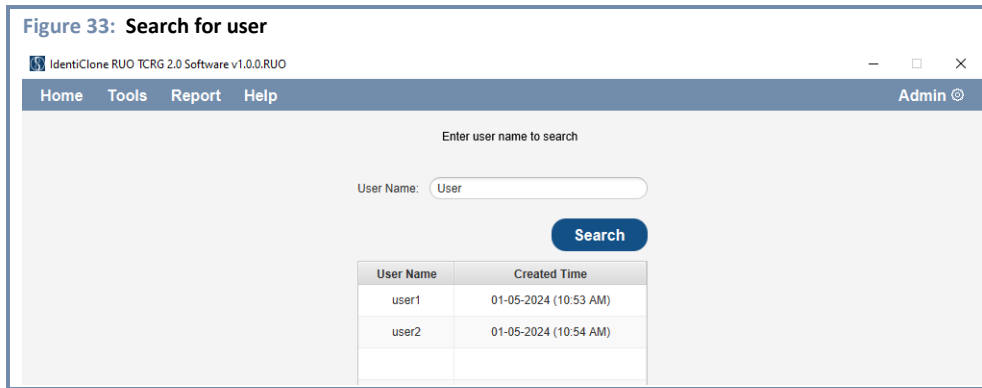
Only users with Admin privileges have the ability to edit their own and other usernames by providing the old (former) username and new username. (Figure 32)



## 13.7. Search Users

Only users with Admin privileges have the ability to search for the users with access to the Software. (Figure 33)

- 13.7.1. Click **Admin** and select **Search** from the dropdown menu, then search by entering part of a username.
- 13.7.2. The software returns the list of users matching the username search criteria.



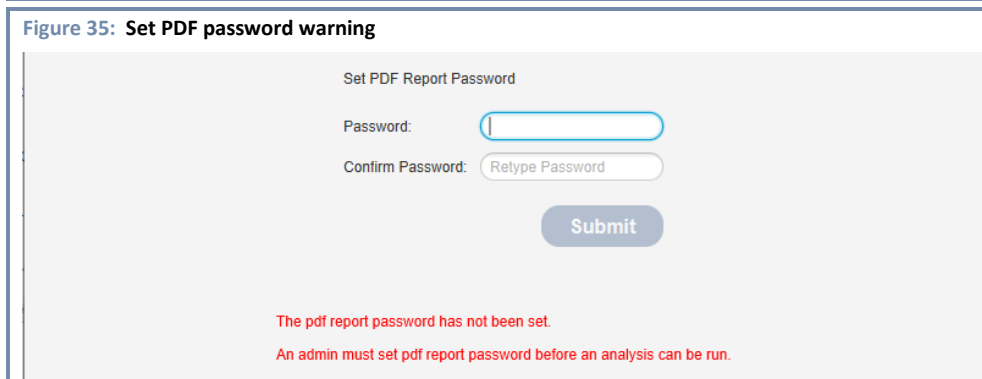
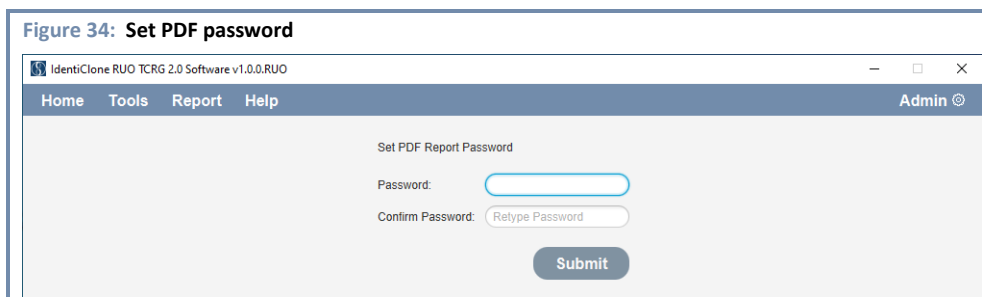
## 13.8. Set PDF Report password

- 13.8.1. Only users with Admin privileges have the ability to set the PDF password. (Figure 34).
- 13.8.2. After the initial Admin user is configured, set the PDF password prior to the first analysis with the Software. If the analysis function is used before setting the PDF password, a prompt will appear, displaying a warning message to *Set PDF report password*. (Figure 35)

**IMPORTANT!** All PDF reports generated by the Software require a password to view.

- 13.8.3. Navigate to the *Home page* of the Software and click **Set Password** or click on the **Report** menu.
- 13.8.4. Enter a password and enter it again to confirm, then select **Submit**.
- 13.8.5. After setting the password, any user can perform analysis by navigating to *Analysis* ⇒ *Dx Analysis*.

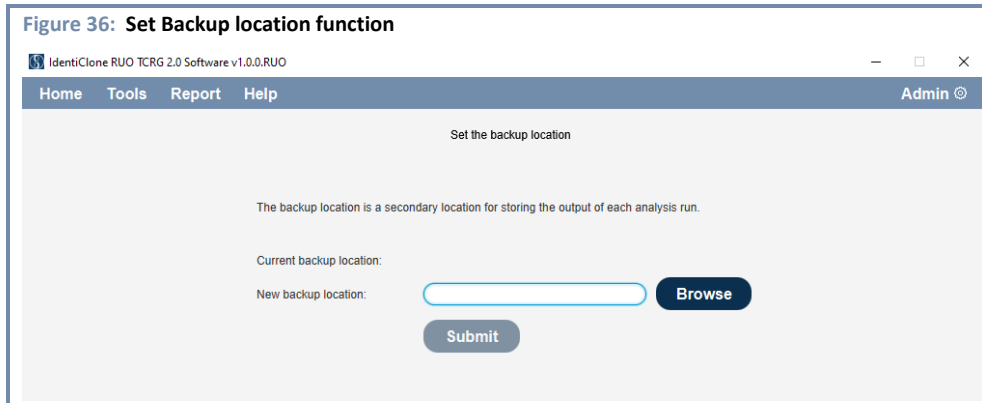
**Note:** The Software default password is **IVS-SoftwareSupportPVVD**; this can be used to reset the PDF report password.



### 13.9. Set Back up location

Only users with Admin privileges have the ability to use the *Set Backup Location*, which allows configuration of the directory filepath to for the PDF reports. The first Admin user can set the PDF report backup location prior to using the *Analysis* function.

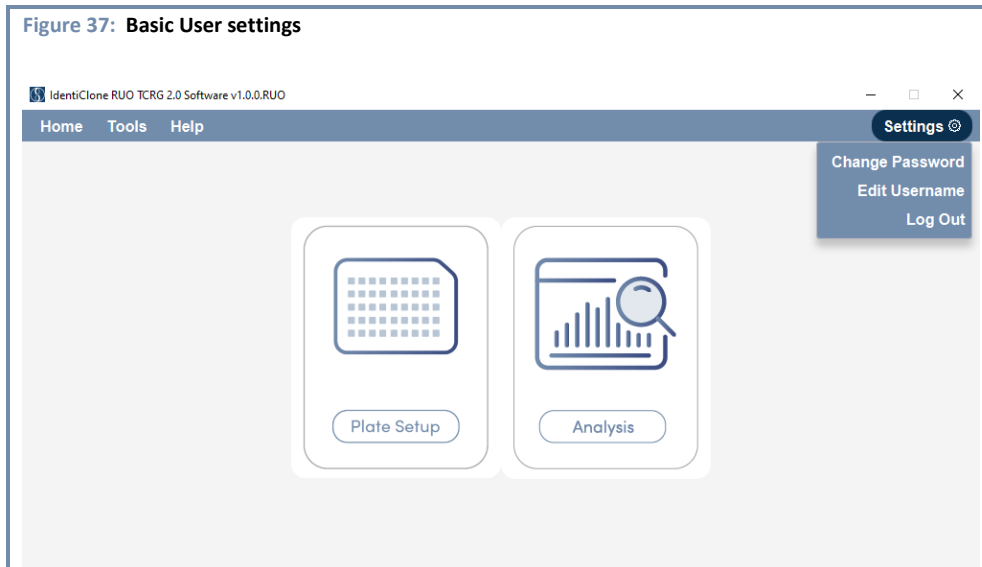
- 13.9.1. Click the **Report** menu and select **Set Backup Location** from the dropdown menu.
- 13.9.2. Click the **Browse** button and navigate to the directory filepath for the PDF report backup files, then click **Submit**. (Figure 36)
  - The filepath for a previously configured backup location will display in the *Current Backup Location* field.
  - The Software will default to use the install directory.



### 13.10. Basic user access

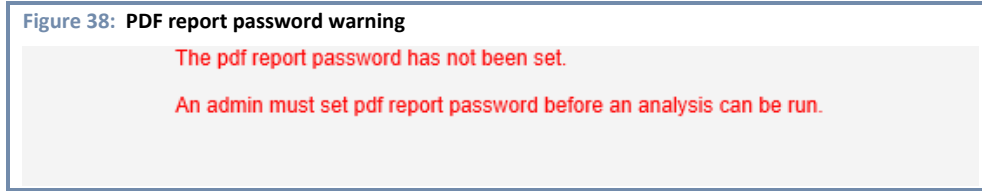
The role of a basic user includes limited permissions, allowing access to perform *Plate Setup*, *Analysis*, *Edit Username* and *Change Password*.

- 13.10.1. User management features are accessed under the *Settings* menu. (Figure 37)
- 13.10.2. Change a basic user password or username by clicking on the respective options in the dropdown menu.



13.10.3. If the *PDF report password* was not configured by an Admin user, a basic user will receive a warning as shown below upon login. (Figure 38)

- An Admin user must first set the *PDF report password* prior to implementing the Software.



### 13.11. User Inactivity

The Software application is programmed to provide a warning after 5 minutes of inactivity, which includes a prompt to *Continue* or *Cancel* the session. If this prompt is ignored, the Software will log out the user and return to the *Login* screen. (Figure 39)

- When the user logs in again, the Software will continue to the same screen / function before the user was logged out.

