## **User's Manual**



# RapidScan Reader Rapid Test View Pro Software

**Pacific Image Electronics** 

#### **Notice**

This version of the RapidScan Reader and the RapidTestView analysis software will allow users to generate new standard curves and cutoff ranges for any existing test profiles. It also has the functions to establish new test profiles for new tests or existing tests of different lots.

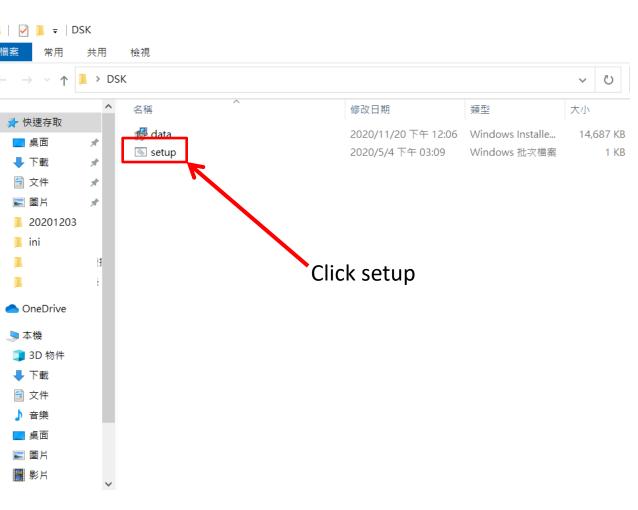
This is not the version of our RapidTestReader Basic which we provide for free to end-users. The RapidTestReader Pro is not a freeware and needs a license with a fee to use it.

#### **Product package contents:**

- 1. Rapid Test Reader x 1
- 2. USB cord x 1

Reader Specifications				
Image Sensor	CMOS			
Light Source	Single light model: White light  Dual light model: White light + UV			
Scanning Media	Rapid test, signal in colorimetric or fluorescent format			
Interface	USB 2.0 ONLY (USB 1.1 not supported)			
Application Software	Rapid Test View Pro w/ License Key			
Supported System	Windows 7 or higher OS with minimum 4G RAM			
Power	5V, 280 mA via host USB port			

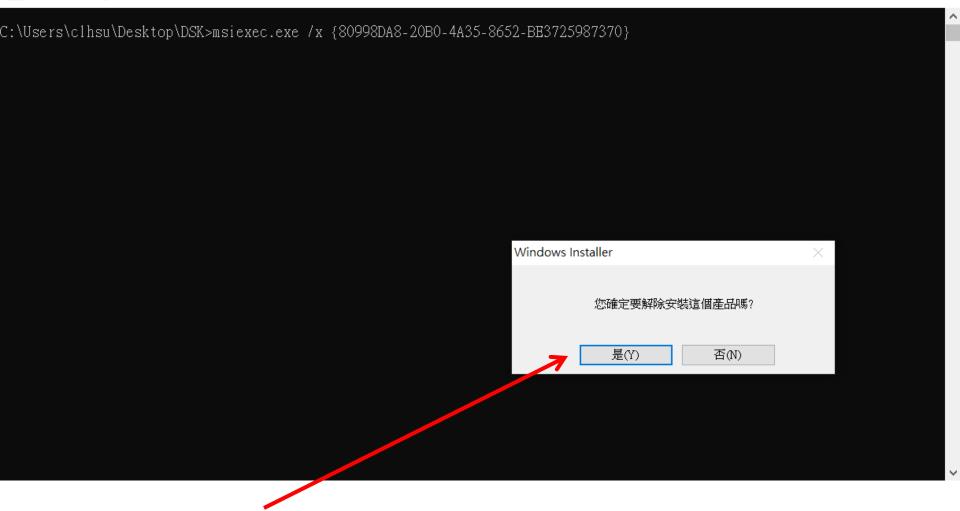
### **Software Installation**



Find the "Setup" file on the provided CD or installation file from supplier. Double click to initiate the software installation.

If the installation is successful, the App icon (see below) will appear on your computer desktop.





After initiating the setup installer, you would see a dialog saying: Are you sure to uninstall this product? Just click "Yes" no matter what.

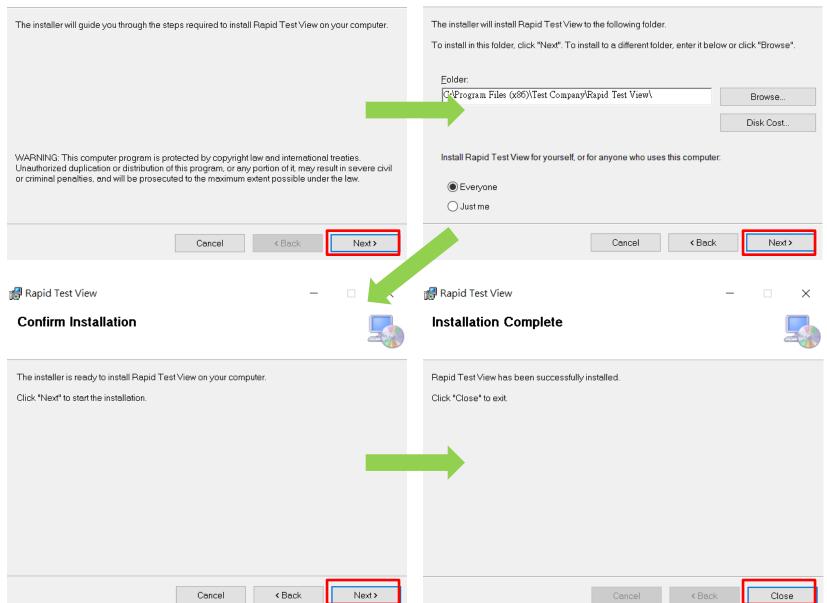


#### Welcome to the Rapid Test View Setup Wizard



#### Select Installation Folder





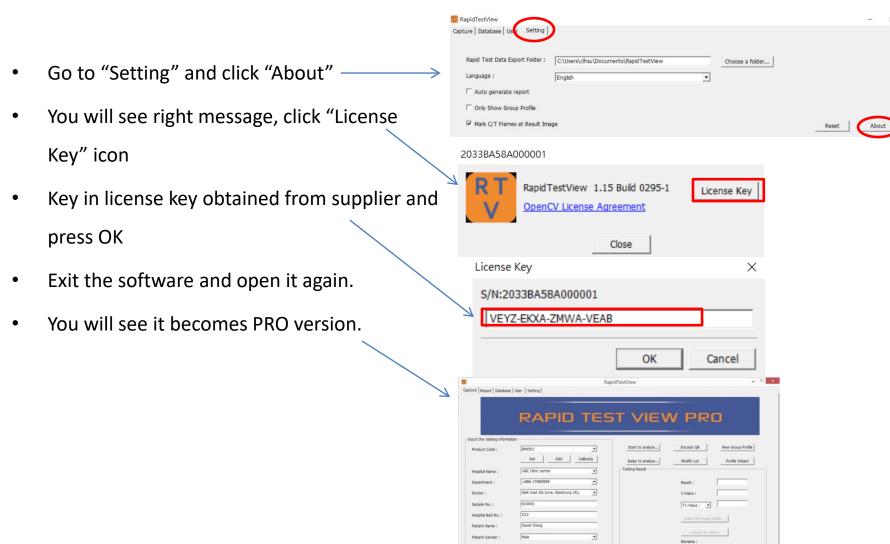
## **Open Rapid Test View**

- Connect reader to your computer running Windows (Windows 7 or above) via USB B to A cable provided in package.
- Double click the RTV icon on the desktop to initiate software. —
- The software will initiate device parameter settings and go\_ through system diagnosis first.
- Once it passes the system diagnosis, the log in window will appear. Please contact supplier to obtain ID & Password.

  For user authority management please refer to p38 User Management
- After successfully log in, UI default page will appear.



## **Enable PRO version via license key**



# How to establish your 1<sup>st</sup> test Kit via software

### **3 Procedures**

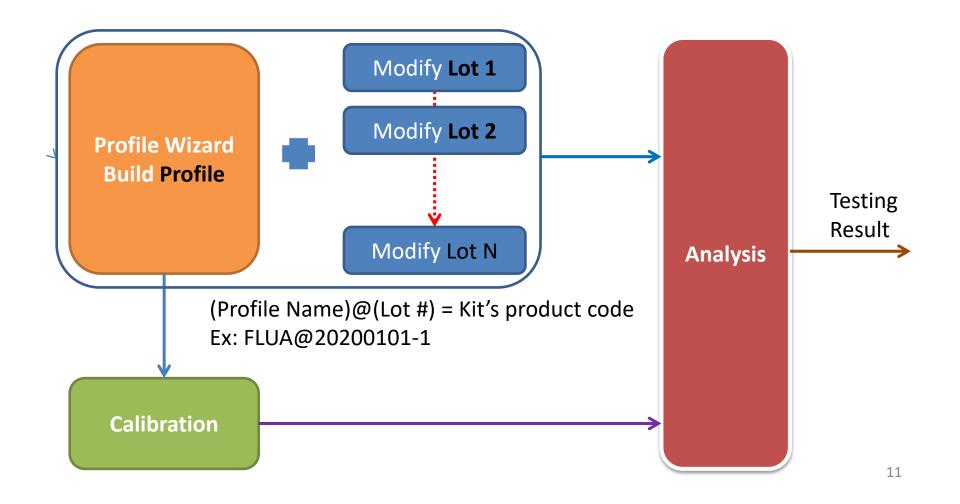
Set Profile: Profile Wizard

Do Calibration of kit profile

Set Modify Lot

## Profile + Lot Info. → Analysis

A Kit's complete parameters are composed by Profile with Calibration data + Lot information.



## A Completed Kit Building

#### Profile Wizard

- Define colorimetric or fluorescent kit
- Define geometric position of detection lines
- Define group/sub profile
- **—** ....
- Fixed for a type of test if strip case is keeping
- Calibration: Using image calibration to obtain optimized image

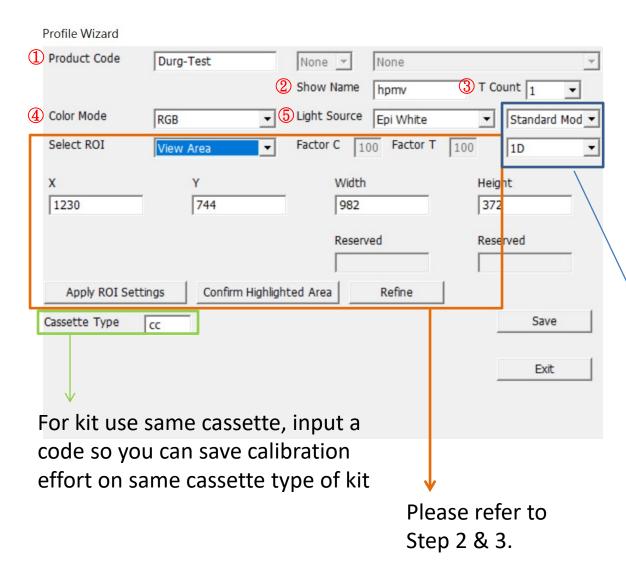
#### Modify Lot

- Define the testing result & basic kit information
- Variable formula/statement setting for each kit

# Using Profile Wizard to create kit's profile

Insert a kit with clear C and T line signals to reader and click Profile Wizard icon to begin

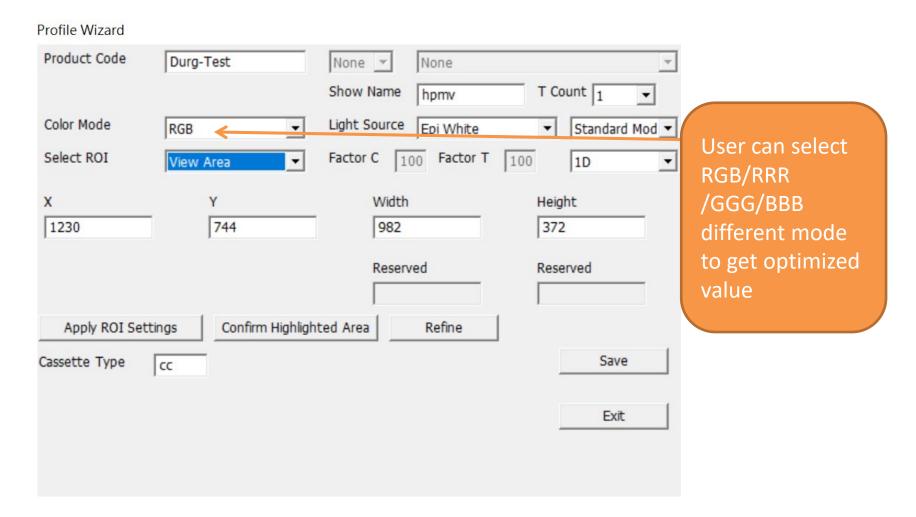
### **Step 1**: Know those parameters on Profile Wizard



- ① **Product code**: Kit's code
- ② Show Name: Set the name of diagnosis item
- (3) T Count: Set T line #
- 4 Color Mode: RGB mode is usually recommended. Please refer to P15-16 for advanced setting
- 5 Light Source:
  Epi White- colorimetric kit
  Epi UV-fluorescent kit

Image method & Integration method. Please refer to page 17-21.

## **Color Mode setting**



## **R/G/B Band Selection**

- Besides colloidal gold, there are colored nano-bead available for lateral flow assay development as well. So C&T line can be presented by different colors.
- 2. RapidScan provides 4 types of image spectrum setting:

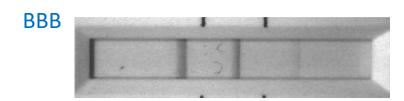
**RGB: Color mode** 

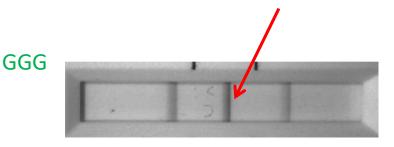
RRR: Red channel spectrum only GGG: Green channel spectrum only BBB: Blue channel spectrum only

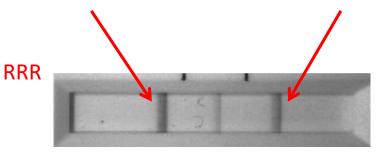
 Each color mode can bring different intensity value according to test line's color. So user can choose a spectrum setting generating the optimized CT line intensity value based on line color.

CH \ Bar	Green	Red	Blue
BBB	1401	1059	162
GGG	1192	1448	710
RRR	1930	545	1148
RGB	1352	1243	615
RGB/Max	70.1%	85.8%	53.6%

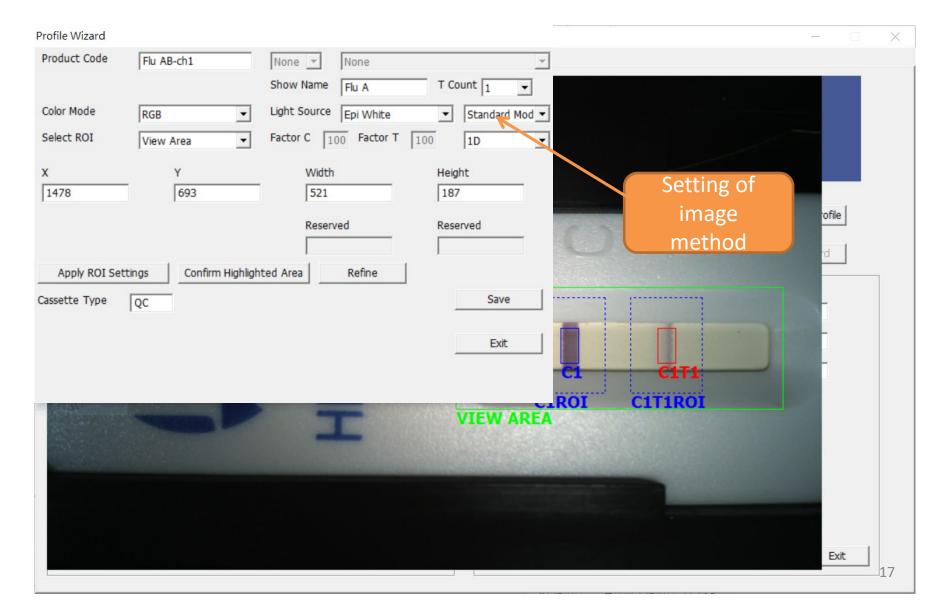








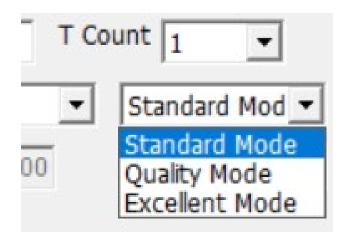
## Image Method: STD/Quality/Excellent



Standard Mode: **Fastest speed**, highest CV

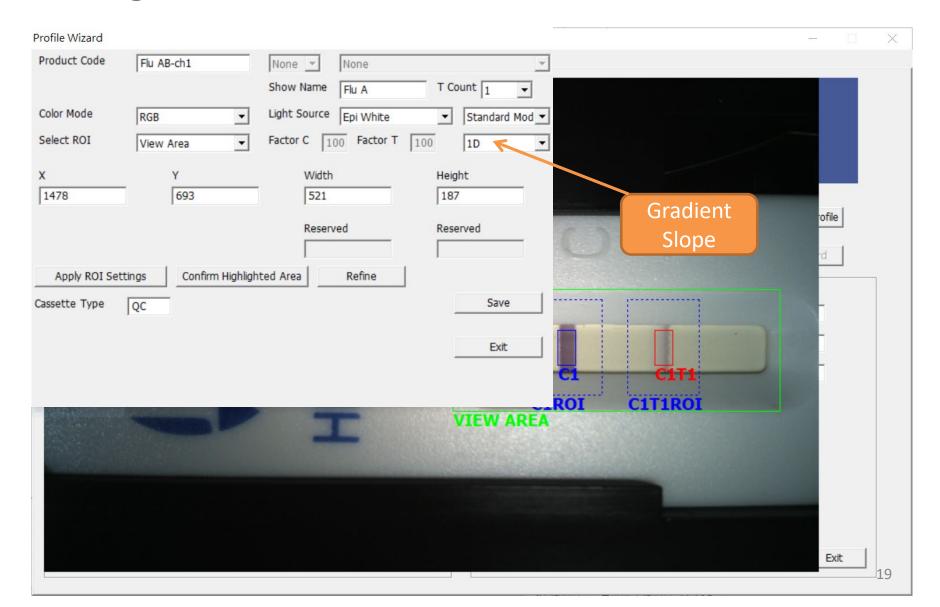
Quality Mode: Medium speed & CV (Recommended)

Excellent Mode: Slowest speed, smallest CV

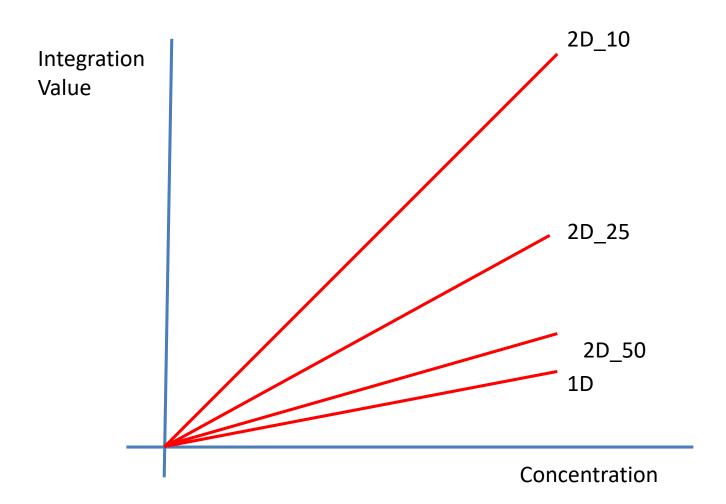


Quality Mode	С	T1	Item	С	Т
Standard	1329	240	Ave	1329.6	245.4
Standard	1327	240	CV%	0.29%	2.67%
Standard	1325	256	Speed	9"	
Standard	1333	246			
Standard	1334	245			
Quality	1328	237	Ave	1332.4	243
Quality	1332	243	CV%	0.27%	1.45%
Quality	1338	246	Speed	12.5"	
Quality	1333	245			
Quality	1331	244			
Excellent	1334	244	Ave	1333.6	241.8
Excellent	1334	240	CV%	0.22%	0.68%
Excellent	1338	241	Speed	16.5"	
Excellent	1331	241			
Excellent	1331	243			

## **Integration Method**



## 30 x 70 (WxH) Case



## **Integration Method**

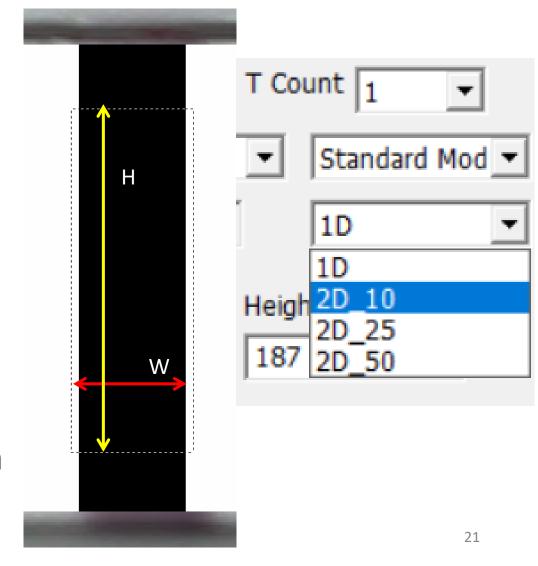
- 1D: Average each H and sum all W
- **2D** : Sum all H x W pixels value =  $V_{2D}$

$$-2D_10 = V_{2D}/10$$

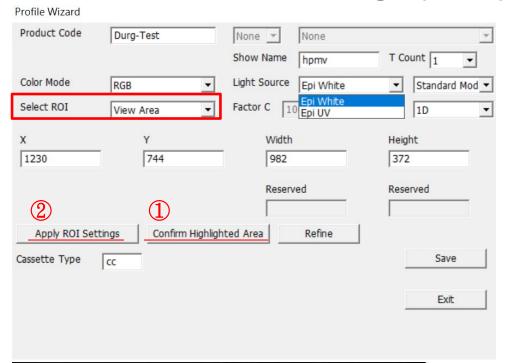
$$-2d_25 = V_{2D}/25$$

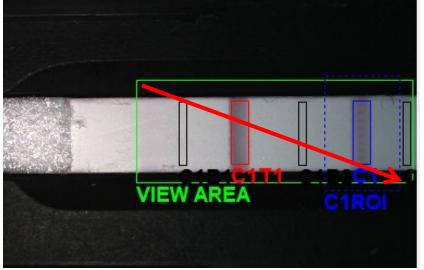
$$-2d_{50} = V_{2D}/50$$

Value big → Slop
 higher → Noise high



## **Step 2**: Select View Area Range (area) of Interest (ROI)





In order to highlight the viewing area, drag mouse from the top of left to the bottom of right corner.

Recommend to highlight the area as close to the edges as possible. Remember to click"① Confirm Highlighted Area" to confirm setting.

If you input value in X/Y, Width/height column remember to click "2 Apply ROI Settings" to save setting.

### Step 3: Define C (Control) & T (Test)Line area

- 1. To define new C or T line area, drag your mouse over an area. It's not necessarily to cover whole C or T line. Instead, you'll get better result when the defined area covers blank area slightly and the most area of C or T line.
- 2. For existing highlighted area, you may simply enter the X/Y or width/height values to adjust the area.
- 3. Continue to define T line with same approach. Ensure C, T highlighted area size is same. You can use "refine" to get same size.
- 4. After setting C & T, click "Refine" to get optimized result. SW would ask shrink % for shrink. **15-20 is recommended**.

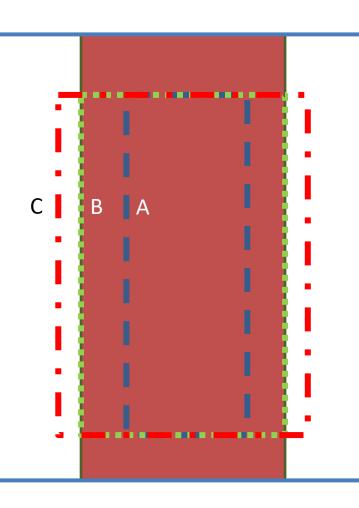


23

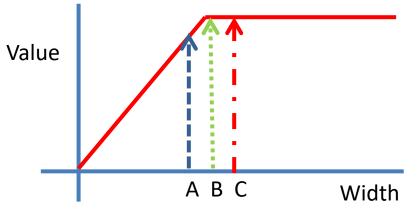
## Tips for optimized setting of

Search area C, T line area

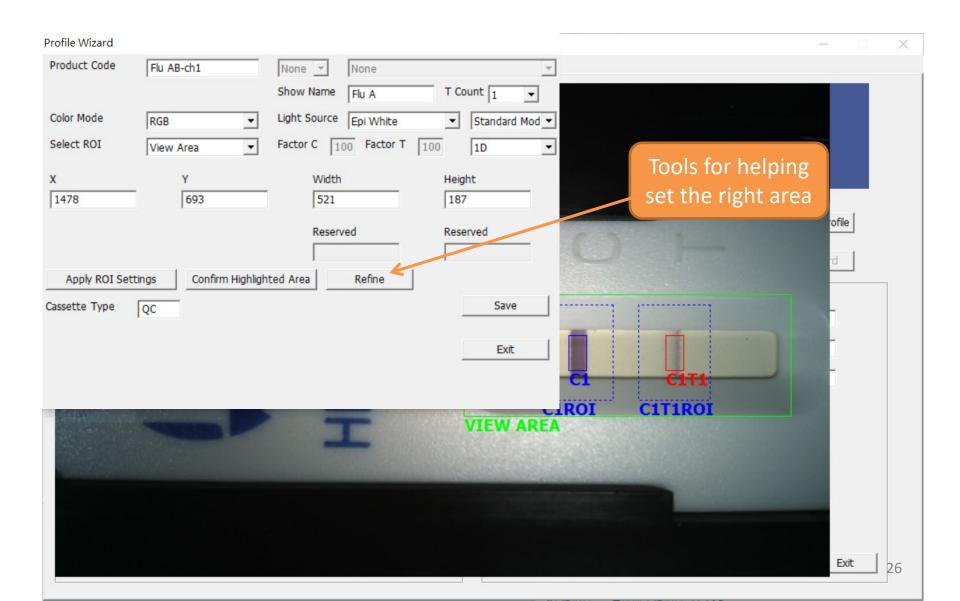
## Tips for setting C, T Line area



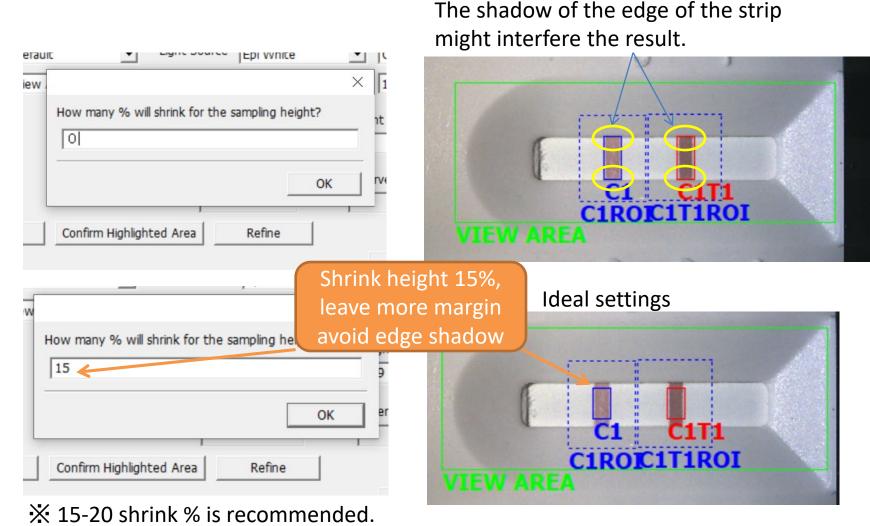
- Width (according to your application's needs)
  - "A" doesn't cover all, may suitable for some line bar check, but it's not recommended.
  - "B" is ideal but not so easy to fit.
  - "C" is the most recommended.
- Height:
  - Shrink 15 ~20%
  - Near the edge of window has some abnormal shadow or reflection.



## **Tips:** Using "Refine" to set suitable CT Line area

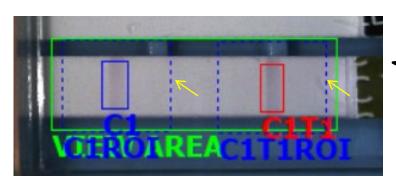


# "Refine" helps you to set equal-sized C, T line area & avoid edge shadow



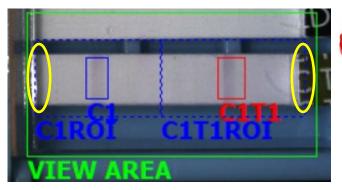
# Definitions about good & bad search areas



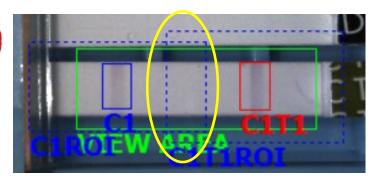


The search areas cover in a perfectly balanced range.









Reader might misread the image if you cover C & T search areas into the edge of the cassette/strip.

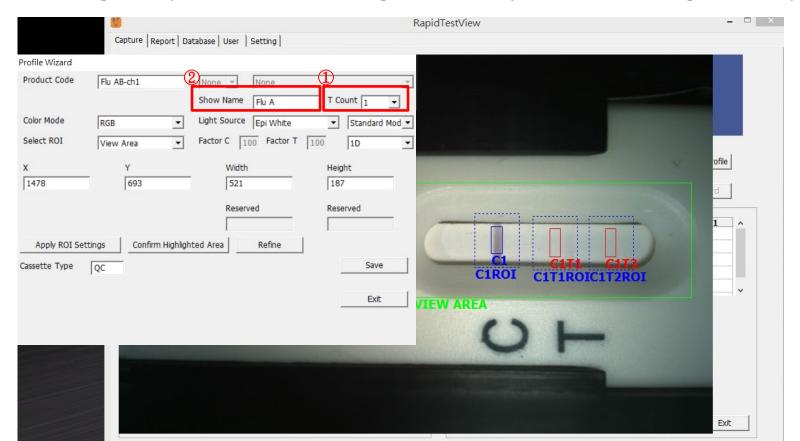
C & T search areas are not recommended to overlapping with each other.

## **Guidance of setting**

Kit with multiple T lines
Kit with multiple strips
Kit with multiple T lines & strips

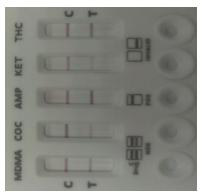
## To set kit with multiple T Lines

- 1. If there is more than 1 T line on test kit. Click "1 T count" to select correct # of T line.
- 2. Use the same approach to define T1, T2, ...as last page's instruction
- 3. You can set testing target name at "2 Show Name" column for each T line.
- 4. There are 3 analysis modes available: standard, quality, excellent. Quality mode is recommended.
- PS. Selecting "Quality" or "Excellent" takes longer time for analysis because more images will be captured.



#### To set C & T Line area for multiple channel cassette

#### Scenario 1: 5 channel test kit with 1 T line in each channel



- 1. Using Profile Wizard to establish profile for each channel.
- 2. In this case, you can set THC, KET, AMP, COC, MOMA 5 independent product codes following previous instructions.
- 3. Then click "New Group Profile". You will be asked how many strips/T lines per strip # are.
- Then set a product code name for this group. 4.
- Follow the instructions below to add those 5 independent product code to this "Group Product 5. MultiChannel Options

Code".

**1.** Click "New Group Profile" on UI default page after you set 5 product codes

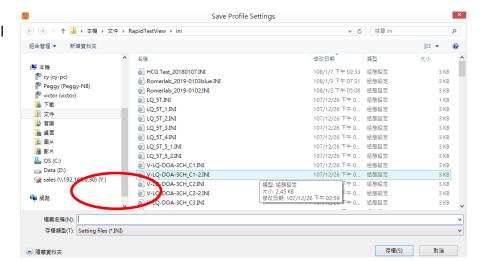
New Group Profile



2. Input strip count #. In this case, input 5 and press OK.



**3**. Then input a new product code for this 5 channel test kit and save . Let's use "DOA 5 channel" as product code



□ Multiple T @ 1 Strip

OK

Note: Input 1~9, but not both of 1

Close

✓ Multiple Strip

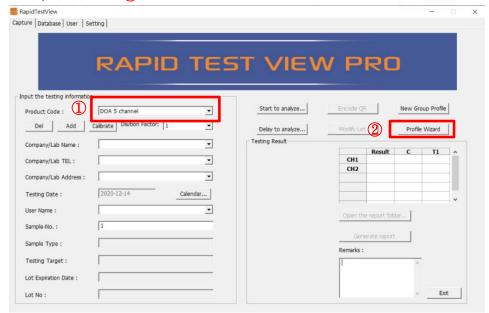
#### To set C & T Line area for multiple channel cassette

Profile Wizard

Product Code

DOA 5 channel

**4.** After saving, back to UI and find "1 DOA 5 channel" product code, then click "2 Profile Wizard".

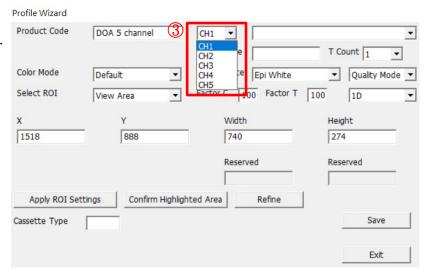


Show Name T Count 1 Flu A -Color Mode Light Source RGB Epi White Standard Mod -Select ROI Factor C Factor View Area 100 100 1D • Height 1478 693 52 187 Reserved Reserved Confirm Highlighted Area Apply ROI Settings Refine Save Cassette Type QC Exit **6.** Follow the same procedure to finish all

CH1

**5.** You will see

(3) CH1 –CH5 available. Go to select each product code correspondent to the channel #.



**6.** Follow the same procedure to finish all 5 channels' product code mapping one by one and then press "Save".

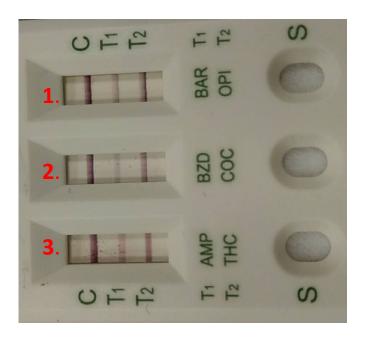
Drug Test MOMA.INI

The Profile Setting is done.

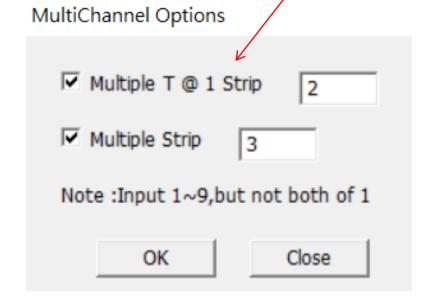
Then you can select "DOA 5 channel" product code to analyze this 5 channel test kit. Analysis result for all channels will be done in one click.

### To set C & T Line area for multiple channel cassette

#### Scenario 2: multiple-channel test kit with 2 x T lines in each channel



- 1. Using Profile Wizard to establish profiles for 3 channels.
- 2. In each channel you set, set 2 T lines.
- 3. Then click "New Group Profile" and set strip & T line #.
- 4. Refer to the description on page 27~29 to finish setting.



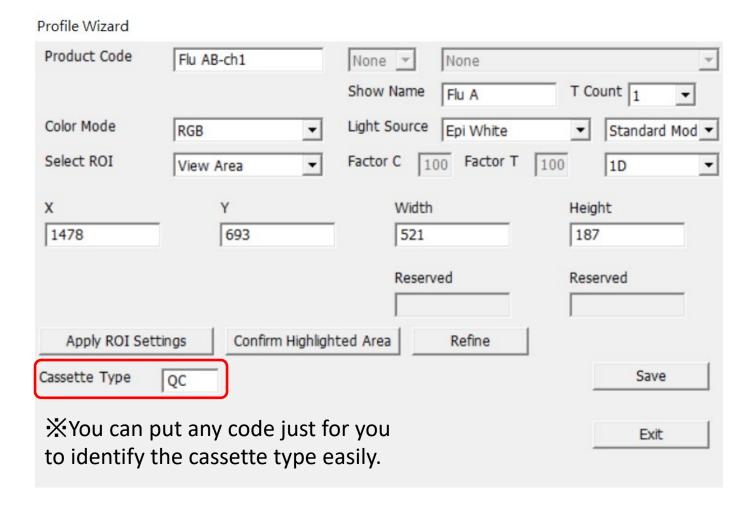
## **Calibration**

Calibration is a necessary setting when developing lateral flow assay kit's profile for each kit to obtain more accurate analysis result.

#### When to do Calibration

- After you set Profile Wizard, <u>please do calibration before</u> set Modify Lot.
- You need to do calibration again if you change following settings in the profile wizard: (refer next page)
  - Change the "Cassette Type"
  - Color Mode
  - Light source
- You also need to calibrate again if you use software to another PC because calibration data is saved in PC's storage.

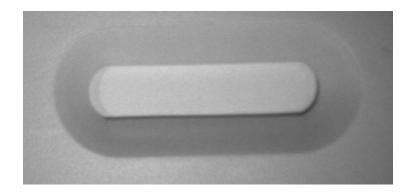
### Remember to set cassette type in profile wizard



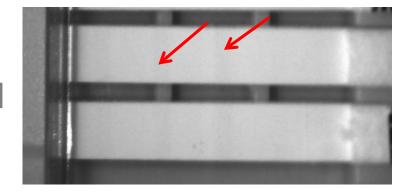
#### **How to do Calibration**

Find a blank kit:
Use the blank strip
without any C & T
lines appear as
calibration chart.

Good

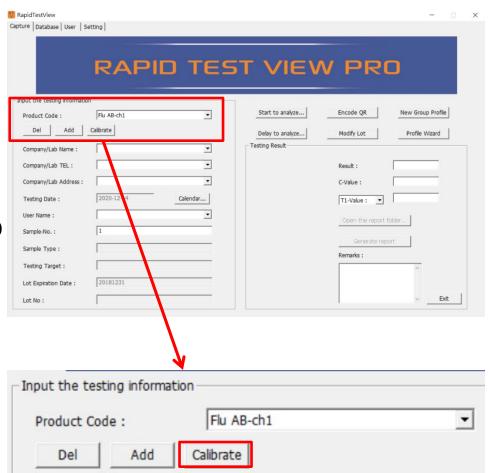


Not Good



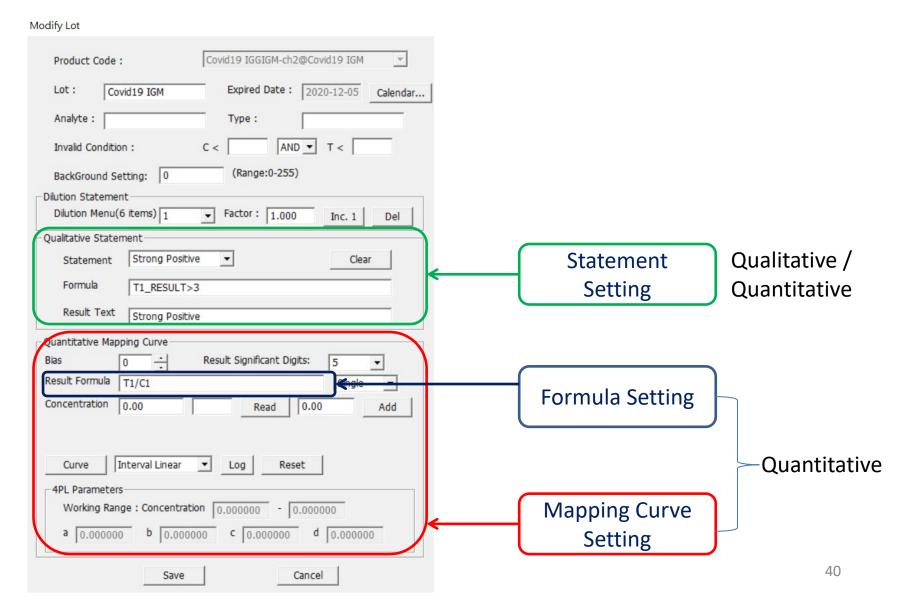
#### **Calibration process**

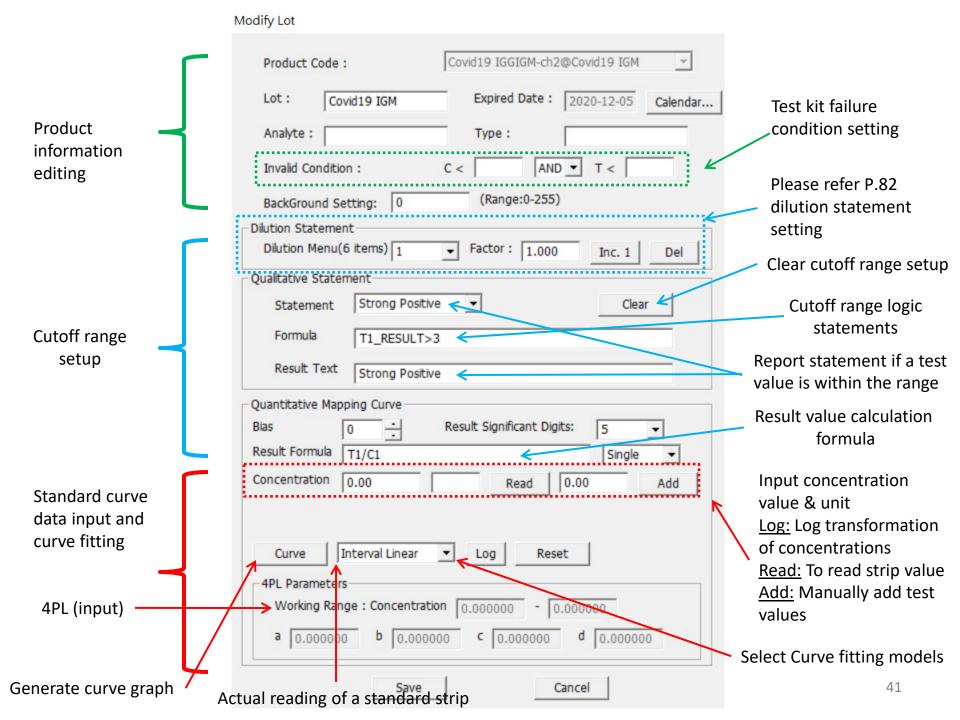
- Go to homepage
- Insert blank kit
- Press "Calibrate" icon
- Follow the instructions to finish calibration



# Using Modify Lot to set analysis formula for obtaining result

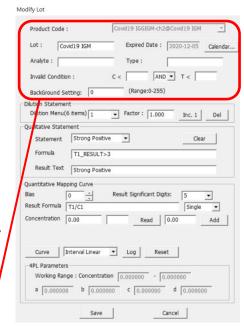
## Modify Lot → Testing Result





#### **Setting Up Lot information**

- Product Code: Selected product code cannot be modified in this section
- Lot: Type Lot Number in Lot column
- Expired Date: Set expiration date in this column
- Analyte: The analyte that the test kit will be analyzing.
- Type: Testing sample type required by this test kit.
- Invalid Condition: Test kit failure condition setting.



Product Code:	Covid19 IGGIGM-ch2@Covid19 IGM	*
Lot : Covid19 IGM	Expired Date : 2020-12-05	Calendar
Analyte :	Type:	
Invalid Condition:	C < AND T T <	
BackGround Setting: 0	(Range:0-255)	

#### **How to set Failure Condition**

- Set Failure Condition to ensure the test kit's quality is qualified according to your company's standard.
- You can set C, T line's intensity value with "And" & "Or" condition
- In case the test kit's result fits the condition you set, "Failure" result is presented.

Product Code :	Covid19 IGGIGM-ch2@Covid19 IGM	¥
Lot : Covid19 IGM	Expired Date : 2020-12-05	Calendar
Analyte :	Type:	
Invalid Condition :	C < AND ▼ T <	
BackGround Setting: 0	(Range:0-255)	

# How to set cut off value in Qualitative Statement

Go to Statement to set Positive and Negative statement.

★ "T1\_RESULT" & "T1\_CONCENTRATION" mean the figure calculated from Result Formula, so it's fixed and the letters must be capitalized. No need to change it into for example: T1/C1\_RESULT...etc.

In Quantitative Mapping Curve section, input your desired formula in Result Formula.

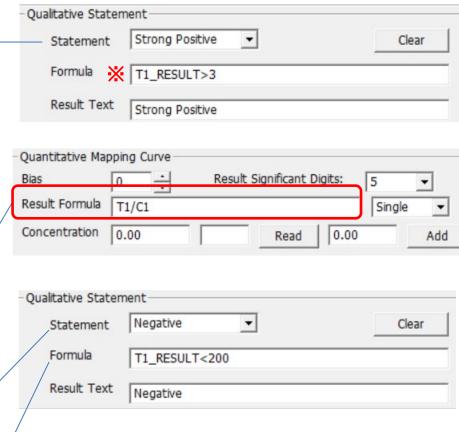
ex. T1 or T1/C1...

If you set T1 in Result Formula, it is the image intensity of T1 line calculated by algorithm. If you set T1/C1, it is figure of T1/C1 intensity ratio.

Then input the result description you would like to show for diagnosis result. Here we use "Negative" as an example. The text you type in Result Text also present in Statement

Set Formula for cut off value. For example: Input T1 RESULT < 200 for Negative.

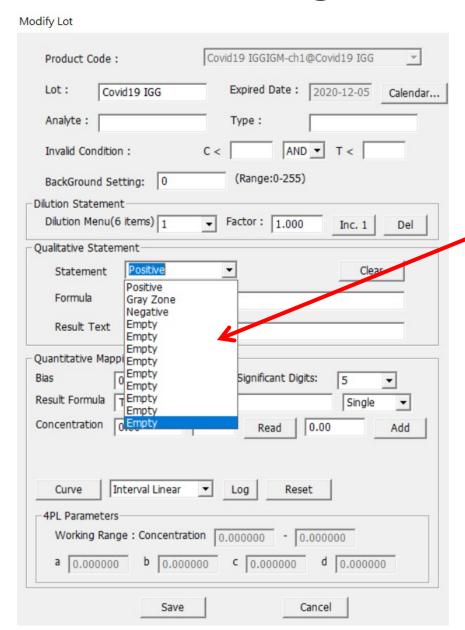
Then set T1\_RESULT >= 200 for Positive to include all possible calculation result.



#### **Setting Up Cut-off Ranges**

- Up to 12 cut-off statements can be set up.
- In the Result Text, enter the report result for a specific cut-off range. Say ~1 ppb. Then in the Formula, define the cut-off range with >, < and =. Say T1\_CONCENTRATON>=0.65 & T1\_CONCENTRATON<1.75. Step by step to finish all of your cut-off ranges and the report results.</li>
- Please remember to save your settings by pressing the "Save" button. Please save in the correct file name as well.
- The final cut-off ranges should be adjusted based on your further validation using more standard strips or actual sample strips before its release.

#### Statement setting



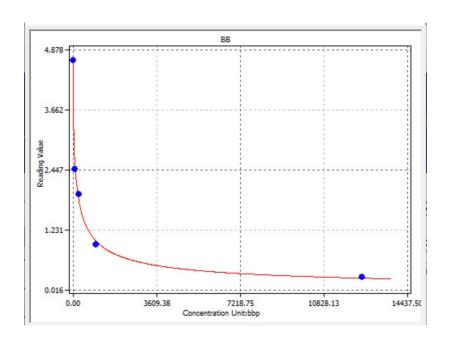
Up to 12 cut-off statements can be added!!

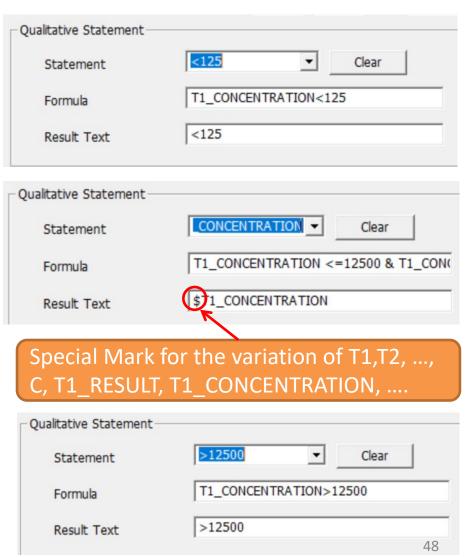
## Summary of Qualitative/Quantitative setting

Result Type	Formula	Mapping Curve	Statement	Note
Qualitative / Quantitative	Quantitative	Quantitative	Qualitative	
Assignment	T1_RESULT	T1_CONCENTRATION	Statement	
Prority	3	2	1	
Operation Type	Arithmetic	Data to Concentration Mapping	Arithmetic + Logic> Logic	
	+	Interval Linear	+	Arithmetic PLUS
	-	Linear	-	Arithmetic MINUS
	*	Quadratic	*	Arithmetic MULTIPLY
	/	4PL	/	Arithmetic DIVIDE
	( )			Parenthesis (Formula only)
			&	Logic AND
				Logic OR
			>, =, <, <>	Logic COMPARE
			\$	Mark for Quantitative Data
Examples	T1/C1		T1/C1 >= 100	
	T1+100		T1<100   C1<50	
	T1/C1-100		T1 + T2 <= C1	
	T1 * T2 / C1		T1_RESULT> 1 & C1 > 50	refer Formula value
	(T1-T2)/(C1-T2)		\$ T1_CONCENTRATION	show Curve Mapping value
	T1+T2-C1		T1_CONCENTRATION < 0.5	refer Curve Mapping value

# How to set Mix of Qualitative/Quantitative statement

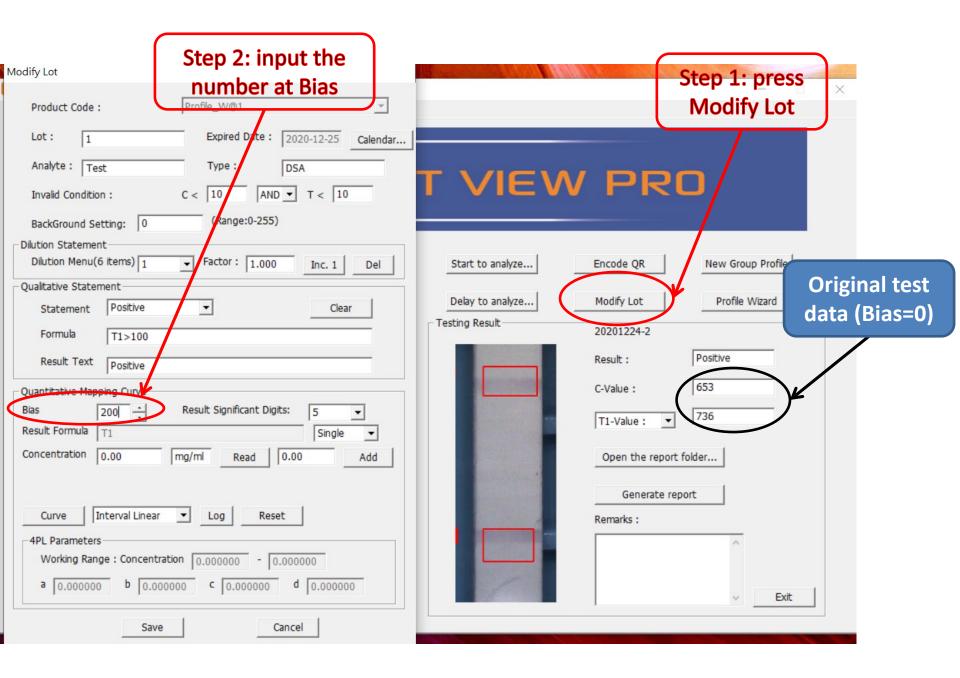
 Using "Statement" to show the quantitative value @ working range

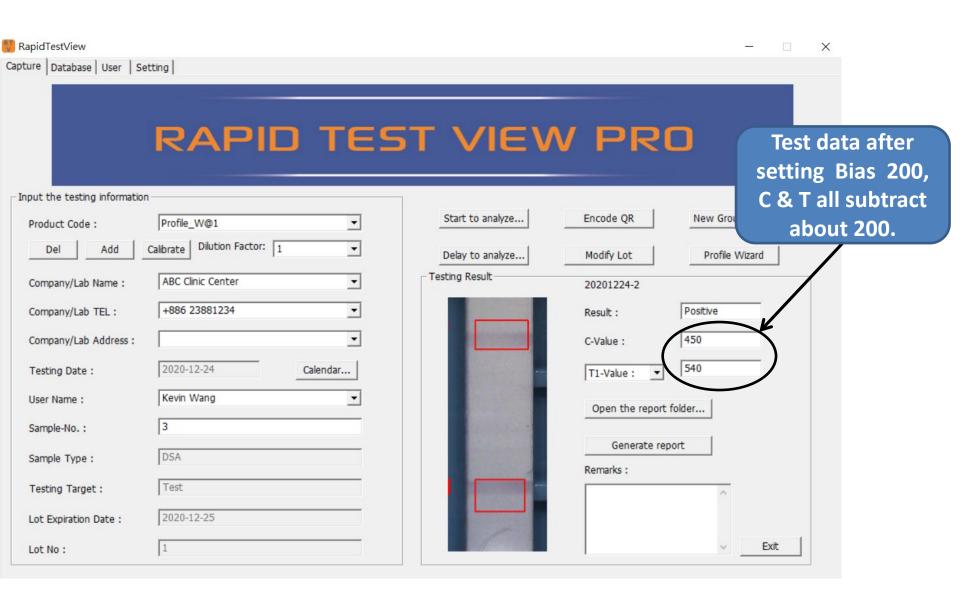




#### Why & How to Use "Bias"

- If you believe the data exist some kind of deviation, use Bias to adjust it to perfect.
- First, set Bias=0
  - The signal you retrieve will be higher than expectation.
  - Get the "Standard Deviation"=Sd
  - -2 or 3 times of Sd = K
- Set Bias = K @ Modify Lot

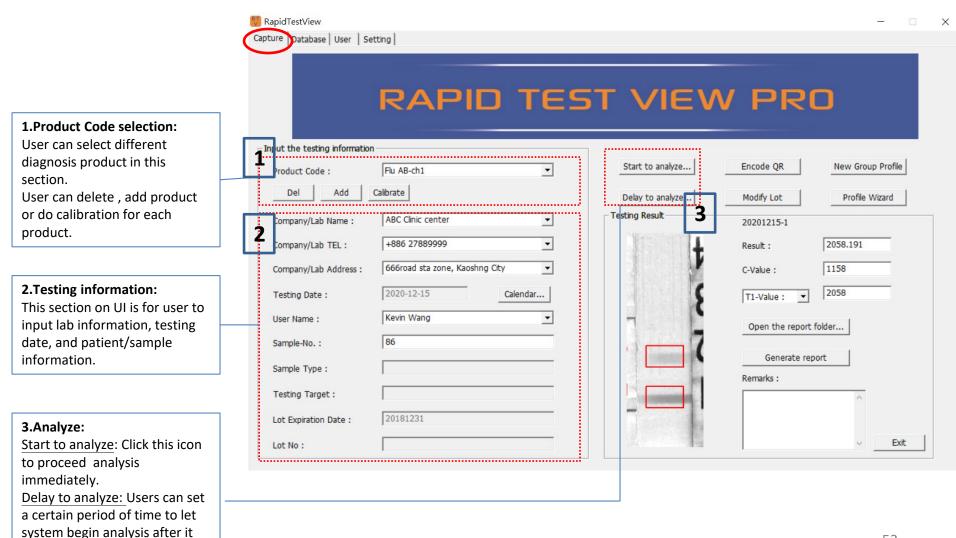




# **Capture & Analysis**

#### **Default page: Capture**

reaches preset time



### Default page: Capture(Cont.)

#### 4.Profile Wizard:

To set each kit's image, C, T line's detection position & area size here.

To set colorimetric/fluorescent kit detection light source.

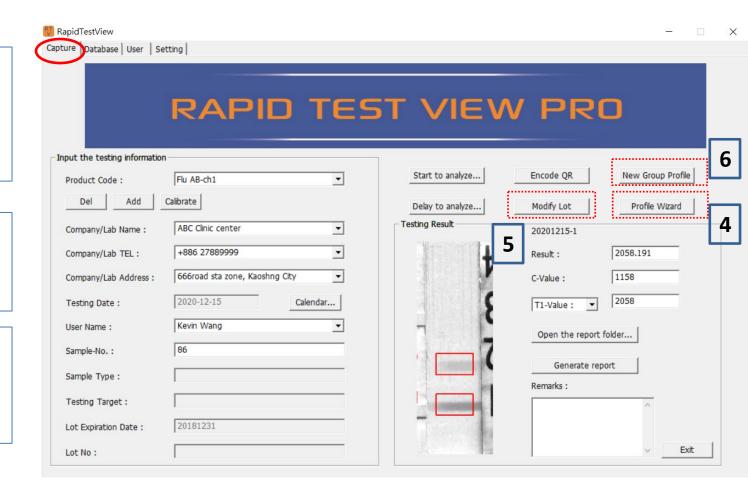
To set algorithm here

#### 5.Modify Lot:

To set Cut Off value. To set Result Formula To set Standard Curve for quantitative analysis

#### **6.New Group Profile:**

For multiple channel assay, users will need to use this function to integrate each channel's profile into 1 single group profile.



### **Default page: Capture(Cont.)**

**7.Encode QR:** To create product profile's QR code image

8.Testing Result: present result information include image.

Result: Can show negative / positive or any statement preset.

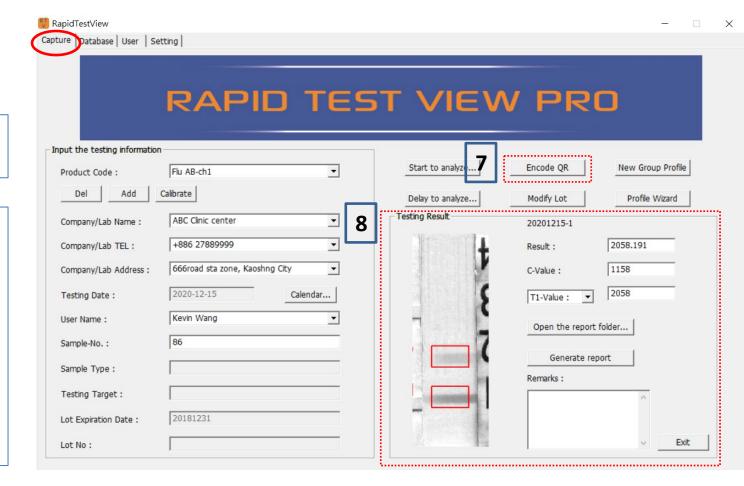
C Value: control line image intensity value

T-1 Value: Test line image intensity value

Open the image folder: To access the preset folder for image saving

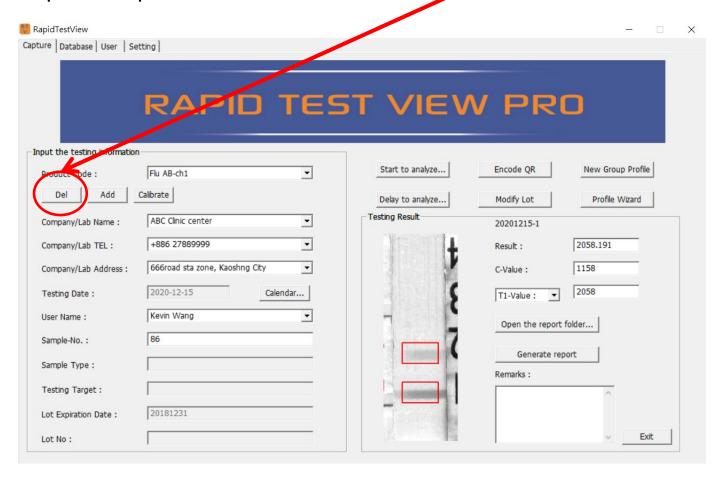
Output to report: Generate

PDF report



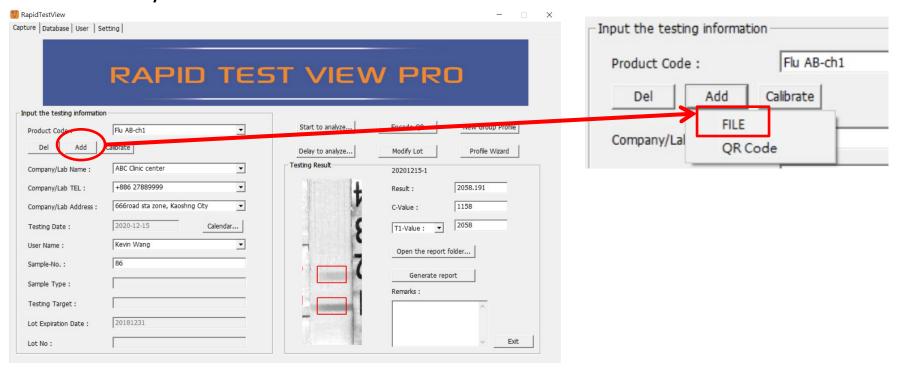
#### **Delete Profiles**

How to delete useless or invalid product profiles in software? Select product code for deletion and then press "Del" to remove selected product profile.



#### **Add Profiles**

Click "Add" to increase product profiles to software
Click "File" to select product profile saved in PC.
(Please contact supplier to know more about QR code function)
Added profiles will display in Product Code column if adding profile step is successfully done.

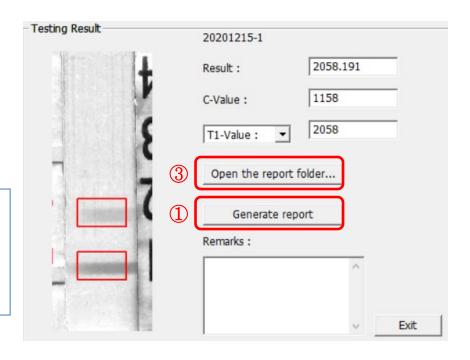


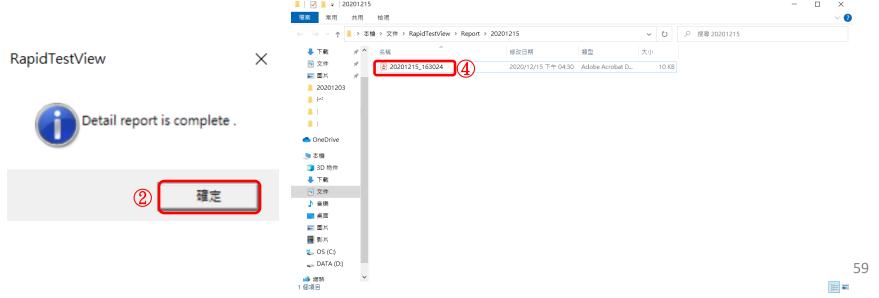
# Report

#### Report

The SW can generate a PDF report by clicking "1 Generate report" on UI home page .

After showing "Detail report is complete", click ② 確定 and then ③ open the report folder. You can see there's ④a PDF report in the folder.





#### **Report**

#### TEL:

#### Inspection Report

Example of PDF report

Testing Target :

Testing Time: 20201215 163024

Lot Number:

Sample Type:

Remarks:

Sample-No.: 2

Name	Result	Note
	2068.586	Fig.1

Fig 1.

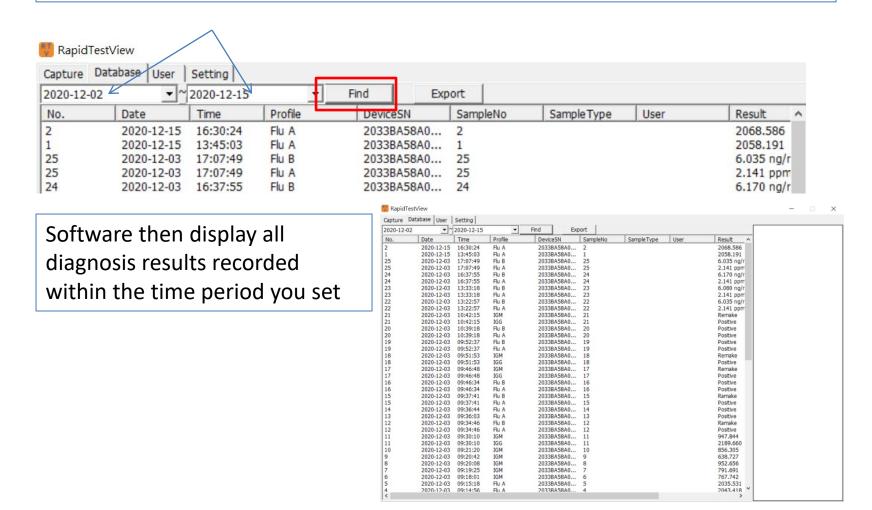


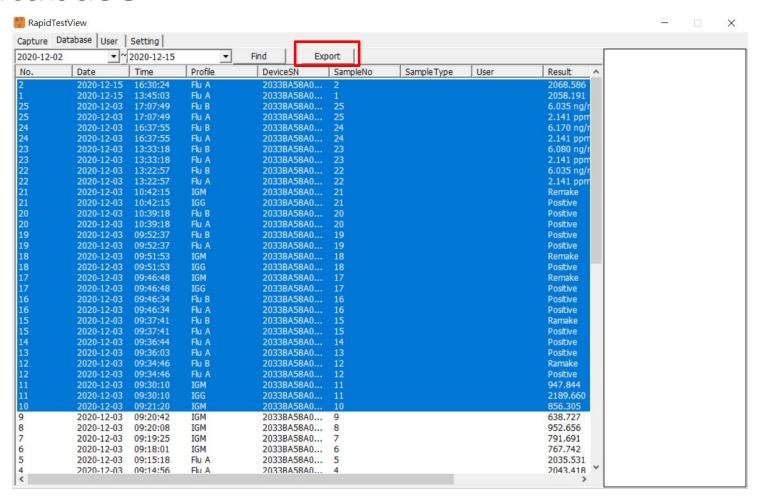
Report Signed

Tester: \_\_\_\_\_(MM/DD/YYYY)

Supervisor: (MM/DD/YYYY)

All level of users can obtain diagnosis history from this section Select testing date or a certain period to show diagnosis result, then click "Find"





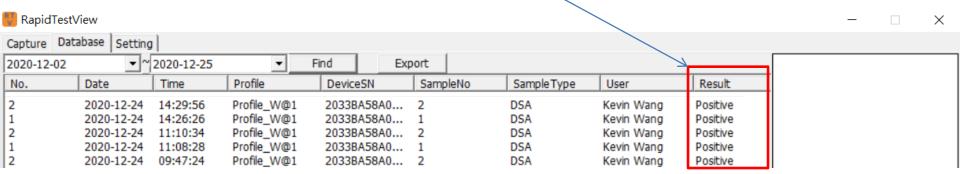
To select multiple results, hold the "shift" key and select the first and the last results. Then press "Export" on the top of the windows. The SW will create "CSV" file immediately.

ADMIN



USER & USER-ALL

**ADMIN user** sees diagnosis result and C, T value. **USER & USER-ALL** can see only results.



# **User Management**

#### **User Management**

 Rapid Test View software has authority management function to let different level of users obtain different diagnosis result

#### ADMIN

- ADMIN is administration level of user. He/She can see all diagnosis results include image.
- ADMIN can add/delete/edit USER-ALL & USER level of users
- Only ADMIN can change ID/PW for USER-ALL & USER level of users

#### USER-ALL

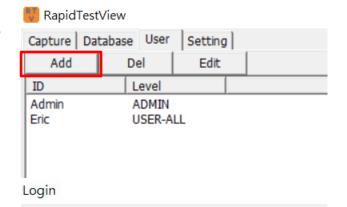
USER-ALL is the leader of his/her team. He/She can see all USERs' diagnosis result

#### USER

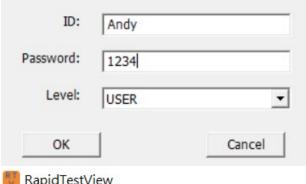
USER can only see his/her own sample's diagnosis result

#### **ADMIN: Add new user**

Go to User section, Click "Add"



Input ID & Password. Select level for user and press OK



New user is successfully added

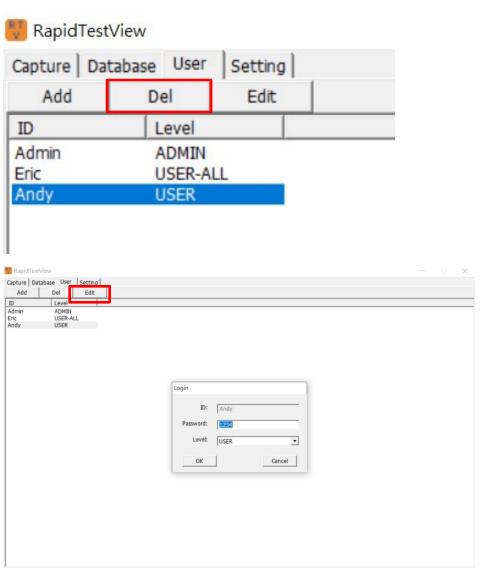
Capture Da	tabase User	Setting
Add	Del	Edit
ID	Level	
Admin	ADMIN	
Eric	USER-A	LL
Andy	USER	

### **ADMIN: Del/Edit user**

How to delete: Simply select user you want to remove and click "Del"

How to edit: Select user you want to edit and click "Edit". Then edit ID, PW, Level press OK to finish

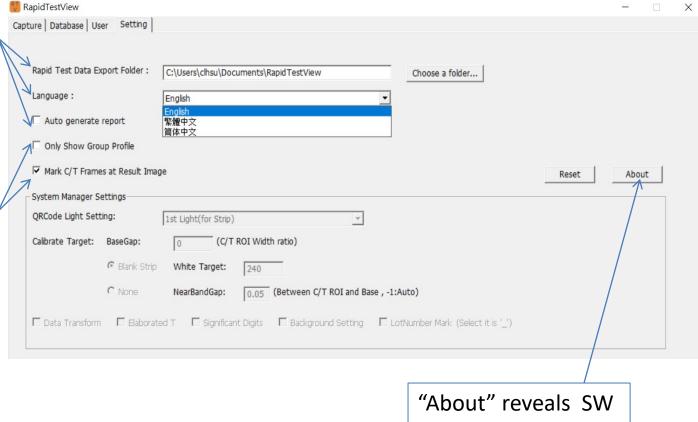
**Note:** If user forget PW, he/she has to ask ADMIN to edit a new PW for his/her ID. There is no PW checking function.



#### Setting

User can set data output folder, language & report auto generation

User can only show Group profile in homepage and choose whether to show C T frame in result image



version and license key information

#### **Encode QR**

Guidance for diagnosis kit developer to create profile QR code image Please contact supplier for QR code generation instruction .

# Step by Step Tutorial: Creating Your First Test Profile

#### Basic settings of new test layout

Step. 1 Select an existing profile to modify



Choose the default profile template. Select any other preset profile in product code column.

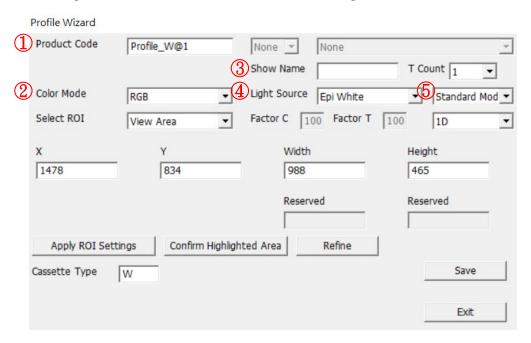
Please contact supplier if yours don't exist any profile in product code column.

# Step. 2 Enter "Profile Wizard" to modify profile

Click the "Profile Wizard" button on UI to initiate the Profile Wizard editor. The software will show a dialog as below.

Profile Wizard			
Product Code	Profile_W@1	None V None	Ψ.
		Show Name	T Count 1 ▼
Color Mode	RGB ▼	Light Source Epi White	▼ Standard Mod ▼
Select ROI	View Area <u>▼</u>	Factor C 100 Factor T	100 ID 🔻
X	Υ	Width	Height
1478	834	988	465
		Reserved	Reserved
Apply ROI Set	tings Confirm Highli	ghted Area Refine	
Cassette Type	W		Save
			Exit

# **Step. 3 Rename and set parameters**

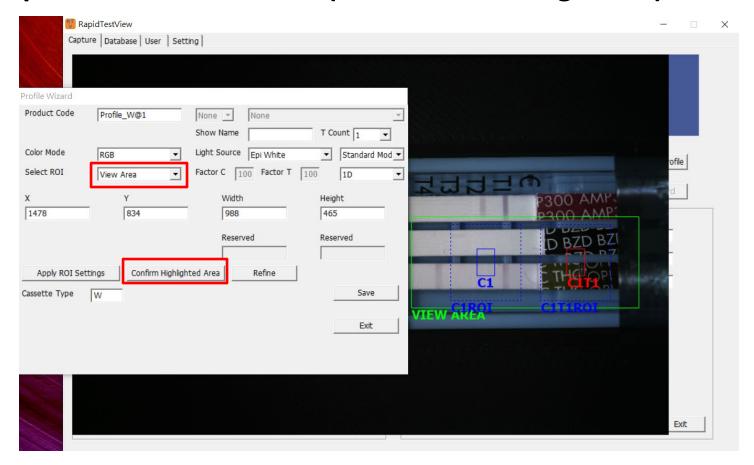


① Rename Product Code. The suggested format is 3 segment connected by dash "-" symbol, and a day code but you can define the segments contents as you want to make a quick sorting.

Example: [Company Name]-[Part No.]-[Application]\_[Day Code or other code]

- ② Set Color Mode: "Default" is recommended. Please consult to supplier before change.
- 3 Show Name: Input application name. T Count: Test line numbers
- 4 Light Source: Epi White For Colloidal Gold . EPI UV for fluorescent applications. (The Device Must support UV function)
- (5) Set the sampling: Standard Mode Sample 1 time for signal calculation. Quality Mode Sample 8 times for signal calculation. Excellent Mode Sample 16 times for signal calculation. [For Colloidal Gold applications]

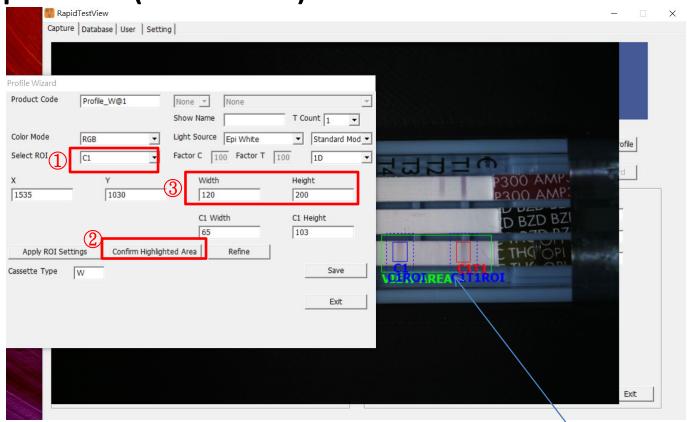
# Step. 4 Set View Area ROI (View Area is image area)



- 1.Set the "Select ROI" to "View Area". Use mouse cursor drag a highlight area on the image viewer.
- 2.Click "Confirm Highlighted Area" to apply the area as "View Area".

The View Area will be displayed on Screen and Test Report as the result image.

# Step. 5 Set C (Control line) detection area

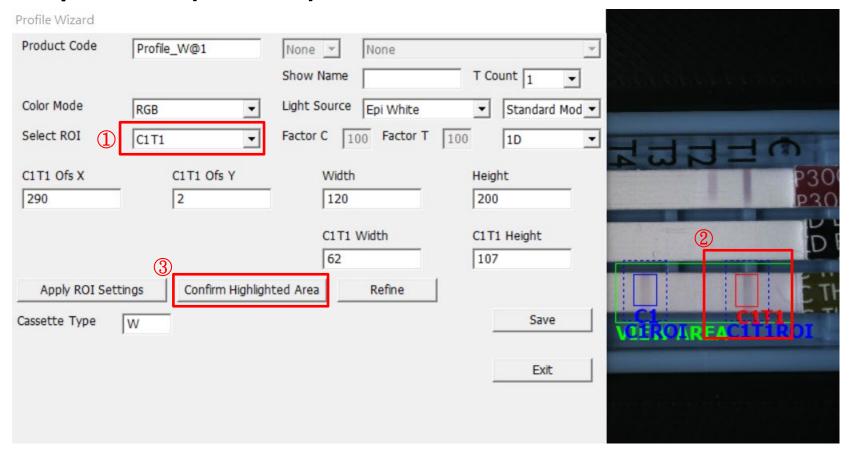


- 1 Set the "Select ROI" to "C1". Use mouse cursor drag a highlight area on the C line area.
- 2 Click "Confirm Highlighted Area" to apply the area as "C1"

Tips: To fine adjust the Area Size and Position, simply input the number in X,Y, C1 Width,C1 Height then click "Apply ROI Settings".

③ Width & Height: This is setting of signal search area. It is shown as above blue dotted line area. SW will search image signal within this area.

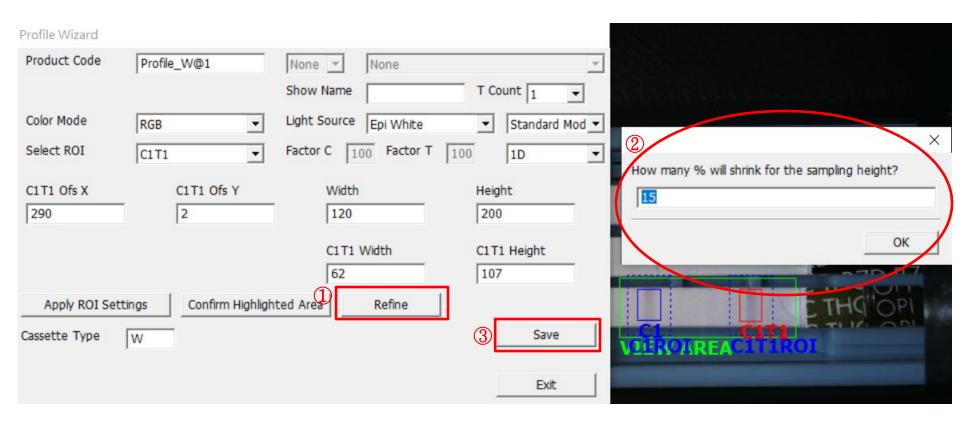
# Step. 6 Set T (Test line) detection area



- 1 Set the "Select ROI" to "C1T1".
- ② Use mouse cursor drag a highlight area on the T line area.
- 3 Click "Confirm Highlighted Area" to apply the area as "C1T1"

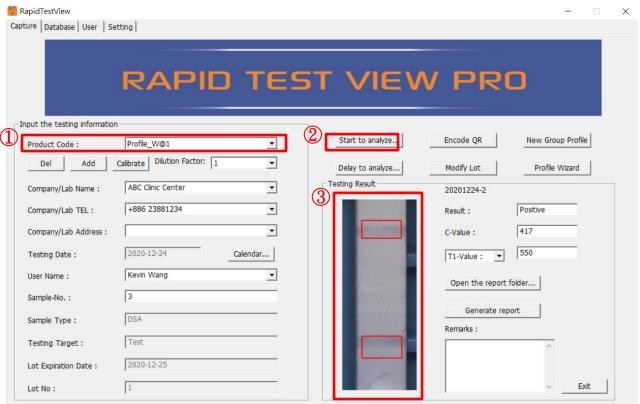
Tips. To fine adjust the Area Size and Position, simply input the number in CT1T Ofs X, C1T1 OfsY, C1T1 Width,C1T1 Height, then click "Apply ROI Settings".

#### Step. 7 Refine settings



- 1 After finish View Area, C, T line setting. Click "Refine"
- ② SW will ask you how many % shrink for height. 15% is recommended. So input 15 and press OK. SW will automatically fine-tune your setting of C, T detection area.
- ③ If you are satisfied with refine result, click "Save" to save your profile setting.

#### Step. 8 Check your profile setting



Now, check if the newly created profile can be executed.

- 1 Select the Product Code with the profile you saved.
- 2 Click "Start to analyze" button to perform an analysis.
- 3 Check the strip image is created and the highlighted areas of C and T line are correct.

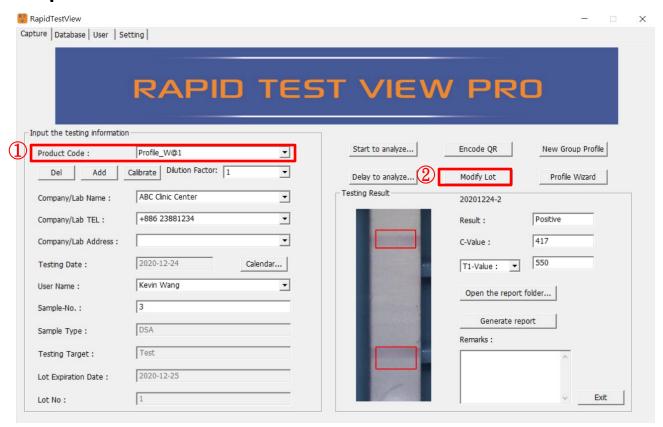
If the profile can be executed, you will see C-Value and T-Value are reported.

At the moment, don't worry about "Result" reported, because you need to set something in "Modify Lot" function to make it output correct data.

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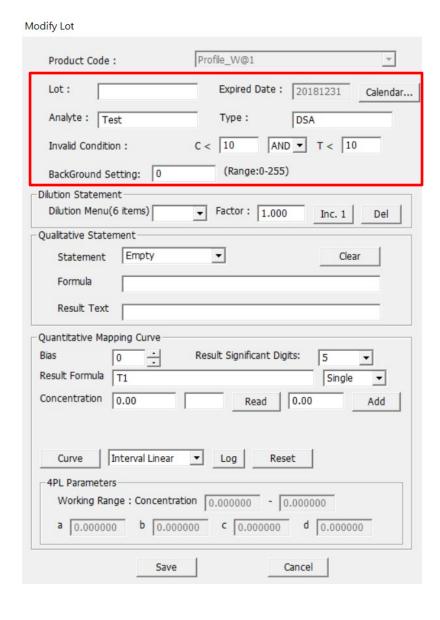
# Strip Lot information & Result calculation formula

#### Step. 1



Check the newly created profile if it can be executed and correctly analyze your test strips.

- ① Select the Product Code with the profile you saved in Phase-1.
- ② Click "Modify Lot" button to open Lot Information / Result setting dialog.



Fill the Basic lot information.

<u>Lot</u> - Test kit lot number.

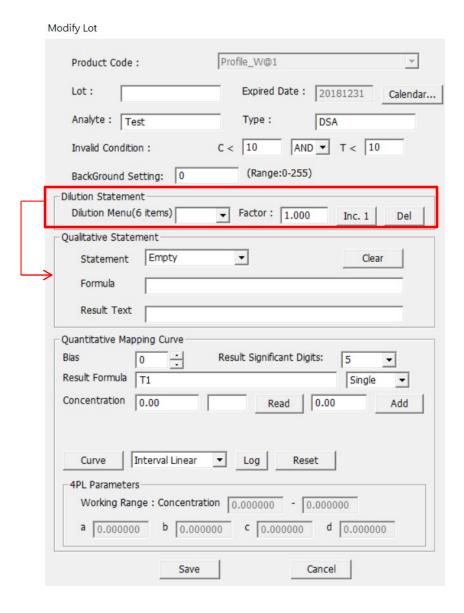
<u>Expired Date</u> - The Expiration Date of the test kit. Software will give out warning when the test kit used is expired.

<u>Analyte</u> - The analyte that the test kit will be analyzing.

<u>Type</u> - Testing sample type required by this test kit.

<u>Invalid Condition</u> - Test kit failure condition setting.

<u>BackGround Setting</u> – It's a tool for users to notice if there's some unbalanced color in the background between C & T line. If the result is under the number you set, a note will show up.



#### Why dilute?

Various specimens may have different active concentrations with the same analyte.

It's a setting for users to set their dilution.



↑Used by users to define the names of the specimens. (Up to 6 items)

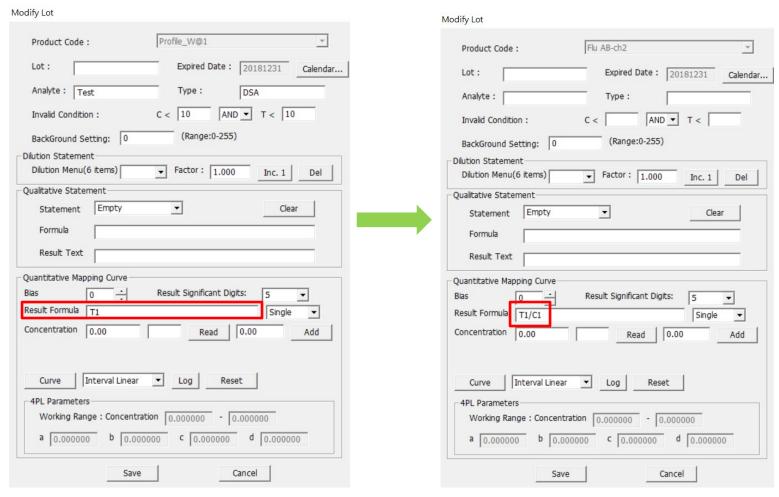
Factor: 1.000

↑Used by users to define their dilution factor.

\*One "Dilution Statement" only corresponds to one "Qualitative Statement".

Modify Lot		Modify Lot	
Product Code : Covid19 IGGI	IGM-ch2@Covid19 IGM  ▼	Product Code :	Profile_W@1
Lot: Covid19 IGM Expired	Date : 2020-12-05 Calendar	Lot:	Expired Date : 20181231 Calendar
Analyte : Type :		Analyte : Test	Type: DSA
Invalid Condition : C <	AND ▼ T <	Invalid Condition:	C < 10 AND T < 10
BackGround Setting: 0 (Range	:0-255)	BackGround Setting: 0	(Range:0-255)
Dilution Statement		Dilution Statement	
Dilution Menu(6 items) 1 Factor :	1.000 Inc. 1 Del	Dilution Menu(6 items)	→ Factor: 1.000 Inc. 1 Del
Qualitative Statement		Qualitative Statement	
Statement Strong Positive ▼	Clear	Statement Empty	▼ Clear
Statement   Strong   State	Clear	Statement	Clear
Formula T1_RESULT>3		Formula	
Result Text   Strong Positive		Danik Tark	
Result Text   Strong Positive		Result Text	
Quantitative Mapping Curve		Quantitative Mapping Curve	
Bias 0 - Result Signific	ant Digits: 5 ▼	Bias 0	Result Significant Digits: 5 ▼
Result Formula T1/C1	Single ▼	Result Formula T1	Single
Concentration 0.00 Re	ad 0.00 Add	Concentration 0.00	Read 0.00 Add
_			
Curve Interval Linear V Log	Reset	Curve Interval Linear	Log Reset
4PL Parameters		4PL Parameters	
Working Range : Concentration 0.000000	- [0.000000		ration 0.000000 - 0.000000
a 0.000000 b 0.000000 c 0.00	0.000000 d 0.000000	a 0.000000 b 0.0	00000 c 0.000000 d 0.000000
Save	Cancel	Sav	e Cancel

When your application requires a quantitative value, you will need to clear all Judgement Statements in "Result Statement Settings" area. Please select the Statement selection and click "Clear" to clear each Statement to "Empty"



Input the Result Value calculation formula in the "Result Formula" field. And click Save to save current settings. Please see the next page for details.

## Additional instruction on how to use Result Formula

The available KEY WORDS are

- C1 The measured value of the C area.
- T1 The measured value of the T area.

For a competition assay, the recommended formula is "T1/C1".

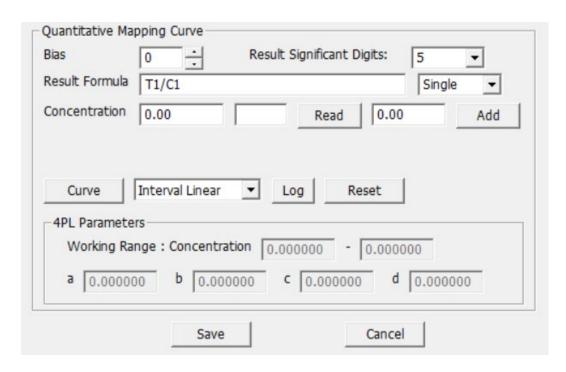
For a direct colorimetric assay, the recommended formula is "T1" or "T1/C1" if desire.

The Result Formula can be input with a simple mathematical equation.

The available calculation symbols are,

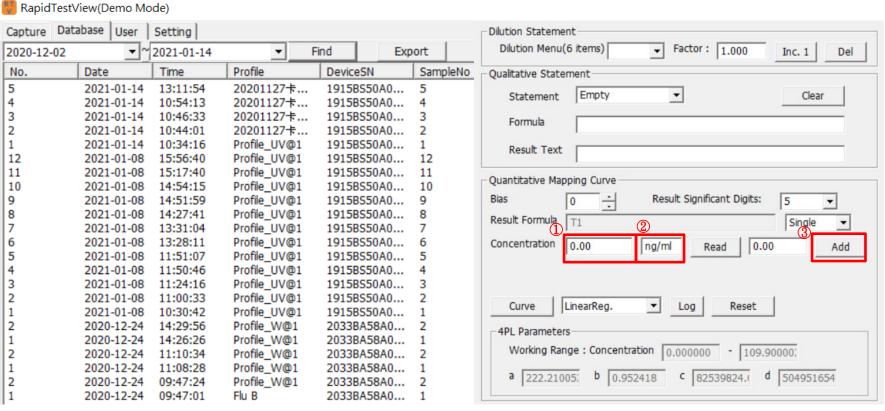
- + Add,
- Subtract,
- \* Multiply, e.g. T1\*100
- / Divide,
- Priority Calculation.

#### Create a standard curve



- For some applications you may need to create a standard curve to calculate the values of unknown samples to a specified unit. You can generate a standard curve by using the input functions shown above.
- These functions will use the signal values calculated by the "Result Formula" and plots a curve with their corresponding concentrations.
- Before you start this phase, we suggest you prepare the following test samples.
- Test samples of maximum/minimum concentrations for 3+ pcs (for quantitative measurement, at least 5 concentrations are recommended. Each concentration with at least three replicates.
- If you don't need this function, you can just skip this phase.

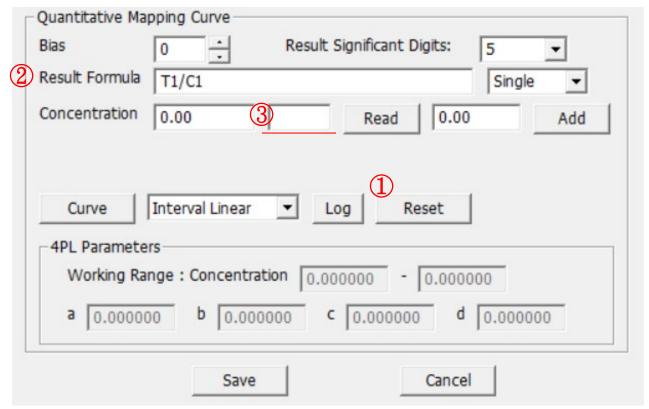
# 1<sup>st</sup> & the most recommended way to establish a standard curve



- 1. Go in Database, and export all the test data you need into CSV profile.
- 2. Use Excel to open the profile, and then you can calculate for example: the T/C value for each concentration.
- 3. Go to Modify Lot and ① fill in the value you just calculate & ② the unit (ppb, ng/ml...etc.) for your result.
- 4. ③ Press Add, and then finish all your concentration step by step like the description above.
- 5. Hereafter, you can choose any standard curve you'd like to establish.
- ☆ The value of standard curve can be set for T1, T1/C1, T1-C1...etc.

# 2<sup>nd</sup> way to establish a standard curve (5 steps)

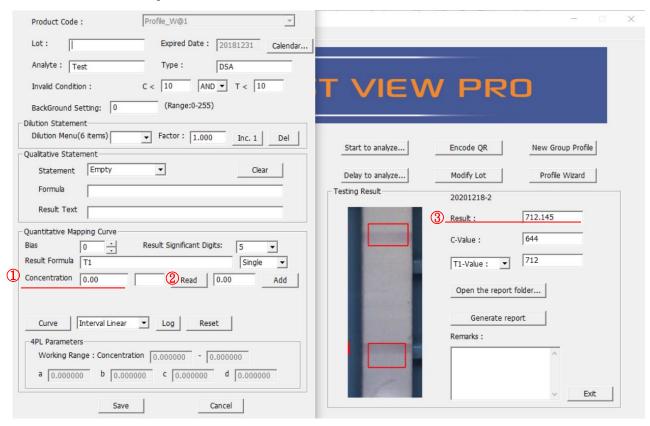
## Step. 1 Set basic information



Make sure the Product Code and each Lot information field are correct.

- 1 Click "Reset" button to remove old curve data before you perform a new curve creation.
- 2 Enter the desired "Result Formula".
- ③ Input the "unit" (for example, ppb or ng/ml....) of new values that will be calculated.

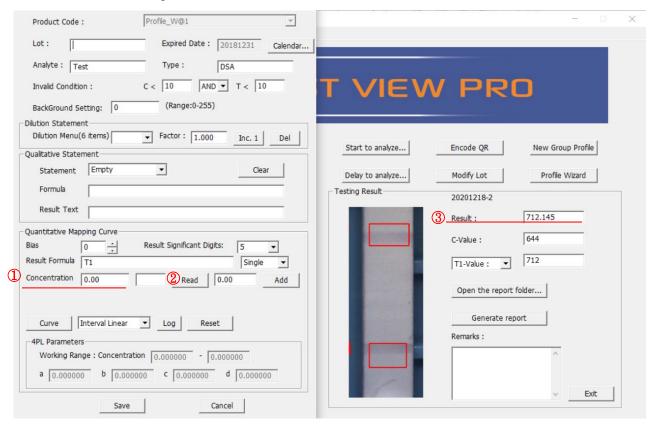
## Step. 2 Read the sample with same concentration value.



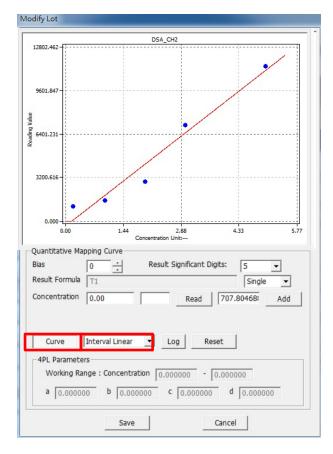
Move the Modify Lot dialog to the left like the picture shown above.

- 1 Input the concentration values. The concentration values should be corresponding to the samples you insert to Reader later.
- 2 Insert the standard test sample of the same concentration to Reader and click "Read" to read the value.
- 3 Check if the reading value and the result image are correct and confirm the Question Dialog.
- ④ Insert the next sample of the same concentration. Repeat the reading and check until all replicates are read and added to the plot.

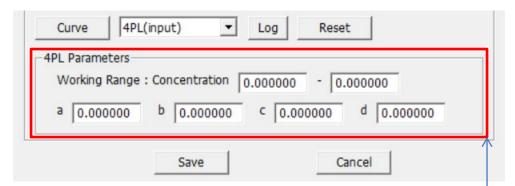
## Step. 3 Read the sample with next concentration value.



- 1 Input next concentration value
- 2 Insert the test sample of the same concentration to Reader and click "Read" to read the value.
- (3) Check if the reading value and the result image are correct and confirm the Question Dialog.
- ④ Insert next sample of the same concentration. Repeat the reading until all replicates are read and added. Repeat all these steps until standard strips of all concentrations are read and added to the plot.



#### 4PL(input)



Click the "Curve" button to show the standard curve you just created. You can select different curve fitting functions. There are 4 curve fitting functions.

- 1. Interval Linear Using interpolation function for curve fitting.
- 2. LinearReg. Using linear regression function for curve fitting.
- 3. 4PL Using 4 Parameter Logistic for curve fitting.
- 4. Quadratic—Quadratic curve Save your settings by click the "Save" button.

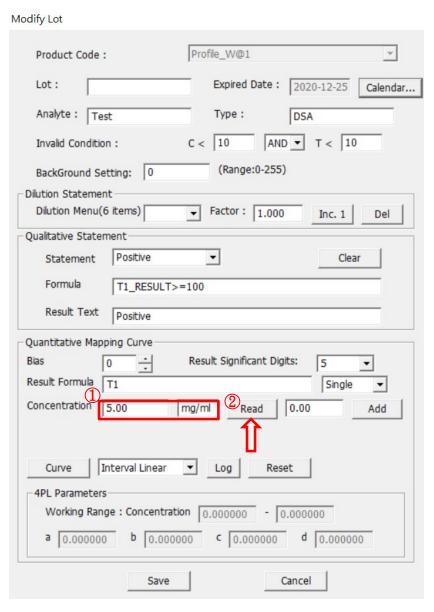
<sup>\*\*</sup> You can apply 4PL value calculated by other software. Select "4PL(input)" then input value in above column to create standard curve.

# Step. 5 Check

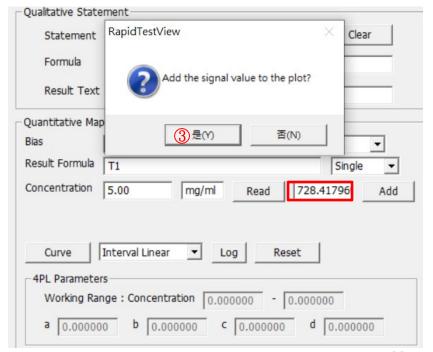
Check if the standard curve setting is OK.

- 1. Select the Product Code with the profile you saved.
- 2. Click "Start to analyze..." button to perform an analysis.
- 3. Check if the result image and the Selection Area of C and T are highlighted at right areas.
- 4. Check if the "Result" is corresponding to the test with a known concentration.

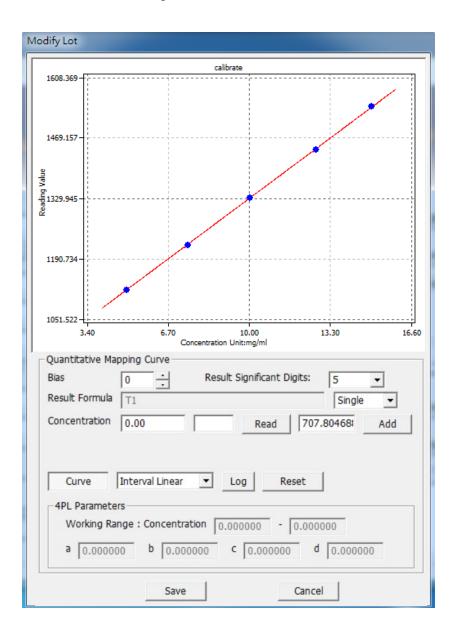
# Example to create standard curve (interval linear)



- ① In "Modify Lot", input the concentration of standard product including its unit. In this example, we took 5.00 mg/ml sample.
- ② Press "Read" next to the concentration column. The value for 5.00 mg/ml is approximately 728.41796.
- 3 Then press "YES" to add the value to the plot.



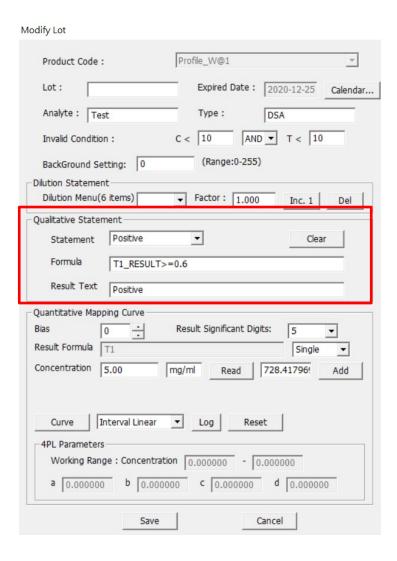
# Example to create standard curve (Interval Linear)



- Add as many values as you can to establish
  calibration curve, you will get higher precise
  curve for quantification purpose. In this example,
  we took 5.00, 7.50, 10.00, 12.50 and 15.00
  mg/ml as standard samples.
- Here "Interval Linear" is selected and press"Curve" that comes with a useful plot on this UI.
- You can save it for quantification purpose for the next sample capture.

# Advanced Tutorial: Creating Your First Test Profile

# Set up cut-off ranges



For qualitative and semi-quantitative measurements, you can use the "Result Statement Settings" to setup the cut-off range for each concentration threshold.

#### **Qualitative testing:**

For Positive/Negative testing,

Formula: Value > 0.6, Result Test: "Positive".

Formula: Value < = 0.6, Result Test: "Negative".

#### Semi-quantitative testing:

Formula: Value >0.6 -> Result Test: 0.6+".

Formula: 0.5<Value<0.6 -> Result Test: "0.5".

Formula: 0.4<Value<0.5, -> Result Test: "0.4".

The available KEY WORD of formula is listed in below.

C1 – The C1 Reading Value

T1 – The T1 Reading Value



T1\_CONCENTRATION -

The calculated T1 concentration value. [The value by interpolation against the standard curve] Supported Operation Symbols

Quantitative Mapping Curve

5.00

Result Formula

Concentration

Result Significant Digits:

Read

728.41796!

mg/ml

- = Equal, e.g. T1=0.5 means, if T1 equals 0.5 the statement return TRUE.
- < Less, e.g. T1\_RESULT<0.1 means, if T1\_RESULT less than 0.1 the statement is TRUE.
- > Above, e.g. T1>0.5 means, if T1 above 0.5 the statement return TRUE.
- <= Equal or Less
- >= Equal or Above
- & AND, e.g. C1>500 & T1>1000
- && Same as '&'
- OR, e.g. T1>10 | T1=10 [Same as T1>=10]
- || Same as '|'

#### A simple example

When we want

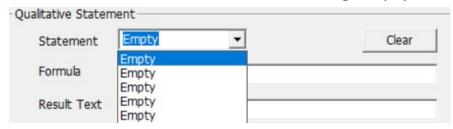
T1 > 100, The result field shows "Positive".

T1 < 50 , The result field shows "Negative".

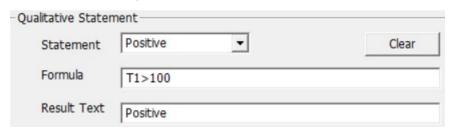
T1 between 100 and 50, The result field shows "Retest".

Please follow steps below to enter your statements.

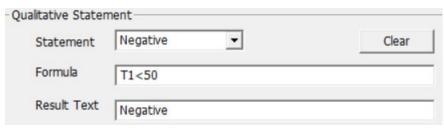
1. Make sure all Statements are showing Empty like below.



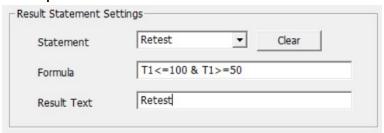
 Choose first "Empty" statement, in Formula Field input "T1>100". And in Result Text Field input "Positive" like below. (The Text Statement will display exactly the same Text as the "Result Test")



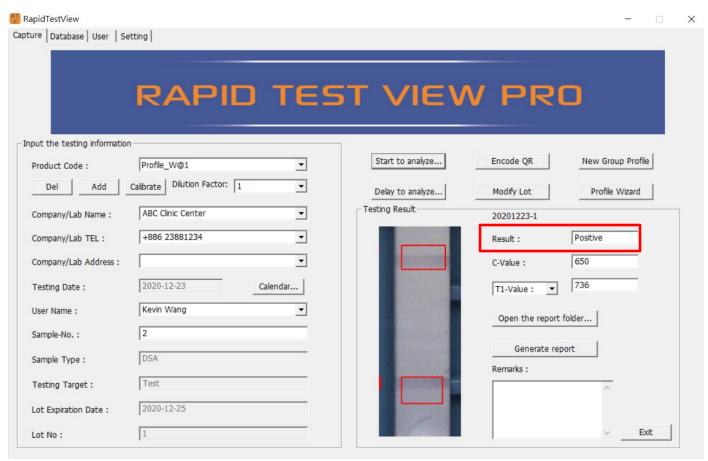
3. Choose next "Empty" Statement and complete the input like below.



4. Complete the last statement



5. Click "Save" to save the settings. And back to main screen. Click the "Start to Analyze" Make sure the Result Field shows the correct result.



# Important things when setting up cut-off statements

Please set the cut-off ranges to cover all ranges the test values would be in.

#### Bad example 1:

Statement 1: T1>50, Positive

Statement 2: T1<50, Negative

Problem: When T1 value is 50 exact, program will return ERROR. It is because software cannot find a suitable range to report this value.

#### Correction,

Statement 1: T1>=50, Positive

Statement 2: T1<50, Negative

The final cut-off ranges should be adjusted based on your further validation using more standard strips or actual sample strips before its release. Different lots of a same test might be manufactured slightly differently. It's always a good practice to generate new standard curve and set up new cut-off ranges for the new lots of a test.

# **Contact Information**

For more information or any question, please contact:

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