User's Manual

RapidScan Reader
Rapid Test View Pro Software

Pacific Image Electronics

Based on RTV1.15_build0347

Content

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.

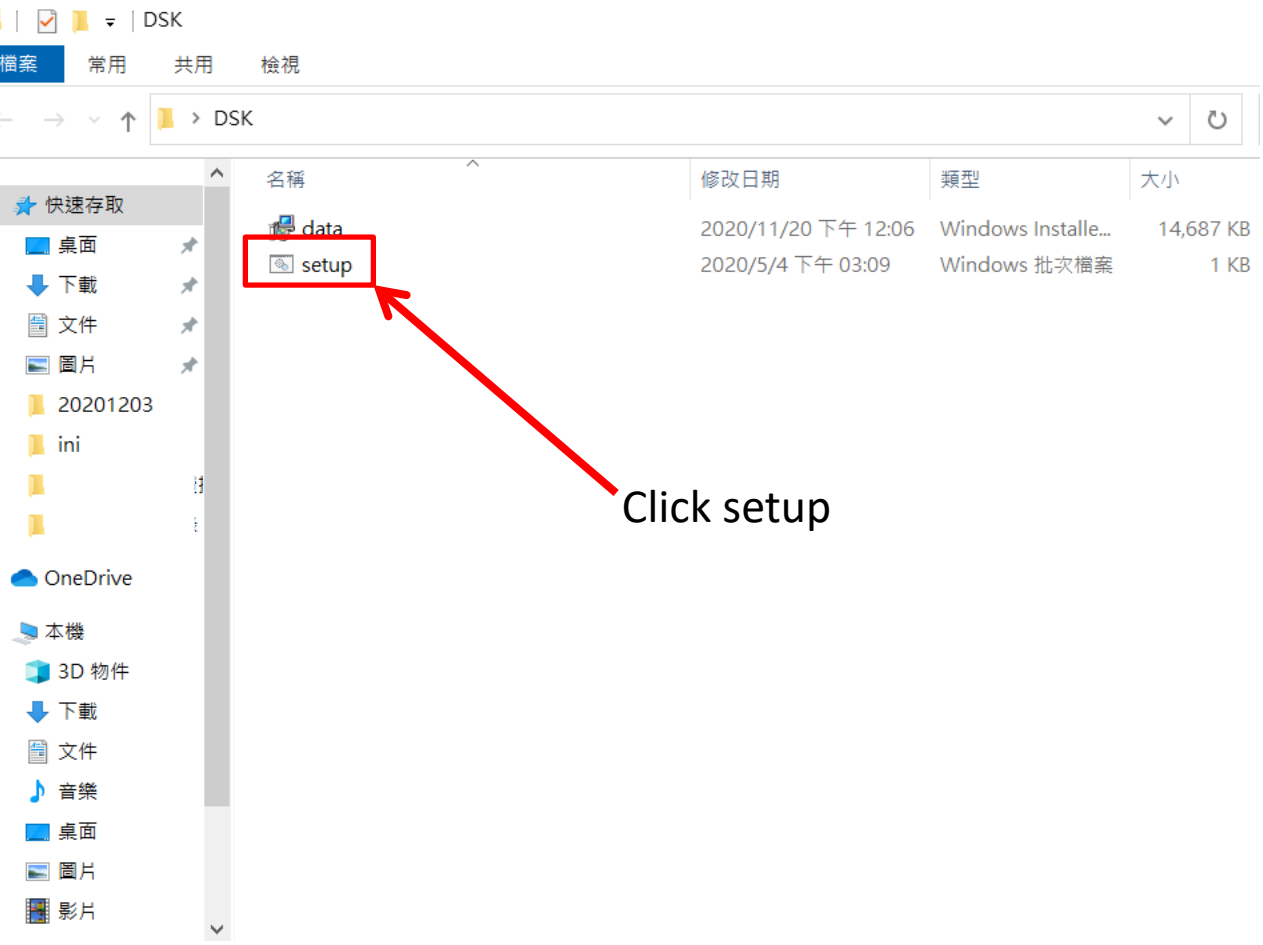
This is not the version of our RapidTestReader Basic which we provide for free to end-users. The RapidTestReader Pro is not a freeware and needs a license with a fee to use it.

Product package contents:

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

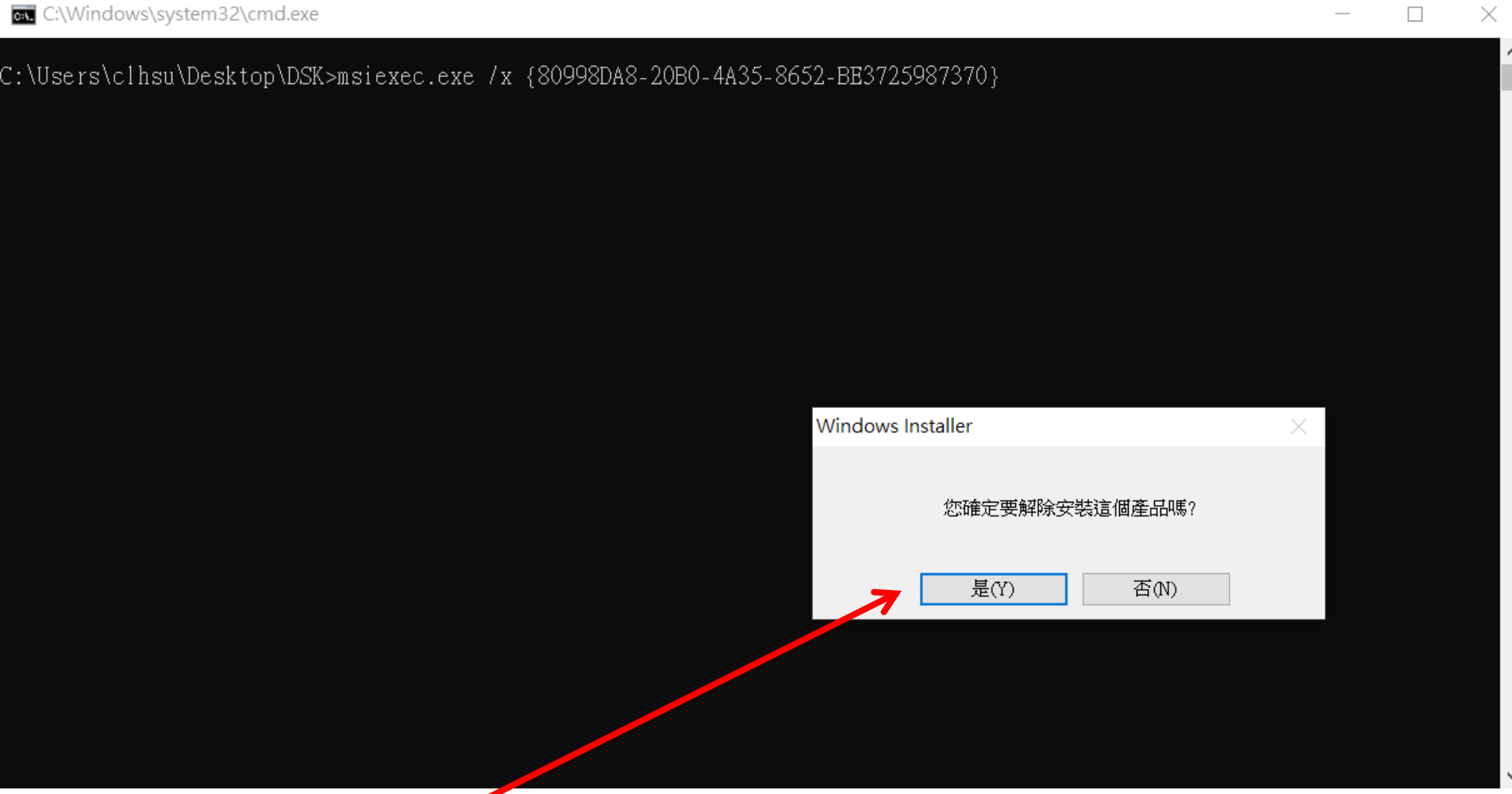
Reader Specifications	
Image Sensor	CMOS
Light Source	Single light model: White light Dual light model: White light + UV
Scanning Media	Rapid test, signal in colorimetric or fluorescent format
Interface	USB 2.0 ONLY (USB 1.1 not supported)
Application Software	Rapid Test View Pro w/ License Key
Supported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

Software Installation

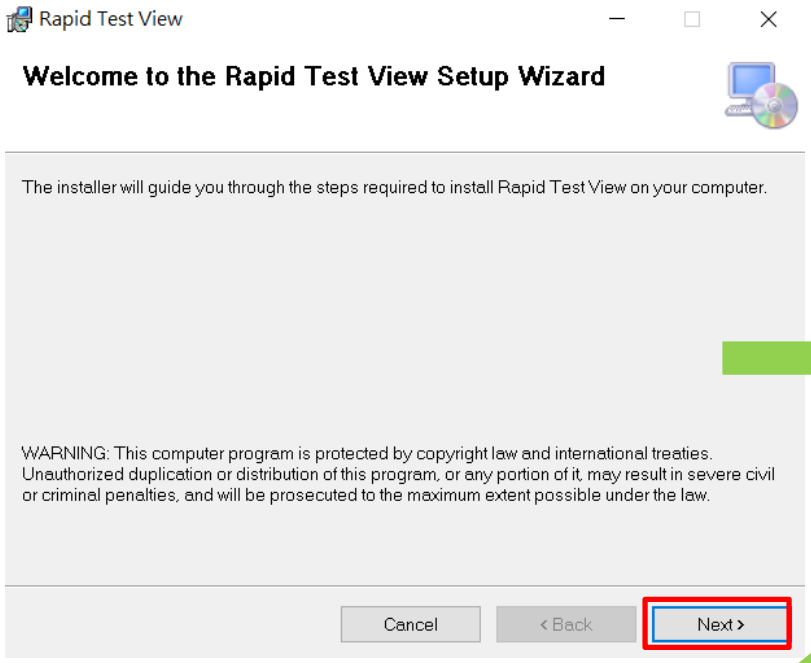


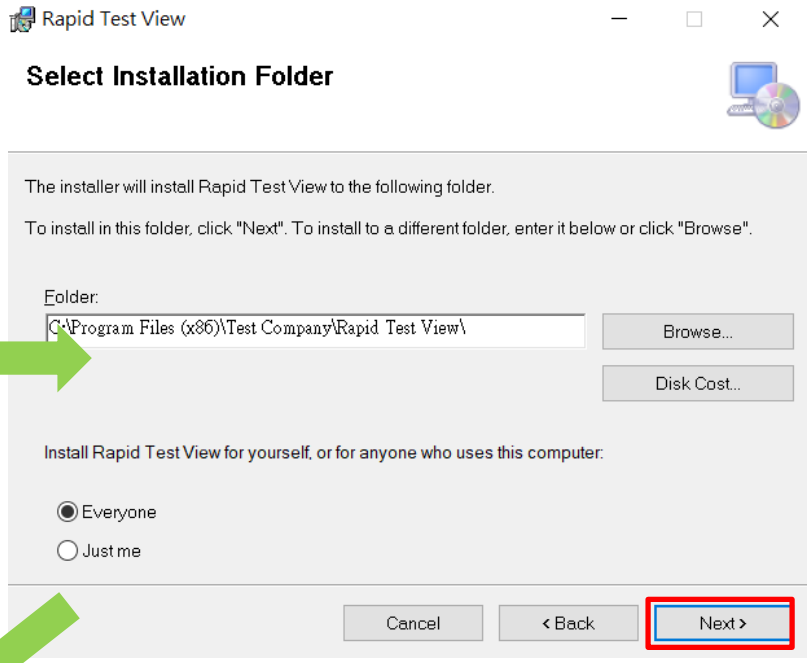
Find the "Setup" file on the provided CD or installation file from supplier. Double click to initiate the software installation.

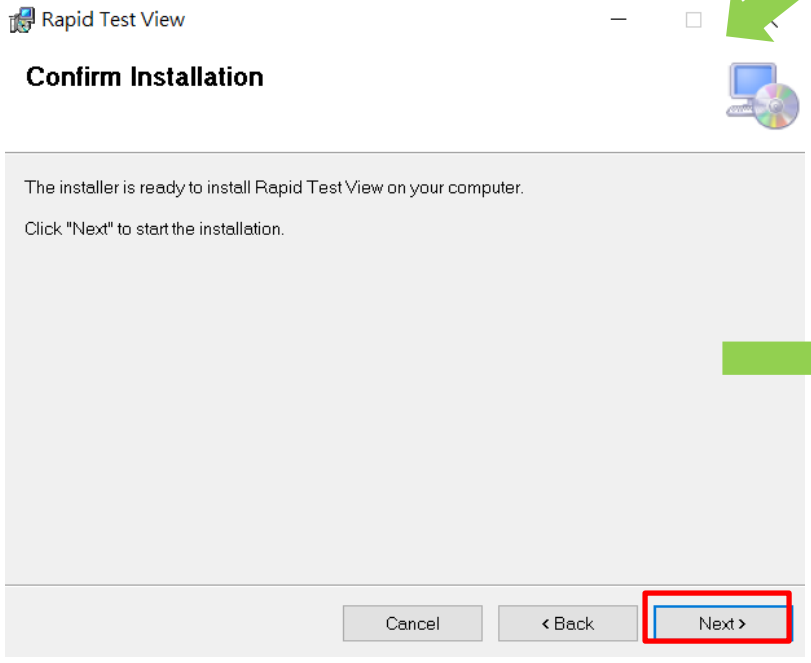
If the installation is successful, the App icon (see below) will appear on your computer desktop.

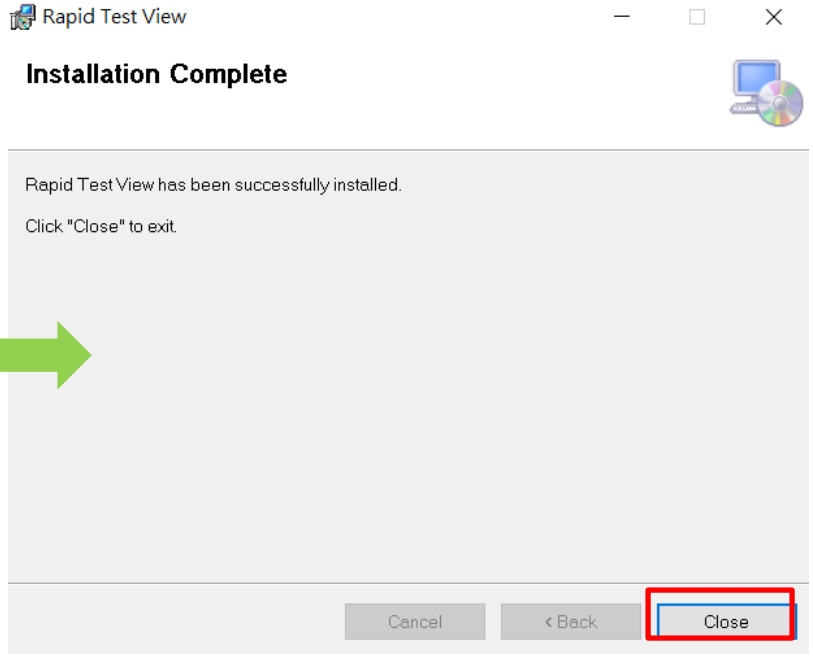


After initiating the setup installer, you would see a dialog saying: Are you sure to uninstall this product? Just click “Yes” no matter what.


Rapid Test View
Welcome to the Rapid Test View Setup Wizard
The installer will guide you through the steps required to install Rapid Test View on your computer.
WARNING: This computer program is protected by copyright law and international treaties. Unauthorized duplication or distribution of this program, or any portion of it, may result in severe civil or criminal penalties, and will be prosecuted to the maximum extent possible under the law.
Cancel
< Back
Next >


Rapid Test View
Select Installation Folder
The installer will install Rapid Test View to the following folder.
To install in this folder, click "Next". To install to a different folder, enter it below or click "Browse".
Folder:
C:\Program Files (x86)\Test Company\Rapid Test View\
Browse...
Disk Cost...
Install Rapid Test View for yourself, or for anyone who uses this computer:
Everyone
Just me
Cancel
< Back
Next >

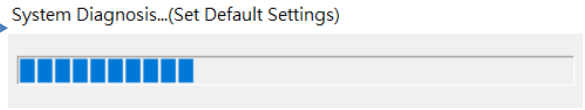

Rapid Test View
Confirm Installation
The installer is ready to install Rapid Test View on your computer.
Click "Next" to start the installation.
Cancel
< Back
Next >


Rapid Test View
Installation Complete
Rapid Test View has been successfully installed.
Click "Close" to exit.
Cancel
< Back
Close

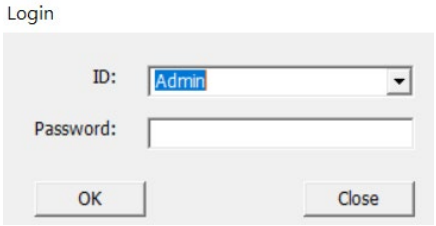
Open Rapid Test View

- 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.



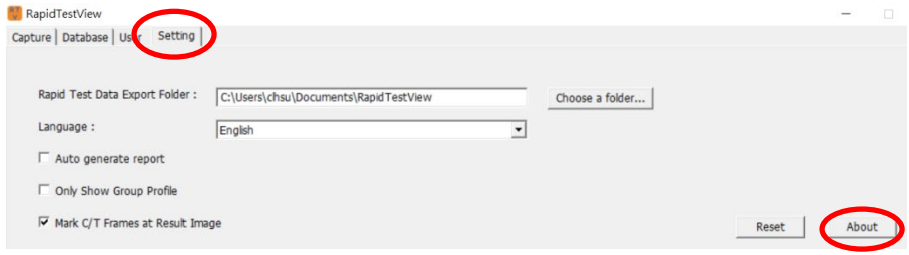
- Once it passes the system diagnosis, the log in window will appear. Please contact supplier to obtain ID & Password.
  For user authority management please refer to p68 User Management

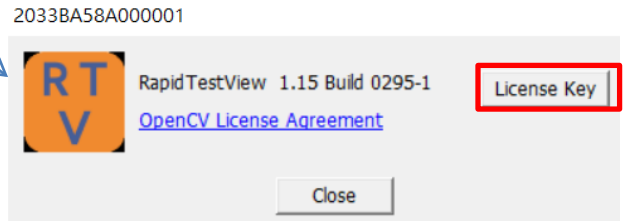


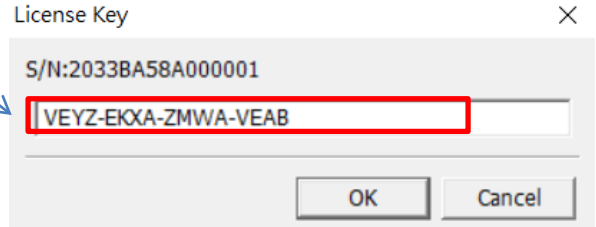
- After successfully log in, UI default page will appear.

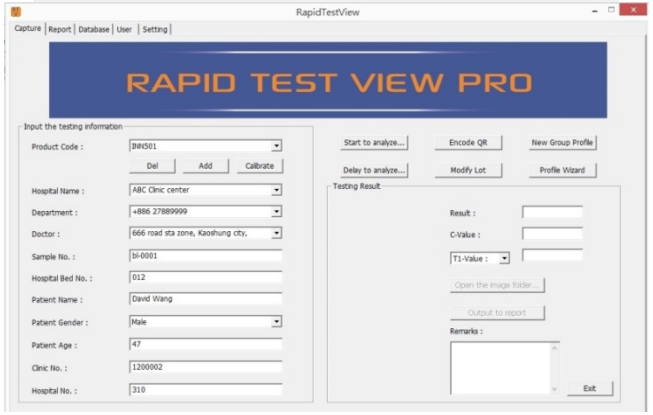
Enable PRO version via license key

- Go to “Setting” and click “About”
- You will see right message, click “License Key” icon
- Key in license key obtained from supplier and press OK
- Exit the software and open it again.
- You will see it becomes PRO version.



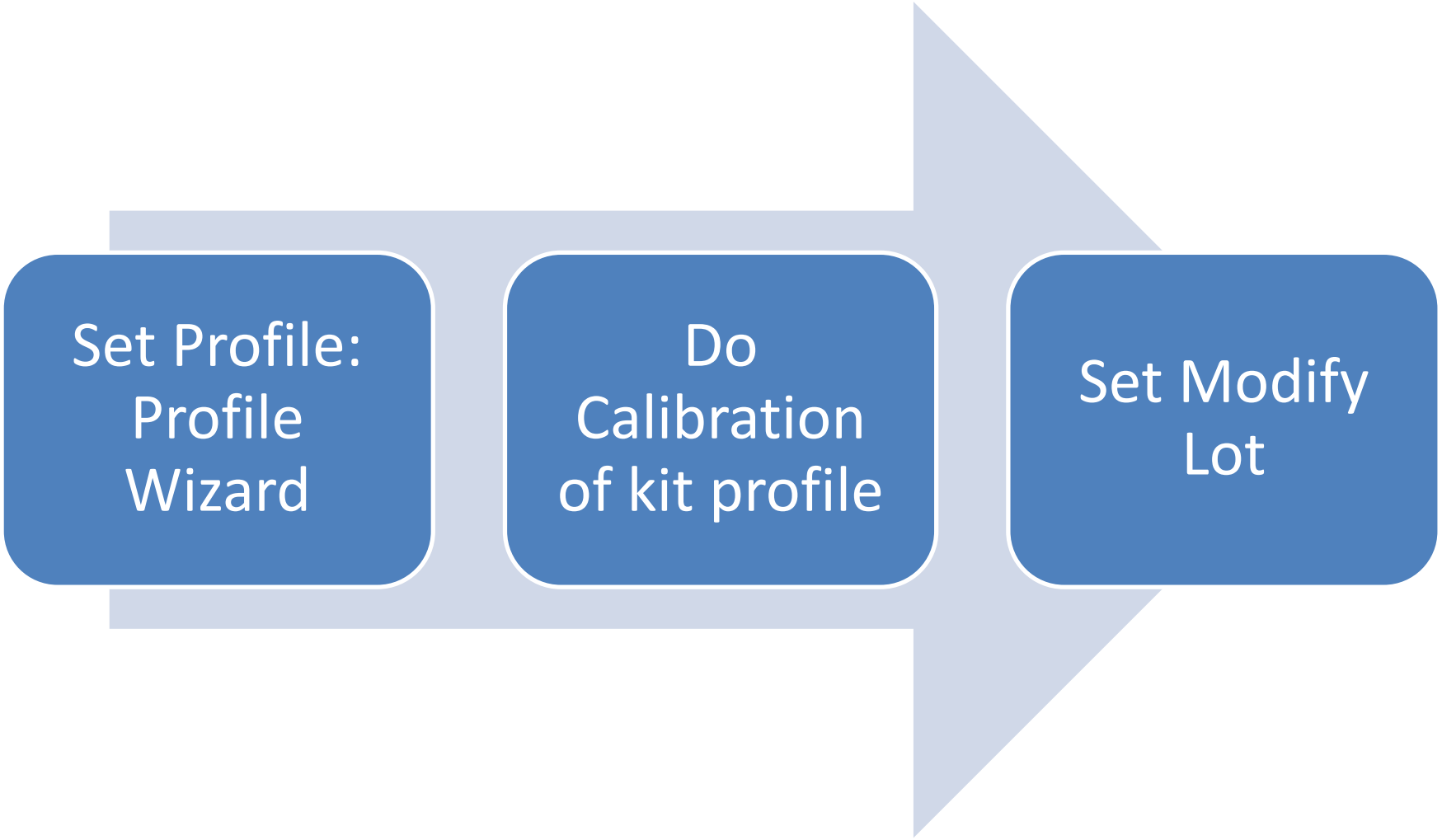






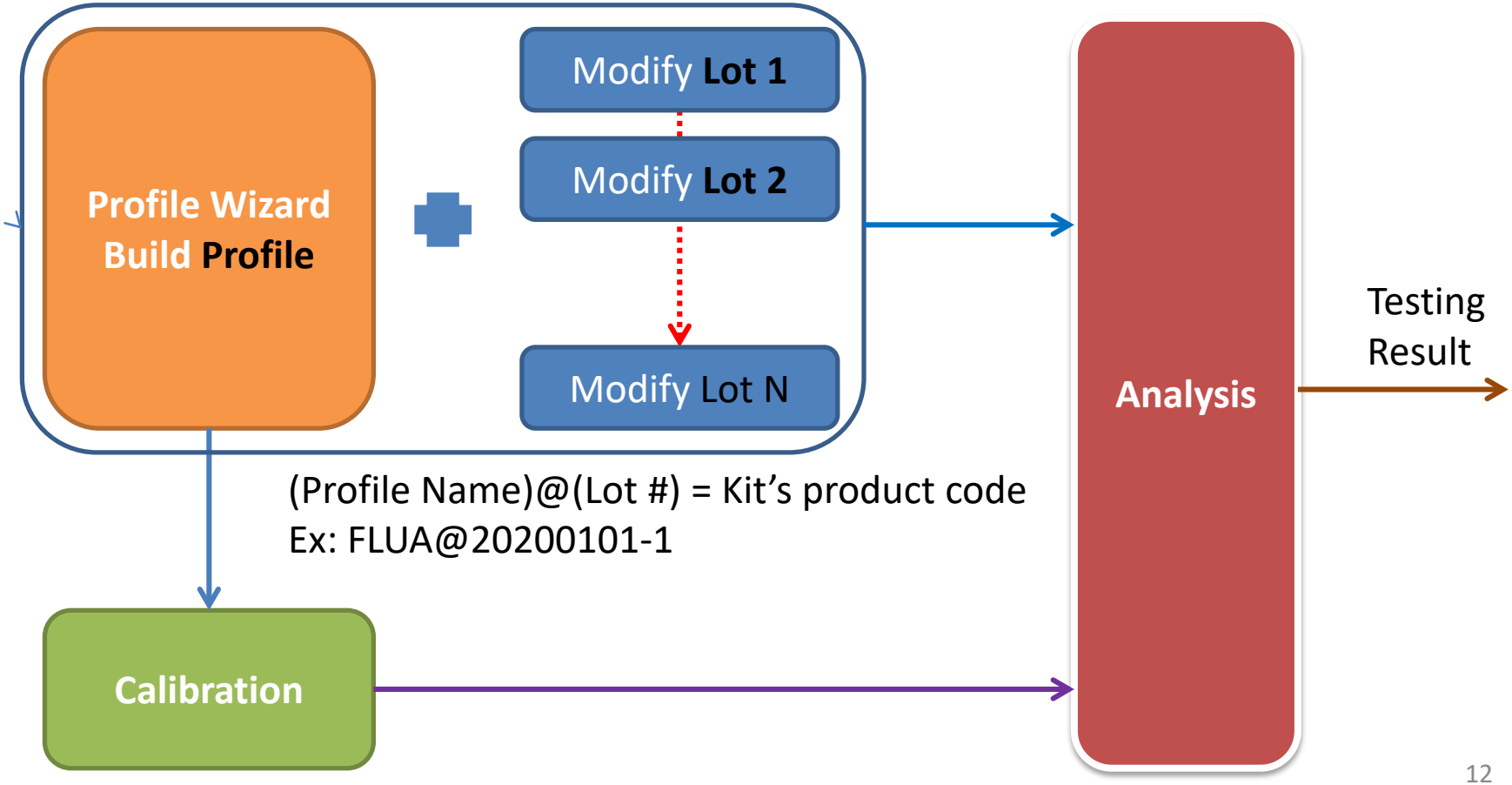
How to establish your 1st test Kit via software

3 Procedures



Profile + Lot Info. → Analysis

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



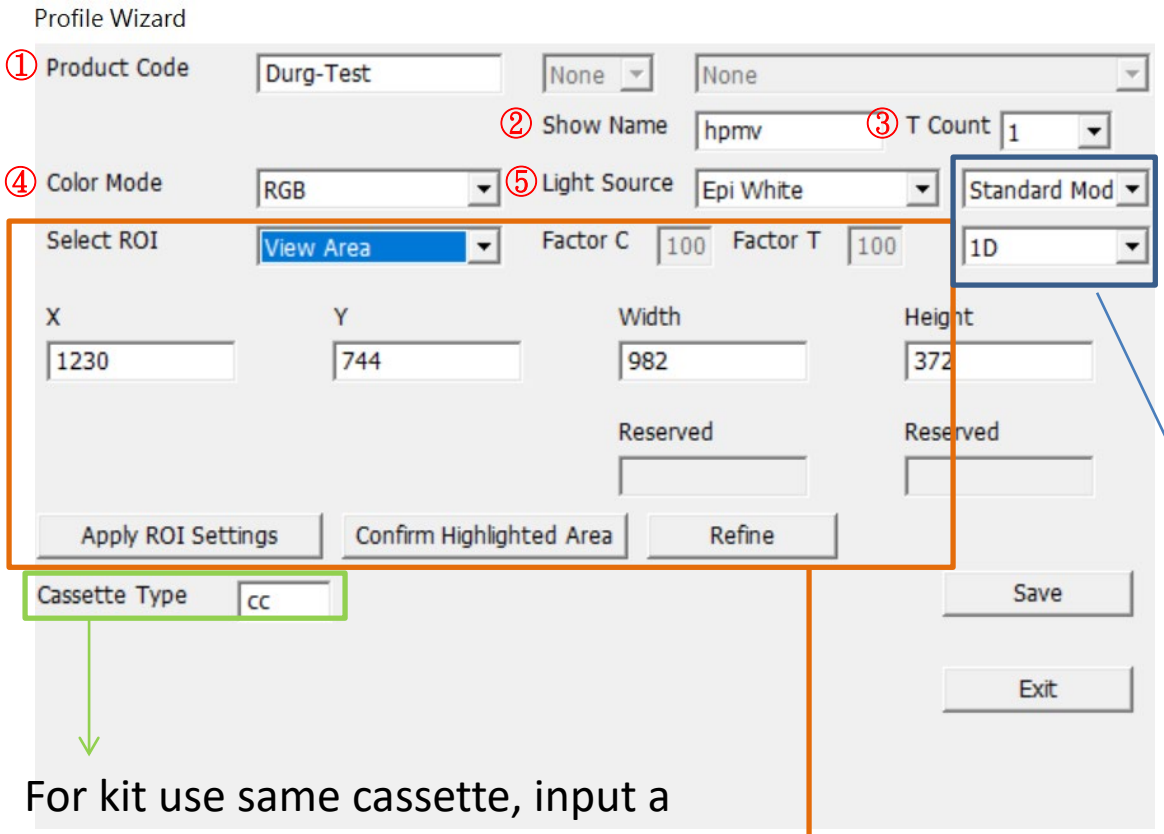
A Completed Kit Building

- **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



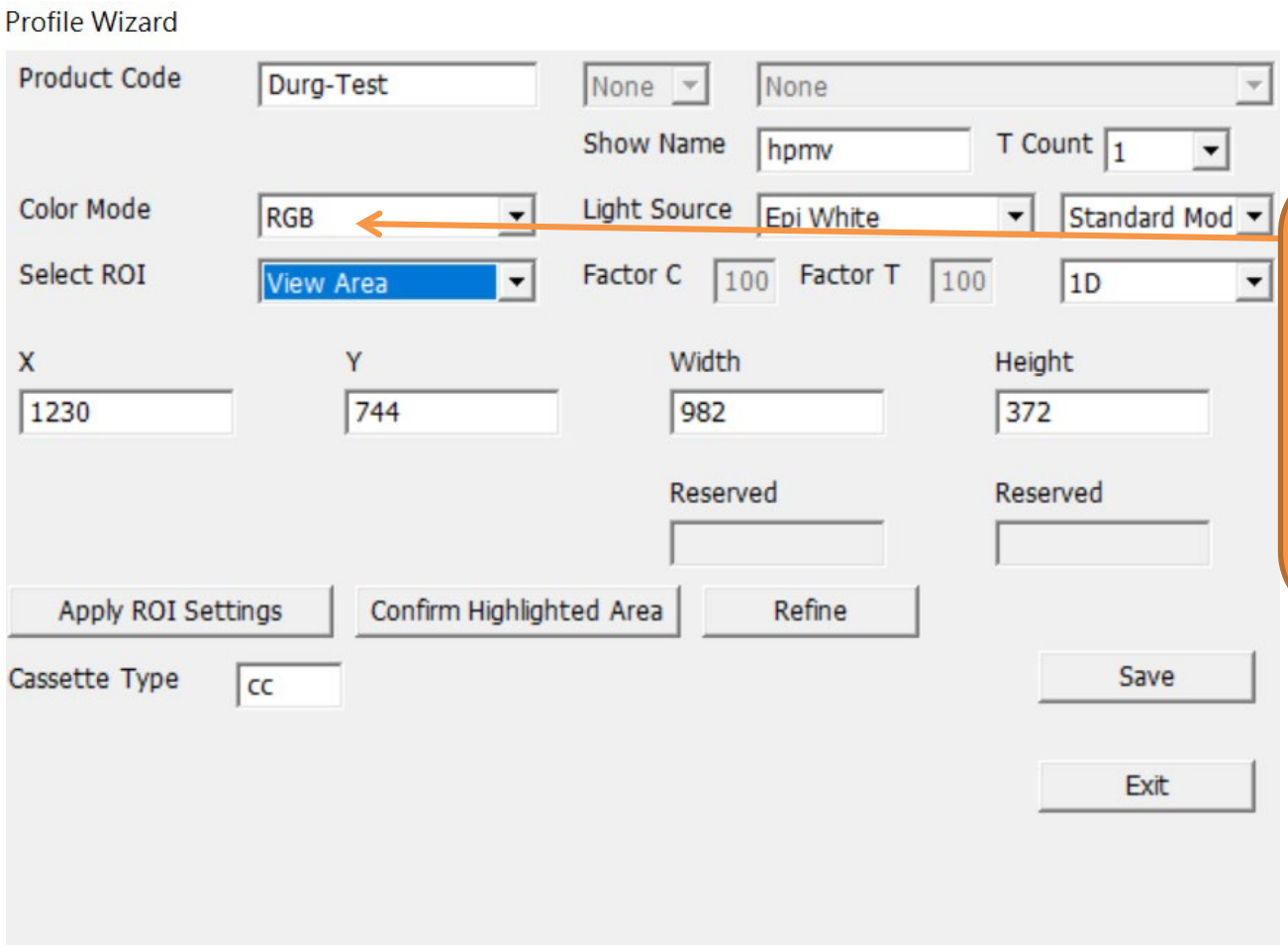
For kit use same cassette, input a code so you can save calibration effort on same cassette type of kit

Please refer to Step 2 & 3.

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

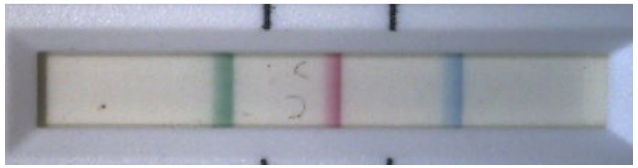
Image method & Integration method. Please refer to page 17-21.

Color Mode setting



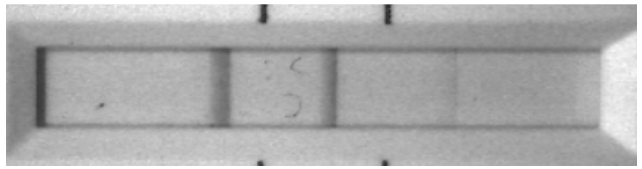
User can select RGB/RRR /GGG/BBB different mode to get optimized value

R/G/B Band Selection

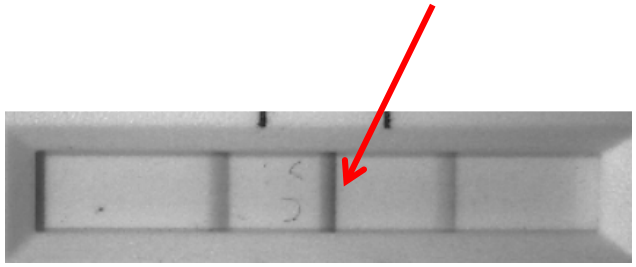


1. Besides colloidal gold, there are colored nano-bead available for lateral flow assay development as well. So C&T line can be presented by different colors.
2. RapidScan provides 4 types of image spectrum setting:
   RGB: Color mode
   RRR: Red channel spectrum only
   GGG: Green channel spectrum only
   BBB: Blue channel spectrum only
3. 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.

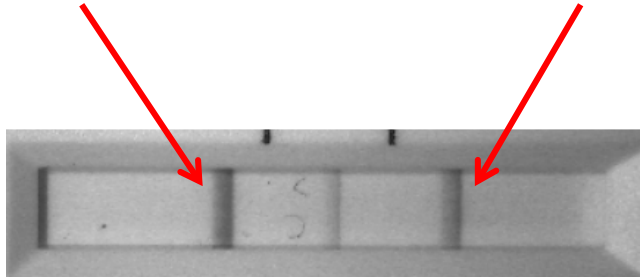
BBB



GGG

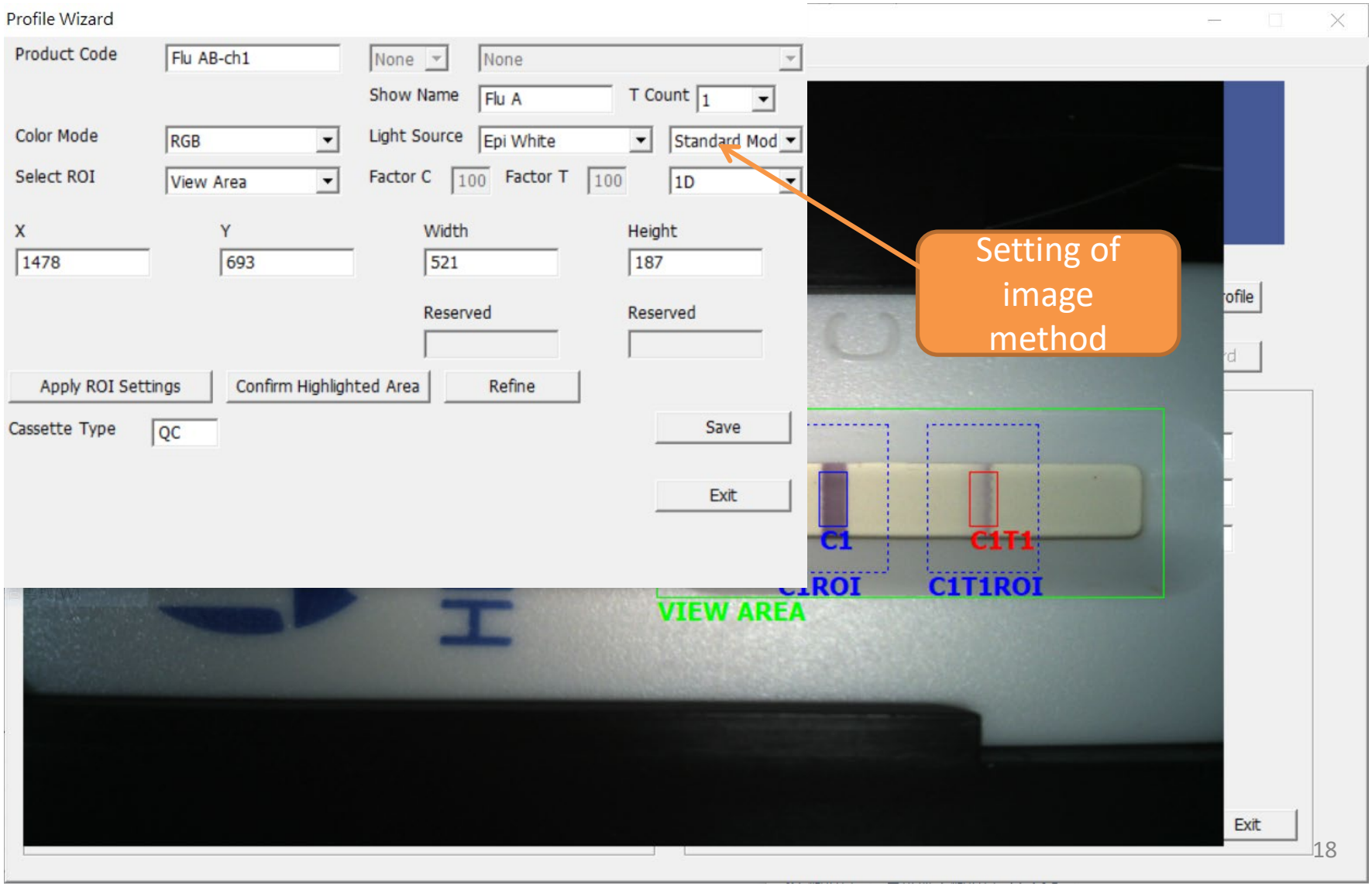


RRR

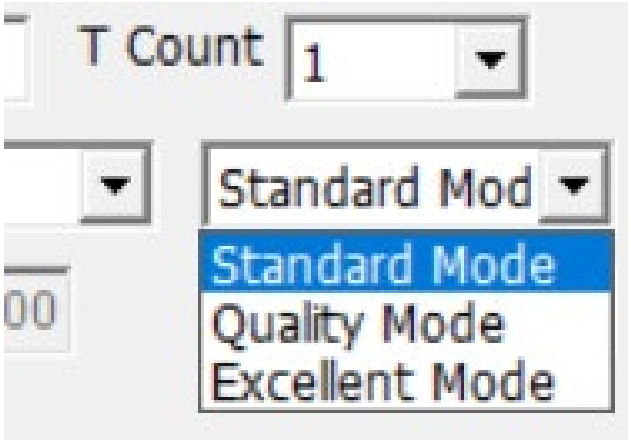


CH \ Bar	Green	Red	Blue
BBB	1401	1059	162
GGG	1192	1448	710
RRR	1930	545	1148
RGB	1352	1243	615
RGB/Max	70.1%	85.8%	53.6%

Image Method: STD/Quality/Excellent

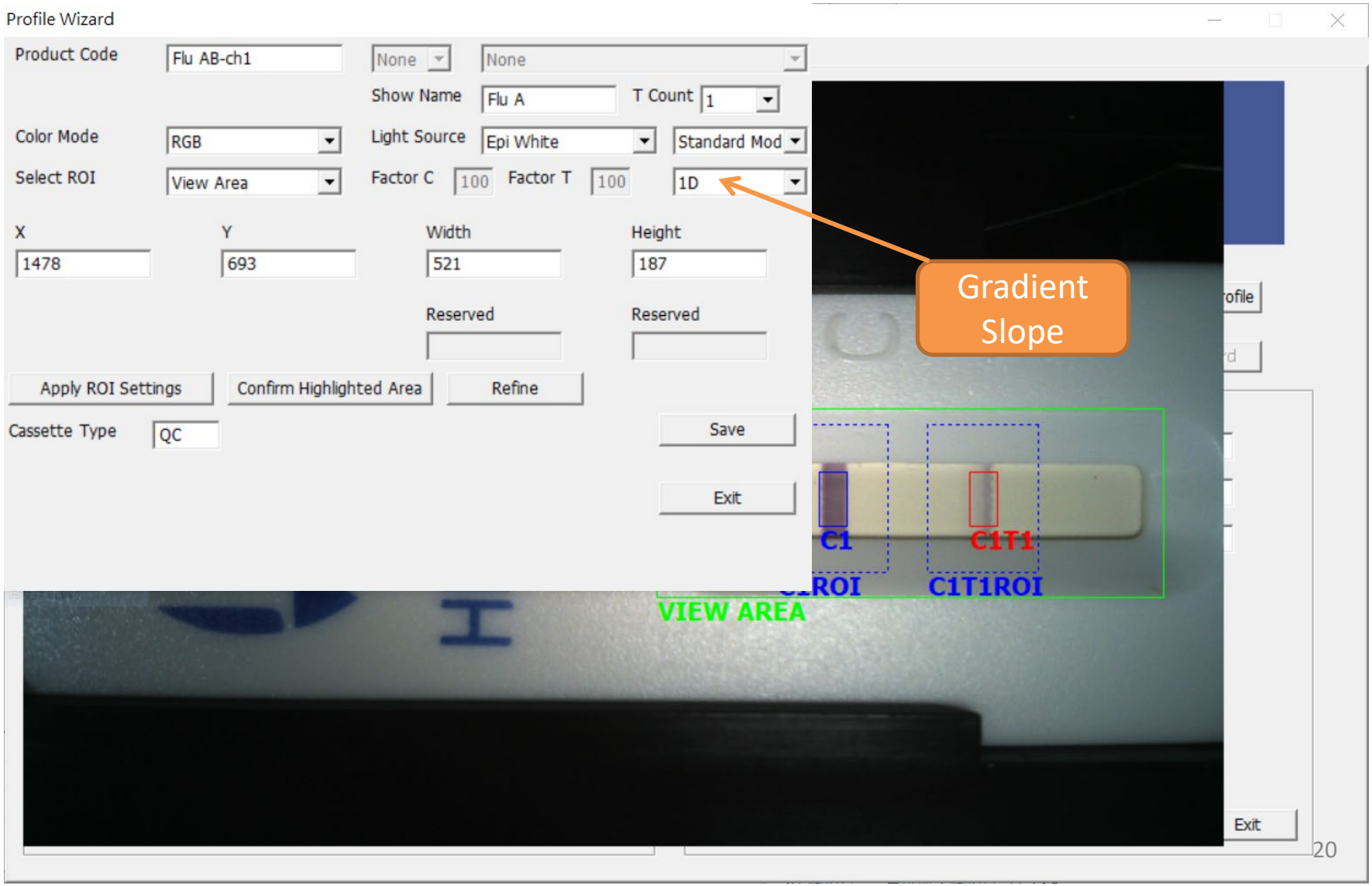


Standard Mode: **Fastest speed**, highest CV
Quality Mode: Medium speed & CV (Recommended)
Excellent Mode: Slowest speed, **smallest CV**

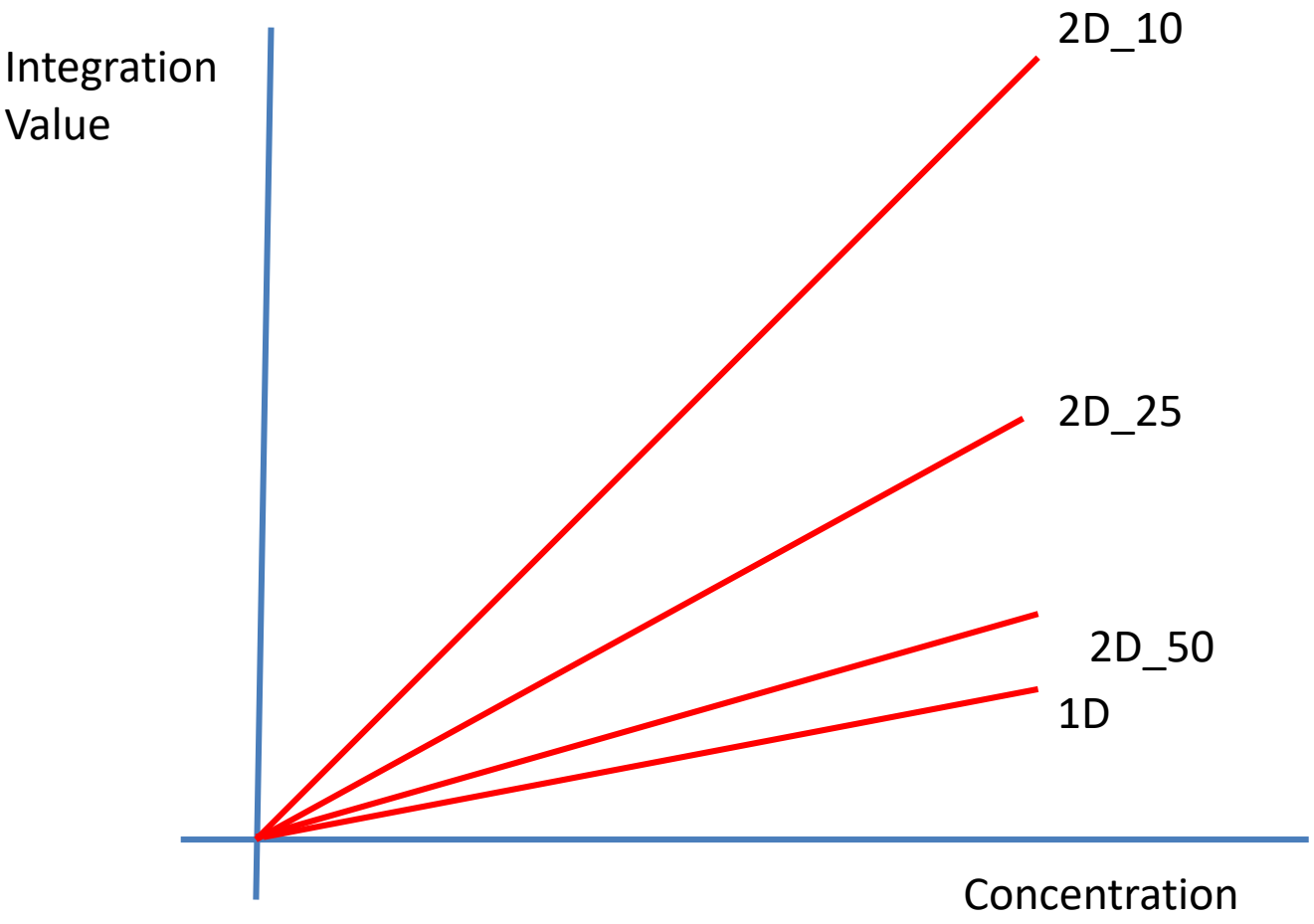


Quality Mode	C	T1	Item	C	T
Standard	1329	240	Ave	1329.6	245.4
Standard	1327	240	CV%	0.29%	2.67%
Standard	1325	256	Speed	9"	
Standard	1333	246			
Standard	1334	245			
Quality	1328	237	Ave	1332.4	243
Quality	1332	243	CV%	0.27%	1.45%
Quality	1338	246	Speed	12.5"	
Quality	1333	245			
Quality	1331	244			
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

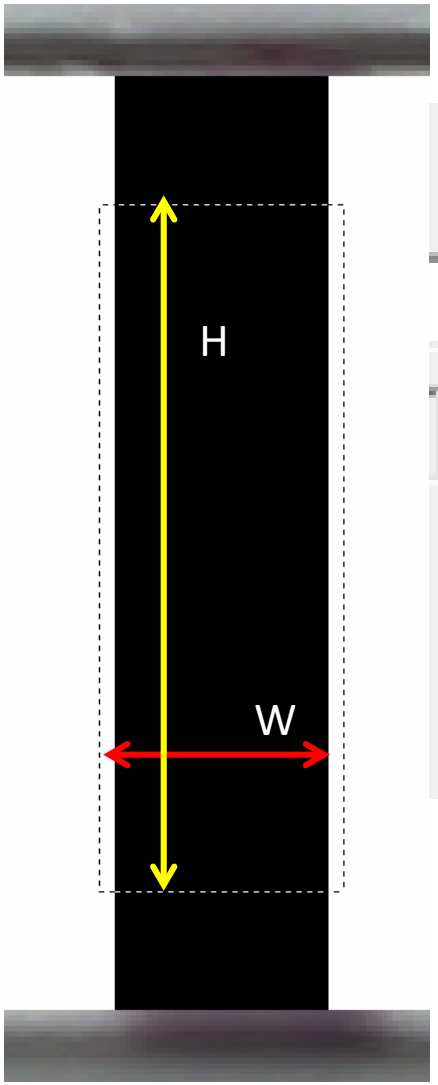


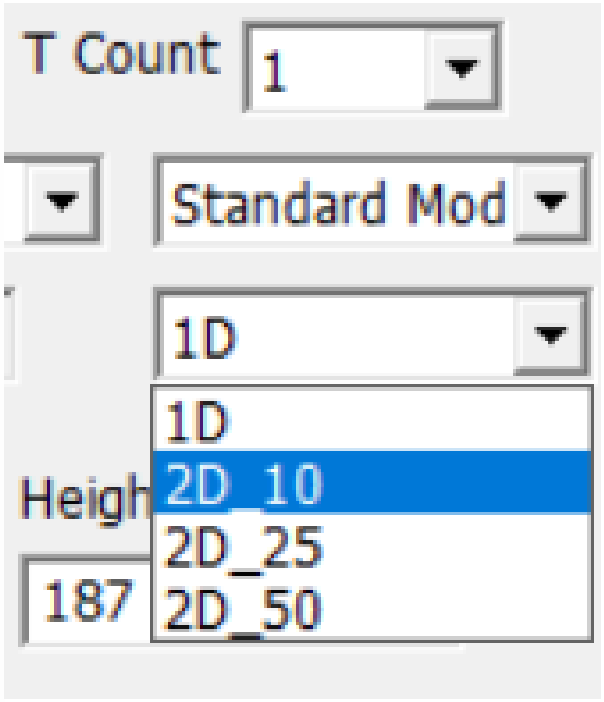
30 x 70 (WxH) Case



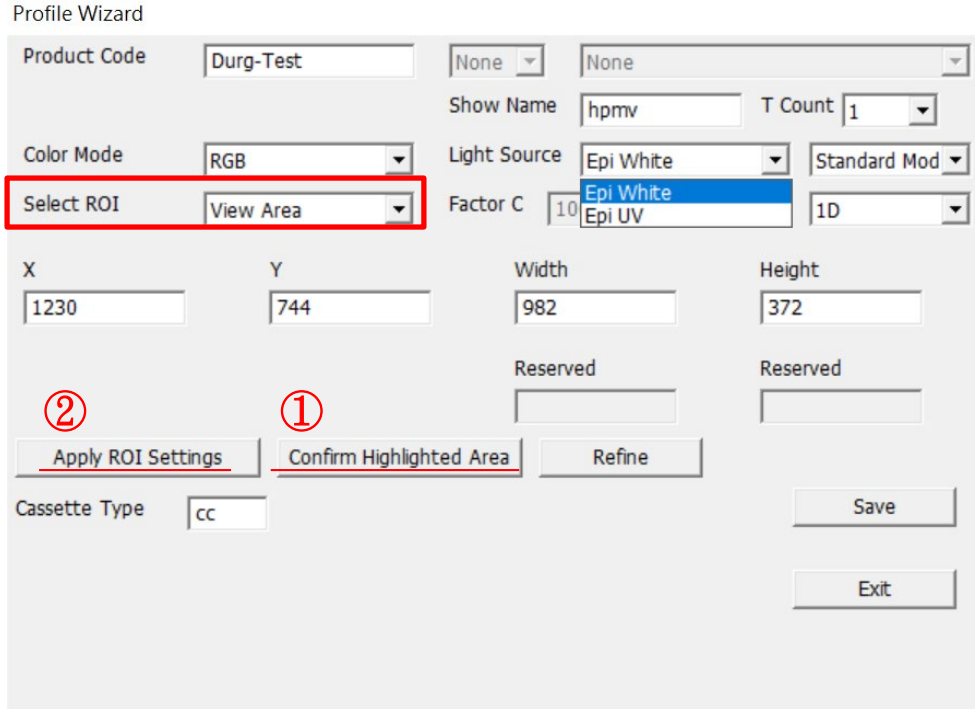
Integration Method

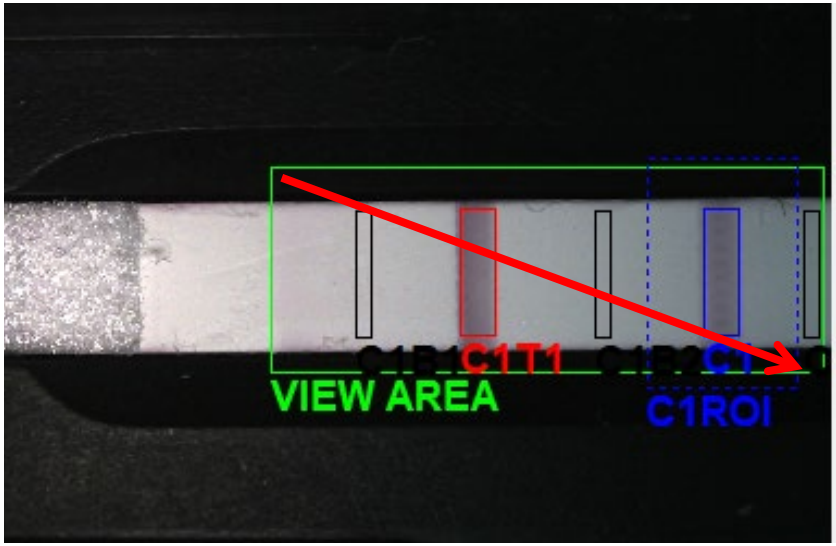
- **1D**: Average each H and sum all W
- **2D** : Sum all H x W pixels value = V_{2D}
  - 2D_10 = $V_{2D}/10$
  - 2d_25 = $V_{2D}/25$
  - 2d_50 = $V_{2D}/50$
- Value big → Slop higher → Noise high





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



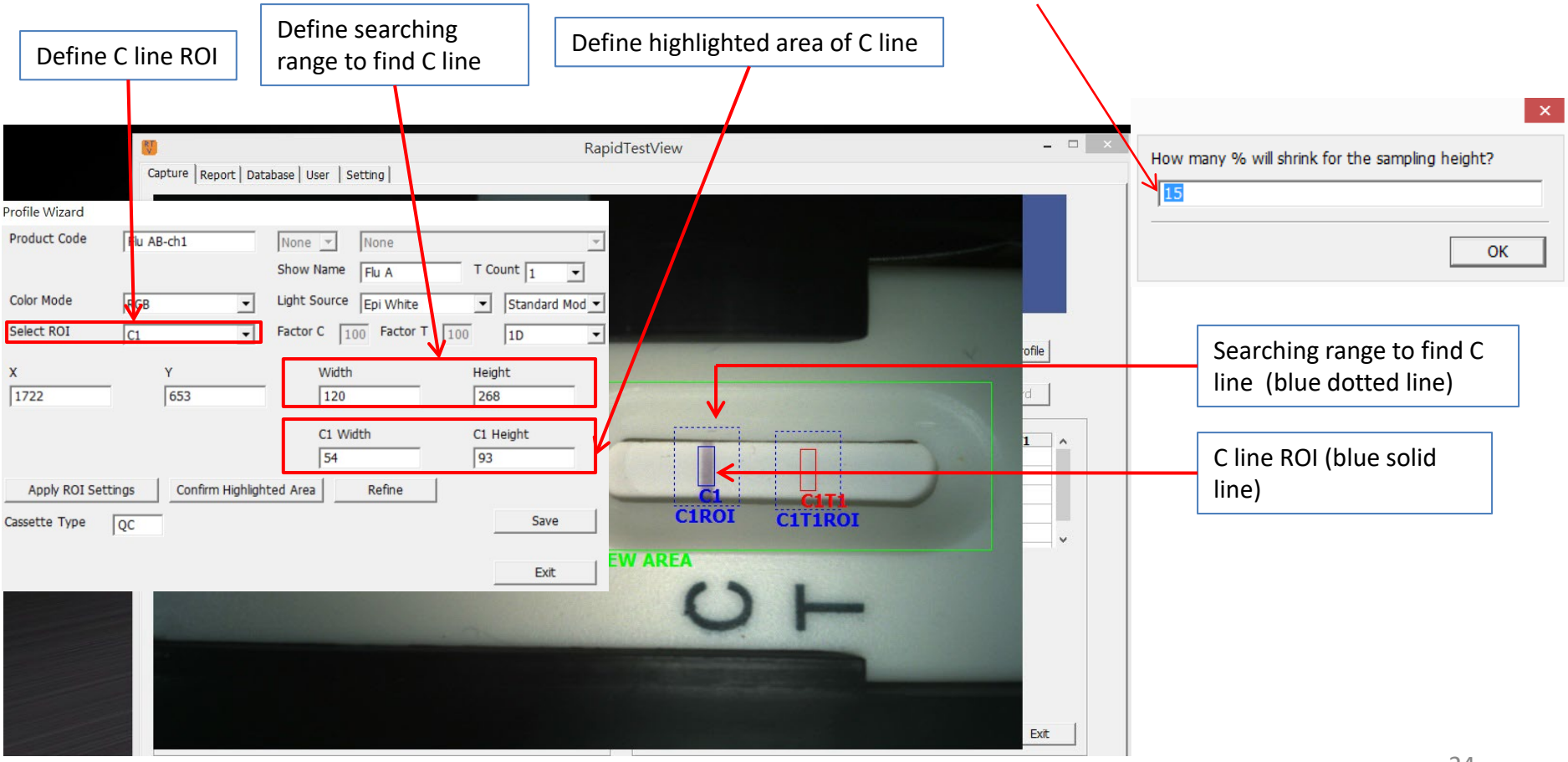


In order to highlight the viewing area, drag mouse from the top of left to the bottom of right corner. Recommend to highlight the area as close to the edges as possible. **Remember to click"① Confirm Highlighted Area" to confirm setting**.

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. **<u>15-20 is recommended</u>**.

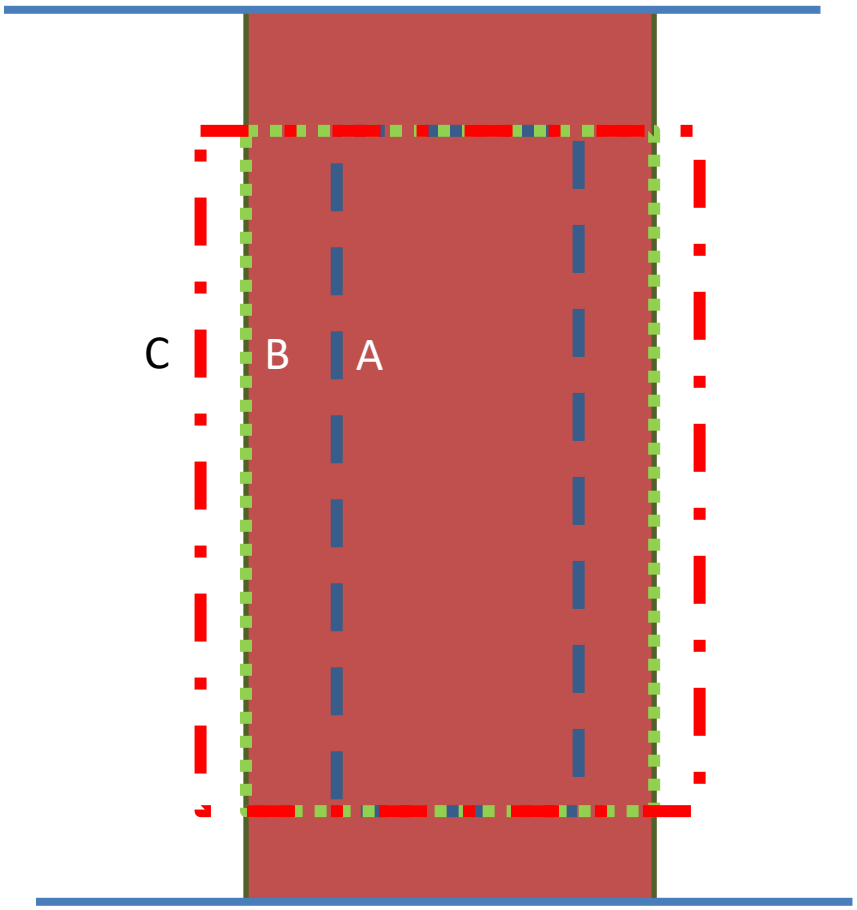


Tips for optimized setting of

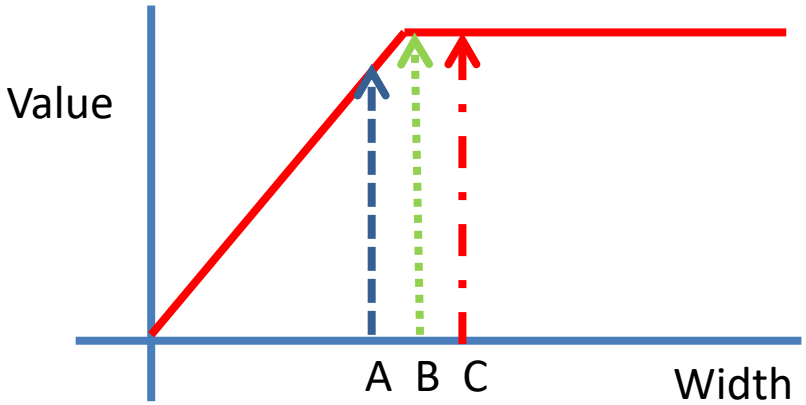
Search area

C, T line area

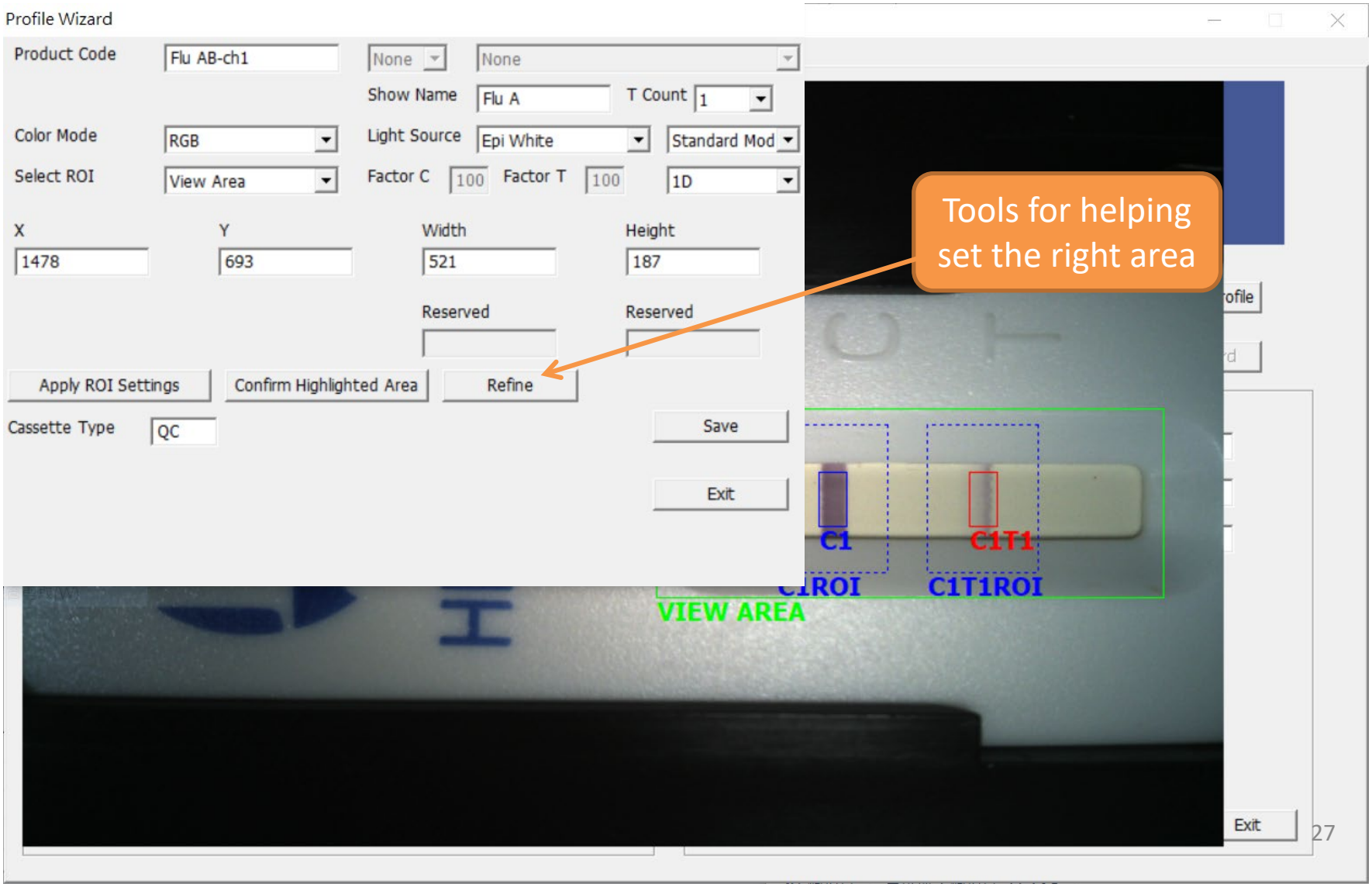
Tips for setting C, T Line area



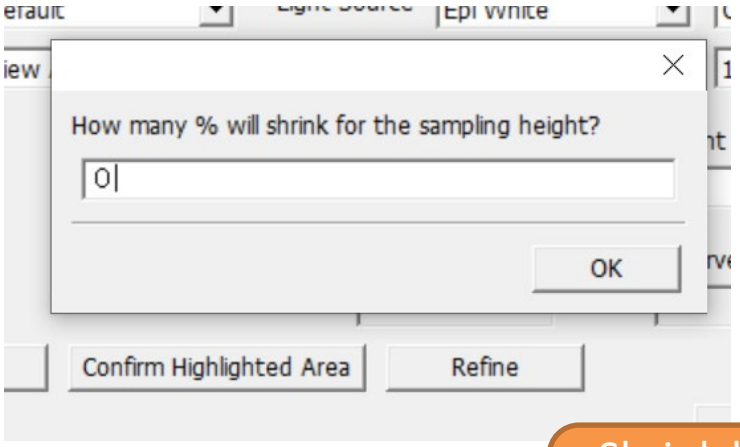
- Width (according to your application's needs)
  - "A" doesn't cover all, may suitable for some line bar check, but it's not recommended.
  - "B" is ideal but not so easy to fit.
  - "C" is the most recommended.
- Height :
  - Shrink 15 ~20%
  - Near the edge of window has some abnormal shadow or reflection.

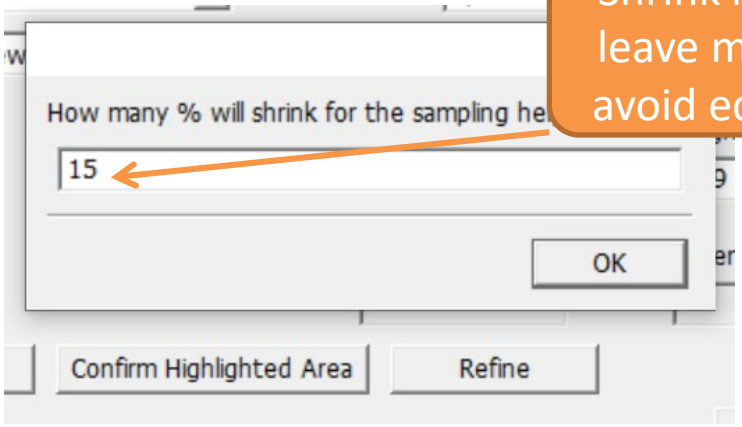


Tips: Using “Refine” to set suitable CT Line area



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

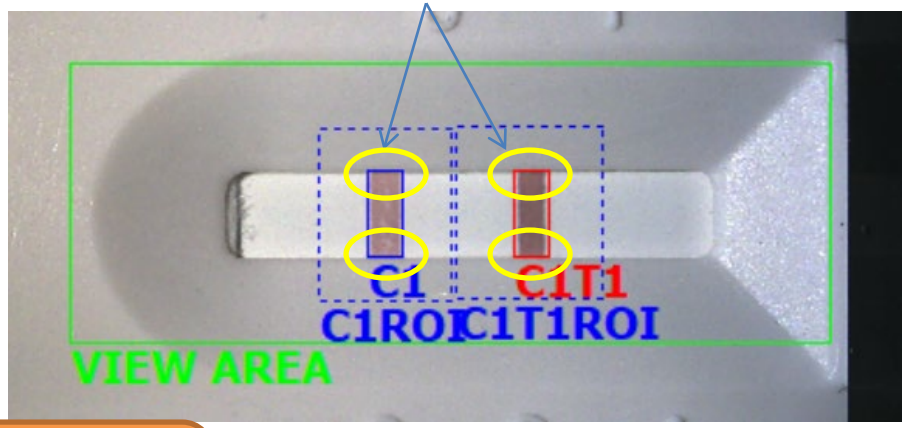




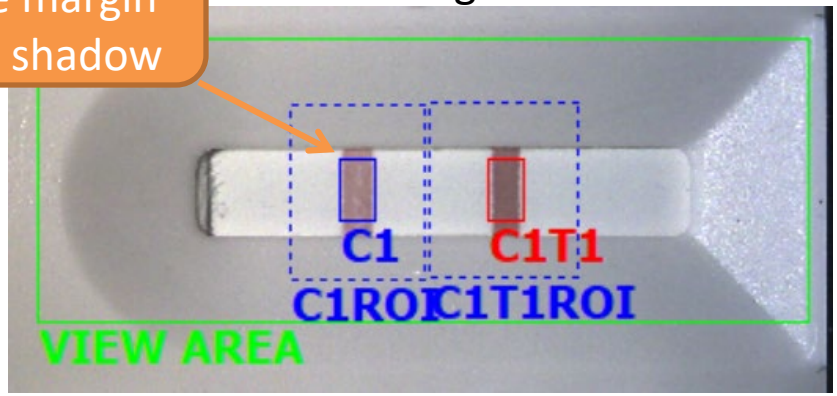
Shrink height 15%, leave more margin avoid edge shadow

※ 15-20 shrink % is recommended.

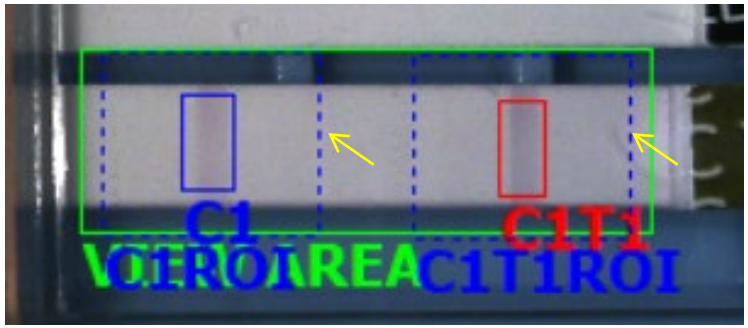
The shadow of the edge of the strip might interfere the result.



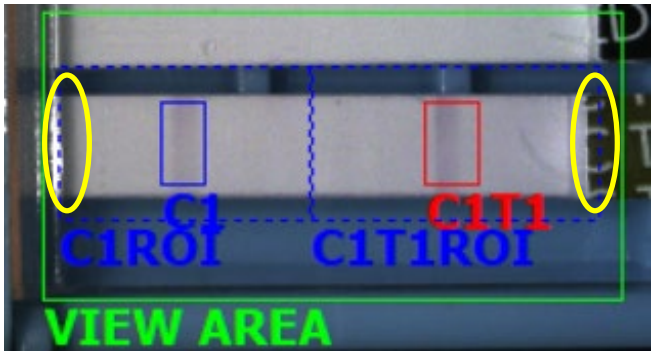
Ideal settings



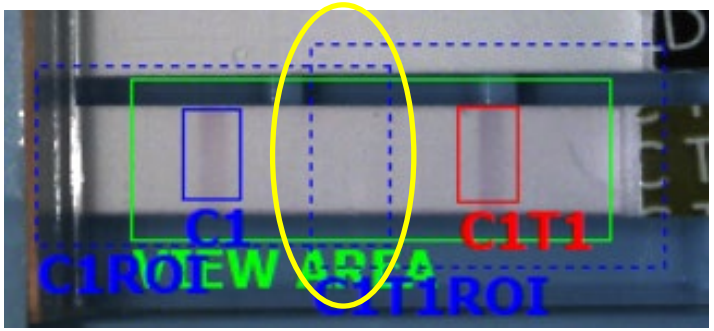
Definitions about good & bad search areas



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.

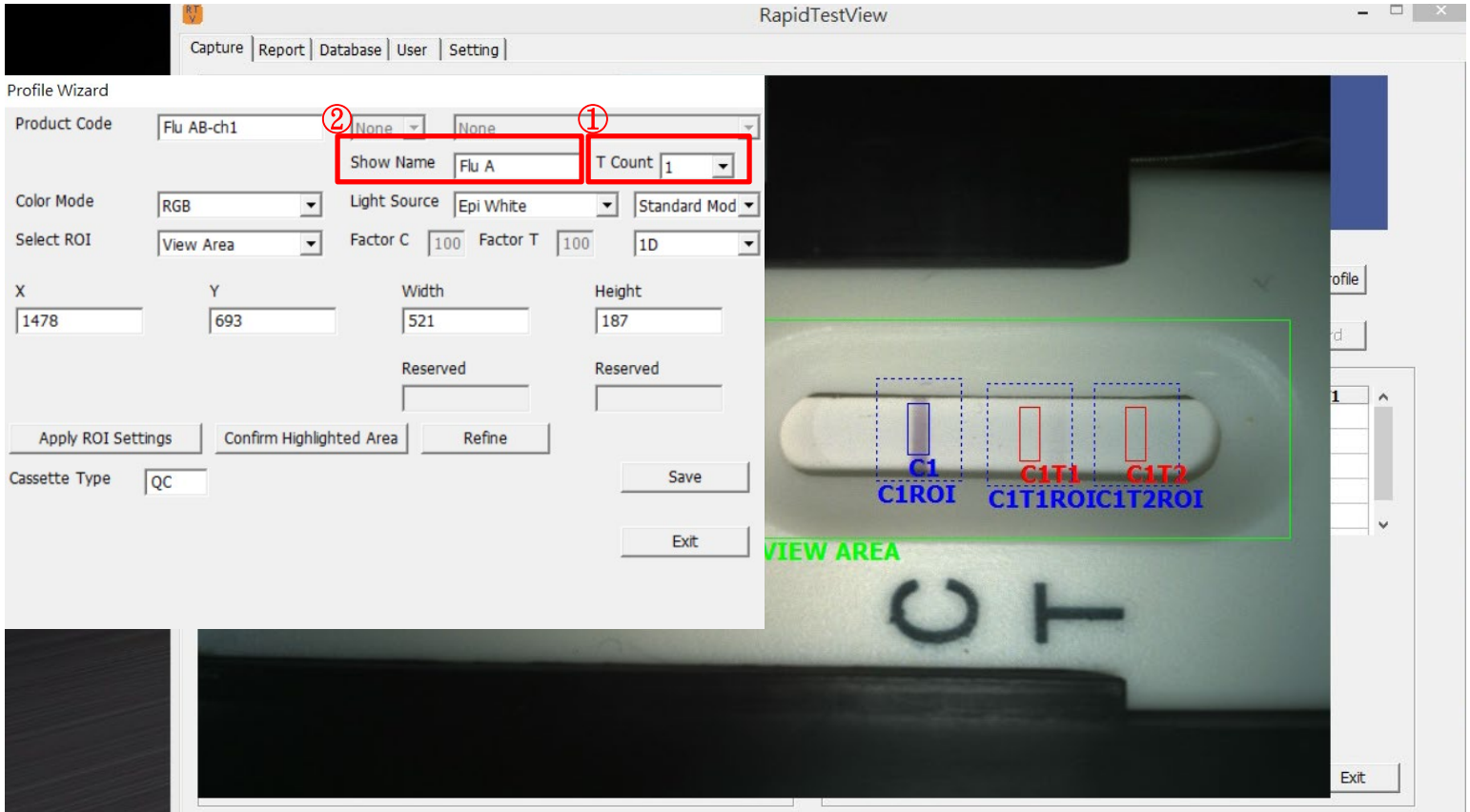
Guidance of setting

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.

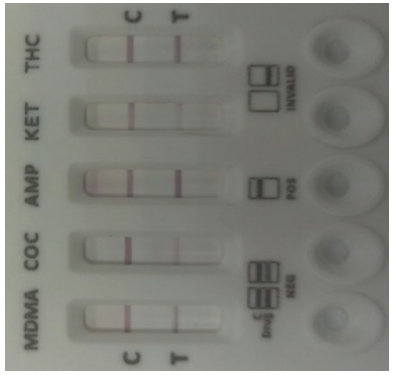
PS. Selecting "Quality" or" Excellent" takes longer time for analysis because more images will be captured.



New Group Profile

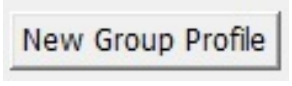
To set C & T Line area for multiple channel cassette

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

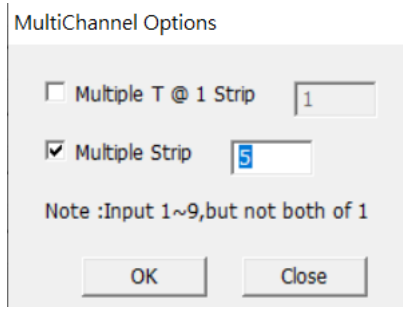


1. Using Profile Wizard to establish profile for each channel.
2. In this case, you can set THC, KET, AMP, COC, MOMA 5 independent product codes following previous instructions.
3. Then click “New Group Profile”. You will be asked how many strips/T lines per strip # are.
4. Then set a product code name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

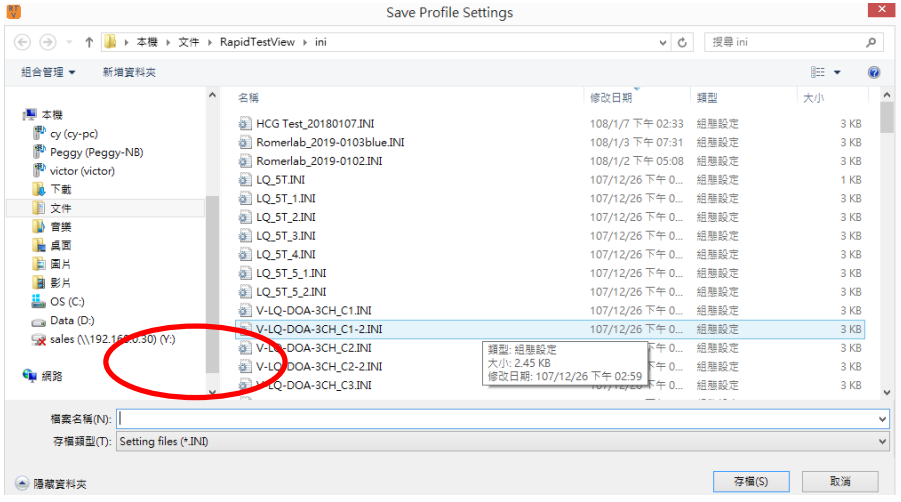
1. Click “New Group Profile” on UI default page after you set 5 product codes



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

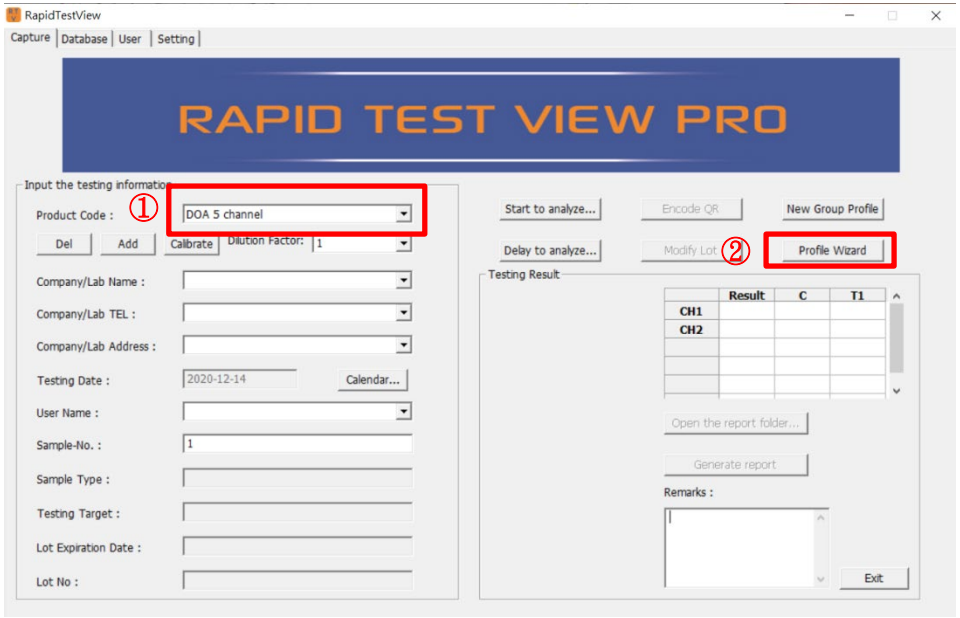


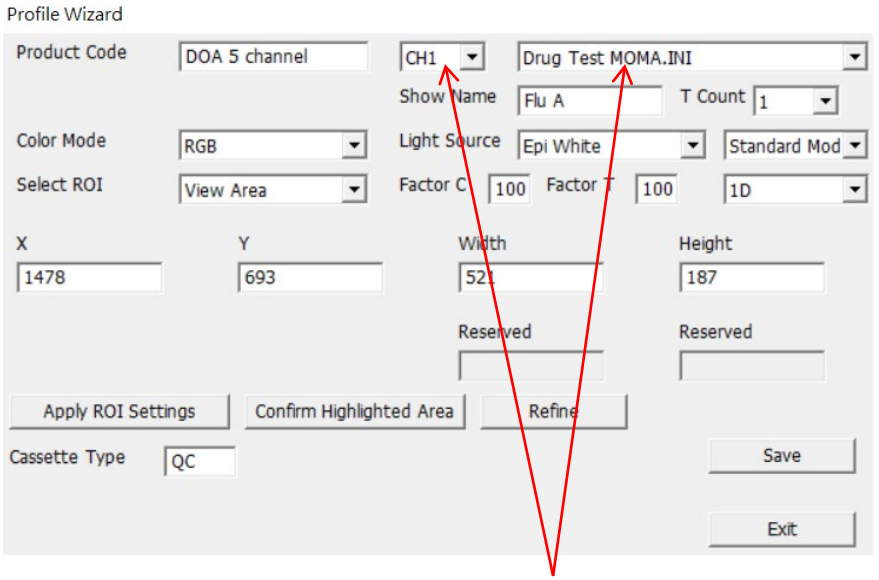
3. Then input a new product code for this 5 channel test kit and save . Let’s use “DOA 5 channel” as product code



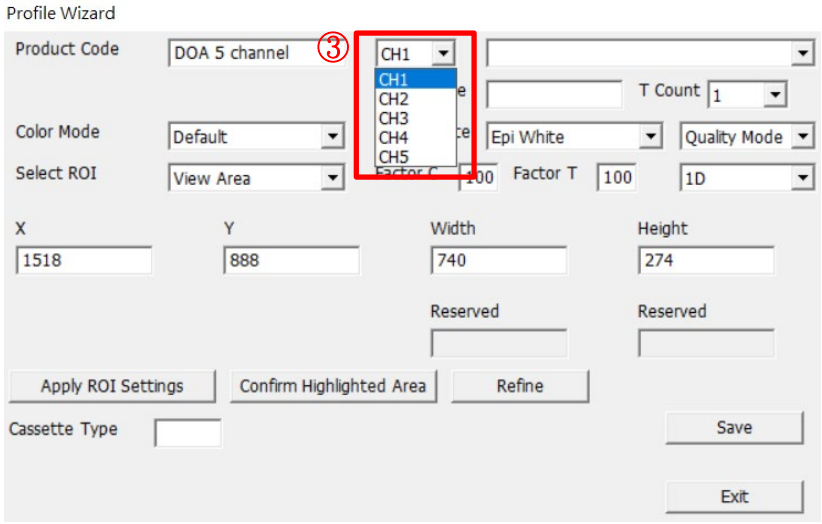
To set C & T Line area for multiple channel cassette

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





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".

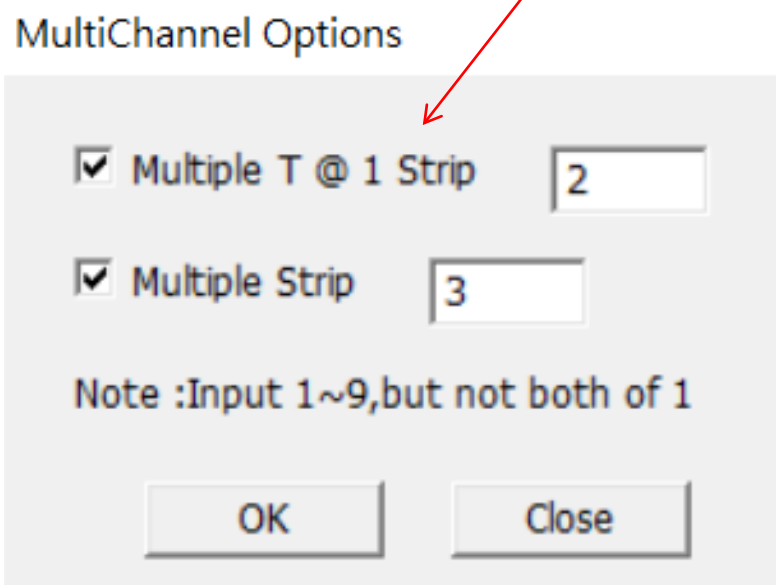
The Profile Setting is done.

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 31~34 to finish setting.



Calibration

1. Auto calibration
2. Manual calibration

1. Auto calibration

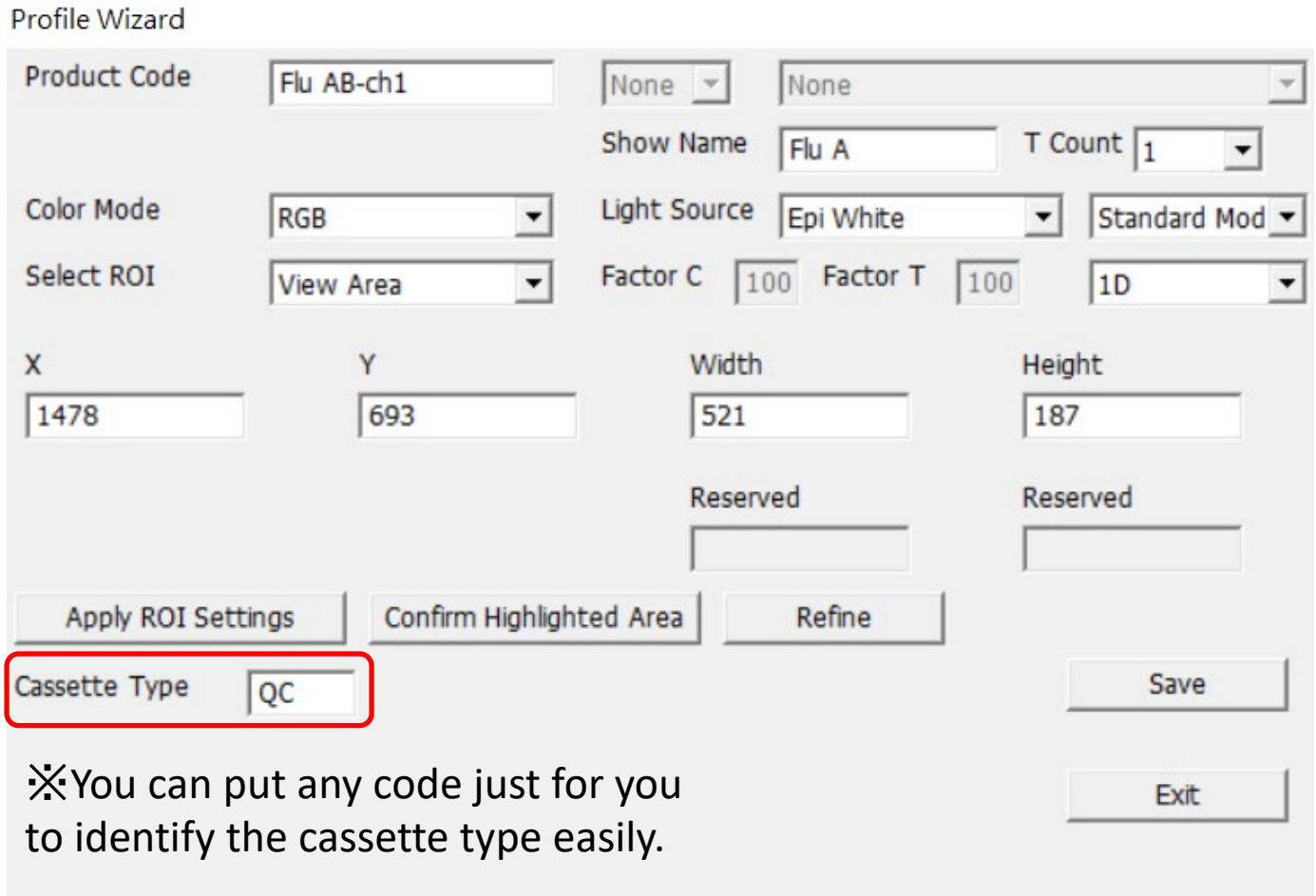
- Engineers have developed a set of algorithms that can automatically calibrate the system, so users of the new version of the DSK software do not need to use the manual calibration function by themselves.

- For users of the old version, please refer to the steps on the next page for manual calibration.

When to do Calibration

- Users of the old version must use the following steps to perform manual calibration.
- After you set Profile Wizard, **please do calibration before 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

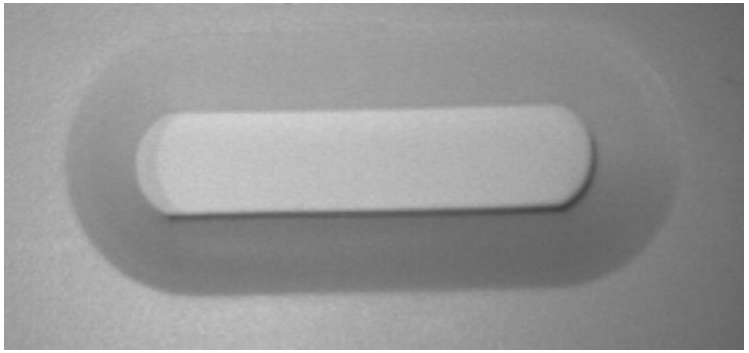


※You can put any code just for you to identify the cassette type easily.

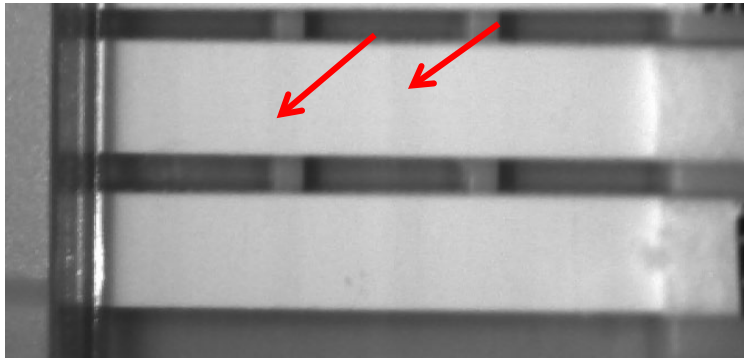
How to do Calibration

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

Good

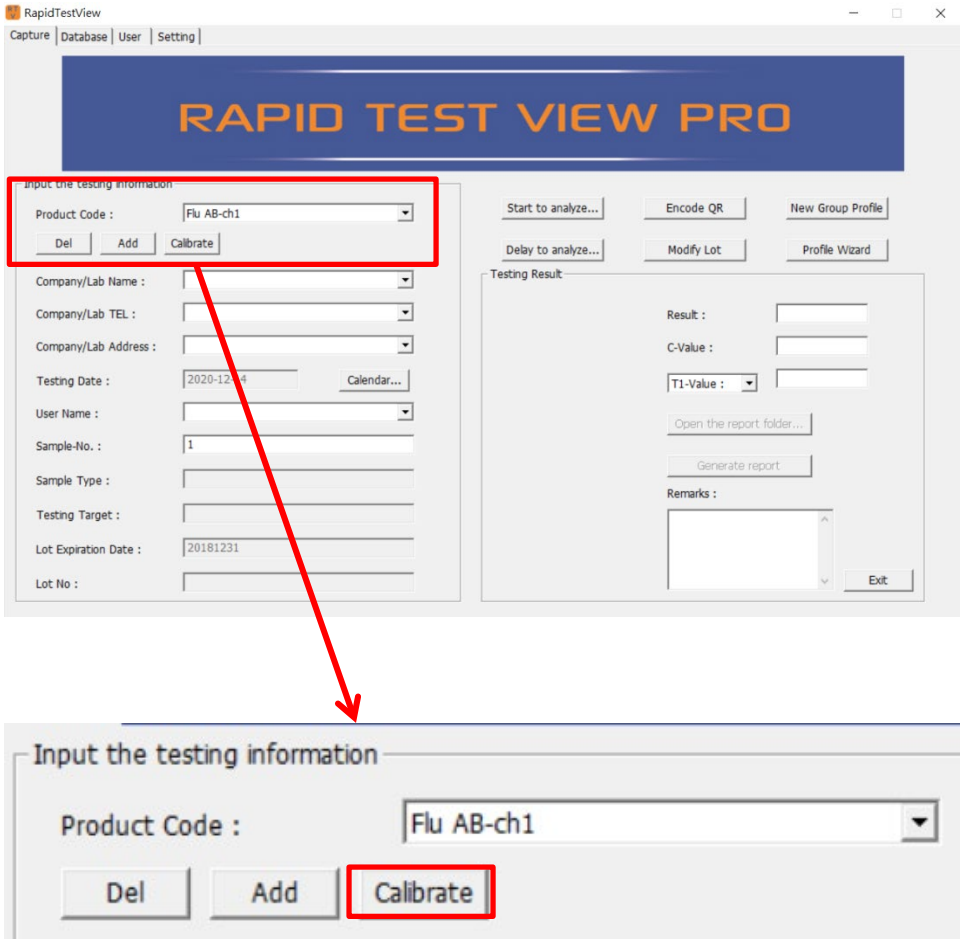


Not Good



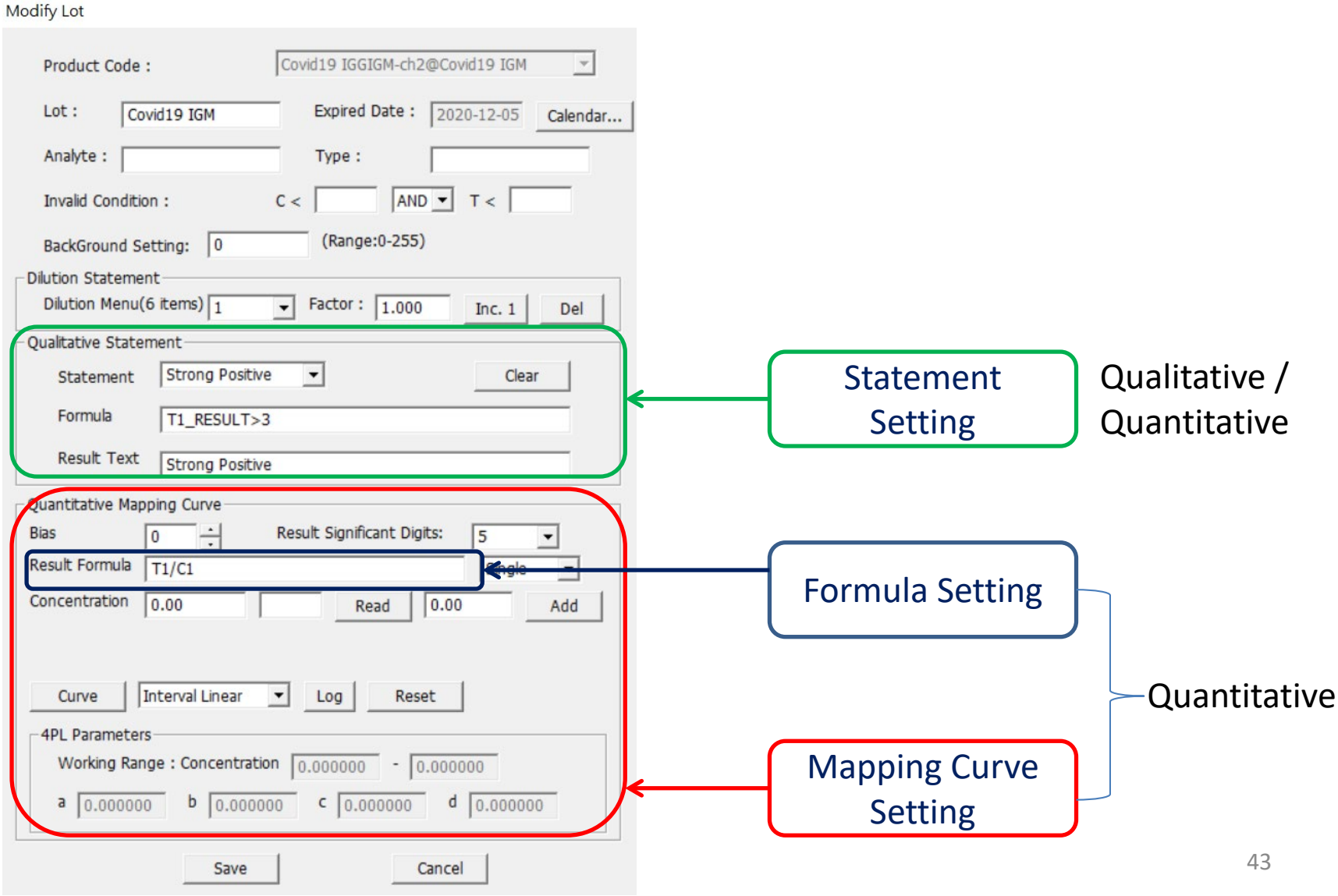
Calibration process

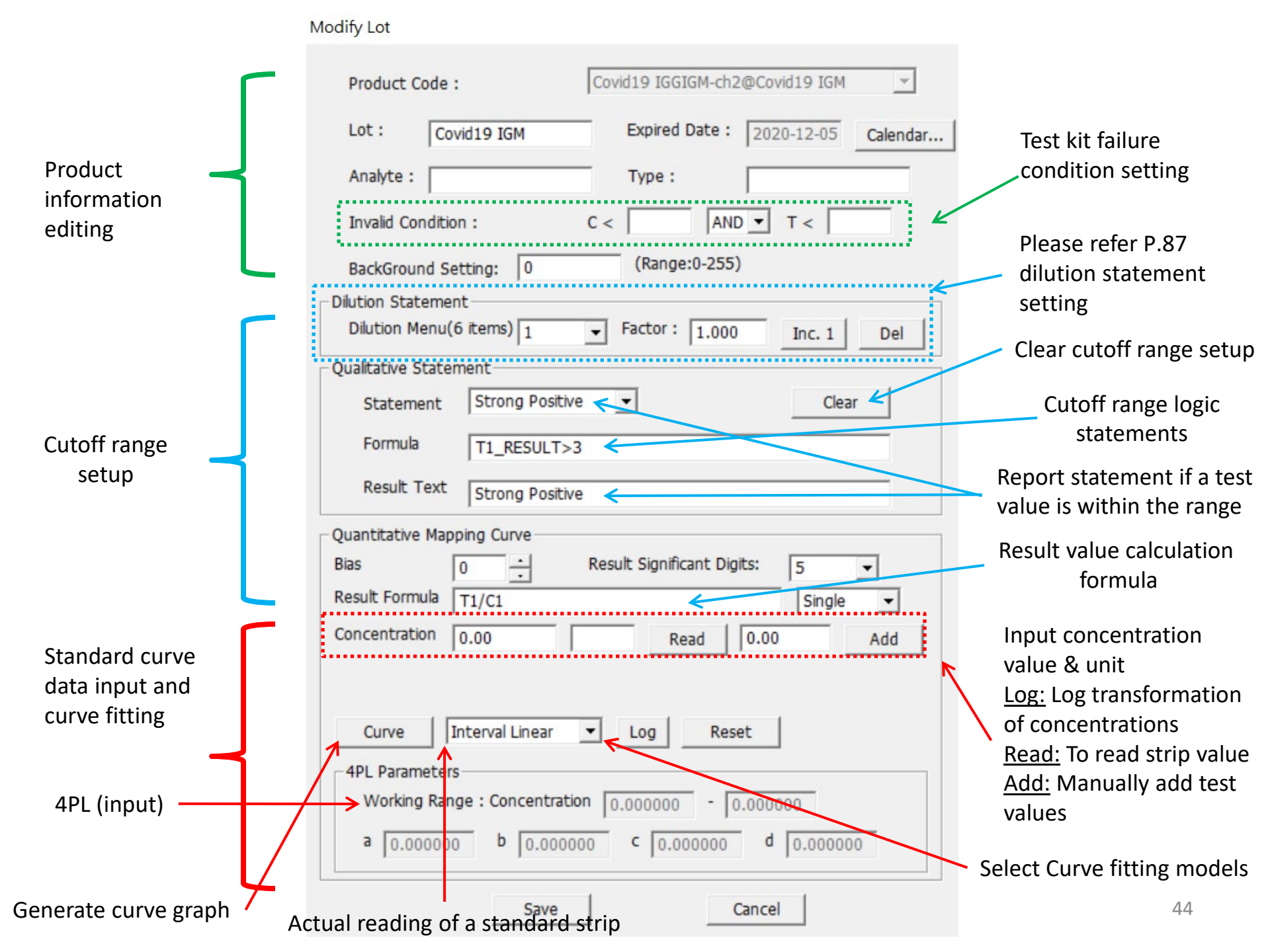
- Go to homepage
- Insert blank kit
- Press “Calibrate” icon
- Follow the instructions to finish calibration



Using Modify Lot
to set analysis formula for obtaining result

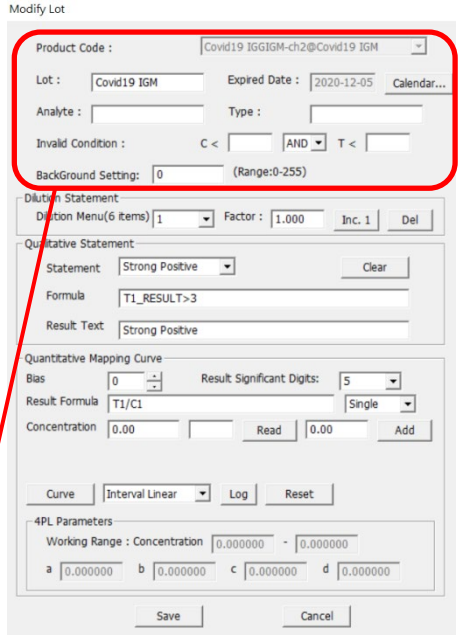
Modify Lot → Testing Result

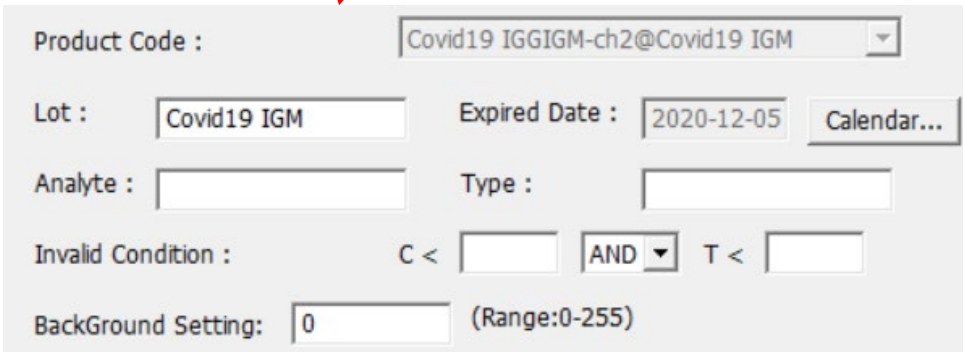



Modify Lot
Product Code :
Covid19 IGGIGM-ch2@Covid19 IGM
Lot :
Covid19 IGM
Expired Date :
2020-12-05
Calendar...
Analyte :
Type :
Invalid Condition :
C <
AND
T <
BackGround Setting:
0
(Range:0-255)
Dilution Statement
Dilution Menu(6 items)
1
Factor :
1.000
Inc. 1
Del
Qualitative Statement
Statement
Strong Positive
Clear
Formula
T1_RESULT>3
Result Text
Strong Positive
Quantitative Mapping Curve
Bias
0
Result Significant Digits:
5
Result Formula
T1/C1
Single
Concentration
0.00
Read
0.00
Add
Curve
Interval Linear
Log
Reset
4PL Parameters
Working Range : Concentration
0.000000
-
0.000000
a
0.000000
b
0.000000
c
0.000000
d
0.000000
Save
Cancel
Product information editing
Cutoff range setup
Standard curve data input and curve fitting
4PL (input)
Generate curve graph
Actual reading of a standard strip
Test kit failure condition setting
Please refer P.87 dilution statement setting
Clear cutoff range setup
Cutoff range logic statements
Report statement if a test value is within the range
Result value calculation formula
Input concentration value & unit
Log: Log transformation of concentrations
Read: To read strip value
Add: Manually add test values
Select Curve fitting models

Setting Up Lot information

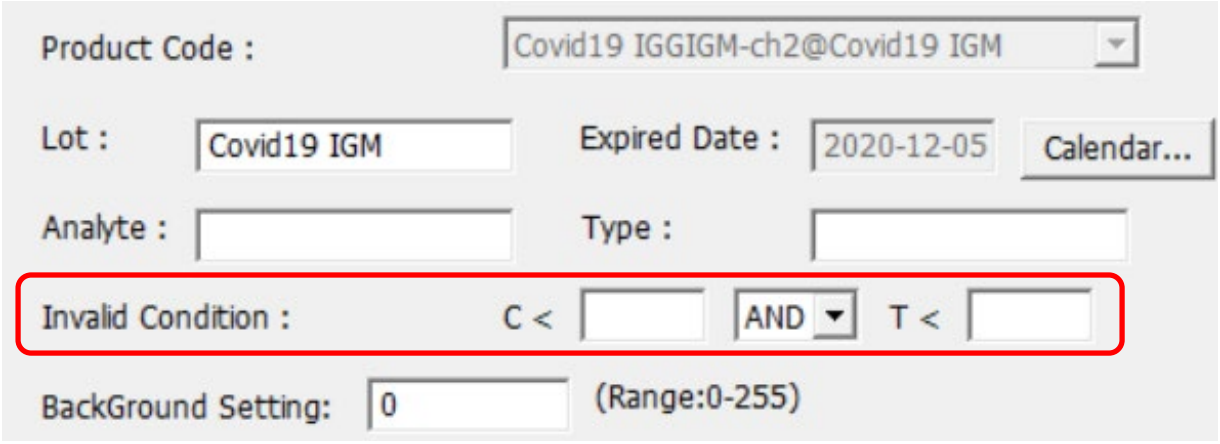
- Product Code：Selected product code cannot be modified in this section
- Lot：Type Lot Number in Lot column
- Expired Date：Set expiration date in this column
- Analyte： The analyte that the test kit will be analyzing.
- Type：Testing sample type required by this test kit.
- Invalid Condition：Test kit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





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.



How to set cut off value in Qualitative Statement

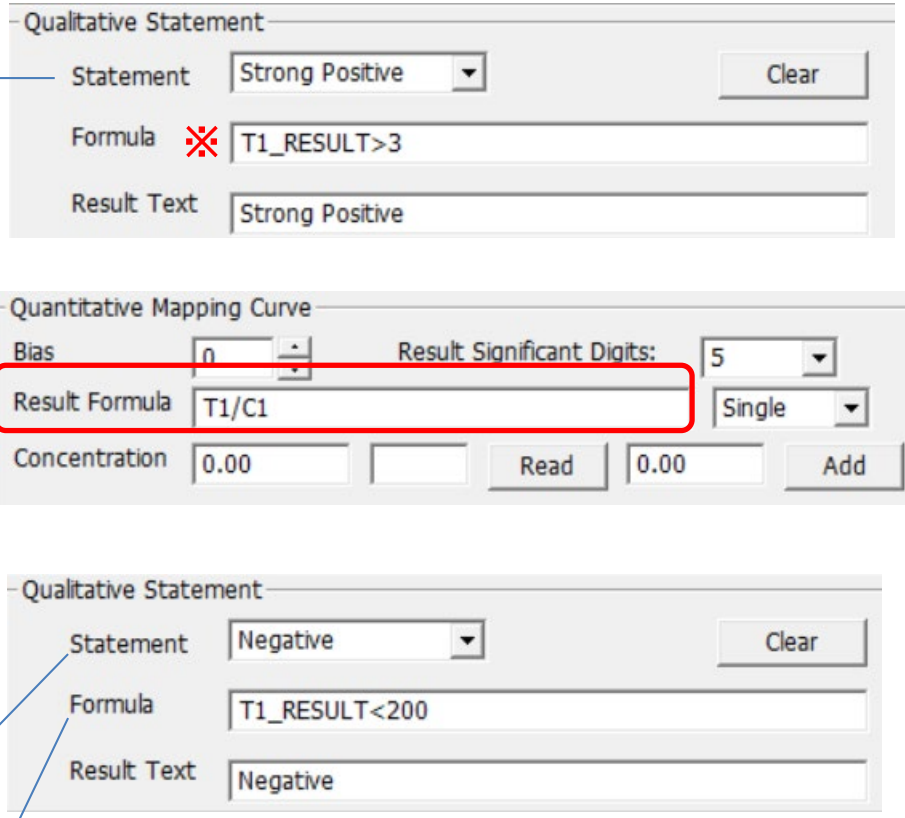
Go to Statement to set Positive and Negative statement.

※ “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

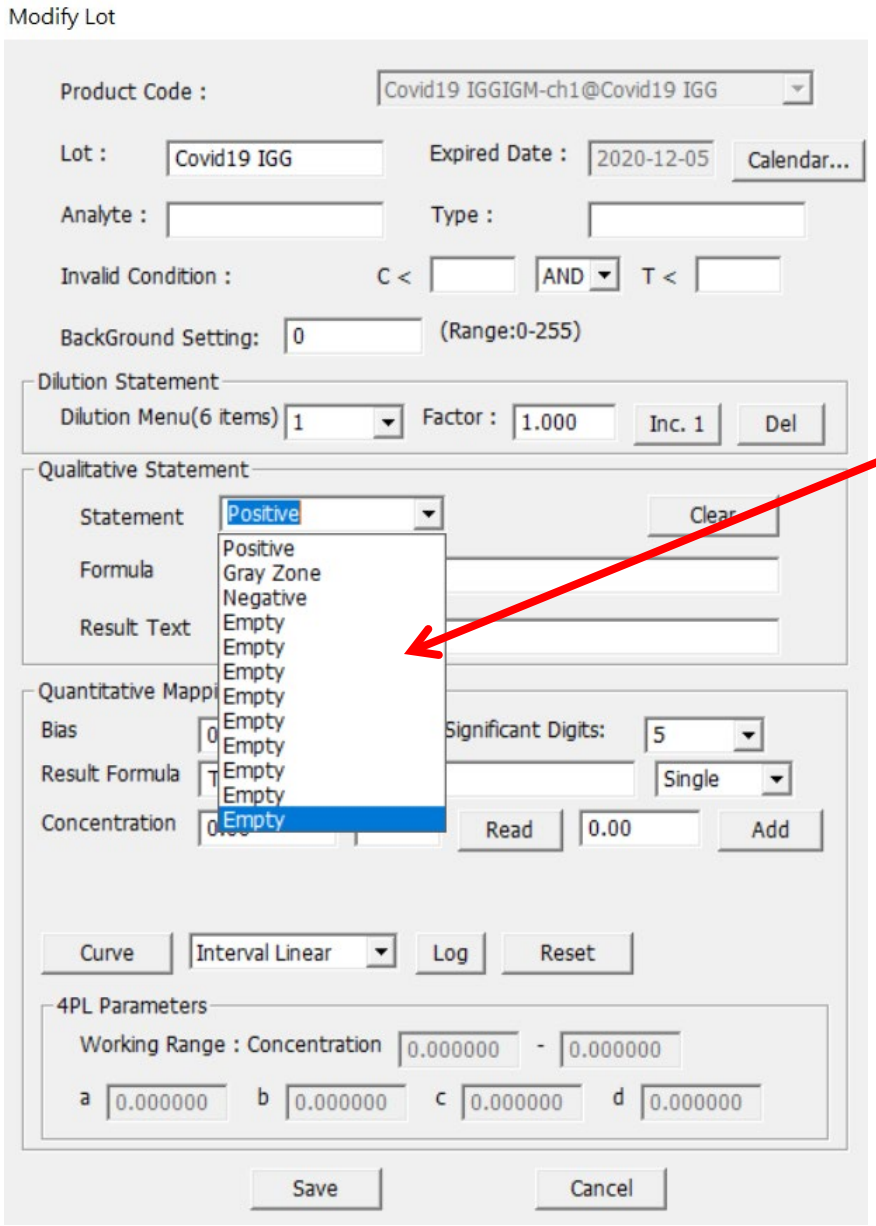
Set Formula for cut off value. For example: Input T1_RESULT < 200 for Negative.
Then set T1_RESULT >= 200 for Positive to include all possible calculation result.



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.
- 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



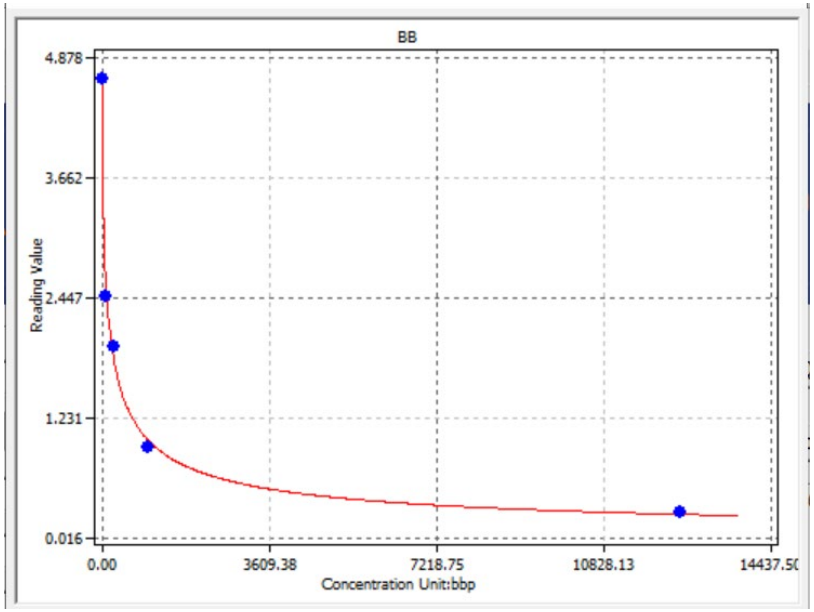
Up to 12 cut-off statements can be added!!

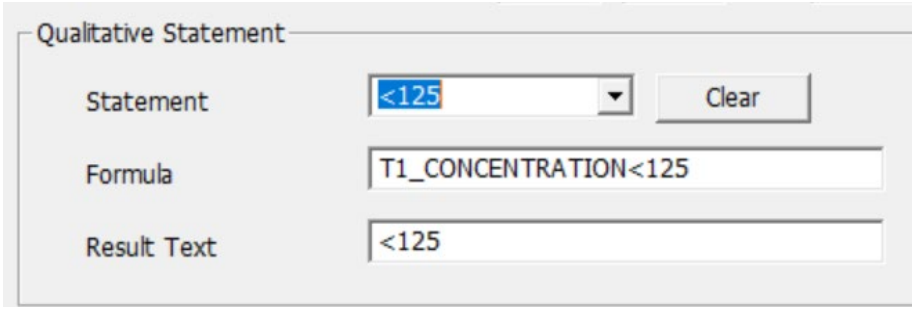
Summary of Qualitative/Quantitative setting

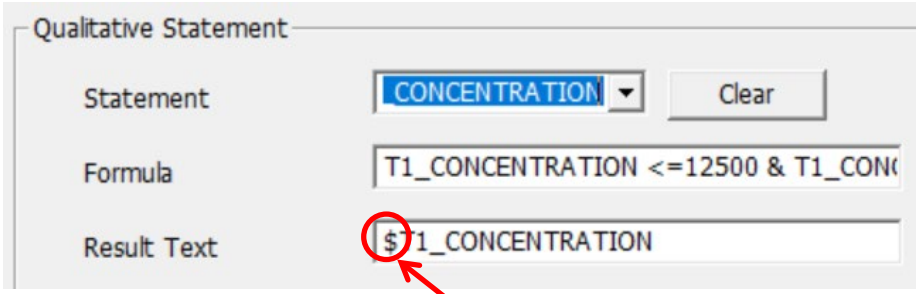
Result Type	Formula	Mapping Curve	Statement	Note
Qualitative / Quantitative	Quantitative	Quantitative	Qualitative	
Assignment	T1_RESULT	T1_CONCENTRATION	Statement	
Prority	3	2	1	
Operation Type	Arithmetic	Data to Concentration Mapping	Arithmetic + Logic --> Logic	
	+	Interval Linear	+	Arithmetic PLUS
	-	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

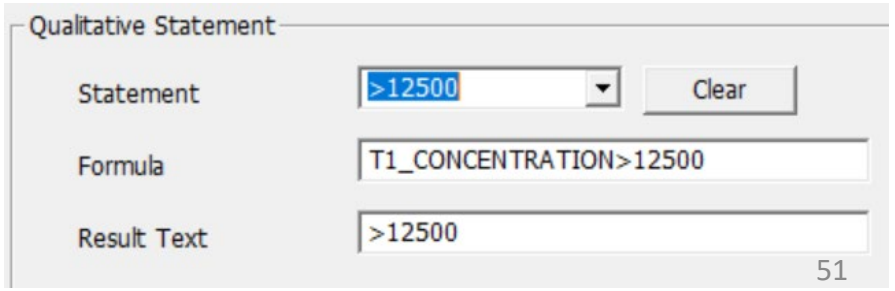
- Using “Statement” to show the quantitative value @ working range





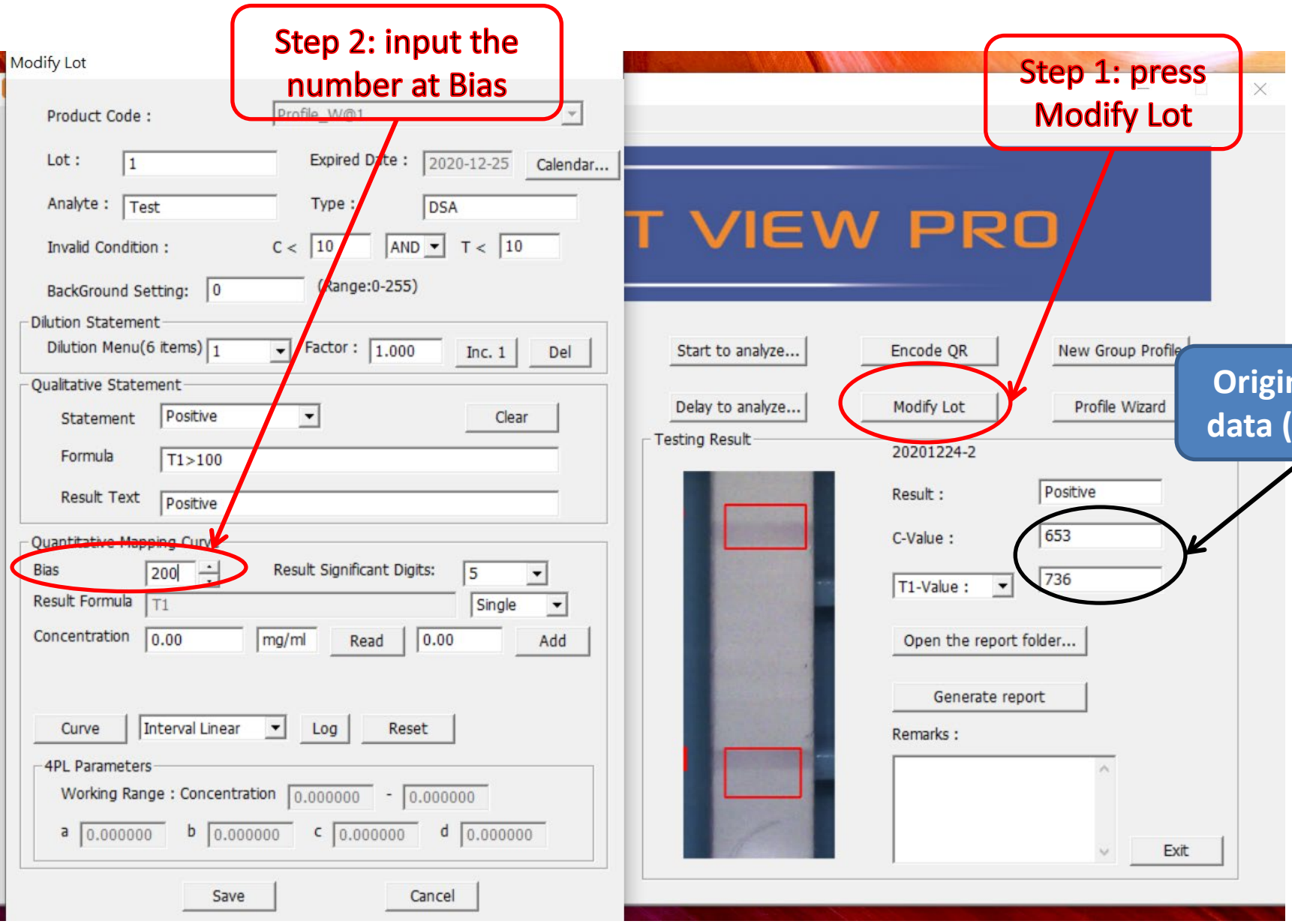


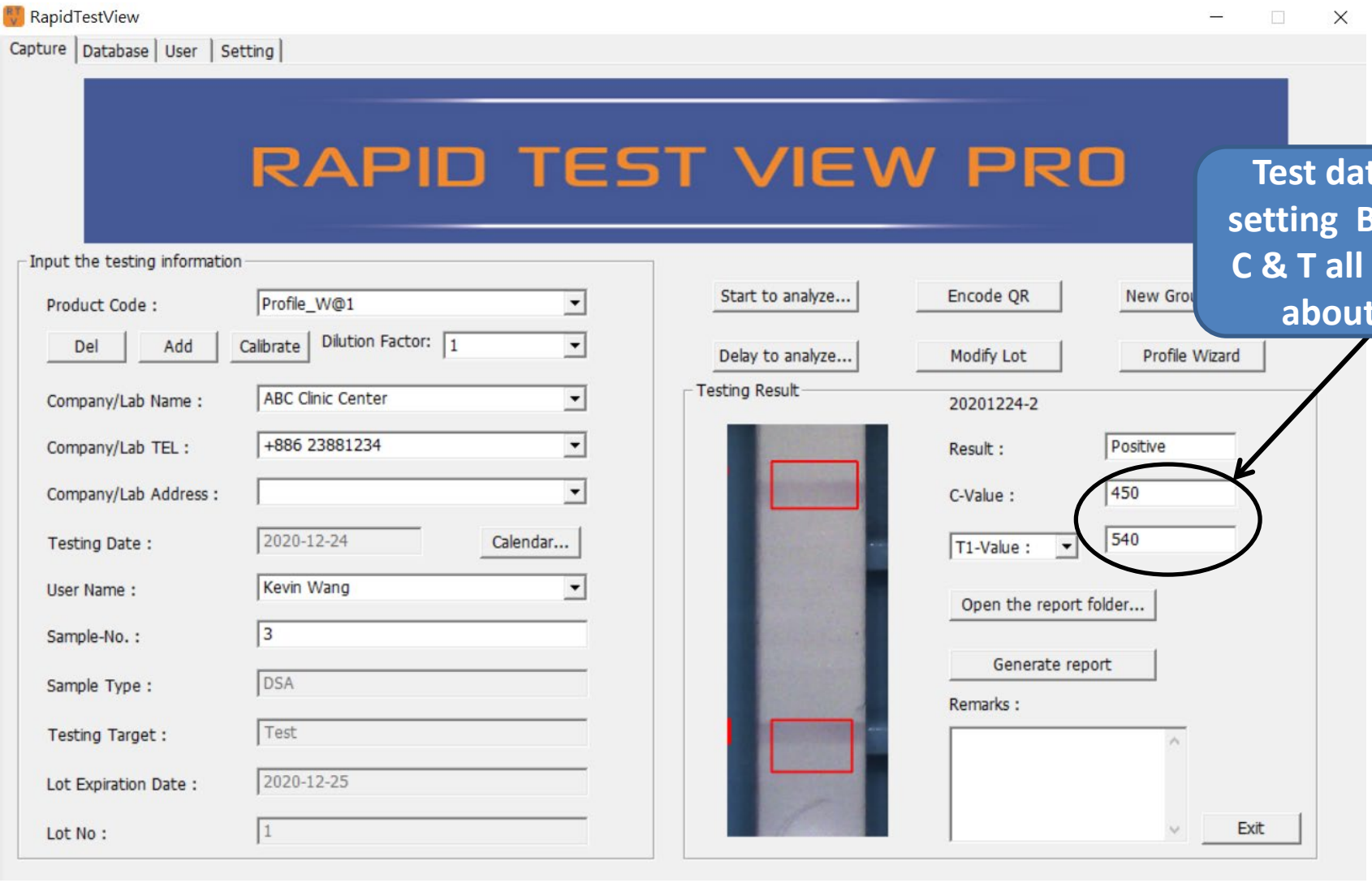
Special Mark for the variation of T1,T2, …, C, T1_RESULT, T1_CONCENTRATION, ….



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


Step 2: input the number at Bias
Step 1: press Modify Lot
Original test data (Bias=0)
Modify Lot
Product Code :
Profile_W@1
Lot :
1
Expired Date :
2020-12-25
Calendar...
Analyte :
Test
Type :
DSA
Invalid Condition :
C <
10
AND
T <
10
BackGround Setting:
0
(Range:0-255)
Dilution Statement
Dilution Menu(6 items)
1
Factor :
1.000
Inc. 1
Del
Qualitative Statement
Statement
Positive
Clear
Formula
T1>100
Result Text
Positive
Quantitative Mapping Curv
Bias
200
Result Significant Digits:
5
Result Formula
T1
Single
Concentration
0.00
mg/ml
Read
0.00
Add
Curve
Interval Linear
Log
Reset
4PL Parameters
Working Range : Concentration
0.000000
-
0.000000
a
0.000000
b
0.000000
c
0.000000
d
0.000000
Save
Cancel
T VIEW PRO
Start to analyze...
Encode QR
New Group Profile
Delay to analyze...
Modify Lot
Profile Wizard
Testing Result
20201224-2
Result :
Positive
C-Value :
653
T1-Value :
736
Open the report folder...
Generate report
Remarks :
Exit


RapidTestView
Capture
Database
User
Setting
RAPID TEST VIEW PRO
Input the testing information
Product Code :
Profile_W@1
Del
Add
Calibrate
Dilution Factor:
1
Company/Lab Name :
ABC Clinic Center
Company/Lab TEL :
+886 23881234
Company/Lab Address :
Testing Date :
2020-12-24
Calendar...
User Name :
Kevin Wang
Sample-No. :
3
Sample Type :
DSA
Testing Target :
Test
Lot Expiration Date :
2020-12-25
Lot No :
1
Start to analyze...
Encode QR
Delay to analyze...
Modify Lot
Profile Wizard
Testing Result
20201224-2
Result :
Positive
C-Value :
450
T1-Value :
540
Open the report folder...
Generate report
Remarks :
Exit
Test data after setting Bias 200, C & T all subtract about 200.

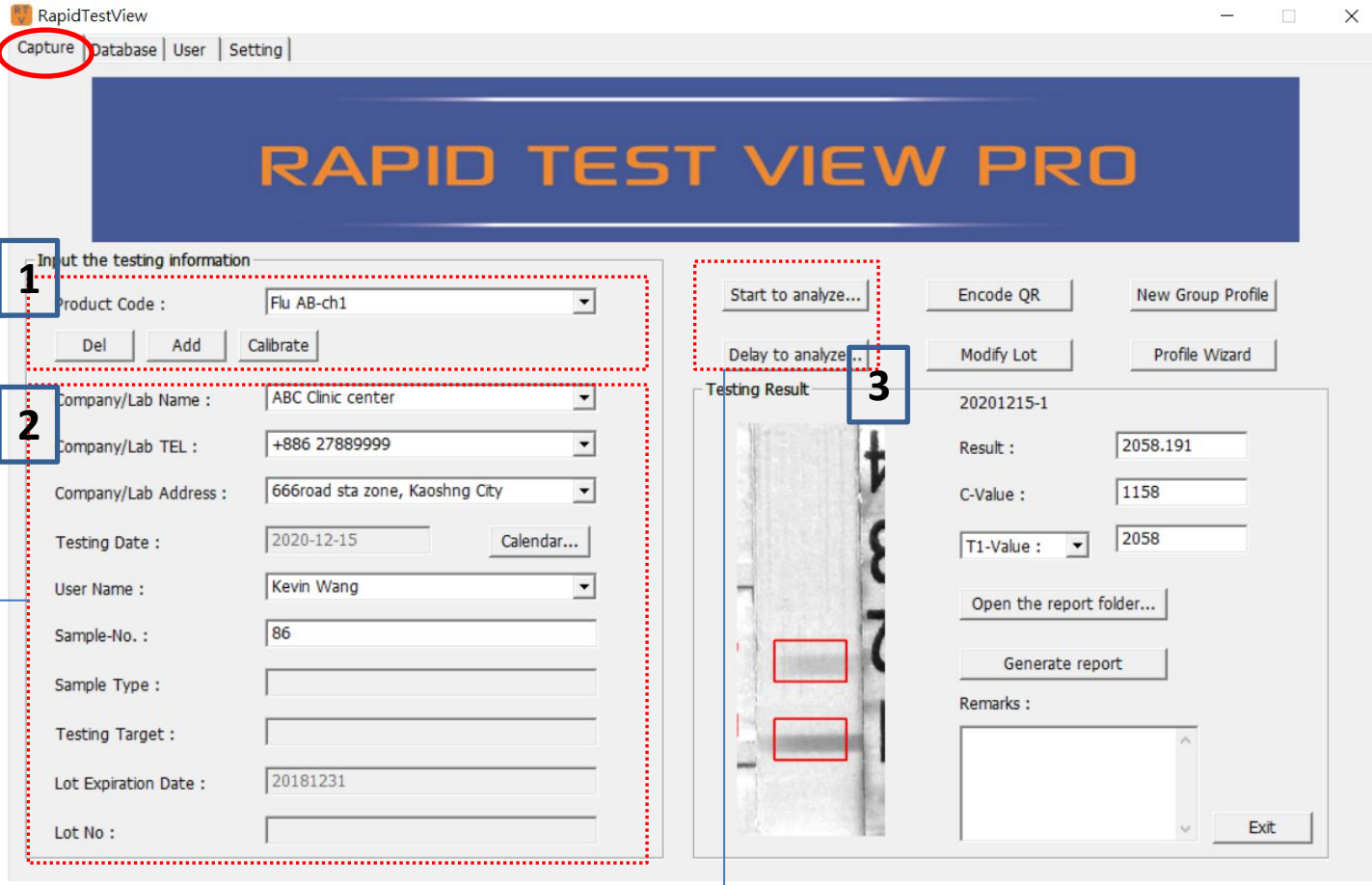
Capture & Analysis

Default page: Capture

1.Product Code selection:
User can select different diagnosis product in this section.
User can delete , add product or do calibration for each product.

2.Testing information:
This section on UI is for user to input lab information, testing date, and patient/sample information.

3.Analyze:
Start to analyze: Click this icon to proceed analysis immediately.
Delay to analyze: Users can set a certain period of time to let system begin analysis after it reaches preset time

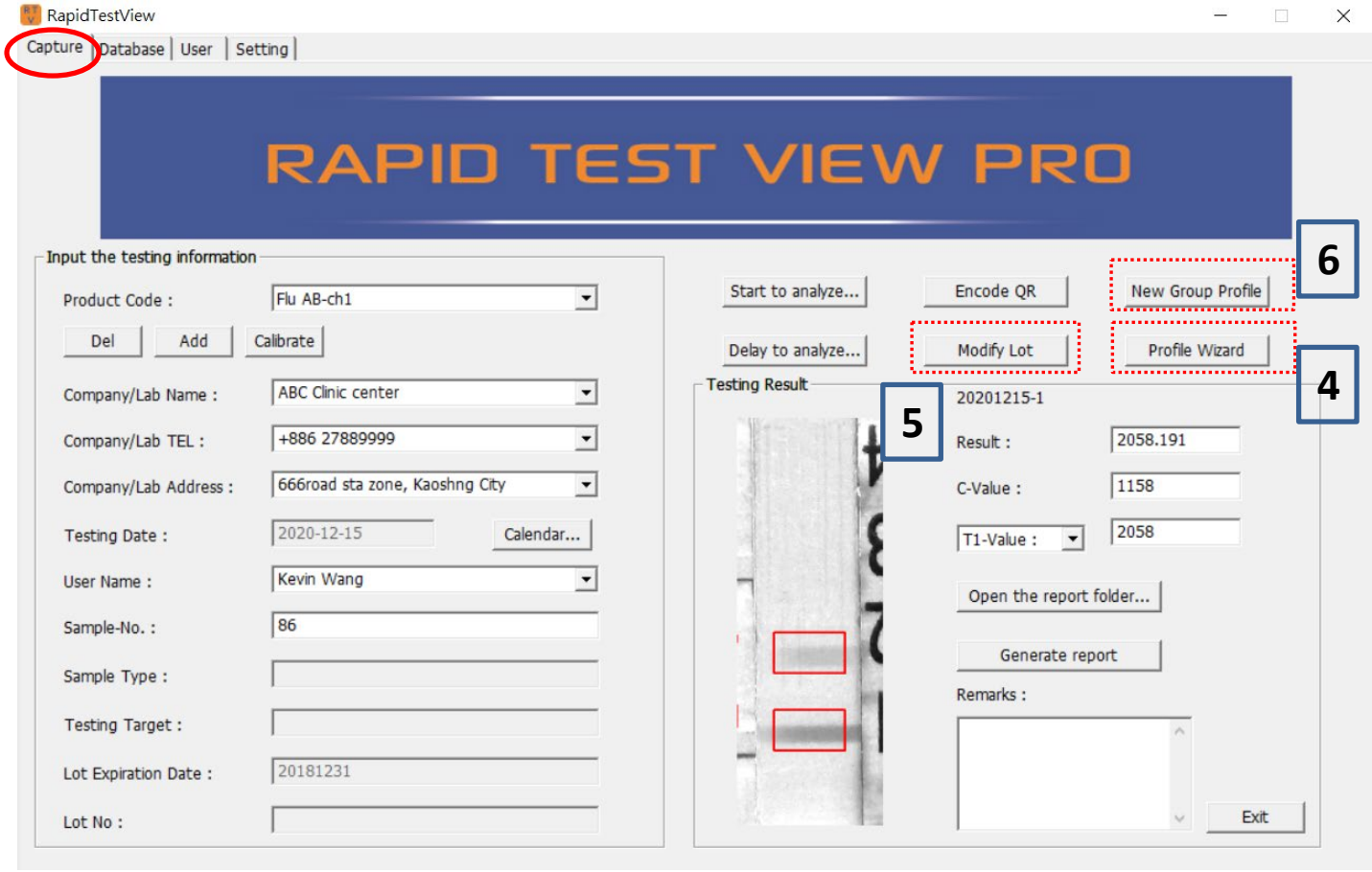


Default page: Capture(Cont.)

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

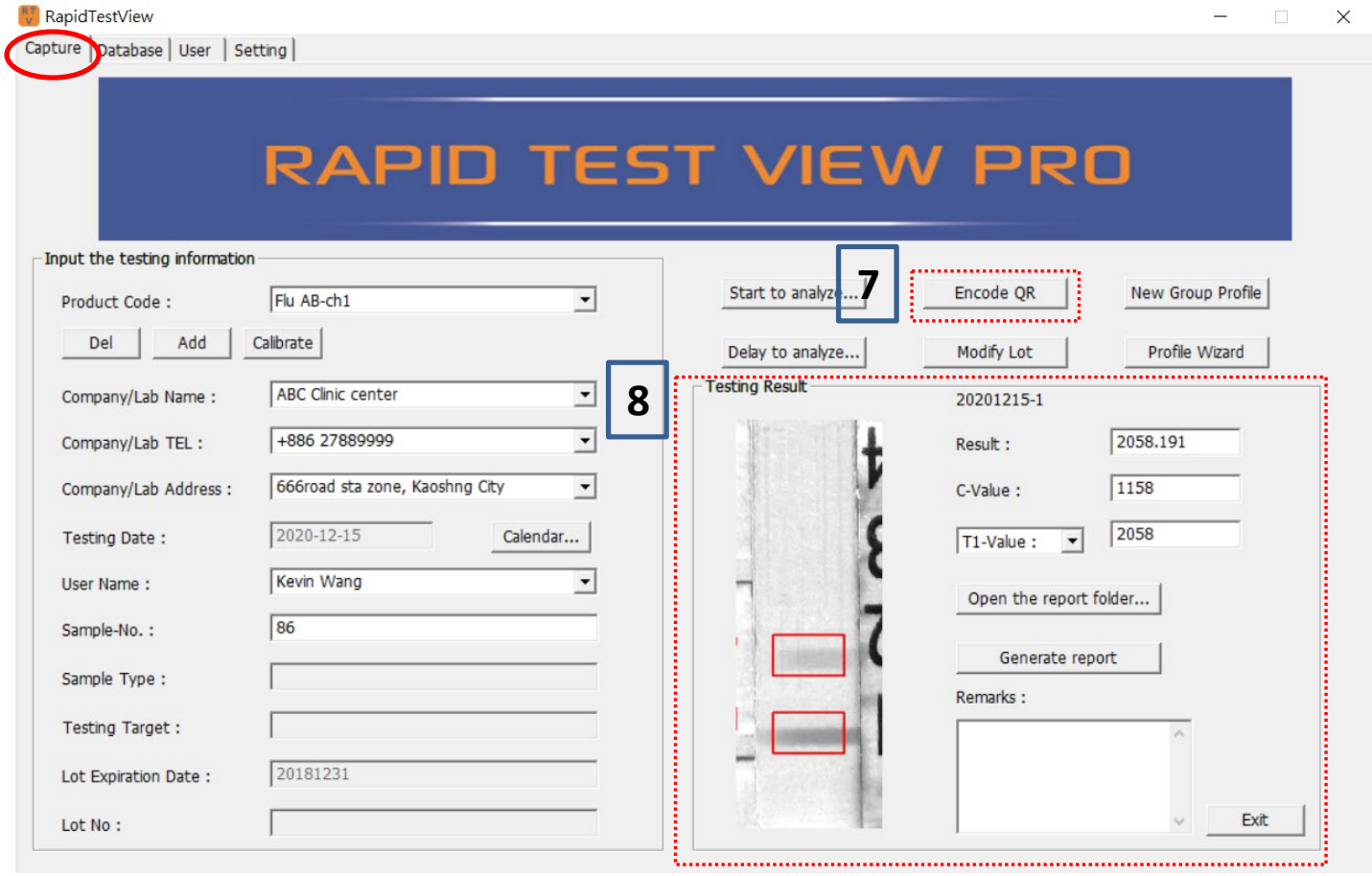
6.New Group Profile:
For multiple channel assay, users will need to use this function to integrate each channel's profile into 1 single group profile.



Default page: Capture(Cont.)

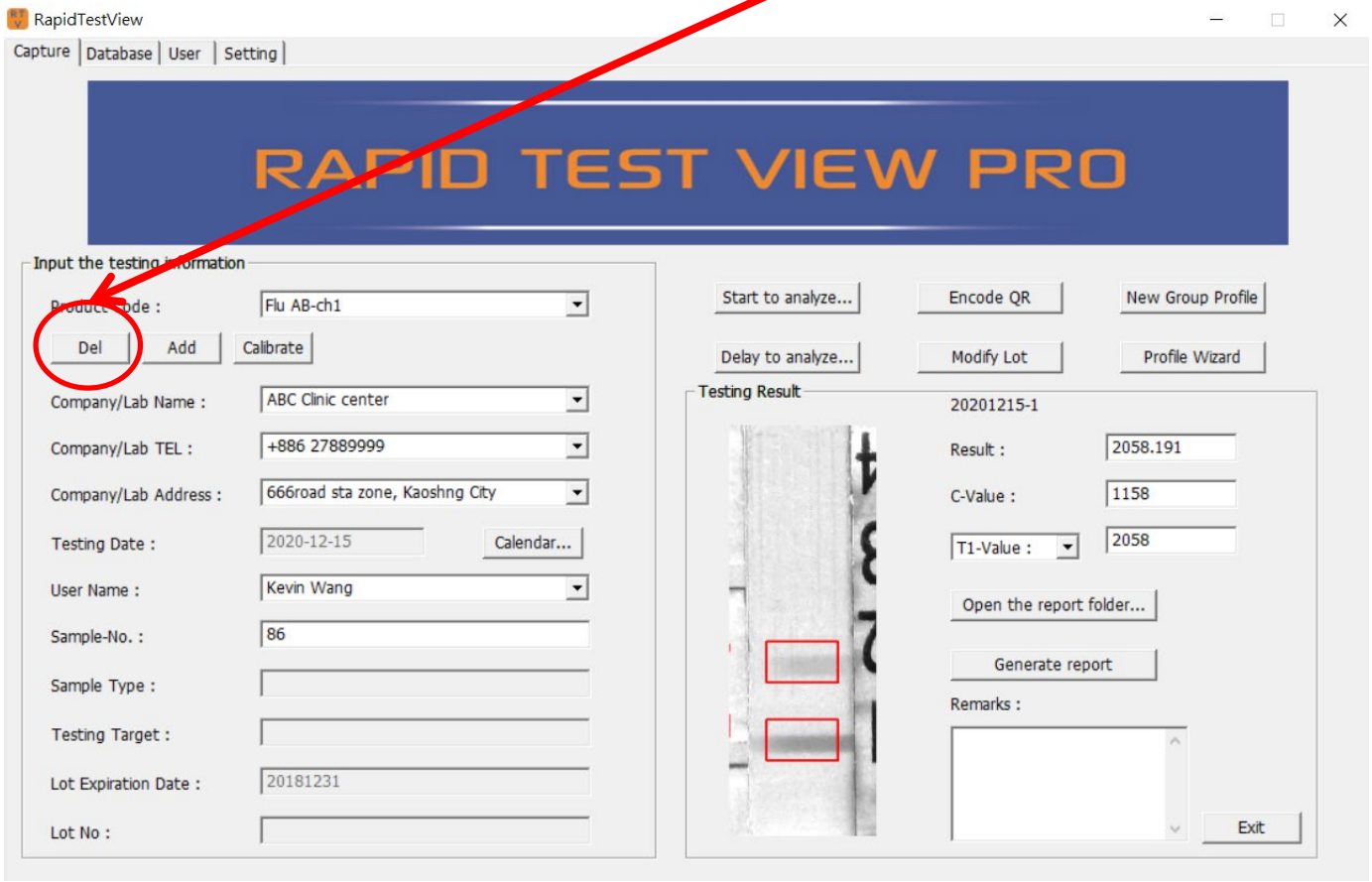
7.Encode QR: To create product profile's QR code image

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



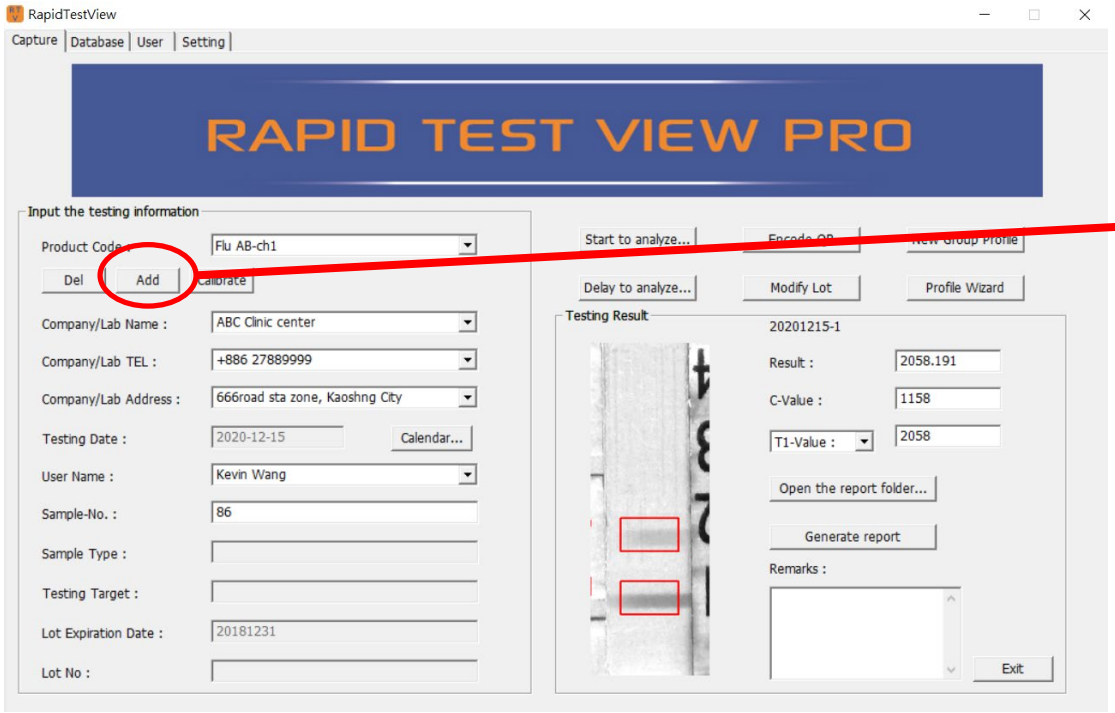
Delete Profiles

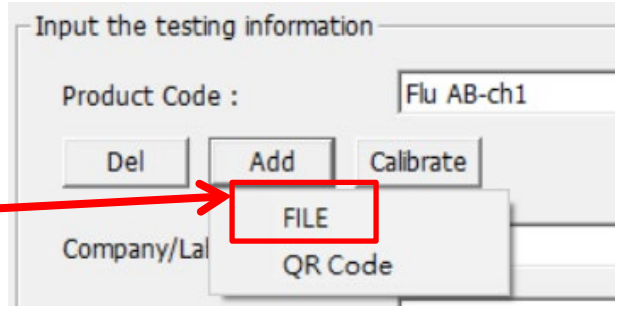
How to delete useless or invalid product profiles in software?
Select product code for deletion and then press “Del” to remove selected product profile.



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.



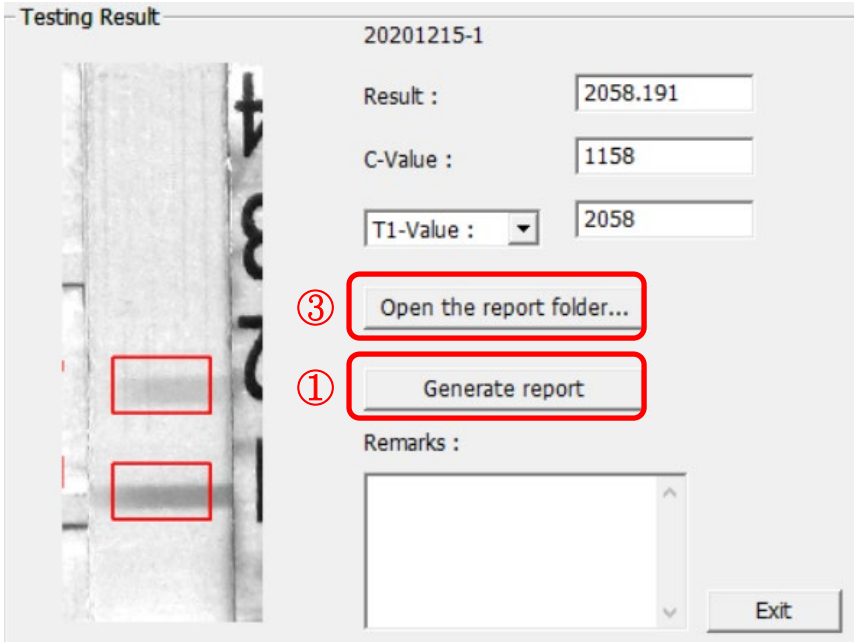


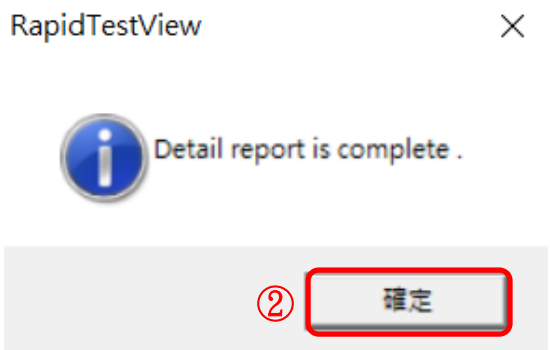
Report

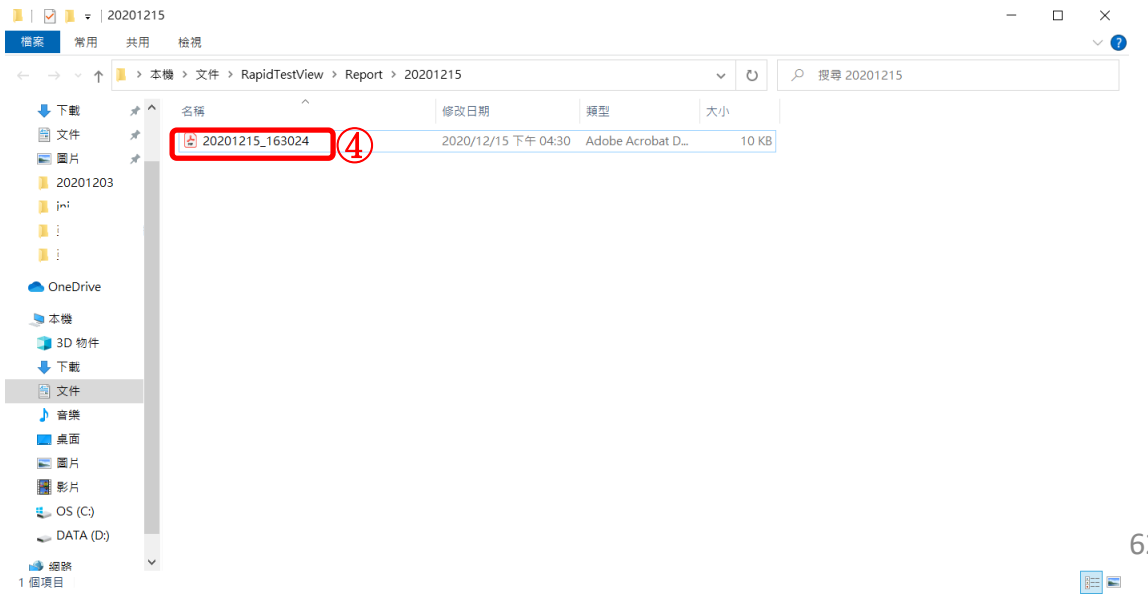
Report

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

Example of PDF report

TEL :

Inspection Report

Testing Time : 20201215 163024

Testing Target :

Lot Number :

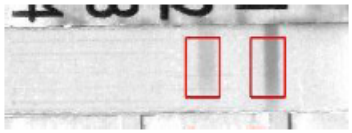
Sample Type :

Remarks :

Sample-No. : 2

Name	Result	Note
	2068.586	Fig.1

Fig 1.



Report Signed

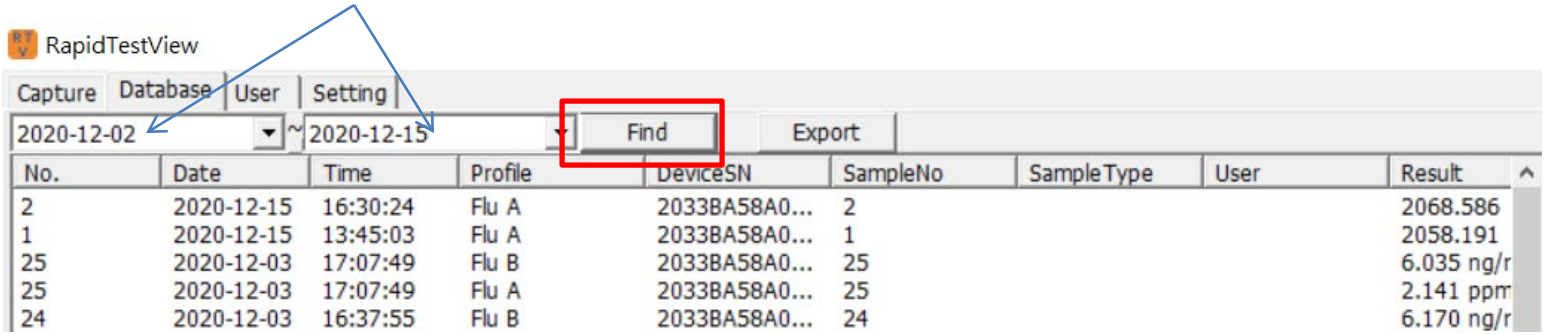
Tester :_____(MM/DD/YYYY)

Supervisor :_____(MM/DD/YYYY)

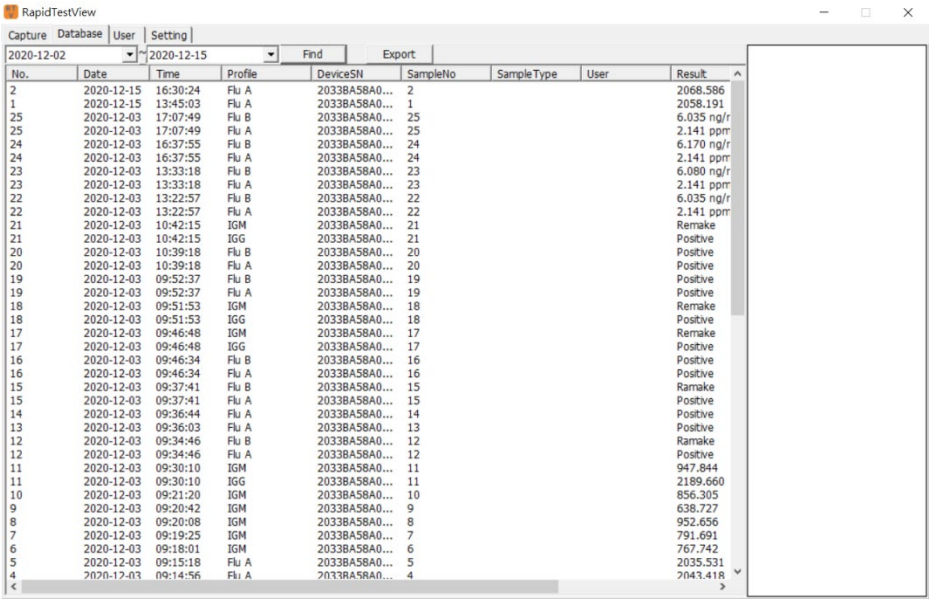
Database

Database

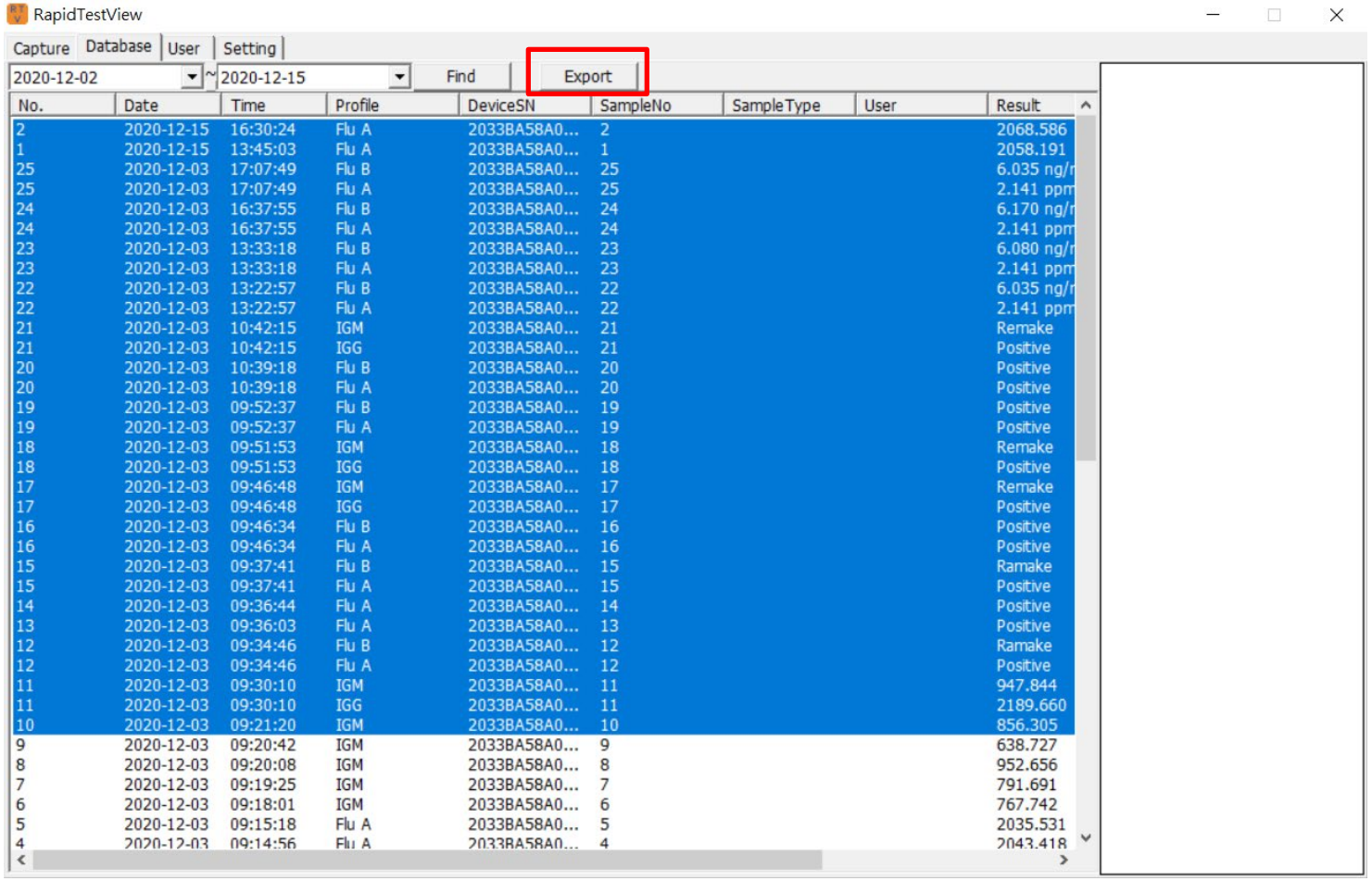
All level of users can obtain diagnosis history from this section
Select testing date or a certain period to show diagnosis result, then click “Find”



Software then display all diagnosis results recorded within the time period you set



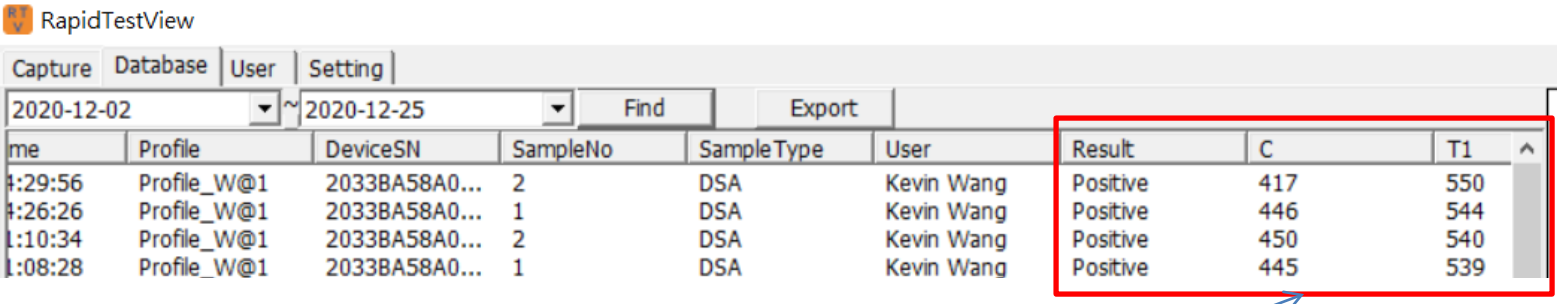
Database



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.

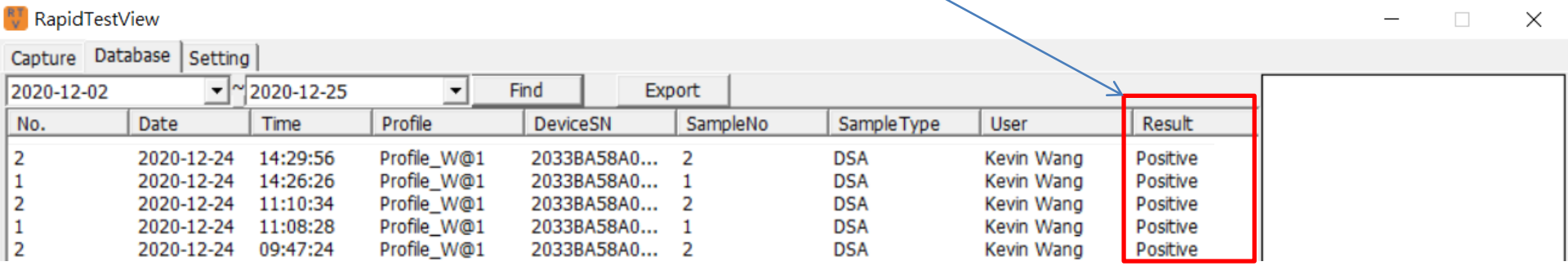
Database

- ADMIN



- USER & USER-ALL

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



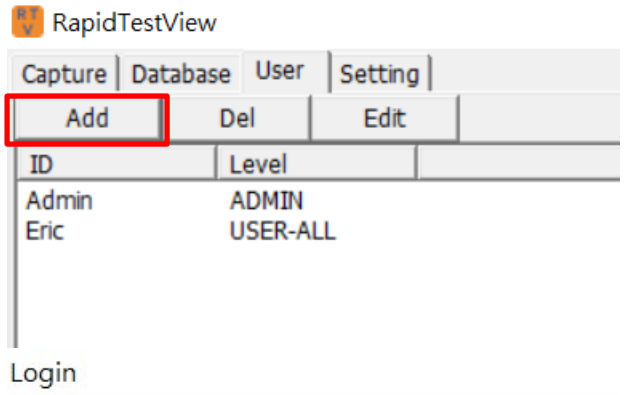
User Management

User Management

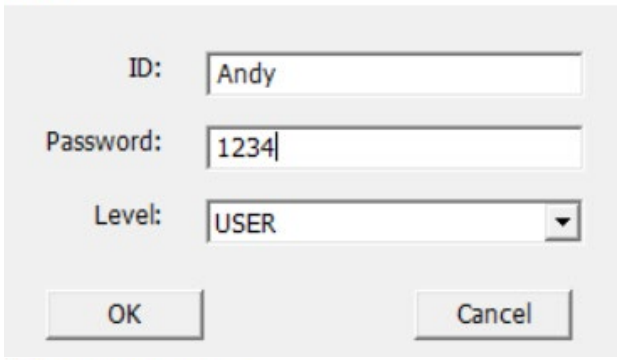
- Rapid Test View software has authority management function to let different level of users obtain different diagnosis result
- ADMIN
  - ADMIN is administration level of user. He/She can see all diagnosis results include image.
  - ADMIN can add/delete/edit USER-ALL & USER level of users
  - Only ADMIN 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

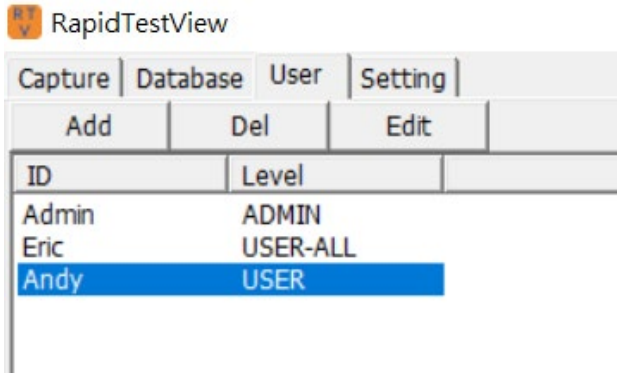
Go to User section, Click “Add”



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

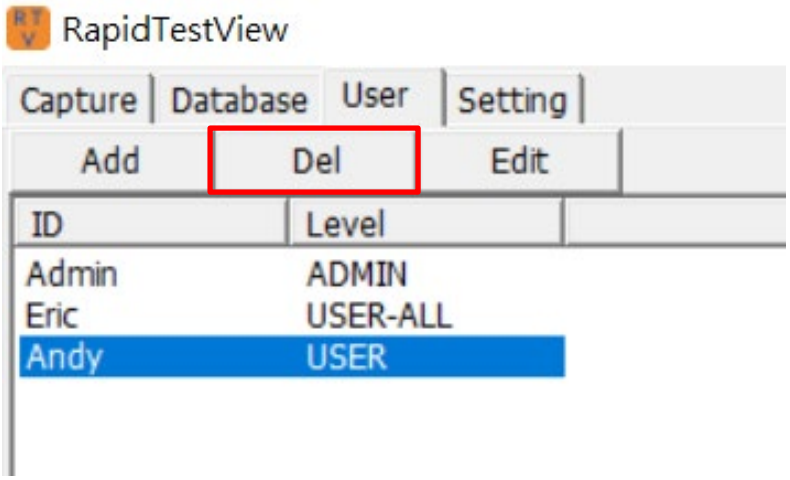


New user is successfully added

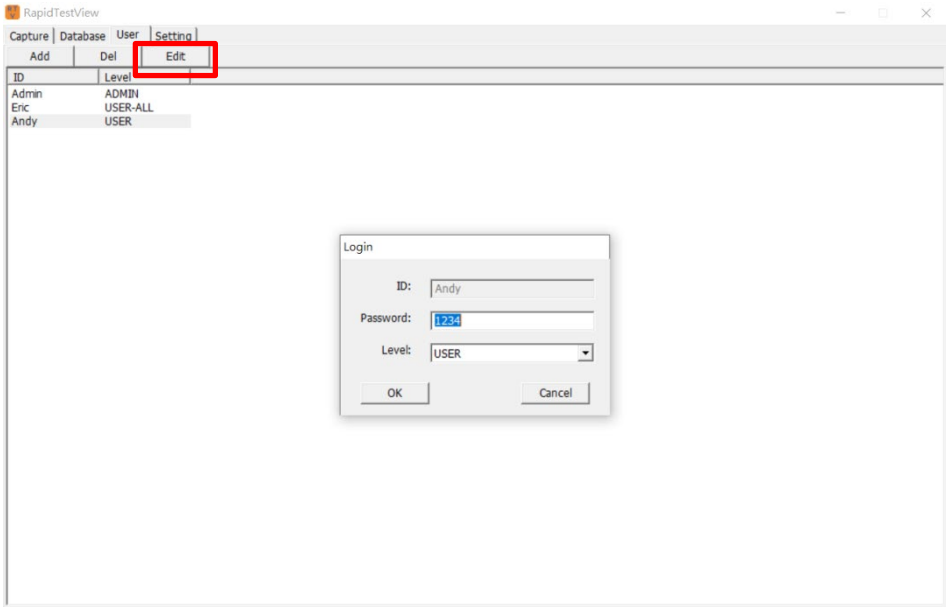


ADMIN: Del/Edit user

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.

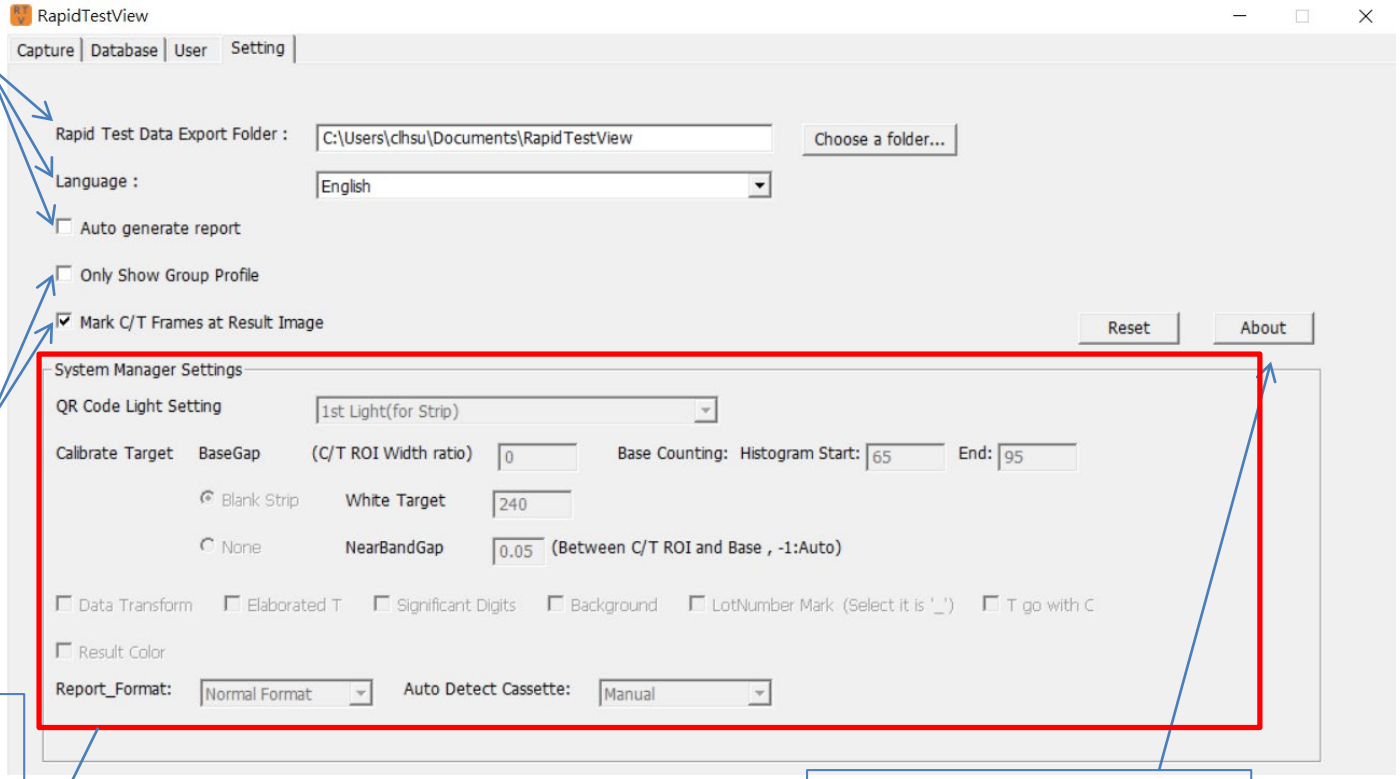
Setting

Setting

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

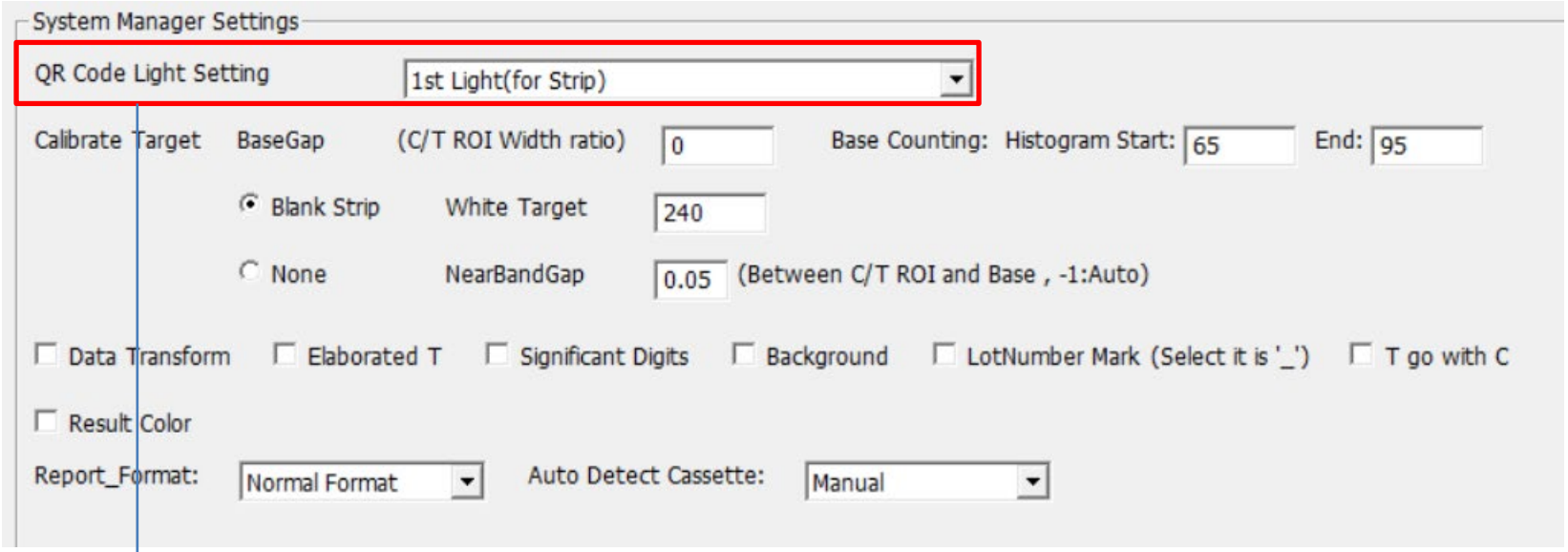
User can only show Group profile in homepage and choose whether to show C T frame in result image

The system manager setting part will not be open to users. If you have any questions, please contact the developer.



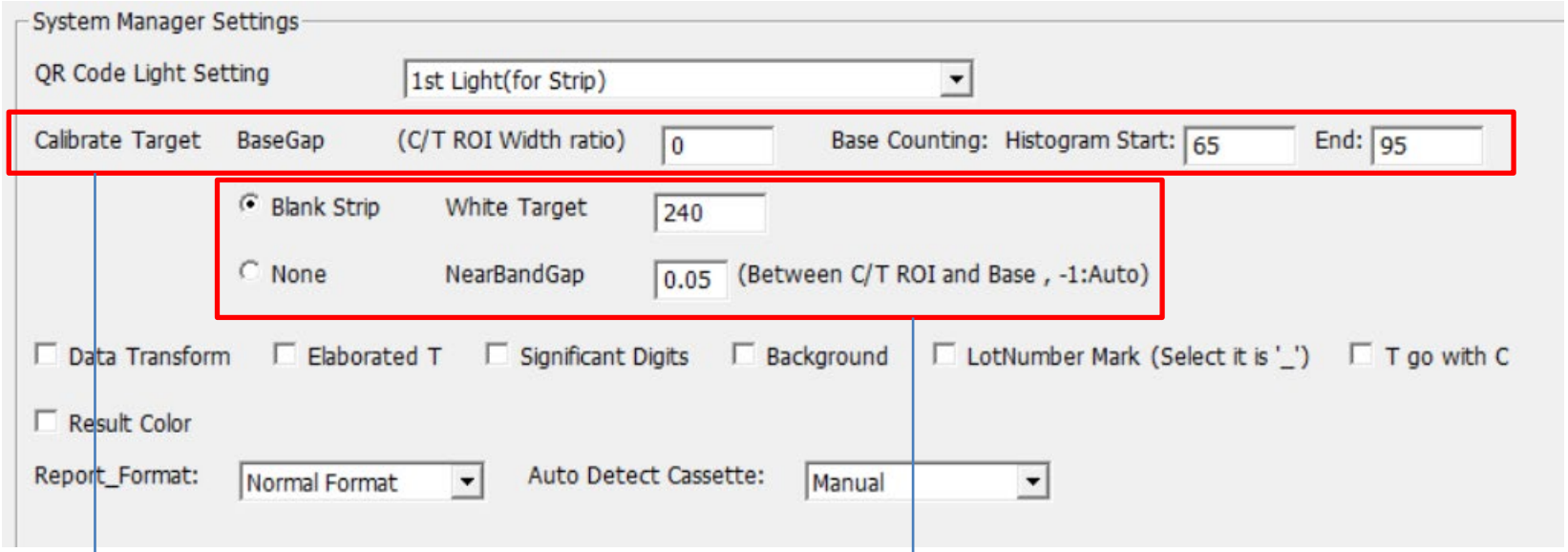
"About" reveals SW version and license key information

Setting



This setting is the light source for capturing the QR code ：
The 1st light is white light.
The 2nd light is UV light.

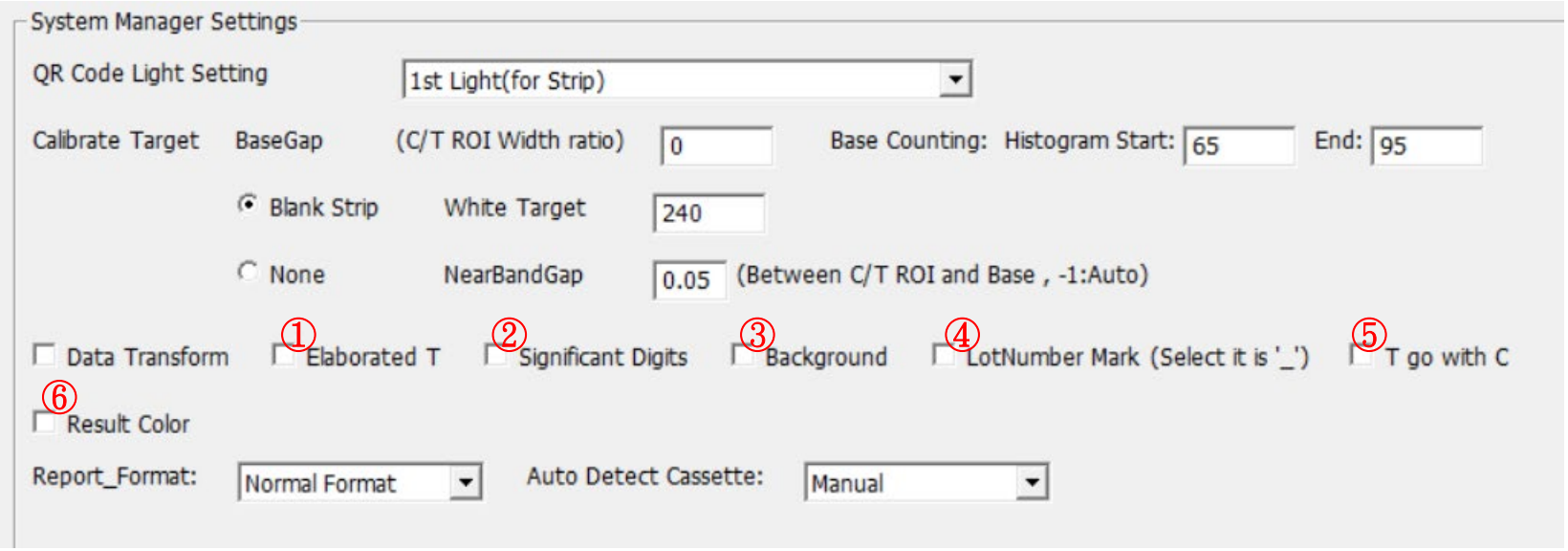
Setting



Please do not change the settings of Calibrate Target by yourself.

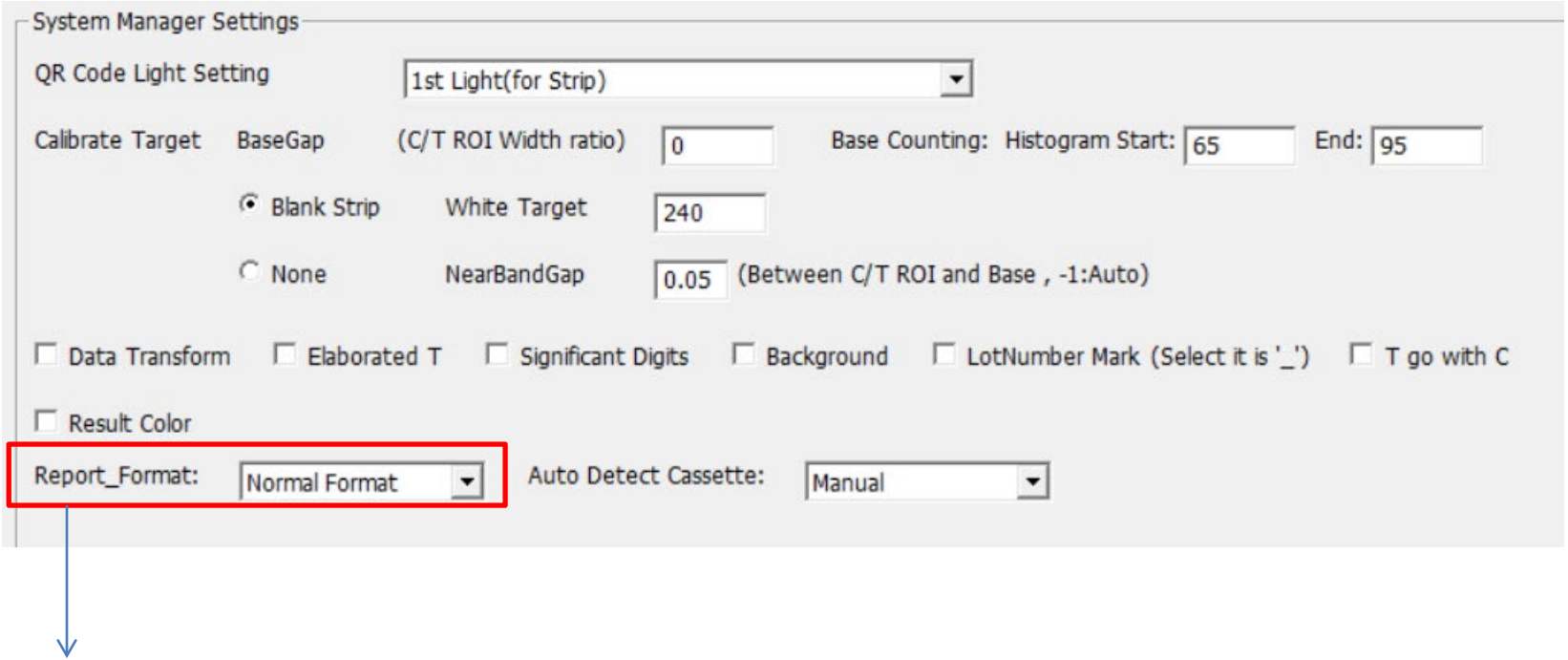
Here you can check whether blank strip or none calibration.
Do not change the rest of the parameters by yourself.

Setting



① Elaborated T：The T value will be caculated by a formula.
② Significant Digits：The result value will have decimal places.
③ Background： A warning message that the background of the C & T line is too dark will show up.
④ LotNumber Mark： The product code formed by the product name and the lot number will be replaced with an underscore "_" instead of "@“.
⑤ T go with C：Ask the manufacturer before making changes.
⑥ Result Color： Words with positive results will turn red.

Setting



The format of the generated report is different:

1. All test pictures are contained in one report.
2. Multiple pictures are divided into multiple reports.

Encode QR

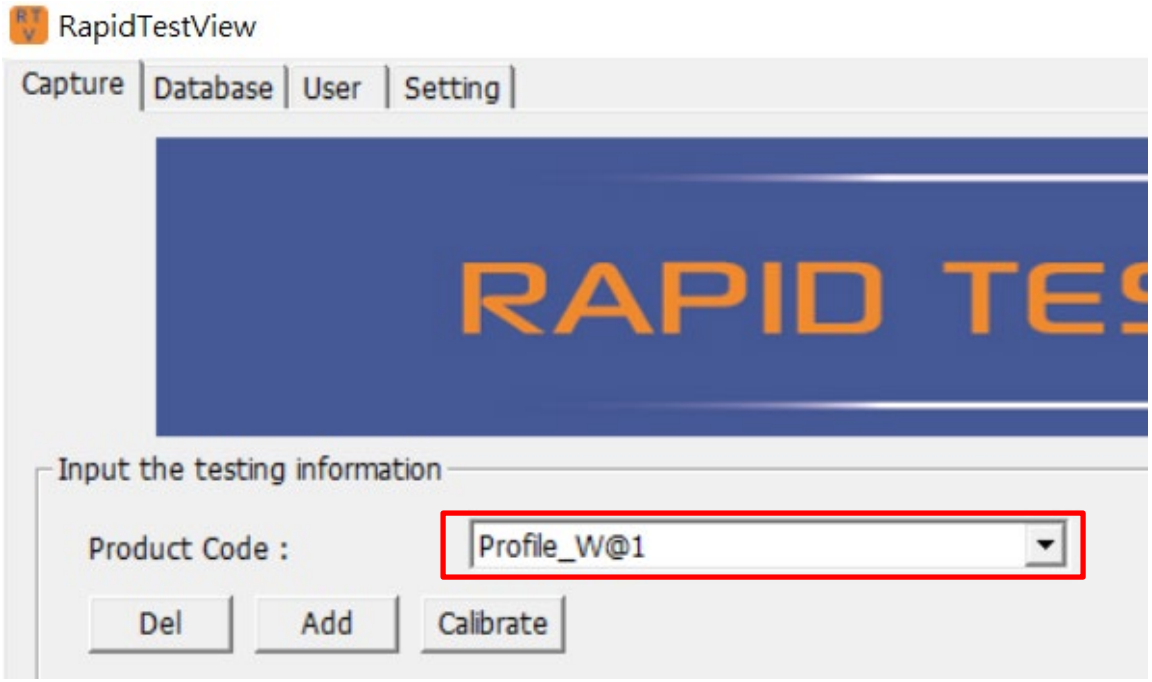
Guidance for diagnosis kit developer to create profile QR code image

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

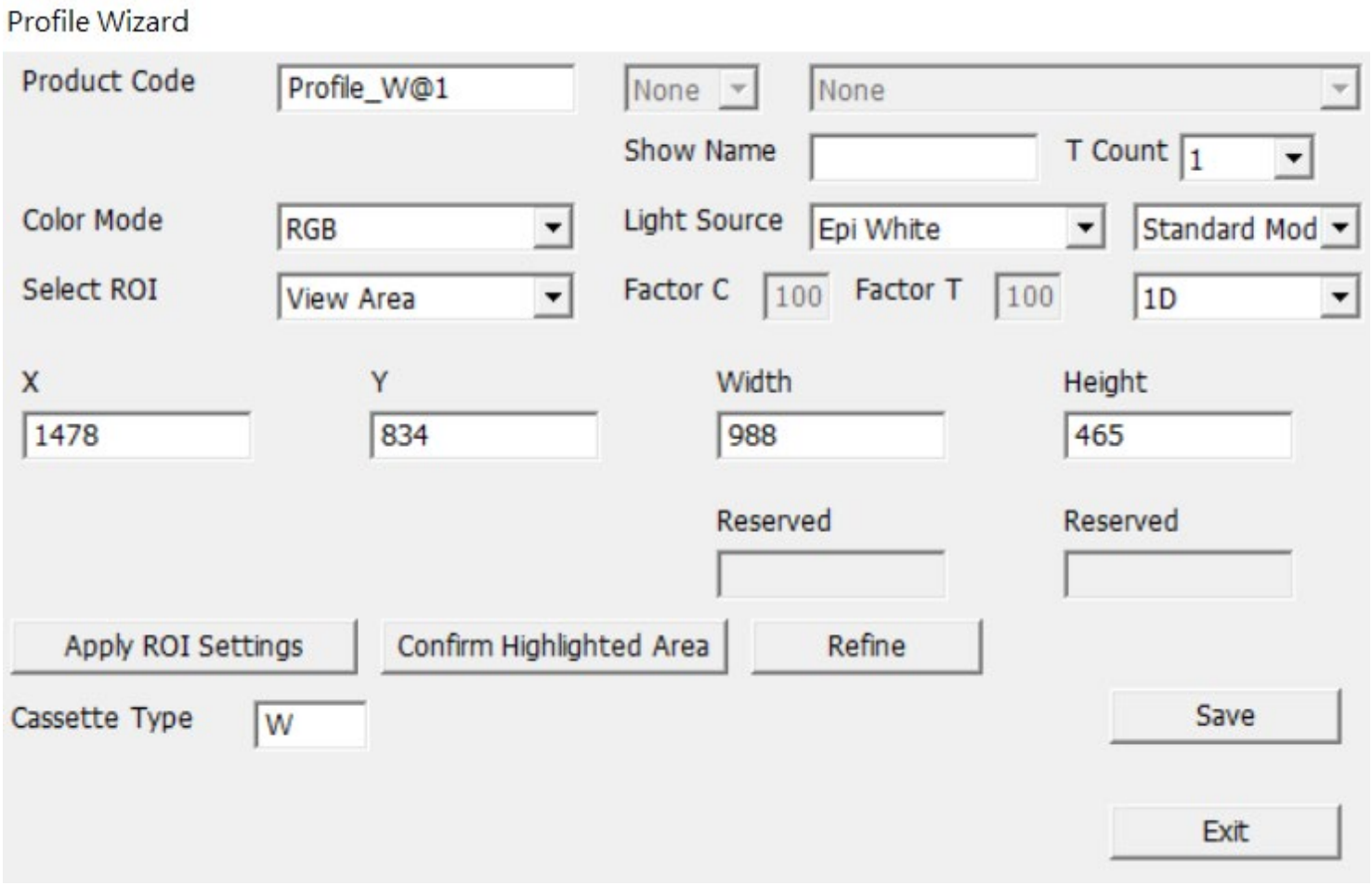


Choose the default profile template. Select any other preset profile in product code column.

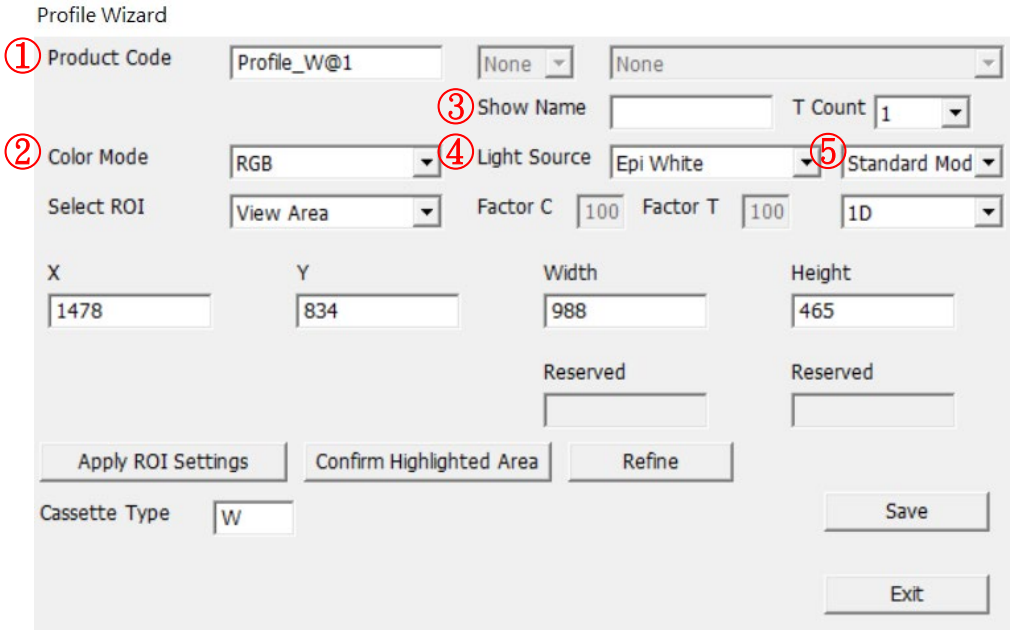
Please contact supplier if yours don’t exist any profile in product code column.

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.



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]

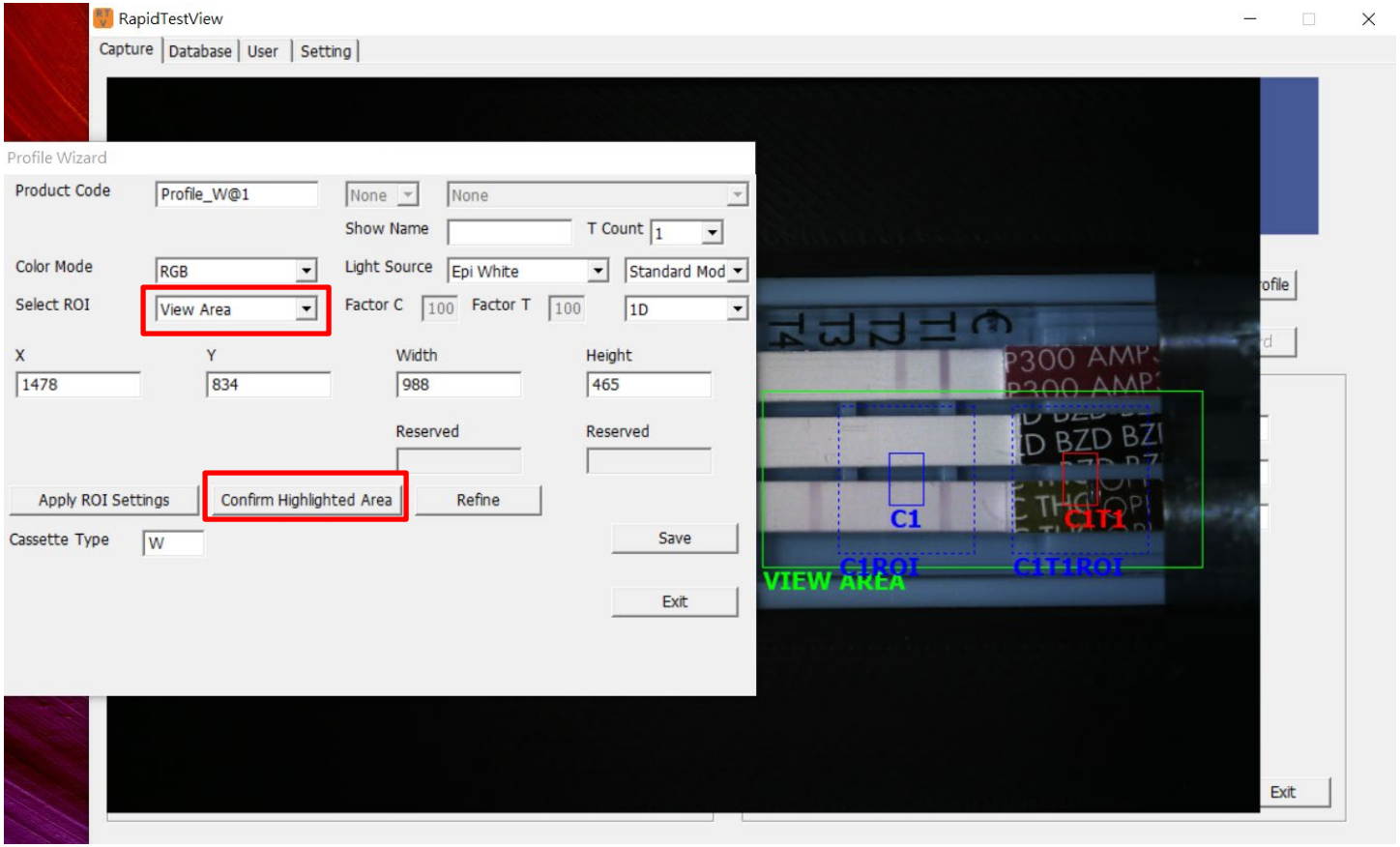
② Set Color Mode: "Default" is recommended. Please consult to supplier before change .

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)

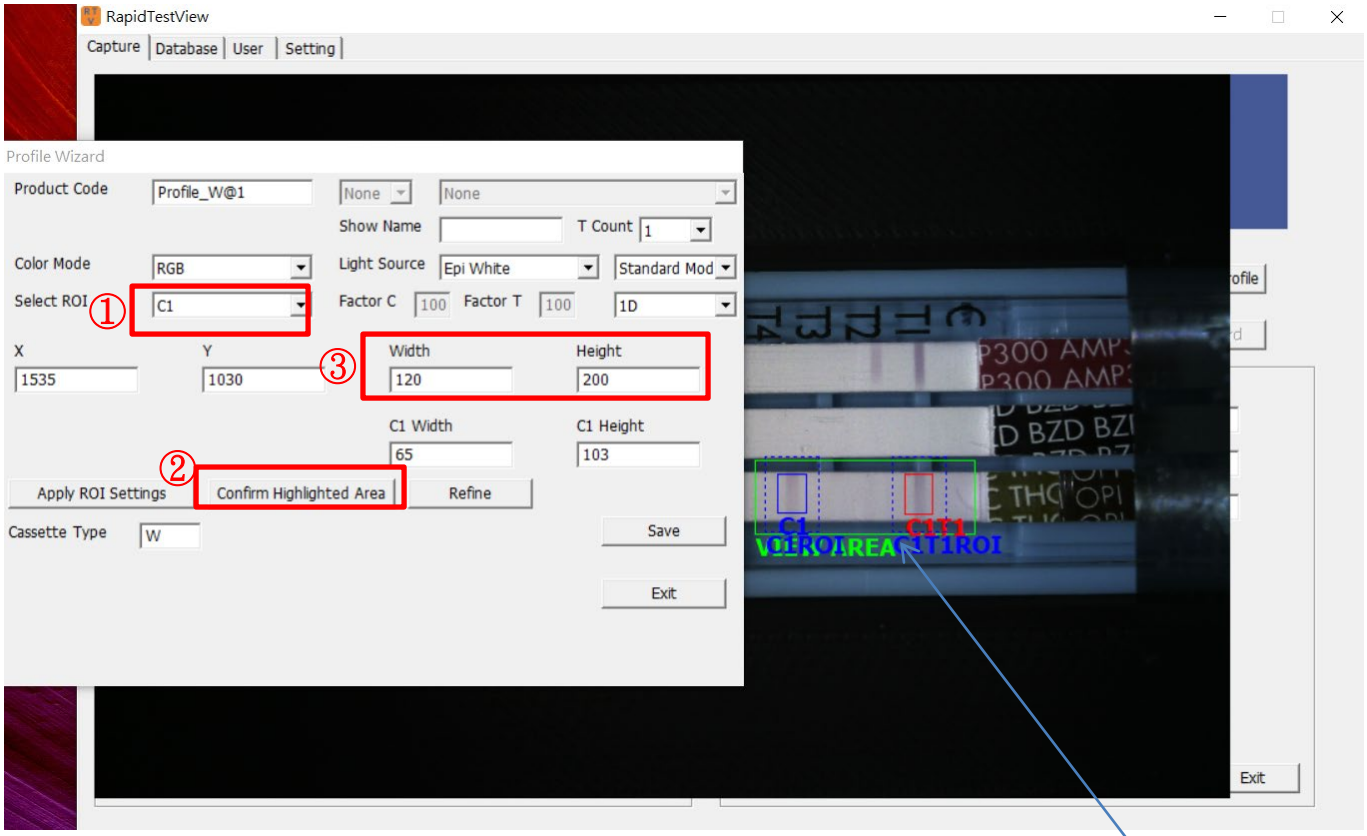


1.Set the “Select ROI” to “View Area”. Use mouse cursor drag a highlight area on the image viewer.

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



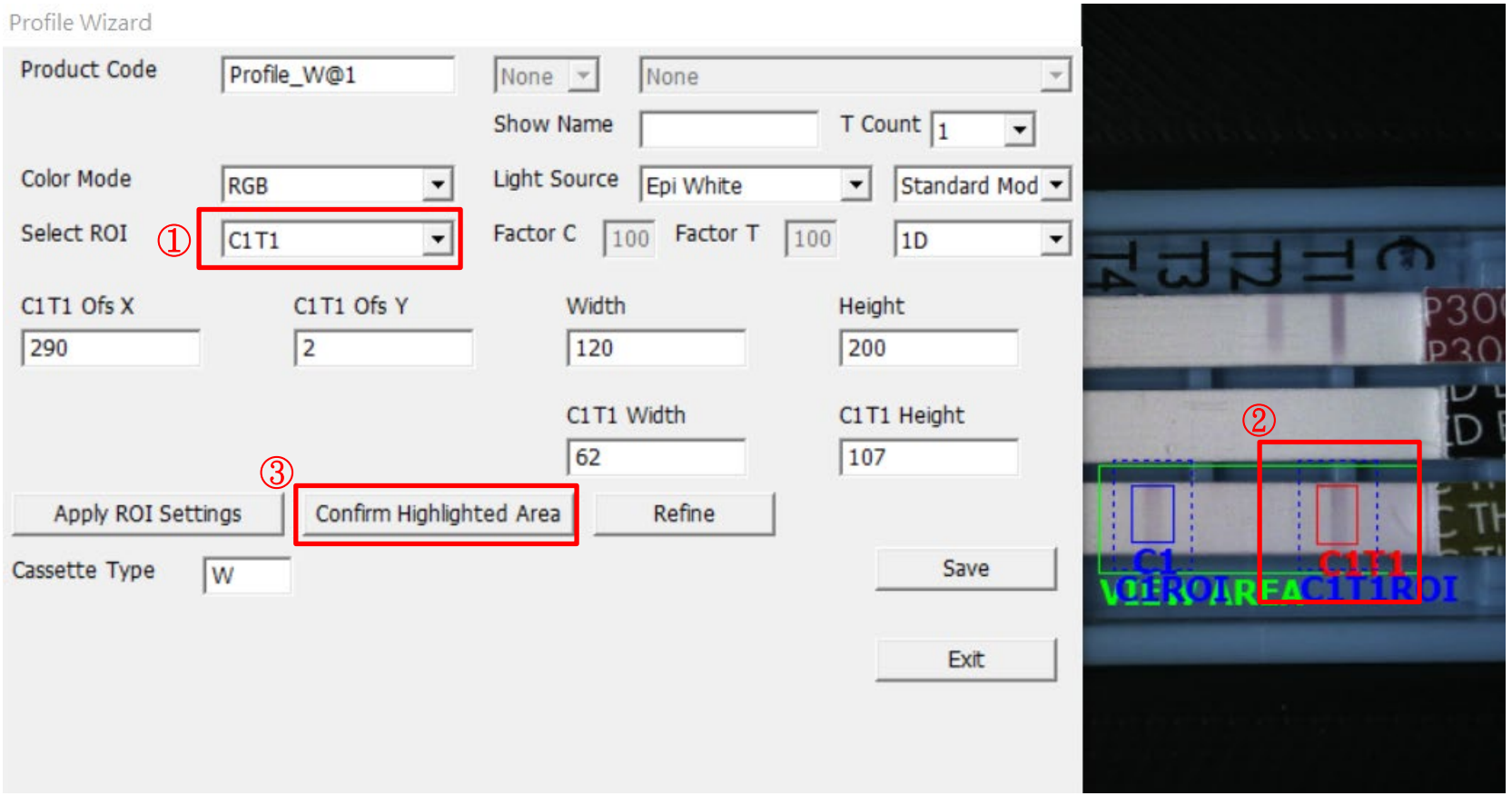
① Set the “Select ROI” to “C1”. Use mouse cursor drag a highlight area on the C line area.

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



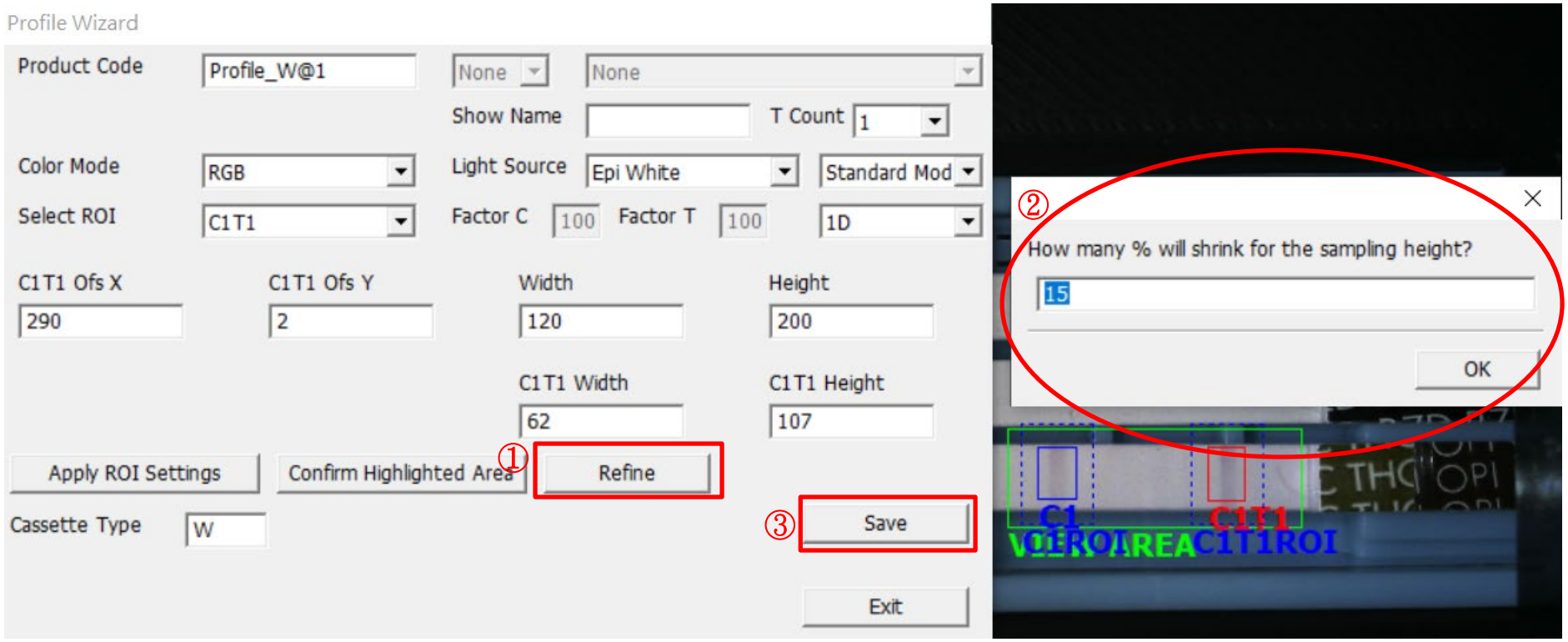
① Set the “Select ROI” to “C1T1”.

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

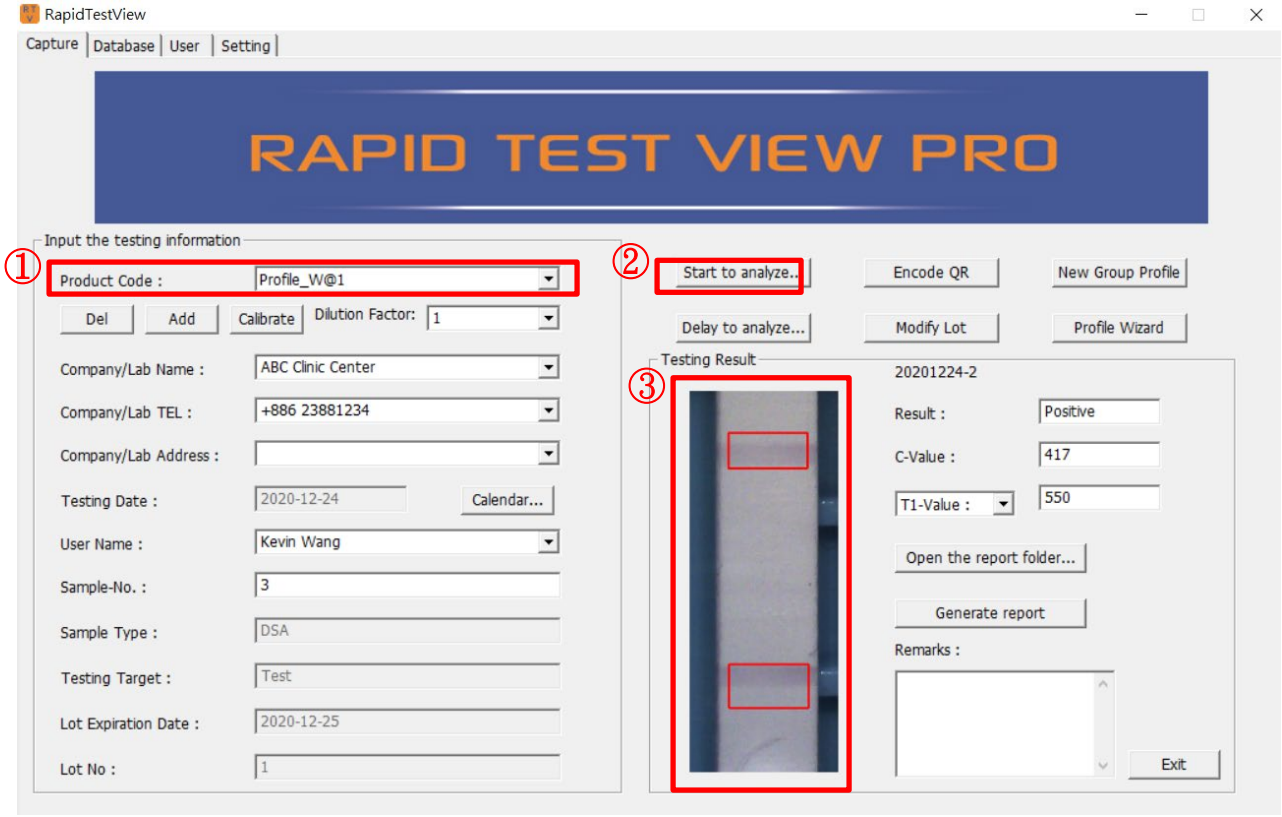


① After finish View Area, C, T line setting. Click “Refine”

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.

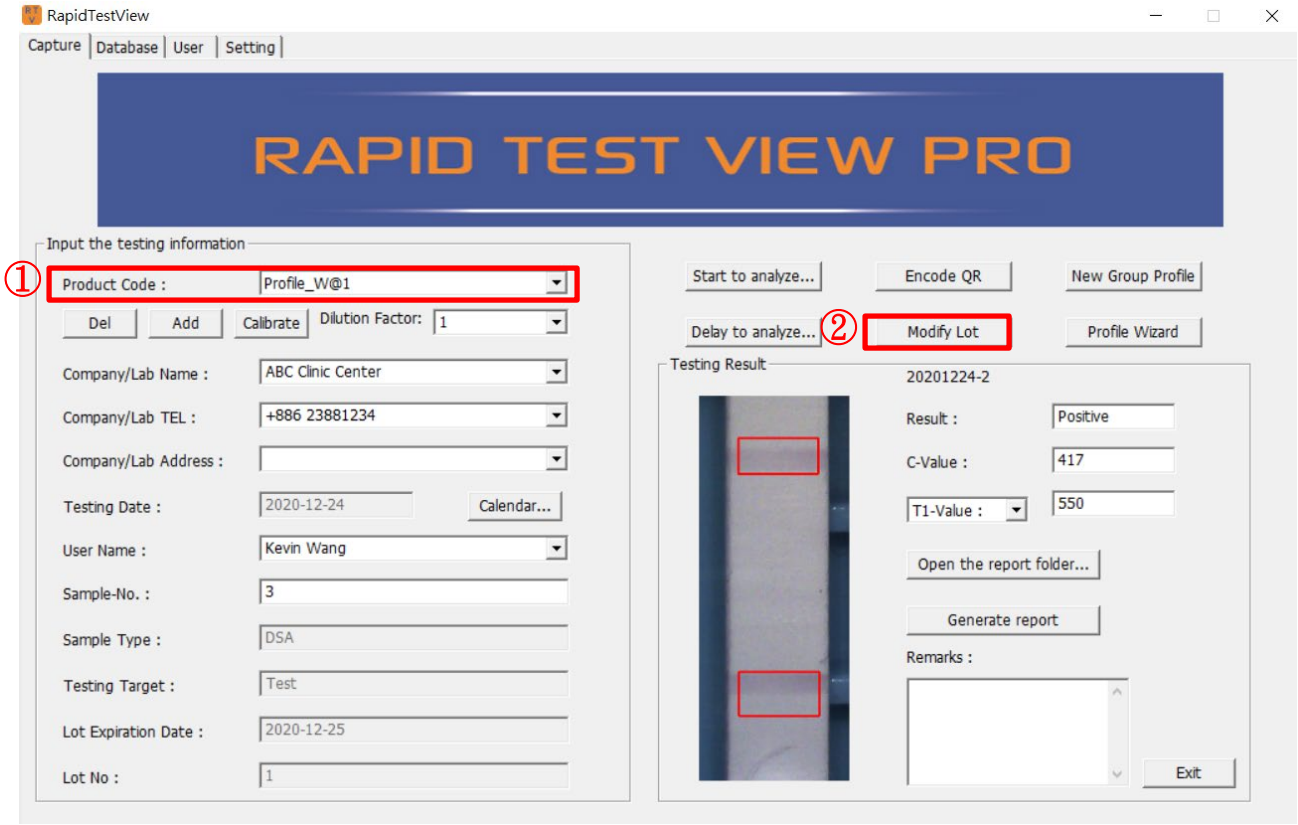
③ Check the strip image is created and the highlighted areas of C and T line are correct.

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.

Strip Lot information & Result calculation formula

Step. 1

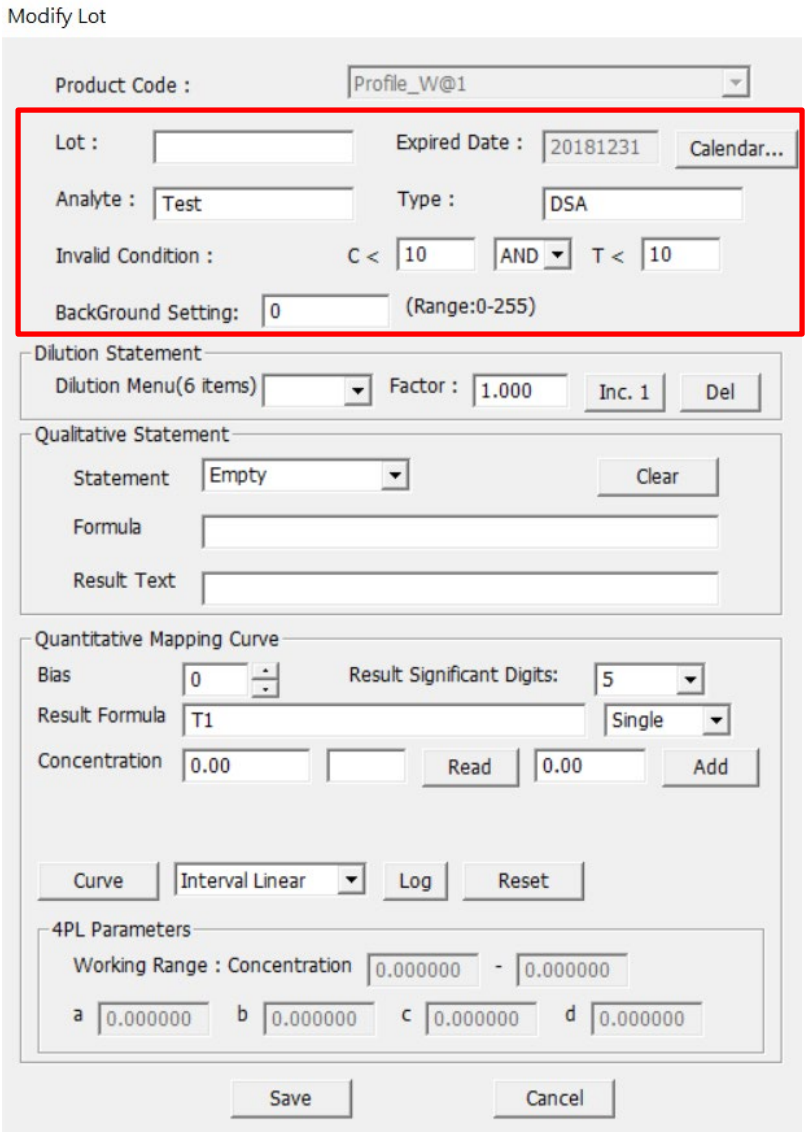


Check the newly created profile if it can be executed and correctly analyze your test strips.

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.

Step. 2



Fill the Basic lot information.

Lot - Test kit lot number.

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

Analyte - The analyte that the test kit will be analyzing.

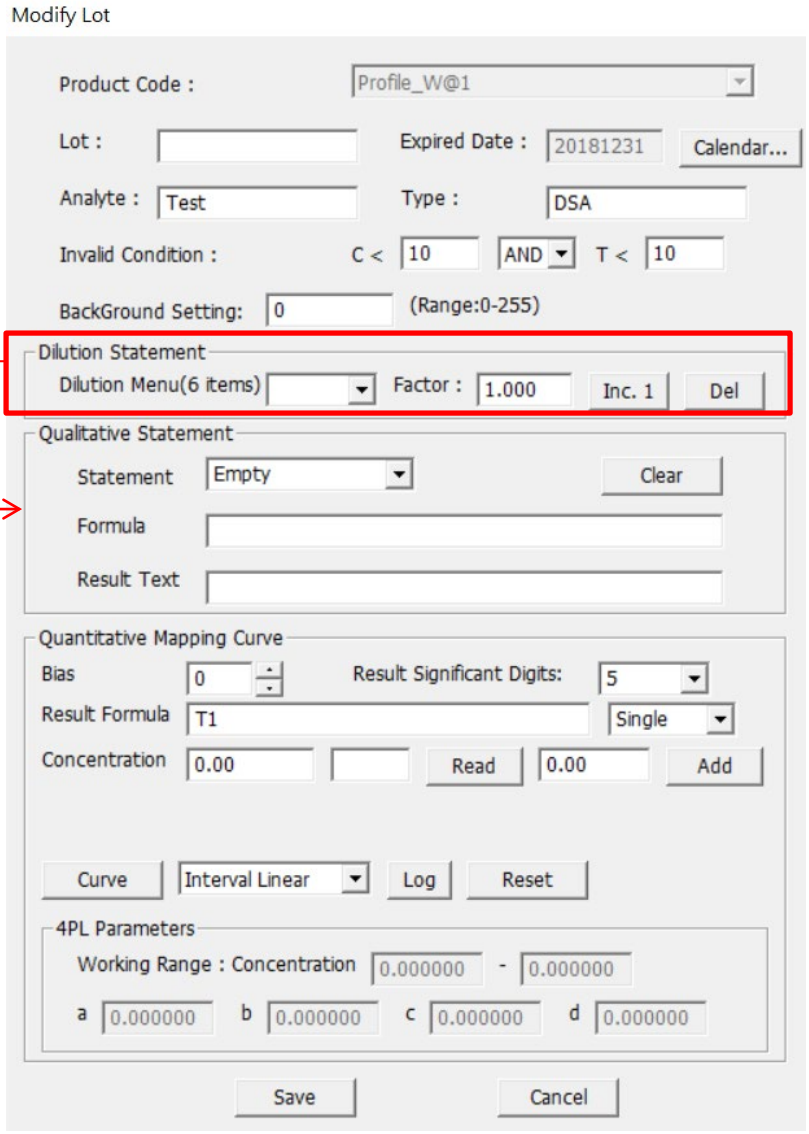
Type - Testing sample type required by this test kit.

Invalid Condition - Test kit failure condition setting.

BackGround Setting – 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.

※Background "much dark 0⟷ 255 much light"

Step. 3



Why dilute?

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

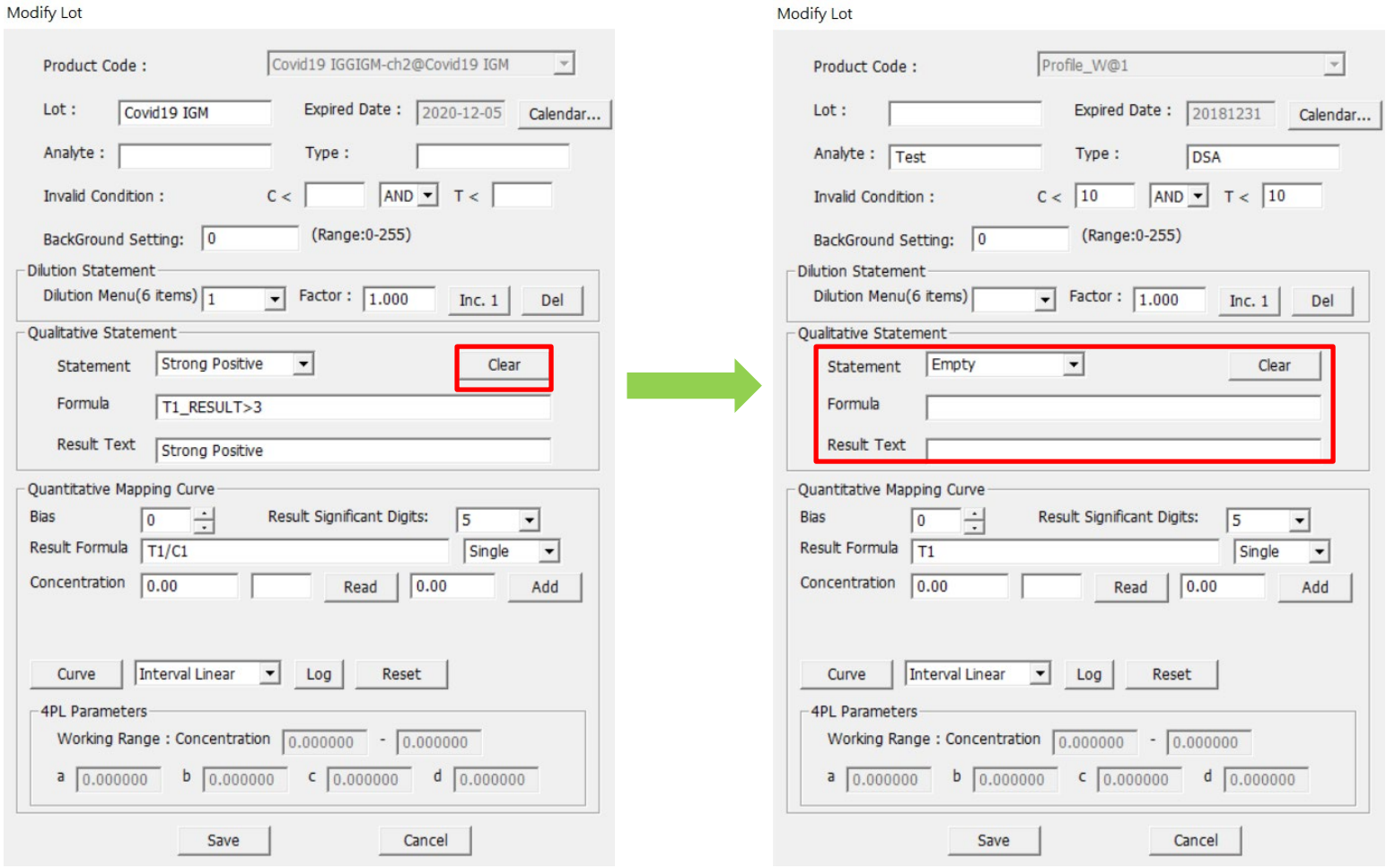
It's a setting for users to set their dilution.

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

↑Used by users to define their dilution factor.

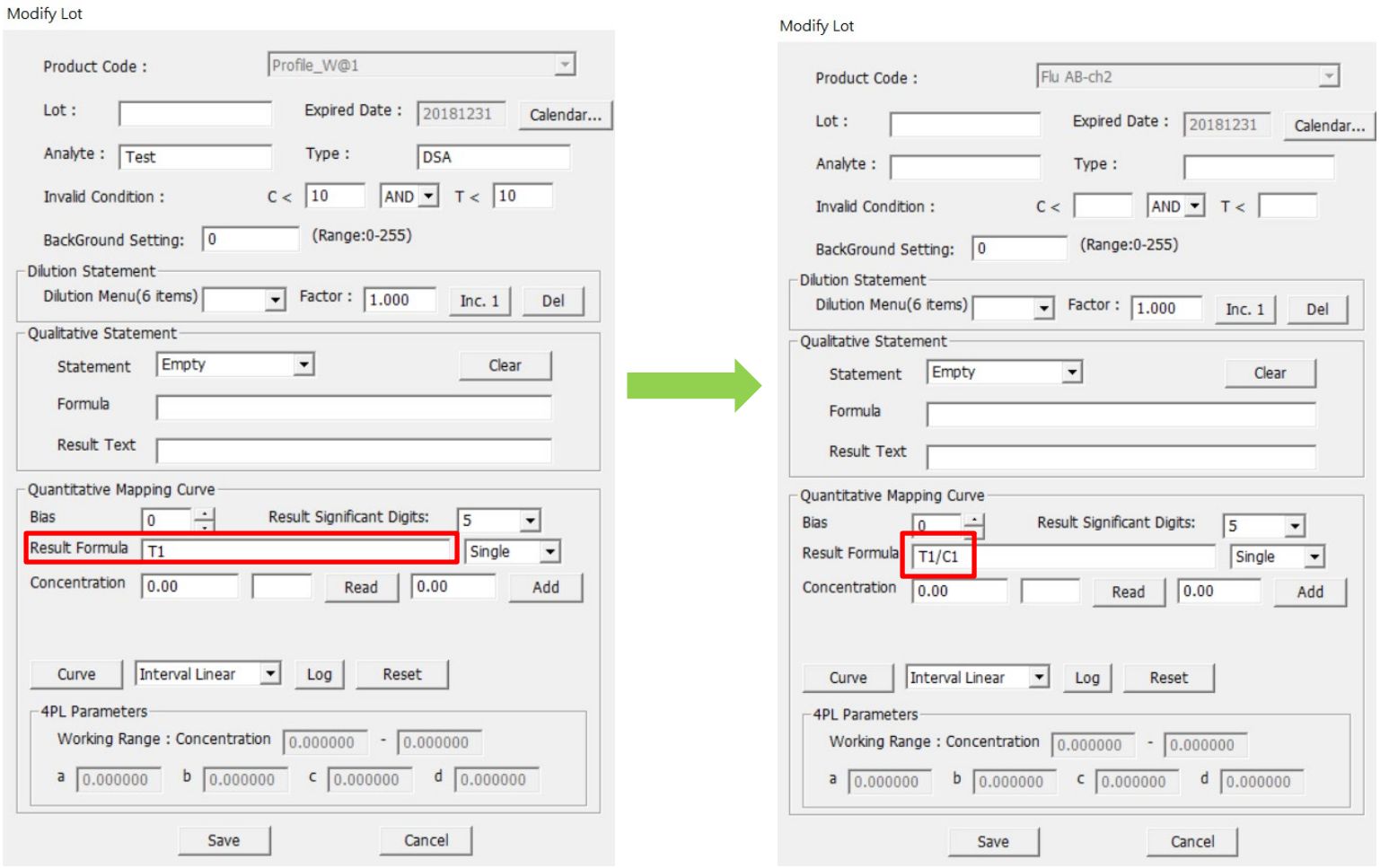
※One "Dilution Statement" only corresponds to one "Qualitative Statement".

Step. 4



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”

Step. 5



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,

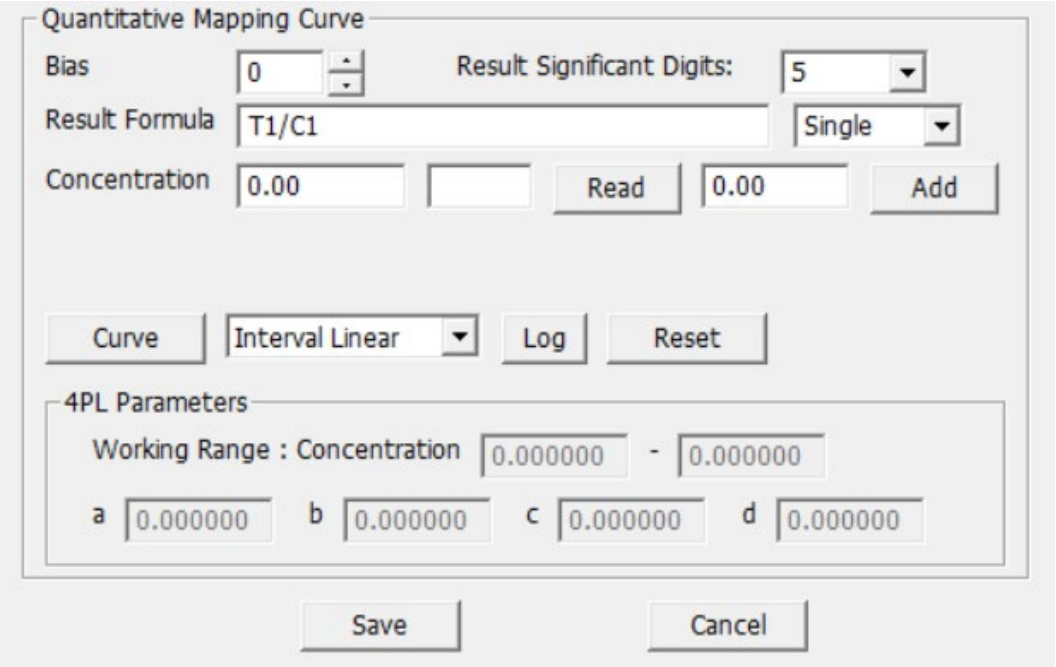
- Subtract,

* Multiply, e.g. T1*100

/ Divide,

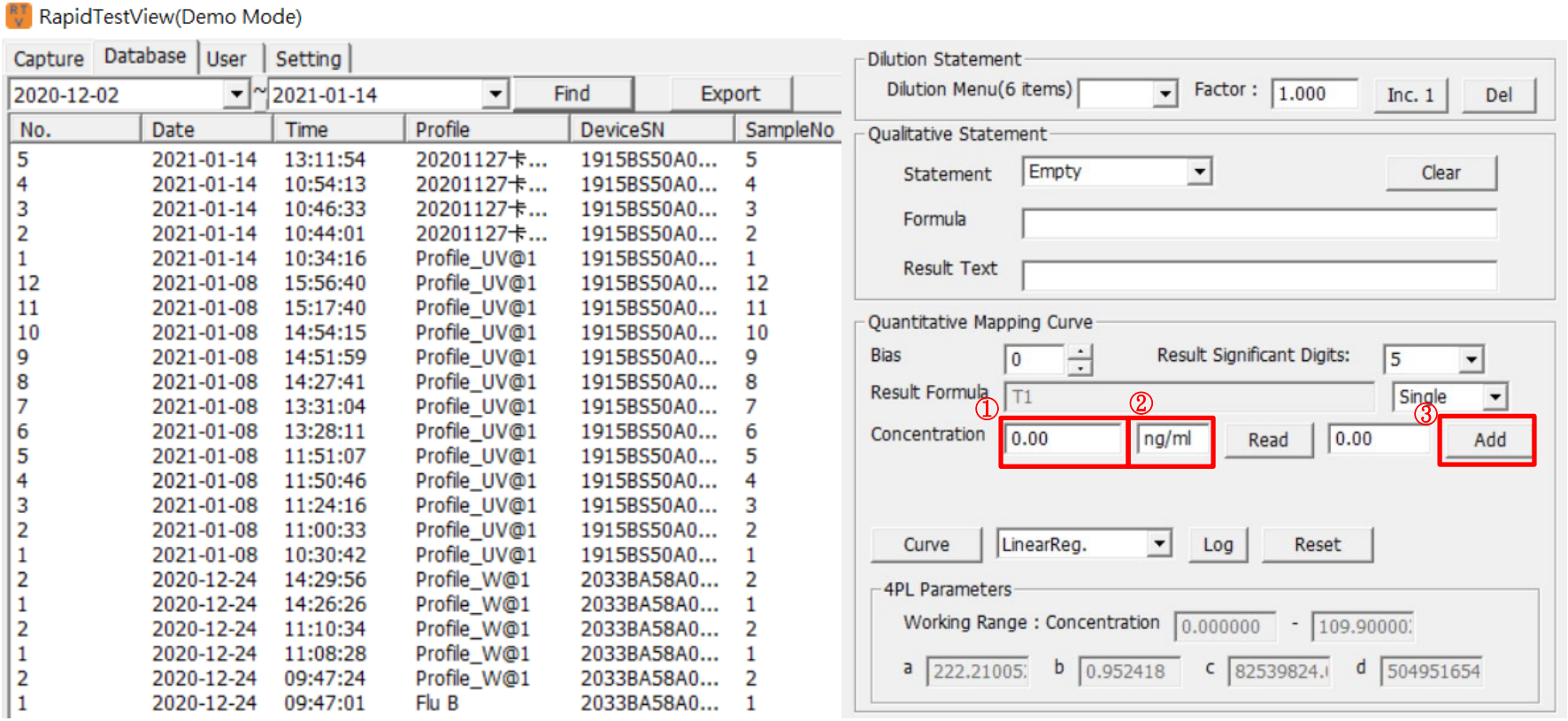
() Priority Calculation.

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.

1st & the most recommended way to establish a standard curve

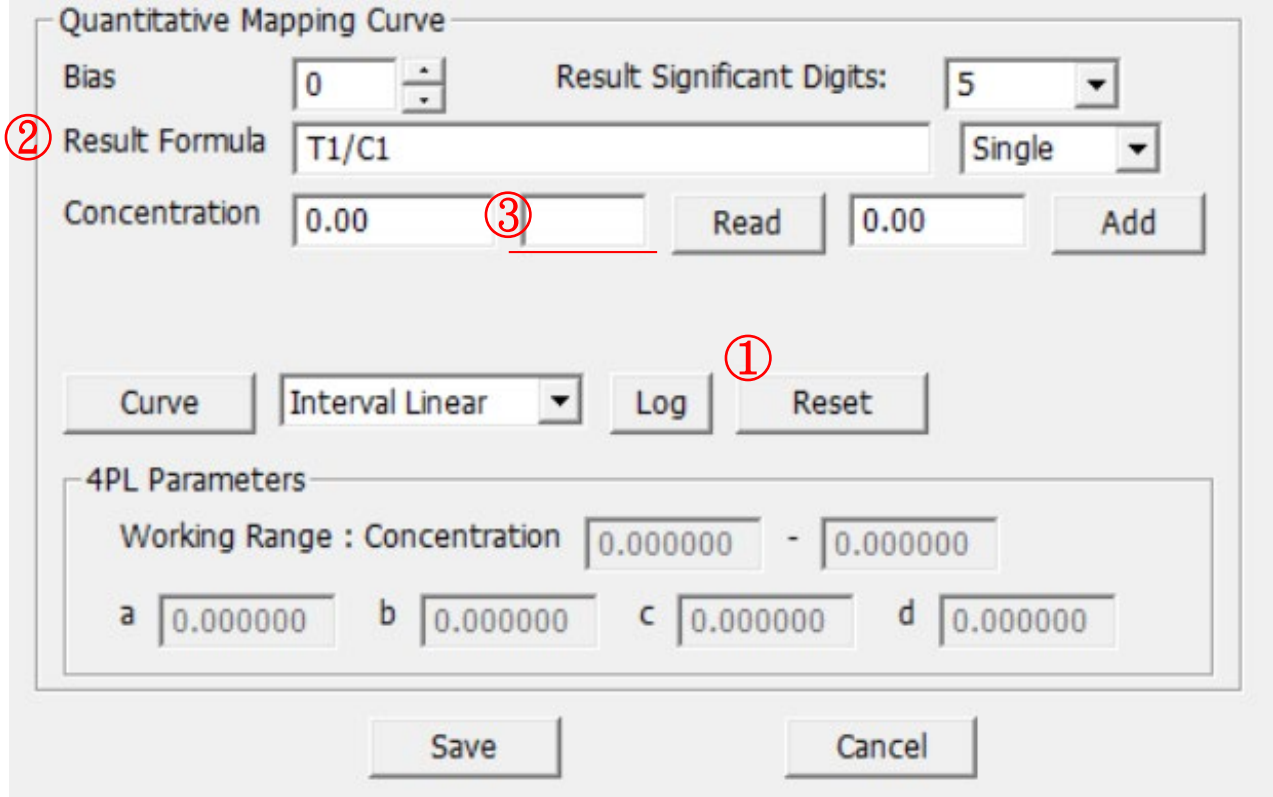


1. Go in Database, and export all the test data you need into CSV profile.
2. Use Excel to open the profile, and then you can calculate for example: the T/C value for each concentration.
3. Go to Modify Lot and ① fill in the value you just calculate & ② the unit (ppb, ng/ml…etc.) for your result.
4. 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.

2nd way to establish a standard curve (5 steps)

Step. 1 Set basic information



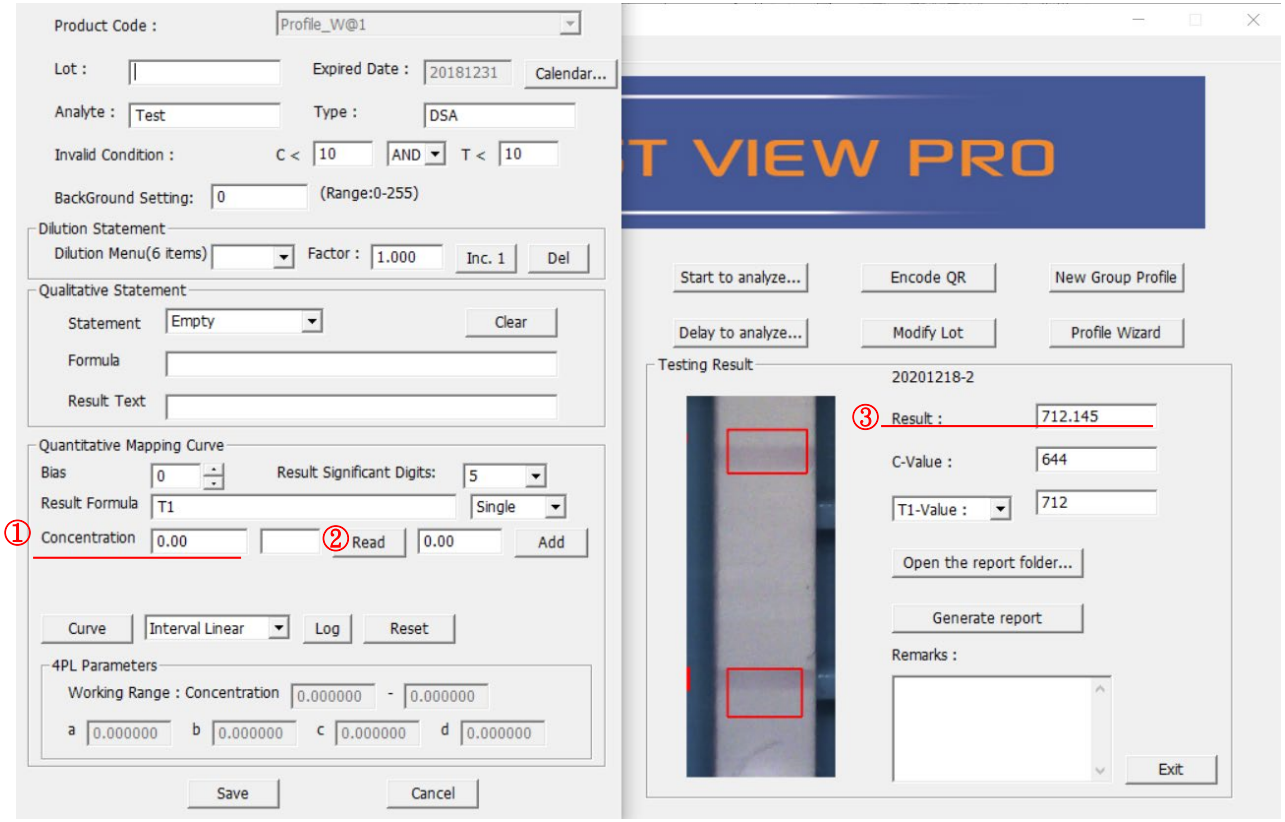
Make sure the Product Code and each Lot information field are correct.

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.

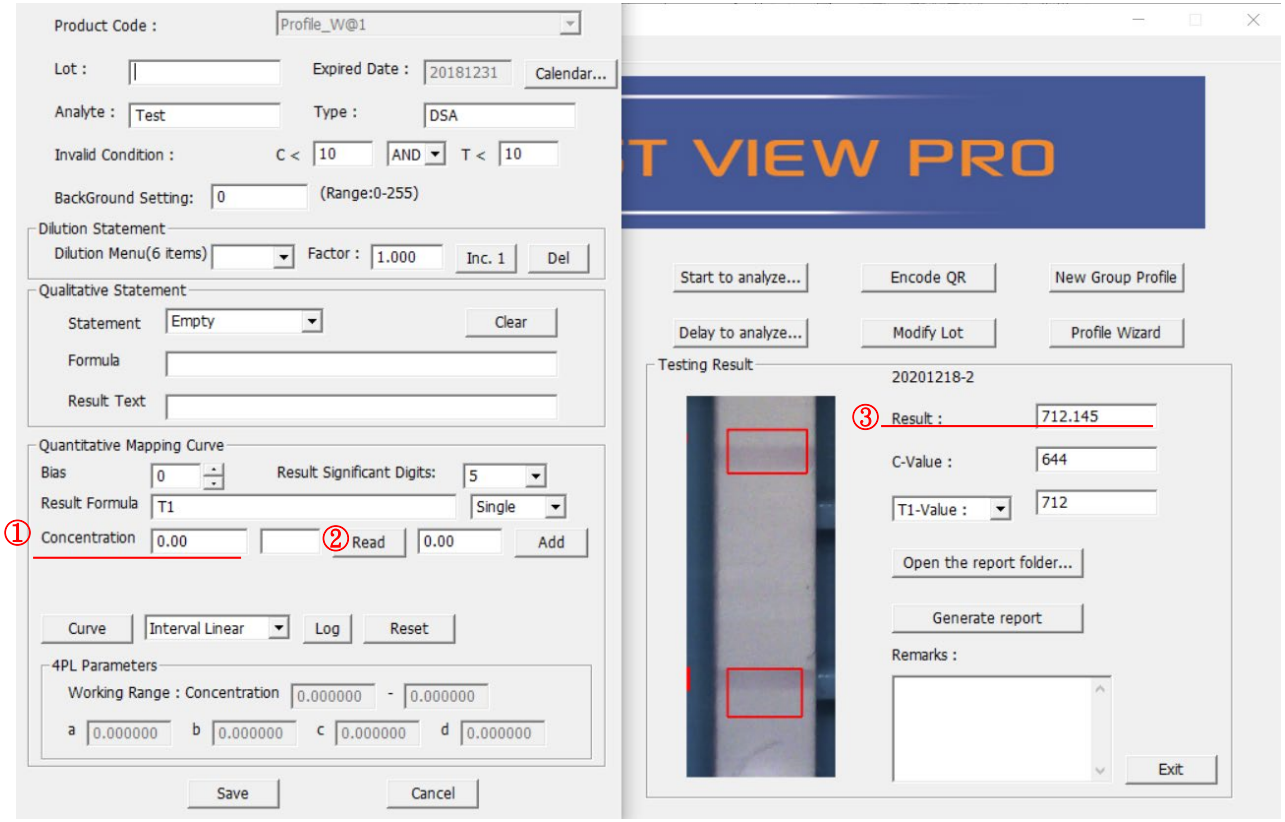
① Input the concentration values. The concentration values should be corresponding to the samples you insert to Reader later.

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.



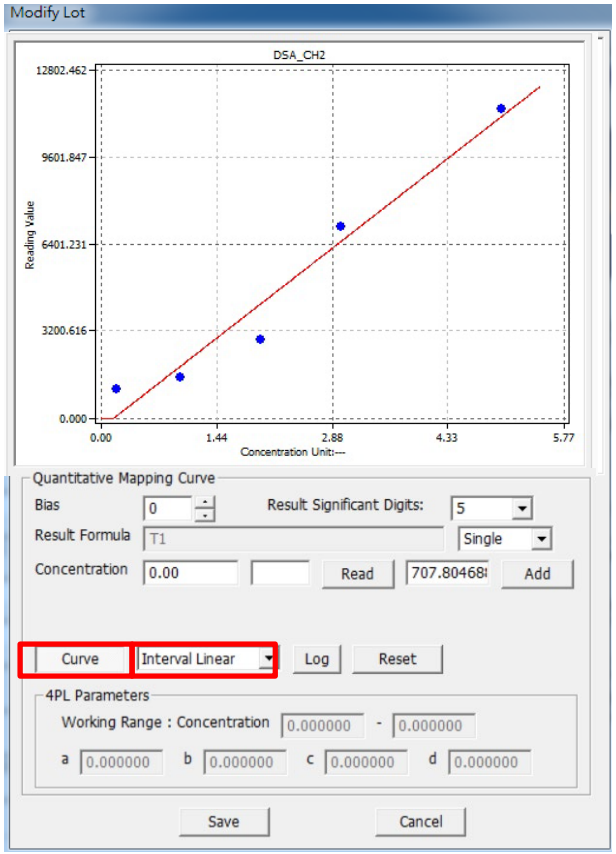
① Input next concentration value

② Insert the test sample of the same concentration to Reader and click “Read” to read the value.

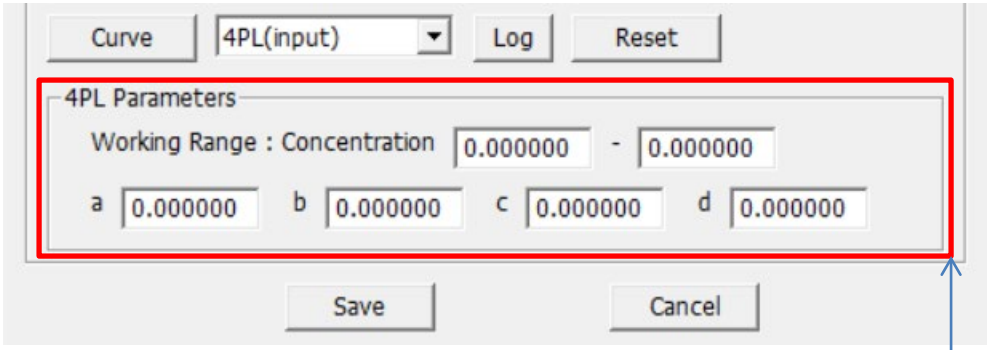
③ Check if the reading value and the result image are correct and confirm the Question Dialog.

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.

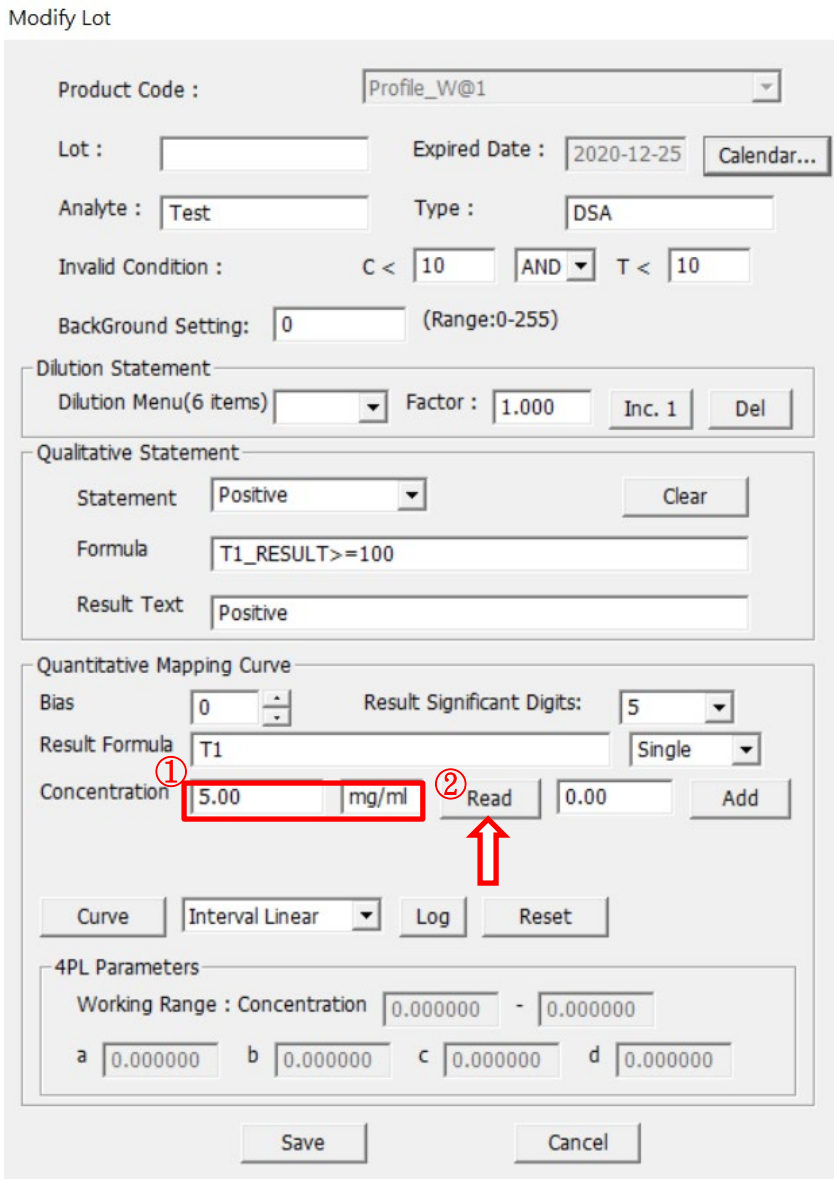
** You can apply 4PL value calculated by other software. Select “4PL(input)” then input value in above column to create standard curve.

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.

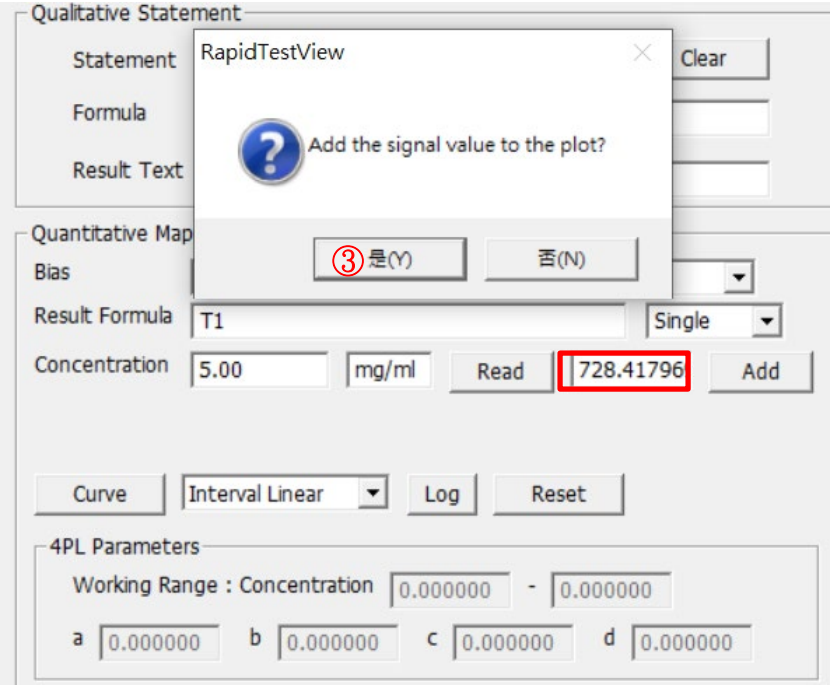
Example to create standard curve (interval linear)



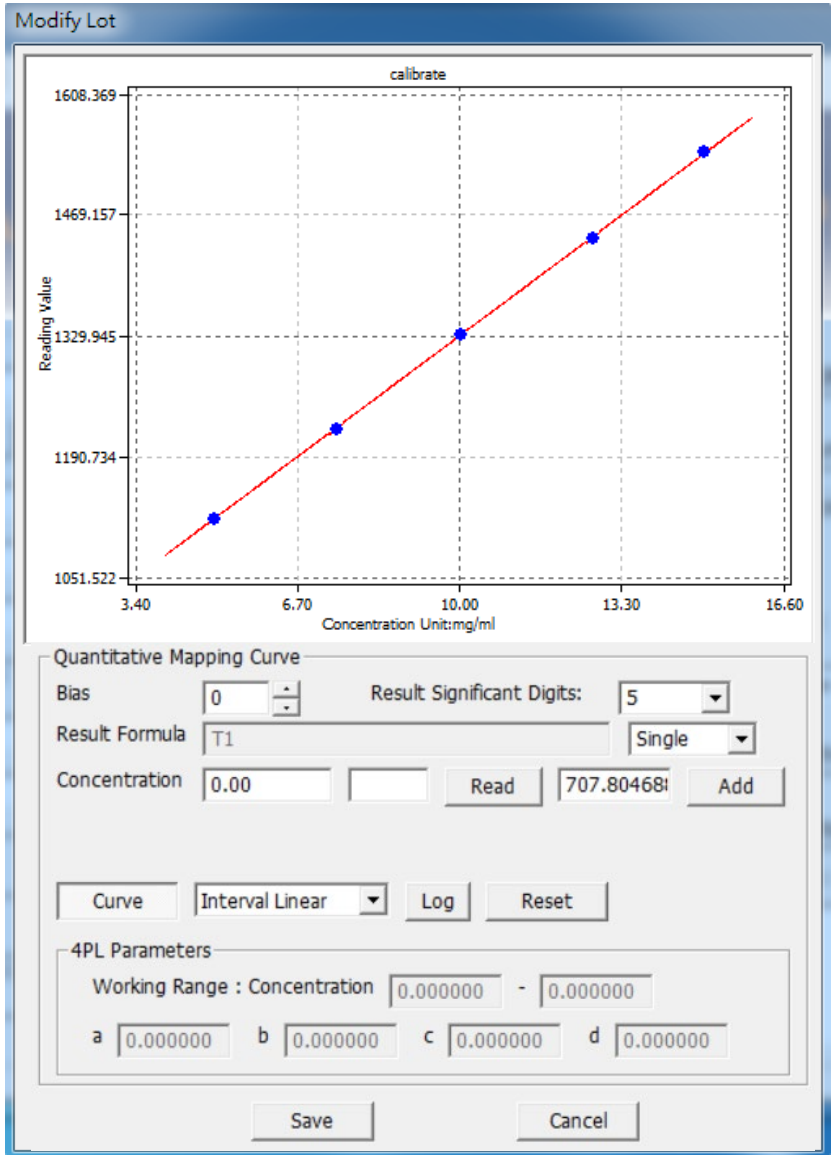
① In “Modify Lot”, input the concentration of standard product including its unit. In this example, we took 5.00 mg/ml sample.

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.



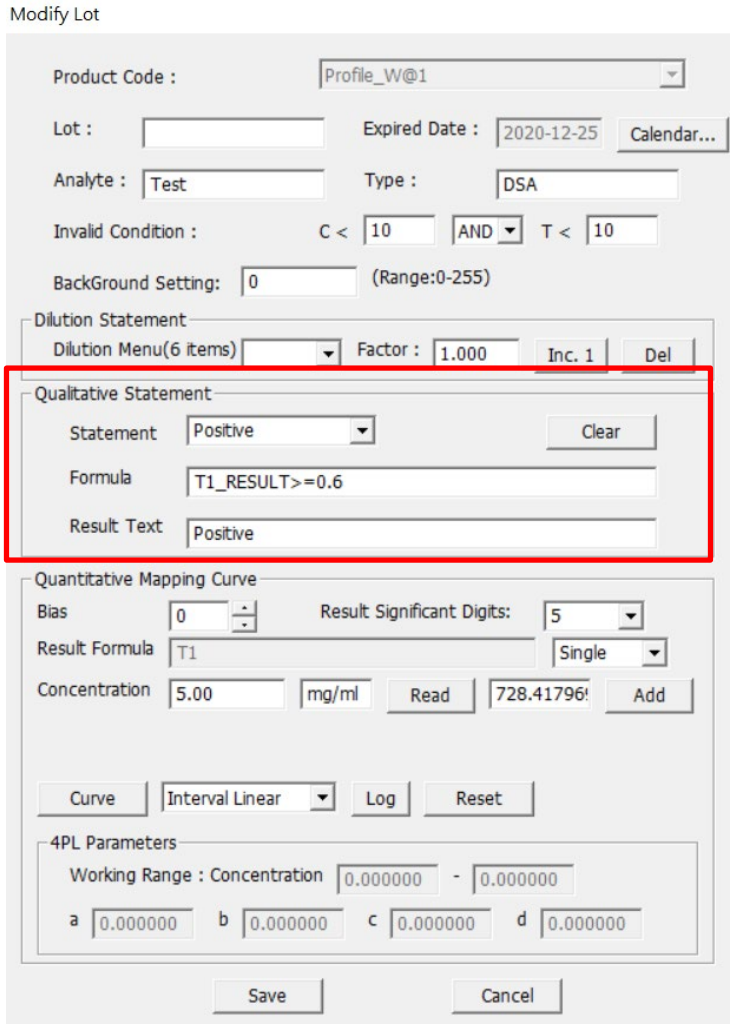
Example to create standard curve (Interval Linear)



1. 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.
2. Here “Interval Linear” is selected and press “Curve” that comes with a useful plot on this UI.
3. 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”.

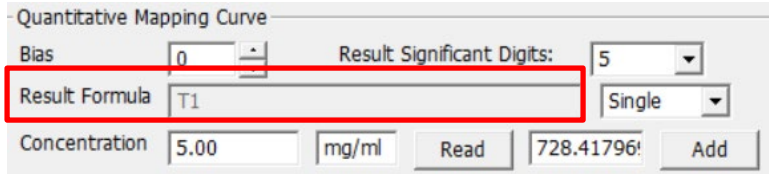
Semi-quantitative testing:

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_RESULT – The resulting value by “Result Formula”

T1_CONCENTRATION –

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

Supported Operation Symbols

= 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

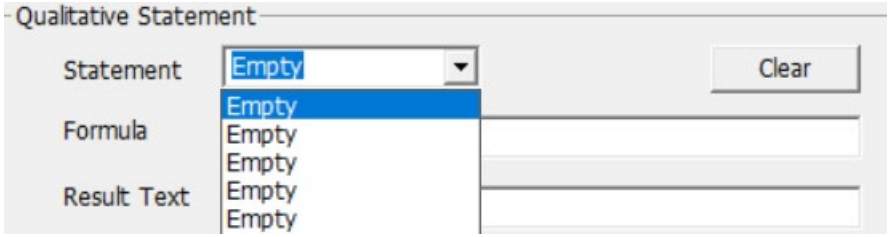
T1 > 100, The result field shows “Positive”.

T1 < 50 , The result field shows “Negative”.

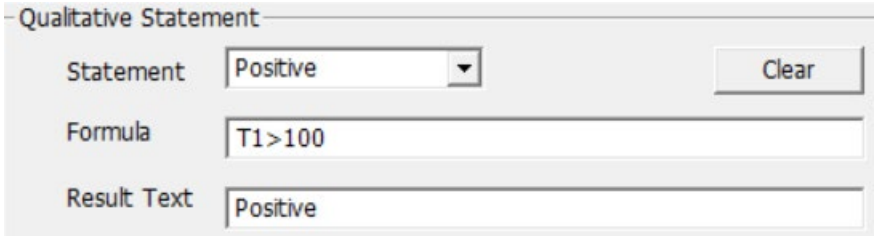
T1 between 100 and 50 , The result field shows “Retest”.

Please follow steps below to enter your statements.

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

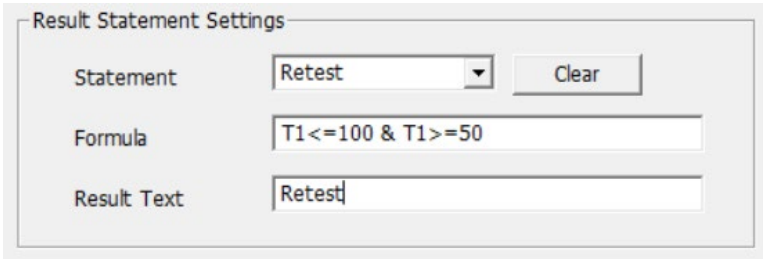


2. Choose first “Empty” statement, in Formula Field input “T1>100”. And in Result Text Field input “Positive” like below. (The Text Statement will display exactly the same Text as the “Result Test”)

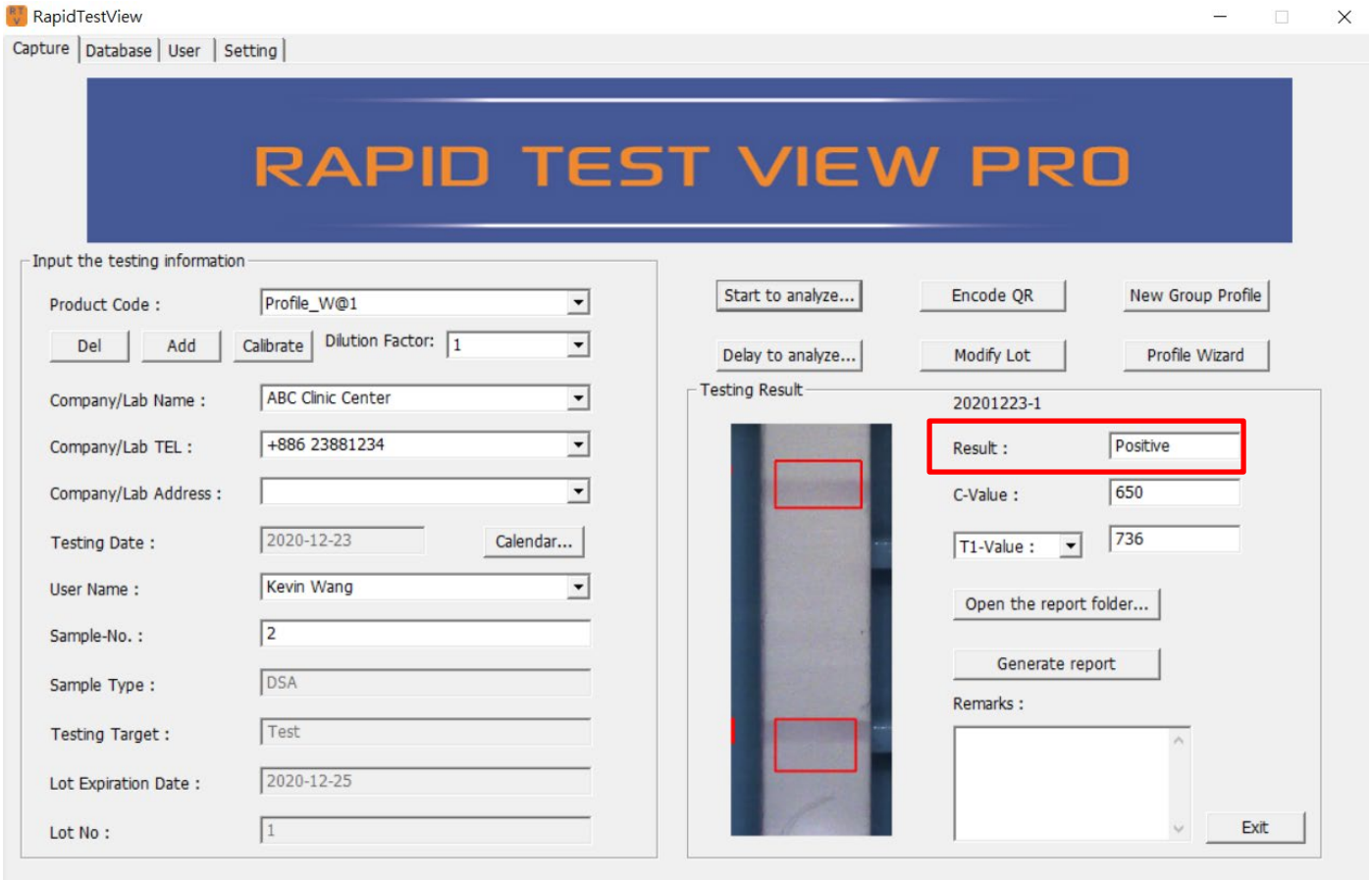


3. Choose next “Empty” Statement and complete the input like below.

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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