Exdia TRF Plus User Manual

PRECISION



Contents

Preface
Specifications
Precautions7
Symbols8
Summary9
Introduction9
Components
System Description11
Installation13
Operation14
Power On
Registration15
Login
Menu
Log Out
Power Off
Testing24
Register a QR Card24
Testing
Result
Print
Share
Detail
New Test

Test Results
Results
View
Delete
Export
External QC Result45
View
Graph
Export Results
Export Samples
Delete
Quality Control
Running IQC
Running EQC61
Settings67
Date/Time/Language67
Network/LIS71
Printer/Sound74
Operator77
Advanced81
Service
Test File Manager
Set Ref.Range91
Quality Control of the Cassette97
Export
Add100
Modify
Delete
Information107
Maintenance110
Replace Printing Paper110
Maintenance112
Troubleshooting114

Preface

Notice

Thank you for purchasing the Exdia TRF Plus.

Exdia TRF Plus is an image based immunochromatography analyzer with time resolved fluorescence analysis technology. It is an in vitro diagnostic device that provides quantitative or qualitative results from the concentration of a substance analyzed using samples of human blood or body fluids.

Before using the Exdia TRF Plus, be sure to read the instruction in user manual carefully and observe all aspects of operation, maintenance, etc.

If you have any questions or need further information, please feel free to contact Precision Biosensor Inc. Customer Support (support@precision-bio.com) or your local distributor.

Warranty

Exdia TRF Plus is manufactured in a proven facility and has passed strict quality control and inspection.

The warranty covers the manufacturing defects and problems that occur when used in compliance with the user manual.

For warranty service, please contact Precision Biosensor Inc. Customer Support (support@precision-bio.com) or your local distributor.

Parts replaced in the repair process become the property of Precision Biosensor Inc.

In the following cases, repair costs will be charged even during the warranty period.

- Use of components, parts, and accessories not included in the analyzer
- Modification or repair of the analyzer without permission
- Malfunction due to user's improper handling
- Failure or damage caused by external force
- · Failure or damage caused by natural disaster
- Non-compliance with Exdia TRF Plus User Manual requirements



Check the specifications before using the product.

Item	Description/Value			
Model name	Exdia TRF Plus			
Operating system	Linux			
Display	7-inch color LCD (Resolution 800 x 480)			
I/O interface	x USB 2.0 / 1 x RJ-45 LAN connector			
User interface	Touch screen			
Supported accessories	Mobile barcode reader, keyboard, mouse, USB memory (optional)			
Test result	10,000 test results can be saved.			
Voltage/Current	12 V DC / 5 A			
Power consumption	20 W			
Dimension (Width x Height x Length)	210 mm x 182 mm x 275 mm			
Weight	1.6 kg			
Operating temperature	10 °C-40 °C			
Storage temperature	-10 °C–50 °C			



- ▶ Use the Exdia TRF Plus as described in this user manual.
- Do not operate this Exdia TRF Plus with accessories that are not provided nor recommended by Precision Biosensor Inc.
- Designate a supervisor who will install and manage the Exdia TRF Plus. The operator should be an expert who is trained to operate the analyzer correctly.
- Check the operating environment before using the Exdia TRF Plus.
- Operating environments.
 - Place with a temperature ranging between 10 °C and 40 °C.
 - Place in which the humidity ranges between 10% and 80% (No Condensation)
 - Place where the altitude is less than 2,000m.
 - Place the analyzer on a flat surface.
 - Place with low levels of dust and proper ventilation.
 - Place where there are no physical or chemical risks.
 - Place where there is no explosive, flammable or perishable materials.
 - Place where direct sunlight can be avoided.
- Installation
 - Only use the power adaptor provided together with the analyzer. If the power is improperly supplied, the analyzer may be damaged and malfunction.
 - Only connect the power adaptor to a grounded electrical outlet.
 - Do not use if the Exdia TRF Plus is damaged or malfunctions
 - Operating the Exdia TRF Plus in an incorrect or inappropriate manner may cause an electric shock, burn, fire or other risks. Use only the power adaptor provided together with the Exdia TRF Plus .
- Use
 - Do not throw, shake or drop the analyzer. Doing so may damage internal parts, causing the analyzer to malfunction.
- Biological risk
 - If the analyzer is contaminated with a sample, be sure to clean it before use.
 - Wear protective equipment such as gloves and masks to prevent infection or contamination.



Symbol	Description
	Direct current (DC)
\triangle	Caution
CE	This analyzer meets the requirements of Directive 98/79/EC on in vitro diagnostic medical devices.
	Look for descriptions or refer to the user manual for the correct and safe use of the analyzer.
REF	Catalog No.
SN	Serial No.
	Manufacturer
EC REP	Agent of the European Community
IVD	In vitro diagnostics medical apparatus
	Limitation of temperature for storage
$[\begin{tabular}{c} \end{tabular} ta$	Manufacturing date
14	Caution! Risk of electrical shock
Ś	Biological risk
	Waste disposal guidelines for electronic and electrical equipment



Before using the product, check the overall information, composition, part name and installation method of the product.

Introduction

The Exdia TRF Plus is an image based immunochromatographic analyzer with time resolved fluorescence analysis technology which provides qualitative and quantitative test results.

Exdia TRF Plus analyzers can be used with Exdia cassettes to analyze specific in vitro analytes in human specimens.

Using the built-in printer and data management software, all patient information can be printed or sent to a central information system.

The wide 7-inch color LCD touch screen and a detailed step-by-step instruction makes the analyzer easy to operate.

<Main Functions>

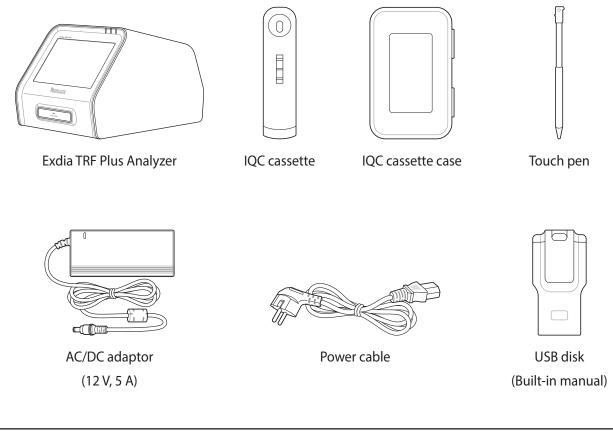
- 7-inch color LCD touch screen
- Quantitative and qualitative analysis for POCT
- LIS/HIS interface software
- Remote access
- Barcode and QR code
- Quality control using external quality material.
- Stores a total of 10,000 sample and quality control data.

<Convenient Functions>

- Data management
- Internal printer (for thermal transfer).
- Operator management
- External printers supported (optional).



This analyzer is composed of the following components.

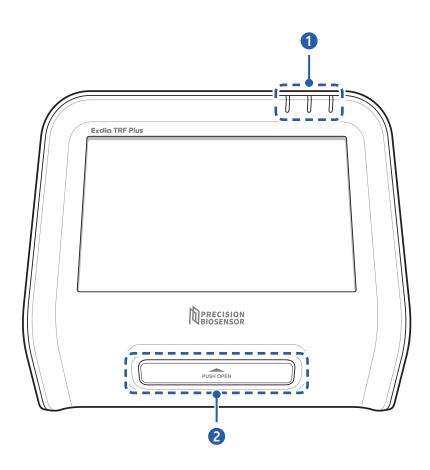


If any component is missing, or if you have any questions regarding the components, contact the
 Note
 Customer Support Team. (e-mail address: support@precision-bio.com)

System Description

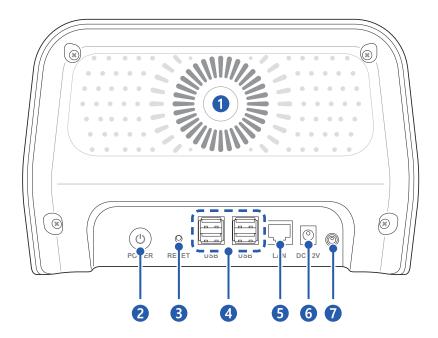
Before installing the analyzer, check the system description below to operate the analyzer efficiently.

Front



No.	Name	Description
1	Status indication LED	Indicates the analyzer status using a colored LED.
		• OFF : The analyzer is turned off.
		GREEN: The analyzer is turned on.
		BLUE: The analyzer is testing a sample.
		 RED: A power supply is not connected to the analyzer, but the analyzer is turned on.
		(Even when the power is not supplied to the analyzer, the analyzer can be operated for up to 1 hour and 30 minutes using the built-in battery. When a power supply is connected, the battery will be charged.)
2	Cassette slot	In addition to the Exdia cassette, the IQC and QR cards can be inserted.

Back side



No.	Name
1	Vent
2	Power button (The power can be turned on or off.)
3	Reset button (Press the Reset button with a thin pin to turn off the system if the analyzer does not operate normally. To turn back on the system, press the Power button.)
4	USB port
5	LAN port
6	DC adaptor jack
7	Temperature sensor

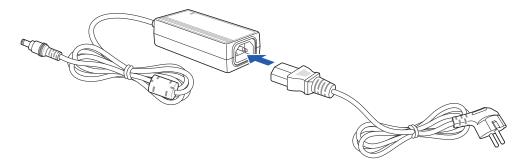


<u>À</u> Caution

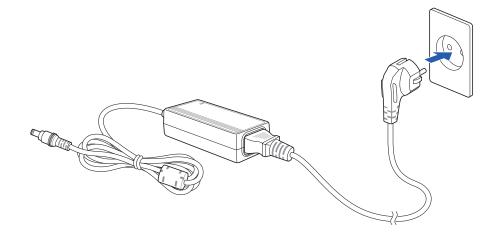
• Install the analyzer on a flat surface.

• Check the voltage supply before connecting the power supply. The voltage range should be between 100 V and 240 V.

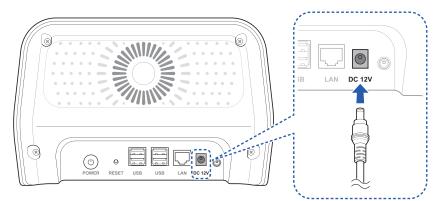
1. Connect the power cable and AC/DC adaptor.



2. Connect the power cable to an electrical outlet.



3. Connect the AC/DC adaptor to the DC adaptor jack on the back of the analyzer.





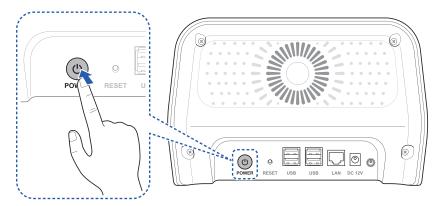
This is the description for using the analyzer after it is installed.



Use the Exdia TRF Plus only for an in vitro diagnostic purposes.



Press the [Power] button on the back of the analyzer.





The analyzer to which this user manual refers to may differ slightly from the actual analyzer according to the customer's requirements.



Note

When you turn on the analyzer for the first time, the Supervisor Registration screen will appear. When you register the supervisor information and press the **[Register]** button, registration will be completed.

• The operator registered initially in the Exdia TRF Plus is registered as the supervisor.

• For registering an additional operator, refer to "Operator" on page 77.

Supervisor Registration

Supervisor Registration						
Supervisor must be registered at this step	for further step					
ID * Password * Confirm(PW) * Name Organization						
Department	Register					
	🖼 🏭 🛃 🌵 🖶 🕎 2017/01/22 12:51 am					

ltem	Description						
Supervisor	Register a supervisor by entering the required information.						
Registration	• ID: Enter ID.						
	Password: Enter the password.						
	Confirm(PW): Enter the password again.						
	• Name: Enter the name.						
	Organization: Enter the organization.						
	• Department: Enter the department.						
	• Register : Press this button to register the entered information.						
	• At least four or more letters should be entered for ID, Password and Confirm(PW), and ID and Password should not be the same.						
	• Up to 20 letters can be entered for ID, Password and Confirm(PW).						

After the supervisor is registered, the initial setting screen will appear.

Initial Settings

Date / Time /	Date	For	mat				1	Time	Form	nat		
Language	Y-I	M-D	D-M-1	r	M-D-	Y			12H		24H	
Network / LIS	Syst	em l	Date				Sync				Set	
Printer / Sound	Y	<	2019	>	М	<	6	>	D	<	20	>
Advanced	Syst	em ⁻	Time									
	h	<	14	>	m	<	2	>		АМ	PI	М
Service												
Quality Control	Lang	Juag	le									
Quality control	✓ E	Inglis	sh		~	简体中	文		\checkmark	italiano		
Confirm	~ y	/краї	нська		~	españ	ol de Espaí	ña				

Set the date and time first, and after completing other settings, press the [Confirm] button.

		In	itia	l Set	ting	IS					i
Date / Time / Language	Date f	Format	-Y	M-D-	Y	-	Time	Form	nat	24H	
Network / LIS	Syste	m Date				Sync				Set	
Printer / Sound	Y <	2019	>	М	<	6	>	D	<	20	>
Advanced	Syste	m Time)				
Service	h <	14	>	m	<	2	>		АМ	PI	1
Quality Control	Langu	✓ 简体中文 ✓ italiano									
Confirm	ј 🗹 ук	раїнська		~	españ	ol de Espa	ña				
				EX EX	8	. v			20 2	2019/06/20	14:02

The 'Initial Setting' screen appears. Press the **[OK]** button to complete the initial registration. When you press the **[Cancel]** button, you can reset the initial setting values.

	Ini	tial Settings	i
Date / Time	Ini	tial Setting	t
Language		~	24H
Network / LIS		(?)	Set
Printer / Soun		\smile	< 20 >
Advanced	Have you che	cked all Menu in Settings?	AM PM
Service	ок	Cancel	
Quality Contre-	✓ English	● ● 简体中文	✓ italiano
Confirm	🗸 українська	🗸 español de España	
	- 	() : :::::::::::::::::::::::::::::::::	2019/06/20 14:03

♦ Login

Log in is required to operate the analyzer. Enter ID and Password and press the [Login] button.

Exdia TRF Plus	Ċ
aaaa	Others
!	!
User ID	Password
Lo	bgin l
*	'
E≰⊒ I	5월 옮 🔹 💼 🔤 2019/06/20 14:41

The 'Test' screen appears.

		Test		
Patient ID	search field			
Sample Type				
Whole Blood	Plasma / Serum	Others		
Incubation Mode				
Auto		Skip		
Test Name				
Cassette ID				
Expiration			Abort	Run
🚺 aaaa			品 🕴 🖙 🗆 🖼	2019/06/20 14:03

• To carry out the test, refer to **"Testing"** on page 24.

Note • To learn more about the menu, refer to **"Menu"** on page 18.

Menu

The analyzer has various menus. Check each menu before using the analyzer.

Exdia TRF Pla	us			(
(
a a	aaa		Others	
				-,
	User ID		Password	
		Login		
				_'
	60		s i 🛊 i 🚍 i	2019/06/20 14

1. Enter ID and the password and press the **[Login]** button.

2. The 'Test' screen appears. Press the 🗄 button.

		Test		
Patient ID	search field			
Sample Type				
Whole Blood	Plasma / Serum	Others		
ncubation Mode				
Auto		Skip		
Test Name				
Cassette ID				
Expiration			Abort	Run
aaaa			品 🕴 🖙 🗆 🖼	2019/06/20 14:0

3. The 'Menu' screen is displayed.

<i>←</i>	Menu	
New Test	Test Result	Quality Control
O Settings		U Power Off
📳 aaaa	G2 Km K V	2019/06/20 14:53

Main menu	Sub menu	Description
New Test		Carry out a new test.
Test Result	Test Result	View the previous test result.
	External QC Result	View the previous external QC result.
Quality Control	Analyzer System Check	Check the normal operation status of the analyzer using the IQC cassette.
	External QC	Carry out the external QC test.
Settings		Change various settings.
Power Off	Log Out	Log out the current operator.
	Power Off	Turn the power off.



Log out and switch the operator.

1. Press the [Power Off] button.



2. Press the [Log Out] button.

\leftarrow	Me	enu	
New Test	Log Out	Power Off	Quality Control
Setti	ngs		U Power Off
🗶 aaaa	ce :	※ 몸 * * *	2019/06/20 14:06

3. Press the [OK] button.

\leftarrow		Menu		
		Logout		
		?		
New T	Do	o you want to logout?		
	ок	Cancel		
			U Power Of	
aaaa		G2 Xia A \$		2019/06/20 14:06



Turn the power off either through the login screen or the menu screen.

Power off from the Login Screen

1. Press the 🖒 button on the login screen.



- 2. The [Power off] screen appears. Press the [OK] button.
 - When you press the [Cancel] button, power off will be canceled.

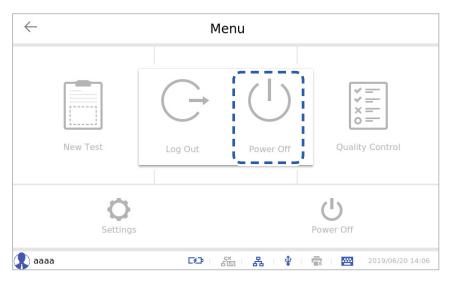


Power off on the Menu Screen

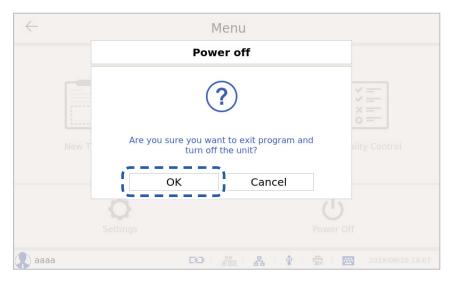
1. Press the [Power Off] button.

<i>←</i>	Menu	
New Test	Test Result	Quality Control
O Settings		U Power Off
🔹 aaaa	G2 🚠 🛃 🌵	2019/06/20 14:53

2. Press the [Power Off] button.



3. Press the [OK] button.





Carry out the test according to the following method. For the detailed method, refer to the user manual included in the cassette box.

Register a QR Card

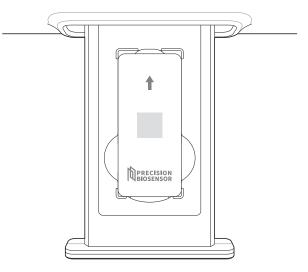
Before carrying out the new test, a QR card should be registered.

 \angle When testing a new Exdia cassette lot, register the QR card included in the cassette box. **Caution**

1. Enter ID and the password and press the [Login] button.

Exdia TRF Plus	\bigcirc
aaaa	Others
User ID	Password
	Login
·	'
	🖼 🚰 🛃 🌵 🛱 🔤 2019/06/20 14:41

2. Insert the QR card into the cassette slot.





Insert the QR card and close the cassette slot to automatically read the QR card.

If the QR card is successfully read, the New QR Code registered message is displayed.

	Test	
Patient ID	Test Information	
Sample Type Whole Blood	\bigcirc	
Incubation Mode Auto Test Name	New QRCode registered. key: FA7B2	
Cassette ID	ОК	
Expiration		
aaaa	G2 🏯 🏦 😨 🚍	

① Note

When the screen shown below appears, contact the Customer Support Team (support@precision-bio.com) and receive a new test file.

	Test	
Patient ID	Test Information	
Sample Type Whole Blood	\checkmark	
Incubation Mode	New QRCode registered. key:	
Test Name	OK	
Cassette ID		
Expiration		
aaaa	G2 28 28 4 1 1 1 1	2019/06/20 14:34

	Test	
Patient ID	Test Information	
Sample Type	\wedge	
Whole Blood Incubation Mode		
Auto	Barcode not found.	
Test Name	ОК	
Cassette ID		
Expiration		
🔷 aaaa	199 i 🚠 i 🎄 i 🛊 i 👼 i 🔤	2019/06/20 14:34

3. Press the [OK] button.

	Test	
Patient ID	Test Information	
Sample Type Whole Blood	\bigcirc	
Incubation Mode Auto	New QRCode registered. key: FA7B2	
Test Name	οκ	
Cassette ID		
Expiration		
👤 aaaa	F9 Ka k v a a B	2019/06/20 14:09



Carry out the Test according to the following method.

1. Enter the patient ID.

		Test		
Patient ID	est			
Sample Type				
Whole Blood	Plasma / Serum	Others		
Incubation Mode				
Auto		Skip		
Test Name				
Cassette ID				
Expiration			Abort	Run
🔹 aaaa			品 🕴 👘 🖂	2019/06/20 14:09

2. Select the sample type.

	Test	
Patient ID to	est	
Sample Type Whole Blood Incubation Mode	Plasma / Serum Others	
Auto	Skip	
Test Name		
Cassette ID		
Expiration	Abort Run	n
😱 aaaa	[5] 🚰 🏪 🌵 🚍 2019,	/06/20 14:09

- Whole Blood
- Plasma/Serum
- Others: influenza A+B/iFOB)



The analyzer to which this user manual refers may differ slightly from an actual analyzer according to the customer's requirements.

Select the correct sample type. If you select an incorrect sample type, the analyzer may display incorrect data.



3. Check the incubation mode.

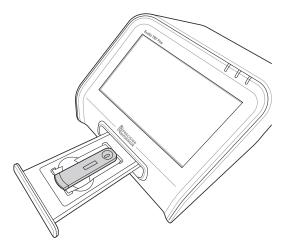
	Test	
Patient ID	test	
Sample Type		
Whole Blood	Plasma / Serum Others	
Incubation Mod	4.	
Auto	o Skip	
Test Name		
Cassette ID		
Expiration	Abort	Run
🕵 aaaa	Ge : 🚟 : 🎝 : 🍨 : 🚔 : 🖼	2019/06/20 14:09

- Auto: The test begins after the incubation in the analyzer is carried out according to the set time.

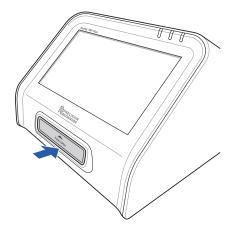
		Test		
Patient ID to	est			
Sample Type				
Whole Blood	Plasma / Serum	Others		
Incubation Mode				i i
Auto		Skip	00:14:20	
Test Name		Exdia 3-in-1		
Cassette ID		FC7B1-00204		
Expiration		18-02	Abort	Run
🔹 aaaa			Ŷ 👘 🖻	2019/06/20 11:10

- Skip: The test begins immediately without incubation in the analyzer.

4. Open the cassette slot and insert the cassette.



5. Insert the sample and close the cassette slot.



- For the test method, refer to the user manual for the Exdia cassette.
 - The cassette ID and the test name are displayed automatically according to the cassette and barcode information.
 - If the lot information of the cassette is registered, it will be displayed in the format of the selected expiration date of the relevant lot.

Note

6. Press the [Run] button to start scanning.

		Test	
Patient ID	test		
Sample Type			
Whole Blood	Plasma / Serum	Others	
ncubation Mode			
Auto		Skip	Sc
Test Name		Exdia 3-in-1	
Cassette ID		FC7B1-00204	
Expiration		18-02	Abort
aaaa		G2 - 20 - 24	• ∲ । ≣ ≥ ।

• Abort a test by pressing the [Abort] button while the test is being carried out.

• Cassettes interrupted during the test cannot be reused.

		Test		
Patient ID	test			
Sample Type				
Whole Blood	Plasma / Serum	Others		
ncubation Mod	2			
Auto		Skip	Aborte	ed
Test Name		Exdia 3-in-1		
Cassette ID		FC7B1-00204		
Expiration		18-02	Abort	Run
aaaa				2019/06

- When the cassette is expired, the following message will be displayed and the test will not proceed.

Note

7. Press the [OK] button.

	Test	
Patient ID	Test Information	
Sample Type Whole Blood Incubation Mode	Ń	
Auto	The Lot Information has been expired : FC7B1	idy
Test Name	OK	
Cassette ID		
Expiration	18-02 Abort	Run
aaaa	59 San A \$ \$ \$	2019/06/20 11:13

8. Press the 🗄 button while a test is being carried out, the following message will be displayed. Press the [OK] button, the recognized cassette information will disappear, and the screen will move to the Menu screen. To cancel a test, press the [Cancel] button.

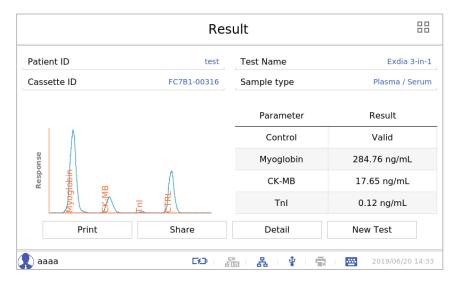
Test Info	Test Information				
	?				
	Are you sure you want to abort the test and go to the Main Menu?				
ОК	Cancel				

9. After running a test, the Result screen will be displayed.

	Res	sult	
Patient ID	test	Test Name	Exdia 3-in-1
Cassette ID	FC7B1-00316	Sample type	Plasma / Serum
		Parameter	Result
Λ		Control	Valid
ouse		Myoglobin	284.76 ng/mL
Response ogtobin MB	Λ	СК-МВ	17.65 ng/mL
LAN MY JO	ŧ.	Tnl	0.12 ng/mL
Print	Share	Detail	New Test
🔹 aaaa	BO I de	‱ 1 品 1 🛊 1 🖷	2019/06/20 14:32

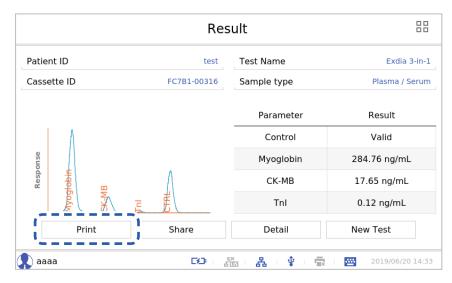


Check the result of a test.



Print

Press the [Print] button to print the test result to the printer connected to the analyzer.



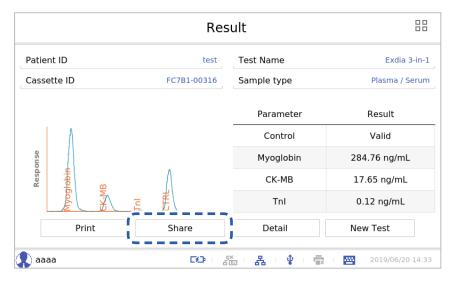
After completing the printing, press the [OK] button.

If printing does not happen, change the printer setting by referring to **"Printer/Sound"** on page 74.

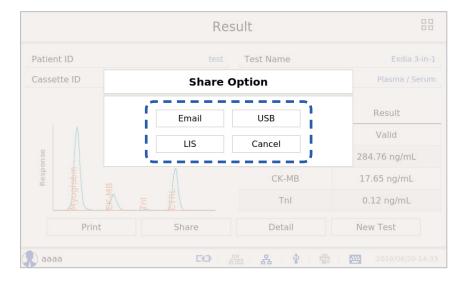
Note

Share

Press the [Share] button to share the test result via Email, USB memory, and LIS.



Select the method to share test result.



Email

Convert test result to PDF format and email the PDF. Enter the email address and press the [Send] button.

	Result	88
Patient	Export E-Mail	a 3-in-1
Casset	Recipient's Email Address	
	Sender's Email Address	
	Password Save 🗸	
nse	SMTP Server	nL
Response	SMTP Port	۱L
		L
	Send Cancel	
aaaa	📭 - Xii - Xi - 🌵 - 🚔 - 🔤 2019/06,	

- Recipient's Email Address: Recipient's Email address
- Sender's Email Address: Sender's Email address
- Password: Password

/Ì

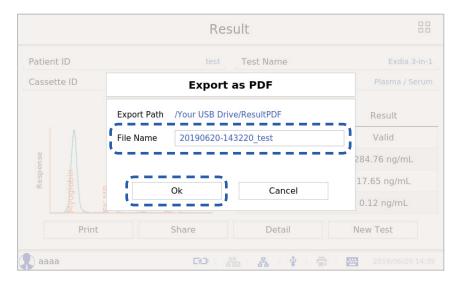
- Save: Save the password
- SMTP Server: SMTP server of sender
- SMTP Port: SMTP port of sender

Check network connection status.

Caution If a network connection is not established, refer to "Network/LIS" on page 71.

USB

After converting a test result to PDF format, save it to a USB memory. Enter the file name and press the **[OK]** button.



Connect a USB memory to the analyzer. **Note**

LIS

Send the test result to a LIS server saved in settings. For setting the LIS server, refer to 'Network/LIS'.

\leftarrow		Settings		i
Date / Time / Language	Set IP Addres	S		Apply
Network / LIS		Auto		Manual
Printer / Sound	Address	192.168.0.22	Sub. Mask	255.255.255.0
Operators	Gateway	192.168.0.1		
Advanced	LIS			Connect
Service	Device ID	Test	Server	192.168.0.147
Quality Control	Port	8282	Mode / Notice	HL7 🔻
aaaa		Be Mark	· • • 🖶 ·	2019/06/20 14:30



Press the [Detail] button to see the details of the test results.

Detail Information			
Parameter	Result	Ref.Range	
Control	Valid	-	
Myoglobin	274.08 ng/mL	< 0.09	
CK-MB	17.14 ng/mL	< 5	
Tnl	0.06 ng/mL	< 0.06	
	ОК		

New Test

Press the [New Test] button to run a new test.

\square	Ì

The analyzer to which this user manual refers may differ slightly from an actual analyzer according to the customer's requirements.



Test results can be confirmed separately in test results and external QC results.



Test results stored on the Exdia TRF Plus can be viewed, deleted, shared and printed.

1. Enter ID and the password and press the [Login] button.

Exdio TRF Plus	Ċ
aaaa	Others
User ID	Password
	Login
	*
69	📅 । 🛃 । 🖞 । 🖶 । 🔤 2019/06/20 14:41

2. Press the **button**.

		Test		
Patient ID	search field			
Sample Type				
Whole Blood	Plasma / Serum	Others		
Incubation Mode				
Auto		Skip		
Test Name				
Cassette ID				
Expiration			Abort	Run
🚺 aaaa			8 · • - 🖶 · 🗃	2019/06/20 14:03

3. Press the [Test Result] button.

<i>←</i>	Menu	
New Test	Test Result	Quality Control
O Settings		Dower Off
💦 aaaa	DD : 200 - 24 - 4	2019/06/20 14:53

4. Press the [Test Result] button.

\leftarrow	Me	enu	
New Test	Test Result	External QC Result	Quality Control
Se	O ttings	I	U Power Off
🐥 aaaa	Dia dia	‱ i & i ∳ i !	2019/06/20 14:42

The 'Test Result' screen will appear.

← Test Result				
Filter Text Patient I) •	Q	All 🗹 0 / 4 Sing	gle
Patient ID	Test Name	Test Date	Operator	
test	Exdia 3-in-1	2019/06/20 14:37	aaaa	
test	Exdia 3-in-1	2019/06/20 14:32	aaaa	
test	Exdia 3-in-1	2019/06/20 14:31	aaaa	
test	Exdia 3-in-1	2019/06/01 14:14	aaaa	
View		Delete	Export	•
aaaa	60	- 🚈 - 🖧 - 🔹 - 🛱	2019/06/20	14:3

• Only one result can be selected in Single mode.

\leftarrow	Те	st Result		
Filter Text Patient ID	•	Q	All 🗹 1/4 Si	ngle
Patient ID	Test Name	Test Date	Operator	
test	Exdia 3-in-1	2019/06/20 14:37	aaaa	
test	Exdia 3-in-1	2019/06/20 14:32	aaaa	
test	Exdia 3-in-1	2019/06/20 14:31	aaaa	
test	Exdia 3-in-1	2019/06/01 14:14	aaaa	
View		Delete	Export	•
aaaa	69	- 羅 - 発 - 章		20 14:3

• More than one result can be selected in Select mode

\leftarrow	Τe	est Result		
Filter Text Patient I) -	Q	All 🗹 4 / 4 Sel	ect
Patient ID	Test Name	Test Date	Operator	
test	Exdia 3-in-1	2019/06/20 14:37	аааа	
test	Exdia 3-in-1	2019/06/20 14:32	aaaa	
test	Exdia 3-in-1	2019/06/20 14:31	aaaa	
test	Exdia 3-in-1	2019/06/01 14:14	aaaa	
View		Delete	Export	-
aaaa	60	1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	2019/06/20) 14:3

The analyzer to which this user manual refers may differ slightly from an actual analyzer according to the customer's requirements.

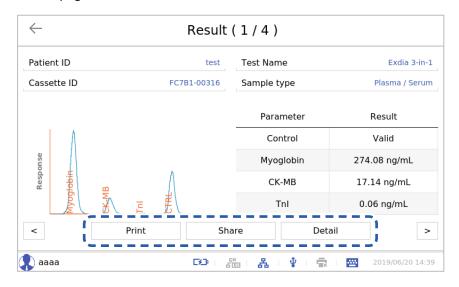
i



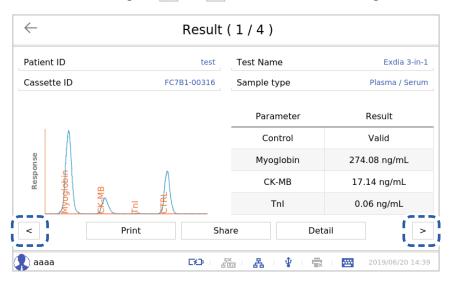
• View the details of a test result by selecting the test result and clicking the [View] button.

\leftarrow	Te	est Result		
Filter Text Patient I	D	Q	All 🗹 4/4 Sele	ect
Patient ID	Test Name	Test Date	Operator	
test	Exdia 3-in-1	2019/06/20 14:37	aaaa	
test	Exdia 3-in-1	2019/06/20 14:32	aaaa	
test	Exdia 3-in-1	2019/06/20 14:31	aaaa	
test	Exdia 3-in-1	2019/06/01 14:14	aaaa	
View		Delete	Export	•
aaaa	69	- 200 - 2 8 - 🕸 - 🖶	2019/06/20	14:4

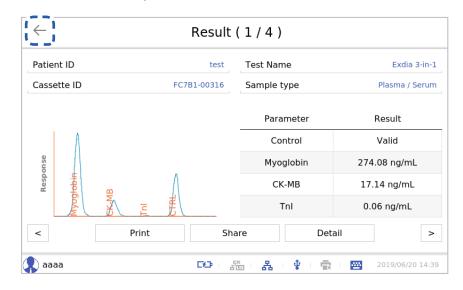
 Press the [Print] button to print the test results, press the [Share] button to share the test results and press the [Detail] button to check the details of the test results.
 Please see "Result" on page 32 for more information.



- View other selected test results using the \checkmark and \triangleright buttons on the left and right.



• Press the <- button to return to the previous screen.





Select a test result and press the [Delete] button to delete the test result.

\leftarrow	← Test Result			
Filter Text Patient	ID v	Q	All 🗸 4 / 4 Sele	ect
Patient ID	Test Name	Test Date	Operator	
test	Exdia 3-in-1	2019/06/20 14:37	aaaa	
test	Exdia 3-in-1	2019/06/20 14:32	aaaa	
test	Exdia 3-in-1	2019/06/20 14:31	aaaa	
test	Exdia 3-in-1	2019/06/01 14:14	aaaa	
View		Delete	Export	•
😱 aaaa	60	2 Ka	2019/06/20	14:41

When the 'Result' window appears, press the **[OK]** button.

\leftarrow	Test Result	
Filter Text Pat	Result	4/4 Select
Patient ID		perator
test	(?)	aaaa
test		aaaa
test	Are you sure you want to delete selected results?	aaaa
test	OK Cancel	aaaa
		-
View	Delete	Export
aaaa	69 Xii Xi 🛊 🛱	2019/06/20 14:40



Save a test result to a USB memory in a different file format or send it to the LIS server by selecting the test result and pressing the **[Export]** button.

\leftarrow	Те	est Result		
Filter Text Patient I	D v	Q	All 🗹 4/4 Sel	ect
Patient ID	Test Name	Test Date	Operator	
test	Exdia 3-in-1	2019/06/20 14:37	aaaa	
test	Exdia 3-in-1	2019/06/20 14:32	aaaa	
test	Exdia 3-in-1	2019/06/20 14:31	aaaa	
test	Exdia 3-in-1	2019/06/01 14:14	aaaa	
View		Delete	Export	•
💦 aaaa	62	200 B	2019/06/20	14:41

Type your password in the Enter User Password window.

\leftarrow	Test Result
Filter Text Patient I	Enter your password.
Patient ID	Operator
test	1 aaaa
test	Confirm Password
test	OK Cancel aaaa
test	aaaa aaaa
	~
View	Delete Export
🗶 aaaa	🖼 । 🏧 । 🤽 । 🌵 । 🚍 । 📴 2019/06/20 14:41

\leftarrow	Export Results
Filter 1	Excel File PDF LIS
	Selected Count 4 Export Path USB:/ResultPDF
	Export Close
View	Delete Export
aaaa	💶 । 🟦 । 🛃 । 🛊 । 🚋 । 🚾 2019/06/2014:4

Connect the USB memory to the analyzer, select storage media and press the [Export] button.

① Note

- If you select 'Excel', the test result will be saved as a file with the extension '.xls'.
- If you select 'File', the test result will be saved as a file with the extension '.sam'.
 - If you select 'PDF', the test result will be saved as a file with the extension '.pdf'.
 - A USB memory is not necessary for sending the test result to the LIS server.

External QC Result

1. Press the **[Login]** button after enter ID and the password.

Exdia TRF Plus	Ċ
aaaa	Others
User ID	Password
	Login
`	'
	🖼 🏭 🛃 🌵 🗮 🔤 2019/06/20 14:41

2. Press the **B** button.

		Test			
Patient ID	search field				
Sample Type					
Whole Blood	Plasma / Serum	Others			
Incubation Mode					
Auto		Skip			
Test Name					
Cassette ID					
Expiration			Ab	ort Rur	
👔 aaaa			品(文)言	2019/	06/20 14:03

3. Press the [Test Result] button.

\leftarrow	Menu	
New Test	Test Result	Quality Control
O Settings		U Power Off
💦 aaaa	G2 1 Xia 1 사	2019/06/20 14:53

4. Press the [External QC Result] button.



Click the "From" or "To" input column in the 'External Quality Control Result' window and select the date you wish to search.

Test Name	Exdia	3-in-1	 Test Lo 	ot	From 20	019/06/01 То 20	19/06/20 🔍		
Search Resu	Search Results: 13 rows selected for Exdia 3-in-1, None, 2019/06/01 2019/06/20 All 🗹 0 / 13 Single								
Test Na	me	Test Lot	Material	Level	Result	Test Date	Operator		
Exdia 3-iı	n-1	FC7B1	PB 3in1	Level 1	Pass	2019/06/20 14:30	aaaa		
Exdia 3-ii	n-1	FC7B1	PB 3in1	Level 1	Pass	2019/06/19 14:30	aaaa		
Exdia 3-ii	n-1	FC7B1	PB 3in1	Level 1	Pass	2019/06/17 14:29	aaaa		
Exdia 3-ii	n-1	FC7B1	PB 3in1	Level 1	Pass	2019/06/15 14:28	aaaa		
Exdia 3-ii	n-1	FC7B1	PB 3in1	Level 1	Fail	2019/06/13 14:26	aaaa		
View		Graph	Expo	ort Results	Expo	rt Samples	Delete		

Prev Month	Year	2019 🔻	Month J	une	v	Next Month
Sun	Mon	Tue	Wed	Thu	Fri	Sat
26	27	28	29	30	31	1
2	3	4	5	6	7	8
9	10	11	12	13	14	15
16	17	18	19	20	21	22
23	24	25	26	27	28	29
30	1	2	3	4	5	6

est Name Exdia	a 3-in-1	▼ Test Lo	ot	From 20	019/06/01 то 20	19/06/20	Q
earch Results: 13						0/13 Sin	-
Test Name	Test Lot	Material	Level	Result	Test Date	Operator	1
Exdia 3-in-1	FC7B1	PB 3in1	Level 1	Pass	2019/06/20 14:30	aaaa	
Exdia 3-in-1	FC7B1	PB 3in1	Level 1	Pass	2019/06/19 14:30	aaaa	
Exdia 3-in-1	FC7B1	PB 3in1	Level 1	Pass	2019/06/17 14:29	aaaa	
Exdia 3-in-1	FC7B1	PB 3in1	Level 1	Pass	2019/06/15 14:28	aaaa	
Exdia 3-in-1	FC7B1	PB 3in1	Level 1	Fail	2019/06/13 14:26	aaaa	
View	Graph	Exp	ort Results	Expo	rt Samples	Delete	2

Change the search conditions as needed and check the result by pressing the Q button.

• Only one result can be selected in Single mode.

\leftarrow		I	External	Quality	Contro	ol Result			
Test Name	Exdia	a 3-in-1	▼ Test L	ot	From 2	019/06/01 To 20	019/06/20	Q	
Search Resu	Search Results: 13 rows selected for Exdia 3-in-1, None, 2019/06/01 2019/06/20 All 🗹 1 / 13 Singl								
Test Nar	me	Test Lot	Material	Level	Result	Test Date	Operator		
Exdia 3-ir	n-1	FC7B1	PB 3in1	Level 1	Pass	2019/06/20 14:30	aaaa		
Exdia 3-ir	n-1	FC7B1	PB 3in1	Level 1	Pass	2019/06/19 14:30	aaaa	_	
Exdia 3-ir	1- 1	FC7B1	PB 3in1	Level 1	Pass	2019/06/17 14:29	aaaa		
Exdia 3-ir	n-1	FC7B1	PB 3in1	Level 1	Pass	2019/06/15 14:28	aaaa		
Exdia 3-ir	n-1	FC7B1	PB 3in1	Level 1	Fail	2019/06/13 14:26	aaaa		
View		Graph	Exp	ort Results	Expo	ort Samples	Delete	;	
👤 aaaa				52 58	- A	Ý I 🖶 I 🔤	2019/06/20 14	4:4	

• More than one result can be selected in Select mode.

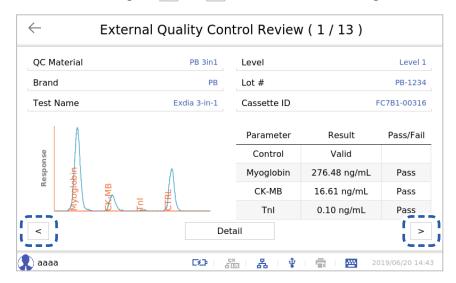
\leftarrow		External	Quality	Contro	ol Result	
Test Name Ex	dia 3-in-1	▼ Test L	ot	From 2	019/06/01 To 20	19/06/20 Q
Search Results:	13 rows selected	for Exdia 3-in-	1, None, 2019/	06/01 2019/	06/20 All 🗸	3/13 Select
Test Name	Test Lot	Material	Level	Result	Test Date	Operator 🔺
Exdia 3-in-1	FC7B1	PB 3in1	Level 1	Pass	2019/06/20 14:30	aaaa
Exdia 3-in-1	FC7B1	PB 3in1	Level 1	Pass	2019/06/19 14:30	aaaa
Exdia 3-in-1	FC7B1	PB 3in1	Level 1	Pass	2019/06/17 14:29	aaaa
Exdia 3-in-1	FC7B1	PB 3in1	Level 1	Pass	2019/06/15 14:28	aaaa
Exdia 3-in-1	FC7B1	PB 3in1	Level 1	Fail	2019/06/13 14:26	aaaa 🗸
View	Graph	Exp	ort Results	Expo	ort Samples	Delete
🗶 aaaa				- A -	🖞 i 💼 i 🔤	2019/06/20 14:43



View the details of a QC result by selecting the QC result and clicking the [View] button.

\leftarrow		E	External	Quality	Contr	ol Result		
Test Name	Exdia	a 3-in-1	▼ Test Lo	ot	From	2019/06/01 To 20	019/06/20 🔍	
Search Results: 13 rows selected for Exdia 3-in-1, None, 2019/06/01 2019/06/20 All 🔽 13 / 13 Select								
Test Nar	me	Test Lot	Material	Level	Result	Test Date	Operator 🔺	
Exdia 3-ir		FC7B1	PB 3in1	Level 1	Pass	2019/06/20 14:30	aaaa	
Exdia 3-ir	n-1	FC7B1	PB 3in1	Level 1	Pass	2019/06/19 14:30	aaaa	
Exdia 3-ir	n-1	FC7B1	PB 3in1	Level 1	Pass	2019/06/17 14:29	aaaa	
Exdia 3-ir	n-1	FC7B1	PB 3in1	Level 1	Pass	2019/06/15 14:28	aaaa	
Exdia 3-ir	n-1	FC7B1	PB 3in1	Level 1	Fail	2019/06/13 14:26	aaaa 🖵	
View		Graph	Exp	ort Results	Exp	ort Samples	Delete	
) aaaa				59 50	a A	· • • 🖶 · 🖾	2019/06/20 14:43	

• View other selected QC results using the \checkmark and > buttons on the left and right.

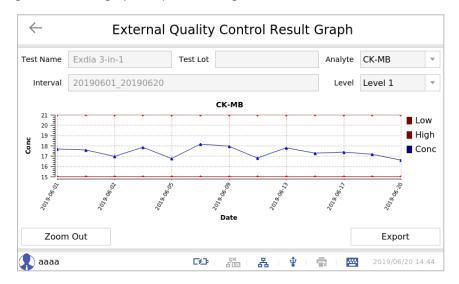




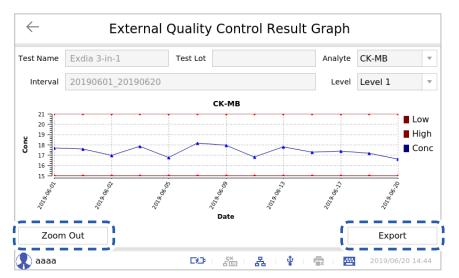
\leftarrow		I	External	Quality	Contro	ol Result			
Test Name	Exdia	3-in-1	▼ Test L	ot	From 2	019/06/01 То 20	19/06/20 Q		
Search Resu	Search Results: 13 rows selected for Exdia 3-in-1, None, 2019/06/01 2019/06/20 All 🗸 13 / 13 Select								
Test Nar	ne	Test Lot	Material	Level	Result	Test Date	Operator		
Exdia 3-ir	n-1	FC7B1	PB 3in1	Level 1	Pass	2019/06/20 14:30	aaaa		
Exdia 3-ir	n-1	FC7B1	PB 3in1	Level 1	Pass	2019/06/19 14:30	aaaa		
Exdia 3-ir	1- 1	FC7B1	PB 3in1	Level 1	Pass	2019/06/17 14:29	aaaa		
Exdia 3-ir	n-1	FC7B1	PB 3in1	Level 1	Pass	2019/06/15 14:28	aaaa		
Exdia 3-ir	1-1	FC7B1	PB 3in1	Level 1	Fail	2019/06/13 14:26	aaaa		
View	(Graph	Exp	ort Results	Expo	ort Samples	Delete		
🗶 aaaa					- & ·	🛊 i 🖶 i 🔤	2019/06/20 14:4		

View a QC result as a graph by selecting the QC result and clicking the [Graph] button.

• When you change an item, the graph shape will change.



• Adjust the magnification by pressing the [**Zoom Out**] button or save the graph image to a USB memory by pressing the [**Export**] button.



Export Results

Select a QC result by clicking the **[Export Results]** button to save QC result to a USB memory as a file with the extension '.csv'. This file can be checked in Excel.

\leftarrow		Externa	al Quality	Contro	ol Result	
Test Name	xdia 3-in-1	▼ Test	Lot	From 2	2019/06/01 To 2	019/06/20 🔍
Search Results	s: 13 rows sele	ected for Exdia 3-i	n-1, None, 2019/	06/01 2019/	/06/20 All 🗸	13 / 13 Select
Test Name	e Test L	ot Material	Level	Result	Test Date	Operator 🔺
Exdia 3-in-1	1 FC7B	1 PB 3in1	Level 1	Pass	2019/06/20 14:30	aaaa
Exdia 3-in-1	1 FC7B	1 PB 3in1	Level 1	Pass	2019/06/19 14:30	aaaa
Exdia 3-in-1	1 FC7B	1 PB 3in1	Level 1	Pass	2019/06/17 14:29	aaaa
Exdia 3-in-1	1 FC7B	1 PB 3in1	Level 1	Pass	2019/06/15 14:28	aaaa
Exdia 3-in-1	1 FC7B	1 PB 3in1	Level 1	Fail	2019/06/13 14:26	aaaa 👻
View	Gr	aph Ex	port Results	Expo	ort Samples	Delete
🚶 aaaa		·		_ - 品	🕴 i 🖶 i 🔤	2019/06/20 14:45

Enter the password in the Input window.

\leftarrow	\leftarrow External Quality Control Result								
Test Name Search Resu			Test L	ot t er your pa		019/06/01	To 2 All 🗸	019/06/20	Q lect
Test Na	me	Test L				,	ate	Operator	
Exdia 3-ii	n-1	FC7B:	Confirm Pas	sword			14:30	aaaa	
Exdia 3-ii	n-1	FC7B:	ОК		Canc	el	14:30	aaaa	
Exdia 3-ii	n-1	FC7B:	·			!	14:29	aaaa	
Exdia 3-ii	n-1	FC7B1	PB 3in1	Level 1	Pass	2019/06/1	5 14:28	aaaa	
Exdia 3-iı	n-1	FC7B1	PB 3in1	Level 1	Fail	2019/06/1	3 14:26	aaaa	-
View		Gra	ph Exp	ort Results	Expo	rt Samples		Delet	e
🔹 aaaa				50 50	- 品	¥ I 🖶		2019/06/20 1	14:45

 \leftarrow External Quality Control Result **External QC Result** Test Name Exdia 3 2019/06/20 Q 13/13 Select Search Results: 13 ro . Test Name Operator EQC Results export is complete. 1 ľ οк J --Graph Export Results Export Samples Delete View CEP STE 品(李)豪) ----aaaa

Press the **[OK]** button in the 'External QC Result' window.

Export Samples

Select a QC result and click the [Export Samples] button to save the QC sample file (*.sam) to a USB memory.

\leftarrow	← External Quality Control Result								
Test Name	Exdia	a 3-in-1	▼ Test Lo	ot	From 2	2019/06/01 то 20	19/06/20 🔍		
Search Resu	earch Results: 13 rows selected for Exdia 3-in-1, None, 2019/06/01 2019/06/20 All 🗸 13 / 13 Select								
Test Na	me	Test Lot	Material	Level	Result	Test Date	Operator 🔺		
Exdia 3-iı	n-1	FC7B1	PB 3in1	Level 1	Pass	2019/06/20 14:30	aaaa		
Exdia 3-ii	n-1	FC7B1	PB 3in1	Level 1	Pass	2019/06/19 14:30	aaaa		
Exdia 3-iı		FC7B1	PB 3in1	Level 1	Pass	2019/06/17 14:29	aaaa		
Exdia 3-iı	n-1	FC7B1	PB 3in1	Level 1	Pass	2019/06/15 14:28	aaaa		
Exdia 3-iı	n-1	FC7B1	PB 3in1	Level 1	Fail	2019/06/13 14:26	aaaa 🗸		
View		Graph	Exp	ort Results	Expo	ort Samples	Delete		
🜔 aaaa						· • • 🖶 · 🖂	2019/06/20 14:46		

Enter the password in the User Password Input window.

\leftarrow			External	Quality	Contro	l Result	t		
Test Name Search Resu			▼ Test Lo Ent	er your pa		019/06/01		19/06/20	Q, lect
Test Na	me	Test L	~·			,	ate	Operator	
Exdia 3-iı	n-1	FC7B	Confirm Pas	sword		i	14:30	aaaa	
Exdia 3-ii	n-1	FC7B:	ОК		Cance	el	14:30	aaaa	
Exdia 3-ii	n-1	FC7B	·			!	14:29	aaaa	
Exdia 3-ii	n-1	FC7B1	PB 3in1	Level 1	Pass	2019/06/1	5 14:28	aaaa	
Exdia 3-ii	n-1	FC7B1	PB 3in1	Level 1	Fail	2019/06/1	3 14:26	aaaa	•
View		Gra	ph Exp	ort Results	Expo	rt Samples		Delet	e
🔹 aaaa				BD : Sta	- A -	¥ - 🖘		2019/06/20 1	4:46

The storage path i	s /ExtQC/ResultSa	mple. Press the	e [Export] button.
--------------------	-------------------	-----------------	--------------------

\leftarrow		
	Export Samples	
Test Nar		0 9
Search R	• File	Select
Test		tor 🔺
Exdia	Selected Count 13 Export Path USB:/ExtQC/ResultSample	а 🗌
Exdia		,
Exdia		
Exdia	Export Close	·
Exdia		a 🗸
View	Graph Export Results Export Samples	Delete
aaaa	69 - São A - 🛊 - 👼 - 🖼	



\leftarrow External Quality Control Result								
Test Name	Exdia	a 3-in-1	▼ Test L	ot	From 2	019/06/01 то 20	19/06/20	Q,
Search Resu	lts: 13	rows selected	for Exdia 3-in-	1, None, 2019/	06/01 2019/	06/20 All 🗸	13 / 13 Sel	ect
Test Nar	ne	Test Lot	Material	Level	Result	Test Date	Operator	
Exdia 3-ir	n-1	FC7B1	PB 3in1	Level 1	Pass	2019/06/20 14:30	aaaa	
Exdia 3-ir	n-1	FC7B1	PB 3in1	Level 1	Pass	2019/06/19 14:30	aaaa	
Exdia 3-ir	n-1	FC7B1	PB 3in1	Level 1	Pass	2019/06/17 14:29	aaaa	
Exdia 3-ir	n-1	FC7B1	PB 3in1	Level 1	Pass	2019/06/15 14:28	aaaa	
Exdia 3-ir	n-1	FC7B1	PB 3in1	Level 1	Fail	2019/06/13 14:26	aaaa	•
View		Graph	Graph Export Results Export Samples Delete					
👤 aaaa					- A -	🛊 i 🖶 i 🔤	2019/06/20 1	4:45

Select the QC result and press the [Delete] button to delete a QC result.

Press the [OK] button in the 'External QC Result' window





The quality of Exdia TRF Plus analyzer and Exdia cassette are carefully controlled with Internal Quality Control cassette (IQC) and External Quality Control (EQC) material.

Running IQC

Please check whether the analyzer is operating normally by using the IQC cassette provided with the analyzer.

- (¹) **Exdio** TRF Plus aaaa Others I User ID Password Login I 60 EX. 놂 Ŷ 2019/06/20 14:41 <u>-----</u>
- **1.** Enter ID and the password and press the **[Login]** button.

The analyzer to which this user manual refers may differ slightly from an actual analyzer according to the customer's requirements.

i

2. Press the **button**.

		Test			
Patient ID	search field				
Sample Type					
Whole Blood	Plasma / Serum	Others			
Incubation Mode					
Auto		Skip			
Test Name					
Cassette ID					
Expiration				Abort	Run
🚺 aaaa			& ∳	Ē. I 🔤	2019/06/20 14:03

3. Press the [Quality Control] button.

<i>←</i>	Menu	
New Test	Test Result	Quality Control
O Settings		b Power Off
😱 aaaa	50 - A - V	2019/06/20 14:53

4. Press the [Analyzer System Check] button.

\leftarrow		Ме	าน	
	New Test	Analyzer System Check	External QC	Quality Control
	O Settings	5	Ρ	U ower Off
🗶 aaaa		CL2 Sta	a i 🗛 i 🖞 i 🕯	2019/06/20 14:47

The 'Analyzer System Check' screen will be displayed.

Analyzer System Check					
Check History		Export	View		
Date/Time	Operator		Result		
Ready					
	Ready		Run		
😱 aaaa	ES I Start B	몸 (🔹) 🖶 (21/06/2019 11:25		

If there is a previous test result, it will be displayed in the Check History table.

Check History		Export	View	
Date/Time	Operator	Re	sult	
2019/06/19 14:30	aaaa	Pa	SS	
2019/06/17 14:29	aaaa	Pa	SS	
2019/06/15 14:28	aaaa	Pa	SS	
2019/06/13 14:27	aaaa	Pa	SS	
2019/06/13 14:26	aaaa	Pa	SS	
2019/06/11 14:25	aaaa	Pa	SS	
2019/06/09 14:23	aaaa	Pa	SS	Ŧ
Ready			L	
			Run	

5. Press the [Run] button.

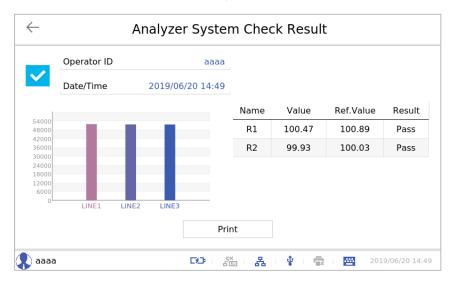
Note

Analyzer System Check					
Check History		Export	View		
Date/Time	Operator		Result		
Ready					
	Ready		Run		
			li		
aaaa		5 · • 🔿	21/06/2019 11:2		

← Analyzer System Check
 Check History Export View
 Date/Time Operator Result
 Ready
 Ready
 ▲ Abort
 ▲ Abort

Scanning will begin. (Scanning may take several minutes.)

After completing the scanning, the result will be displayed.



Check the intensity of each test line on a graph. The horizontal axis indicates each test line of the IQC cassette and the vertical axis indicates the measurement value. The table shows each parameter tested by the analyzer.

ltem	Description/Value
Name	Name of test standard
Value	Value calculated from the measurement value
Ref.Value	Reference value set by the manufacturer
Result	 Validity of the measurement value Pass: The measurement value is within the set range of the reference value. Fail: The measurement value is out of the set range of the reference value.

Running EQC

Quality control of an Exdia cassette can be carried out using designated quality control material.

Exdia TRF Plus	ථ
aaaa	Others
·	1
User ID	Password
	Login
·	'
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1. Enter ID and the password and press the **[Login]** button.

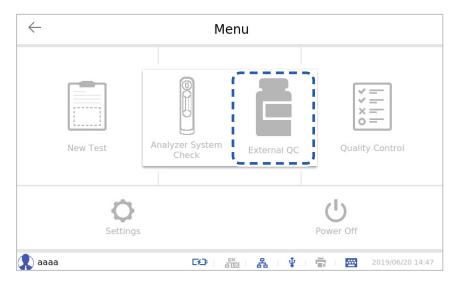
2. Press the **B** button.

		Test		
Patient ID	search field			
Sample Type				
Whole Blood	Plasma / Serum	Others		
Incubation Mode				
Auto		Skip		
Test Name				
Cassette ID				
Expiration			Abort	Run
퇹 aaaa			A 🕴 🖶 📼	2019/06/20 14:41

3. Press the [Quality Control] button.

\leftarrow	Menu	
New Test	Test Result	Quality Control
O Settings		U Power Off
😱 aaaa	G2 S2 A \$	2019/06/20 14:53

4. Press the [External QC] button.



The 'External Quality Control' screen will be displayed.



5. Press the Q button.

	Exte	rnal Quality	Control	
QC Material	PB 3in1			٩
Brand / Lot				
PB / PB-1234				
Level				
Level 1	Level 2	Level 3		
Test Name				
Cassette ID				
			Abort	Run
😱 aaaa			& · • · 🖶 · 📾	2019/06/20 14:50

6. Select QC data and press the [OK] button.

	Select	Material	
Filter Text Name			Q
Name	Brand	Lot	Expire
PB 3in1	РВ	PB-1234	2020/06/01
	ОК	Cancel	

	QC Name/Brand/Lot/Expire information will be displayed.
Note	

7. Select the level of QC data and insert a cassette into the cassette slot.

	Exte	rnal Quality (Control	
QC Material	PB 3in1			Q
Brand / Lot				
PB / PB-1234				
Level				
Level 1	Level 2	Level 3	Ready	
Test Name		Exdia 3-in-1		
Cassette ID		FC7B1-00316		
			Abort	Run
🕵 aaaa			8 · • 🛊 · 👼 · 🔤	2019/06/20 14:50

8. Press the [Run] button.

	Exte	rnal Quality	Control	
QC Material	PB 3in1			Q,
Brand / Lot				
PB / PB-1234				
Level				
Level 1	Level 2	Level 3	Ready	
Test Name		Exdia 3-in-1		
Cassette ID		FC7B1-00316		
			Abort];
, aaaa			<u>ዳ ፣ 🛊 ፣ 👼 ፣ 🔤</u> 2019/06/2	20 14:50

• If the QC material is partially missing the concentration value of an analyte corresponding to the inserted cassette, 'The QC Material has no one or more invalid conc. Ranges for the selected test and level. Do you want to continue anyway?' message will be displayed on the screen.



• If the QC material is entirely missing the concentration value of the analyte corresponding to the inserted cassette, 'The QC Material has no valid conc. range for the selected test and level.' message will be displayed on the screen.

External Quality Control
<u> </u>
The QC Material has no valid conc. range for the selected test and level.
ОК

9. The 'External Quality Control Result' screen appears.

QC Material PB 3in1	Level		Level
Brand PB	Lot		PB-123
Test Name Exdia 3-in-1	Cassette ID	F	C7B1-0031
Λ.	Parameter	Result	Pass/Fai
es est	Control	Valid	
opily	Myoglobin	286.45 ng/mL	Pass
Resp MB MB	CK-MB	17.36 ng/mL	Pass
	Tnl	0.12 ng/mL	Pass
	Deta	il Na	ew QC

10. Press the **[Detail]** button to check the detailed information.

Parameter	Result	Ref.Range	Pass/Fail
Control	Valid	-	-
Myoglobin	286.45 ng/mL	250 - 310 ng/mL	Pass
CK-MB	17.36 ng/mL	15 - 21 ng/mL	Pass
Tnl	0.12 ng/mL	0.03 - 0.2 ng/mL	Pass



In Setting, you can set Date/Time/Language, Network/LIS, Printer/Sound, Operator, Advanced, Service and Quality Control.



To change network-related settings, a LAN cable should be connected. Connect a LAN cable to the analyzer.

Date/Time/Language

You can check the data format, time and language.

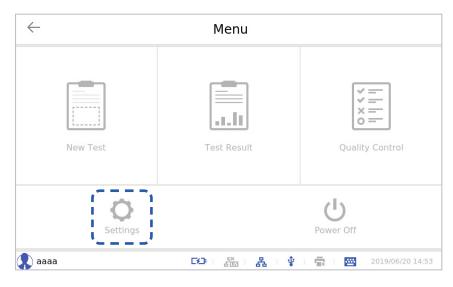
1. Enter ID and the password and press the **[Login]** button.

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a	aaa		Others		
Ē				-1	
I	User ID		Password		
		Login] [
·				-'	
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2. Press the **B** button.

		Test		
Patient ID	search field			
Sample Type				
Whole Blood	Plasma / Serum	Others		
Incubation Mode				
Auto		Skip		
Test Name				
Cassette ID				
Expiration			Abort	Run
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3. Press the [Setting] button.



4. Press the [Date/Time/Language] button.

\leftarrow	← Settings								
Date / Time / Language	Date Format	-Y M-	D-Y	-		ormat 2H	24H		
Network / LIS	System Date			Sync			Set		
Printer / Sound	Y < 2019	> N	1 <	6	>	D <	20 >		
Operators	System Time	> n	n <	57	>	АМ	PM		
Advanced				57	/	AM			
Service	Language		✓ 简体中	۲Ż		🗸 italian	0		
Quality Control	🗸 українська		🗸 espai	ñol de Espai	ña				
😱 aaaa		CC I A	× S	£ ∲			2019/06/20 14:57		

Date/Time/Language

_			Setti	ngs				i	
Date / Time / Language	Date Fo			1	1T	ime Forn		1	
Network / LIS	Y-M-D System	2223	M-	D-Y	Sync	12H	Set		
Printer / Sound	Y <	2019	> N	1 <	10	> D	< 29		
Operators	System								
Advanced	h < Langua	10 ge	> r	n <	37	>	АМ		
Service	Engli			✓ 简体中	ν文	~	italiano	i	
Quality Control	🗸 укра	їнська		🗸 espaŕ	iol de España	a 🗸	čeština	•	

No.	ltem	Description
1	Date Format	 Press and select the date format. Y-M-D: Year-Month-Day D-M-Y: Day-Month-Year M-D-Y: Month-Day-Year
2	Time Format	Press and select a time format.12H: Time displayed using AM and PM24H: Time displayed in 24-hour format
3	System Date	 Set the date using the and buttons. You can also enter the date directly. Y: Year M: Month D: Day
	System Time	 Set the time using the and buttons. You can also enter the date directly. h: Hour m: Minute AM / PM: Set AM or PM for the entered time. It applies only when the 12H system in No. is selected.

	Set Sync	 Sets the entered date / time as the current date / time of the reader. If the Sync reader is connected to the Internet, the current date / time are imported from a designated time server. The correct date / time can be set only when the time zone of the region where the reader is installed is set correctly.
4	Language	Press and select a language. • English: English • 简体中文: Chinese • Italiano: Italian • Українська: Ukrainian • Español de españa: Spanish • Čeština: Czech • Deutsch: German



Connect to a network and the LIS server.

1. Enter ID and the password and press the **[Login]** button.

Exdio TRF Plus			Ċ
aaaa		Others	
·			1
User ID		Password	
	Login		
·			,
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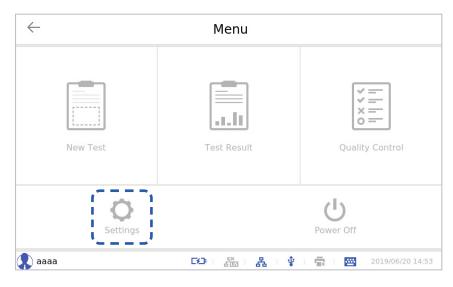
2. Press the **B** button.

		Test		
Patient ID	search field			
Sample Type				
Whole Blood	Plasma / Serum	Others		
Incubation Mode				
Auto		Skip		
Test Name				
Cassette ID				
Expiration			Abort Ru	IN
aaaa			品(🖞 🗮 🚾 2019	9/06/20 14:4

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The analyzer to which this user manual refers may differ slightly from an actual analyzer according to the customer's requirements.

3. Press the [Setting] button.



4. Press the [Network/LIS] button.

\leftarrow	← Settings								i	
Date / Time /	Date Format	M-Y	M-D-	ſ	٦	Time I	Forma 12H	at	24H	
Network / LIS	System Date				Sync				Set	
Printer / Sound	Y < 201	9 >	М	<	6	>	D	<	20	>
Operators	System Time	>	m	<	54	>		АМ	PM	1
Advanced										
Service	Language		~	简体中	Ì文		~	italiano		
Quality Control	🗹 українська		~	espaŕ	iol de Espar	ia				
🔹 aaaa		DØ I	5×	đ	£ ∲			2	019/06/20	14:54

Network/LIS

		Settings		i
Date / Time / Language	Set IP Address	5		Apply
Network / LIS		Auto		Manual
rinter / Sound	Address	192.168.0.22	Sub. Mask	255.255.255.0
Operators	Gateway	192.168.0.1		
Advanced	LIS			Connect
Service	Device ID	Test	Server	192.168.0.147
uality Control	Port	8282	Mode / Notice	HL7 🔻
aaa	Port	8282		HL7 2019/06/20 14:54

No.	ltem	Description
1	Set IP Address	Press and select the IP address setting method.
		 Apply: Apply the set IP address setting method.
		Auto: IP address is set automatically.
		 Manual: IP address is set manually. To set it manually, enter Address, Sub. Mask and Gateway address.
2	LIS	Press and select whether or not to connect the LIS server.
	(LIS server connection	Connect: Connect to LIS system.
	information)	Connecting: Attempting to connect to the LIS server.
		Disconnect: Disconnect from LIS system.
		 Device ID: Characters as identifier for one-on-multiple communications.
		Server: IP of the server to connect
		Port: Port of the server to connect
		Mode: Communication protocol (HL7/ASTM/Custom)
		Notice: Indicates success or failure after sending data to the LIS.

Printer/Sound

Set the printer, printing items and the sound volume.

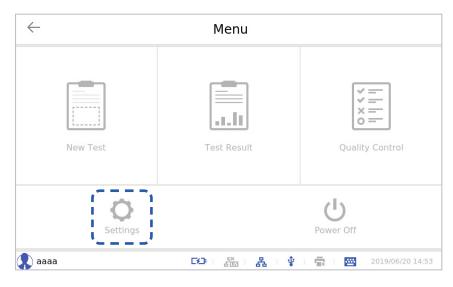
1. Enter ID and the password and press the **[Login]** button.

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)		
aaaa		Others	
User	ID	Password	
	Login		
·			'
	CC Star S	• • • •	2019/06/20 14:41

2. Press the **button**.

		Test		
Patient ID	search field			
Sample Type				
Whole Blood	Plasma / Serum	Others		
Incubation Mode				
Auto		Skip		
Test Name				
Cassette ID				
Expiration			Abort	Run
aaaa			8. L 🛊 L 🗟 L 🖾	2019/06/20 14:41

3. Press the [Setting] button.



4. Press the [Printer/Sound] button.

\leftarrow		Settir	ngs					i
Date / Time / Language	Date Format Y-M-D D-M-1	Y M-D	-Y]		Forma 12H		24H
Network / LIS	System Date			Sync			Set	
Printer / Sound	Y < 2019	> M	<	6	>	D	< 2	0 >
Operators	System Time	> m	<	55	>		АМ	PM
Advanced								
Service	Language Comparish	~	简体中	·文		√ it	aliano	
Quality Control	🗸 українська	~	espař	iol de Espaí	ĩa			
👔 aaaa	E		- <i>8</i>	4 V		-	2019/0	06/20 14:55

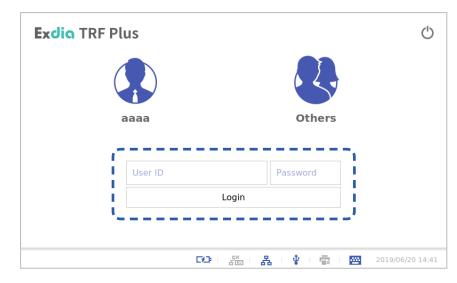
Printer/Sound

_	Setting	js	i	
Date / Time / Language	Printer		1	
Network / LIS	Thermal		pcal	
Printer / Sound	Thermal Printing Items		1	
Operators	Organization Name Organization	Patient ID 🗸	Test Date 🗸 🖡	(
Advanced	Test Name 🗸	Cassette ID 🗸	Operator ID <	
Service	Speaker			
Quality Control	<		■()) Mute 🖌	
aaaa		- 品 + ♥ + 南 + ⊠	2019/06/20 14:55	

No.	ltem	Description
0	Printer	 Press and select the printer type. Thermal: Printing is done by the built-in printer in the analyzer. Local: Printing is done by a printer connected to the analyzer. The printer can be connected to the analyzer through USB port. Only a HP LaserJet model can be connected to the analyzer. (HP LaserJet 1020/Plus, HP LaserJet Pro P1106, HP LaserJet Pro P1108, HP LaserJet Pro P1102w HP LaserJet Pro CP1025) When a printer is connected to the analyzer, the color of the printer icon at the bottom of the screen will light up (-).
2	Thermal Printing Items (Items printed when the built-in printer is used)	 Set the items printed when the thermal printer of the analyzer is used. Select the value of an item to be printed by entering or selecting the value. Organization Name: Organization name Organization: Organization Patient ID: Patient ID Test Date: Test date Test Name: Test name Cassette ID: Cassette ID Operator ID: Operator ID
3	Speaker	Adjust the sound volume by moving the bar in the middle or turn off the sound by selecting Mute.

Operator

View the list, register an additional operator, modify or delete an existing operator.



1. Enter ID and the password and press the **[Login]** button.

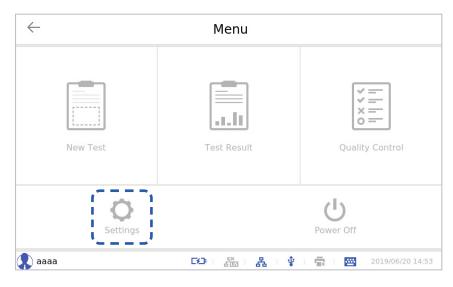
2. Press the **B** button.

		Test		()
Patient ID	search field			
Sample Type				
Whole Blood	Plasma / Serum	Others		
Incubation Mode				
Auto		Skip		
Test Name				
Cassette ID				
Expiration			Abort	Run
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The analyzer to which this user manual refers may differ slightly from an actual analyzer according to the customer's requirements.

3. Press the [Setting] button.



4. Press the [Operators] button.

\leftarrow	S	ettings		i
Date / Time / Language	Date Format	M-D-Y	Time Format	24H
Network / LIS	System Date	Sy	nc	Set
Printer / Sound	Y < 2019 >	м <	6 > D <	20 >
Operators	System Time	• m < 5	56 > AI	M PM
Advanced				
Service	Language	✓ 简体中文	🗸 ital	ano
Quality Control	🗸 українська	🗹 español de	España	
🔹 aaaa	D9	200 8	🕴 i 🔿 i 🖂	2019/06/20 14:56

Operators

Date / Time / Language	Filter Text	D 🔹			٩	-
Network / LIS				All 🗸 0	/1 Single	
Printer / Sound	ID	Name	Authority	Organization	Department	
Operators	aaaa		Supervisor			
Advanced Service						
Quality Control		New	Modify	Del	lete	
aaaa			*	1	2019/06/20 14:56	

No.	ltem	Description
1	Filter Text	 Select an item category and enter the keyword to search. Then press the button. ID: Search for an ID.
		Name: Search for a name.
		Authority: Search for an authority.
		Organization: Search for an organization.
		Department: Search for a department.
2	New	Register a new operator by pressing the New button.
		ID: Enter ID.
		Password: Enter the password.
		Confirm(PW): Enter the password again.
		Name: Enter the name.
		Organization: Enter the organization.
		Department: Enter the department.
		 Authority: Select the authority. A supervisor holds all authorities but an operator can only modify and delete information.
		OK: Press this button to register the entered information.
		Cancel: Press this button to cancel registration.

No.	ltem	Description
3	Modify	Modify the information of an operator by selecting the operator and pressing the [Modify] button. • ID: Enter ID.
		Password: Enter the password.
		Confirm(PW): Enter the password again.
		Name: Enter the name.
		Organization: Enter the organization.
		Department: Enter the department.
		 Authority: Select the authority. A supervisor holds all authorities but an operator can only modify and delete information.
		OK: Press this button to register the entered information.
		Cancel: Press this button to cancel registration.
4	Delete	Delete the information regarding an operator by selecting the operator and pressing the [Delete] button. When the screen verifying whether or not to delete appears, press the [OK] button. Press the [Cancel] to cancel deletion.



Advanced settings.

1. Enter ID and the password and press the **[Login]** button.

Exdia TRF Pl	us		Ċ
(
	aaaa	Others	
-		,	
	User ID	Password	
	Login		
- -		'	
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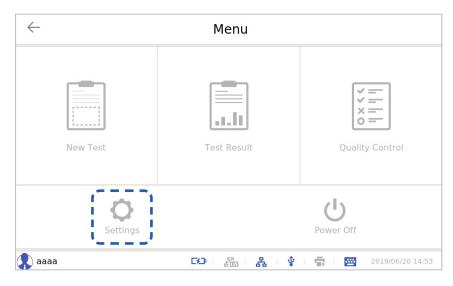
2. Press the **B** button.

		Test			
Patient ID	search field				
Sample Type					
Whole Blood	Plasma / Serum	Others			
Incubation Mode					
Auto		Skip			
Test Name					
Cassette ID					
Expiration				Abort	Run
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The analyzer to which this user manual refers may differ slightly from an actual analyzer according to the customer's requirements.

3. Press the [Setting] button.



4. Press the [Advanced] button.

\leftarrow		Setting	S			i
Date / Time / Language	Date Format	M-D-Y		Time For		24H
Network / LIS	System Date		Sync			Set
Printer / Sound	Y 🔇 2019	> M	< 6	> [> <	20 >
Operators	System Time	> m	< 57	>	AM	PM
Advanced						
Service	Language	~ ²	饰体中文	-	/ italiand)
Quality Control	українська	 ✓ 	spañol de Espa	aña		
😱 aaaa	C:) 500	品 🕴			2019/06/20 14:57

Advanced

\leftarrow	S	ettings		i
Date / Time / Language	Regular instrument cl	neck		lays
Network / LIS	=======		======	
Printer / Sound	Reuse Cassette			
Operators	Units Conversion(iFOI	B) ng/mL	µg/g	_ ; (
Advanced	Incubation Mode	Auto	Skip	
Service	Patient Registration			
Quality Control	Patient ID	Auto prefix	Empty	
	Auto Prefix	Auto Prefix Digits	1	
aaaa	627	- 🏦 - 🛃 - 🛊 - 🚍 -	2019/10/29 1	1:13

No.	ltem	Description
1	Regular instrument check (Set the 'instrument check' period)	Set the 'instrument check' period. When the number of days en-tered has passed, a message saying 'Instrument Check' will be dis-played each time the Run button is pressed on the Test screen.
2	Reuse Cassette	If it is checked, the previously used cassette can be reused.
3	Units Conversion (iFOB)	 ng/mL(default): If pressed, the unit will be changed to ng/mL. μg/g: If pressed, the unit will be changed to μg/g.
4	Incubation Mode	 Adjust total test duration, including incubation time. Auto: The test begins after the incubation in the analyzer is carried out according to the set time. Skip: The test begins immediately without incubation in the analyzer.
5	Patient Registration	 Register patient ID or leave it blank. Auto prefix: A patient ID on the Test screen is created automatically with the combination of a character entered on Auto Prefix and a digit entered on Auto Prefix Digits. Enter a value on Auto Prefix and Auto Prefix Digits. Empty: A patient ID on the Test screen is set blank.

Service

This function enables communication between the equipment and a remote supporter with the remote support server (SSH server).

Connect to the SSH server by entering the SSH server information (Address/Port/ID/Password), and the remote supporter can connect as a local host of the server and provide remote support.

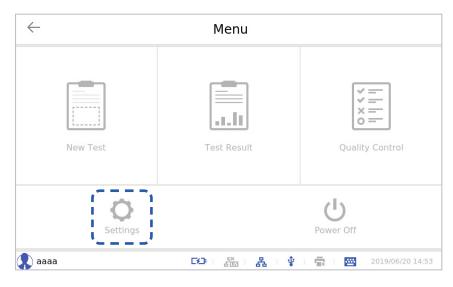
1. Enter ID and the password and press the **[Login]** button.

Exdia TRF Pl	us				Ċ
(2.		
	aaaa		Others		
r				-1	
	User ID		Password		
		Login			
·-				_*	
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2. Press the **B** button.

		Test			
Patient ID	search field				
Sample Type					
Whole Blood	Plasma / Serum	Others			
Incubation Mode					
Auto		Skip			
Test Name					
Cassette ID					
Expiration				Abort	Run
🚶 aaaa			品 •		2019/06/20 14:41

3. Press the [Setting] button.



4. Press the [Service] button.

← Settings						i			
Date / Time / Language	Date Fo		M-D-	Y			Format 12H	24H	
Network / LIS	System	Date	·		Sync			Set	
Printer / Sound	Υ <	2019	> M	<	6	>	D <	20	>
Operators	System	Time							
Advanced	h <	14	> m	<	58	>	AN	1 P	М
Service	Langua	5	~	简体中	文		🗸 itali	ano	
Quality Control	🗸 укра	аїнська	~	españ	ol de Espa	ña			
】 aaaa		60	ç× E US	뢂	¥			2019/06/20) 14:58

The Service Settings screen will appear.

\leftarrow	Settings	i
Date / Time / Language	Remote Support Address	
Network / LIS	Port	
Printer / Sound	ID	
Operators	Password	
Advanced	Connect	
Service		
Quality Control	Test File Manager	
🗶 aaaa	🍱 : 🏦 : 몷 : 🌵 : 🖶 : 📴 2019/06/20	14:58

Test File Manager

Import a new test method or manage the previously saved test method. Before executing the Test File Manager, connect a USB memory to the analyzer.

\leftarrow	Settings	i
Date / Time / Language	Remote Support Address	
Network / LIS	Port	
Printer / Sound	ID	
Operators	Password	
Advanced	Connect	
Service		
Quality Control	Test File Manager	
🕵 aaaa	🍽 📇 R i 🖞 i 🚋 i 🔤 2019/0	06/20 14:59

Press the [Test File Manager] button.

Import

• To import all test files from a USB memory, press the [Select All] checkbox and press the 🔀 button.

USB	Select All];	Instrument	Select All
exdia			📕 fluoro	
exdia tst			Exdia 3-in-1.tst	
ExtQC			Exdia beta-hCG.tst	
img			Exdia iFOB.tst	
keyboard		<	Exdia Influenza A+B.ts	;t
log			Exdia NT-proBNP.tst	
mobile			Exdia PCT.tst	
nano			Exdia Thi tst	•
′ou can view, delete	e and set test files in	the Instrun	nent only.	
View	Delete	Set Ref.R	ange	Close

• If a file with the same name exists, a message window asking whether or not to overwrite will be displayed. To overwrite, press the **[OK]** button, or press the **[Cancel]** button if you do not wish to overwrite.

Test File Manager					
USB	Test Files	Select All 🗸			
 Exdia D-Dim Exdia iFOB.ts Exdia Influer 	?	•			
 Exdia NT-pro Exdia PCT.ts Exdia Tnl.tst Exdia Vitami 	The same file exist. Do you want to overwrite?	st			
You can view, d	elete and set test files in the Instrument only.				
View	Delete Set Ref.Range	Close			

• Press the [OK] button.

	Test File Manager	
USB	Test Files	Select All 🧹
 Exdia D-Dim Exdia iFOB.t: Exdia Influer 	\bigcirc	
 Exdia NT-pro Exdia PCT.ts Exdia Tnl.tst Exdia Vitami 	Test files are imported.	st 🗸
You can view, d View	elete and set test files in the Instrument only. Delete Set Ref.Range	Close

Export

• To export all test files to a USB memory, press the [Select All] checkbox and press the <u> </u>button.

JSB	Select All 🗸		Instrument	Select All 🗸
		1	🖿 fluoro	
]	🗎 Exdia 3-in-1.tst	
All-New			📙 Exdia beta-hCG.tst	
Exdia 3-in-1.tst			📙 Exdia D-Dimer.tst	
Exdia D-dimer.tst		<	🗎 Exdia iFOB.tst	
Exdia iFOB.tst		·/	📕 Exdia Influenza A+B.	tst
🗎 Exdia Tnl.tst	-		Exdia NT-proBNP.tst	-
Fydia Vitamin D tst	•		🗎 Exdia PCT tst	•
ou can view, delete and	set test files in t	he Instrun:	nent only.	
View	Delete	Set Ref.R	ange	Close

• If a file with the same name exists, a message window asking whether or not to overwrite will be displayed. To overwrite, press the **[OK]** button, or press the **[Cancel]** button if you do not wish to overwrite.

JSB	Tes	st Files	Select All 🚽
i .	(?	
All-New		<u> </u>	
Exdia 3-in-1.			
Exdia D-dime	The same file exist. [Do you want to overwrite?	
Exdia iFOB.ts			st
Exdia Tnl.tst	ОК	Cancel	
Fxdia Vitami	· · · · · · · · · · · · · · · · · · ·		
'ou can view, delet	e and set test files in the	e Instrument only.	
View	Delete S	et Ref.Range	Close

• To select and export a specific test file to a USB memory, select the file and press the **(OK)** button. Then press the **[OK]** button.

	Test File Manager	
USB	Test Files	Select All 🧹
	\bigcirc	
 All-New Exdia 3-in-1. Exdia beta-h 	Test files are exported.	
 Exdia D-Dim Exdia iFOB.ts Exdia lpfluer 	ОК	st
	elete and set test files in the Instrument only.	
View	Delete Set Ref.Range	Close

View Detail

• To view the detail of a test file, select the test file and press the [View] button.

JSB	Select All 🗸		Instrument	Select All
i .			fluoro	
i			Exdia 3-in-1.tst]_
All-New		>	= EXUIA DELA-IICO.LSL	
Exdia 3-in-1.tst		/	Exdia D-Dimer.tst	
Exdia beta-hCG.tst		<	Exdia iFOB.tst	
Exdia D-Dimer.tst			Exdia Influenza A+	B.tst
Exdia iFOB.tst	-		Exdia NT-proBNP.ts	t 📃
■ Fydia Influenza Δ+R	tet		Fydia PCT tst	•
'ou can view, delete ar	d set test files in the I	nstru	ment only.	

View the detail of a selected test file.

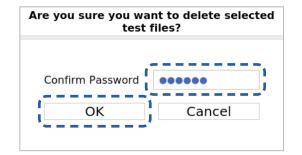
		Exdia 3-in-1.tst	
USB	Test Name	Exdia 3-in-1	lect All 🗸
i .	Window	1	•
All-Ne	Window Name	Window1	
Exdia	Description	Myoglobin, CK-MB, TnI, CTRL	
Exdia	Test Line No.	4	
Exdia	Sample Type	Plasma, Whole Blood, Serum	-
You can	TestCode (LID)	55	
Vi		ОК	lose

Delete

• To delete a test file, select the test file and press the [Delete] button.

JSB	Select All 🧹		Instrument	Select All 🧹
			fluoro	
		1	Exdia 3-in-1.tst]
All-New			= EXUId Deta-IICG.LSL	
Exdia 3-in-1.tst		-	Exdia D-Dimer.tst	
Exdia beta-hCG.tst		<	Exdia iFOB.tst	
Exdia D-Dimer.tst			Exdia Influenza A+B.	st
Exdia iFOB.tst	_		Exdia NT-proBNP.tst	-
È Frdia Influenza Δ+R tst	•		Frdia PCT tst	•
'ou can view, delete and s	et test files in the	e Instrum	ent only.	

The screen for entering the password will appear. Enter the password and press the **[OK]** button.



Set Ref.Range

Change and apply a reference range directly to a test result. Changed reference range will be applied to the test result immediately.

1. Press the [Set Ref.Range] button.

			fluoro	
				-
		_	Exdia beta-hCG.tst	
All-New		\rightarrow	Exdia D-Dimer.tst	
Exdia 3-in-1.tst			Exdia iFOB.tst	
Exdia beta-hCG.tst		<	🗎 Exdia Influenza A+B.t	tst
Exdia D-Dimer.tst			Exdia NT-proBNP.tst	
Exdia iFOB.tst	_		Exdia PCT.tst	
È Exdia Influenza ∆+R tst	•		🖹 Exdia Thi tst	

2. Select a test.

Tests	Reference range o	f selected test
Exdia beta-hCG	Name	Reference Range
Exdia D-dimer		
Exdia iFOB	PCT	< 0.5
Exdia Influenza A+B		
Exdia NT-proRNP		
Exdia PCT		
Exdia Vitamin D		
GAIN TEST GLASS		

3. Press the reference range you wish to change.

	5	Set Reference	e Range	
Tests		Reference r	ange of selected test	
Exdia beta-hCG		Nan	ne Ref	erence Range
Exdia D-dimer				
Exdia iFOB		РСТ	< 0.5	, <u> </u>
Exdia Influenza A+	В			
Exdia NT-proBNP				
Exdia PCT				
Exdia Tnl				
Exdia Vitamin D				
GAIN_TEST_GLASS				
Reset All	Reset	Import	Export	Close

4. After changing the reference range, press the **[Enter]** button.

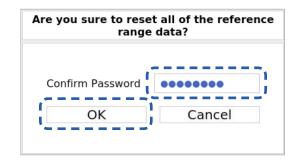
				Set	Refere	ence R	ange				
Tests					Referer	nce range	e of seleo	cted test	:		
Exdia	beta-hCC	6				Name		Re	ference F	Range	
Refere	nce Rar	nge	< 0.5							Car	ncel
q	w	e	r	t	у	u	i	ο	р	+	-
а	s	d	f	g	h	j	k	I	*	/	1/2
caps	5	z >	((:	v	b	n r	n =	=		Back
123/9	Sym	En							Clear	E	nter

Reset All

To reset the reference range for all test files, press the [Reset All] button.

	Set Reference	Range	
Tests	Reference rar	ge of selected test	
Exdia beta-hCG	Name	Refe	rence Range
Exdia D-dimer	DOT		_
Exdia iFOB	РСТ	< 0.5	
Exdia Influenza A+B			
Exdia NT-proBNP			
Exdia PCT			
Exdia Tnl			
Exdia Vitamin D			
GAIN_TEST_GLASS			
Reset All Reset	Import	Export	Close

The screen for entering the password will appear. Enter the password and press the **[OK]** button.



Reset

To reset the reference range of a specific test file, select the test file and press the [Reset] button.

Set Reference Range				
Tests Reference range of selected test				
Exdia beta-hCG	Name	Name Reference Range		
Exdia D-dimer	DOT			
Exdia iFOB	РСТ	< 0.5		
Exdia Influenza A+B				
Exdia NT-proRNP				
Exdia PCT	}			
	'			
Exdia Vitamin D				
GAIN_TEST_GLASS				
Reset All Reset	Import	Export	Close	

The screen asking whether to reset the reference range will appear. Press the **[OK]** button.

Question				
?				
Are you sure to reset this reference range only?				
OK Cancel				

Import

A reference range file in a USB memory can be imported.

Connect the USB memory containing the reference range file and press the [Import] button.

Set Reference Range					
Tests Reference range of selected test					
Exdia beta-hCG	Name	Refere	ence Range		
Exdia D-dimer	0.07	0.5	_		
Exdia iFOB	РСТ	< 0.5			
Exdia Influenza A+B					
Exdia NT-proBNP					
Exdia PCT					
Exdia Tnl					
Exdia Vitamin D					
GAIN_TEST_GLASS					
Reset All Reset	Import	Export	Close		

When the 'Import Reference Range' screen appears, select a reference range file (.conf) and press the [Import] button.

Import Reference Range				
Reference Range Files refList_PTH60-A00004.conf	Import			
	Close			

The screen asking whether or not to import the reference file will appear. Press the **[OK]** button.

Question				
?				
Are you sure to import this reference range file?				
OK Cancel				

Export

Reference ranges included in the analyzer can be exported as a file.

Connect a USB memory and press the [Export] button.

Set Reference Range					
Tests Reference range of selected test					
Exdia beta-hCG	Name	Referen	ce Range		
Exdia D-dimer			-		
Exdia iFOB	РСТ	< 0.5			
Exdia Influenza A+B					
Exdia NT-proBNP					
Exdia PCT					
Exdia Tnl					
Exdia Vitamin D					
GAIN_TEST_GLASS					
Reset All Reset	Import	Export	Close		

A screen saying that the reference range files have been exported will appear. Press the **[OK]** button.

Export	
\bigcirc	
Reference range file are exported.	
ОК	

Quality Control of the Cassette

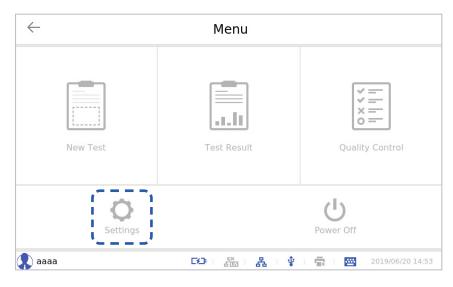
For the quality control of the Exdia cassette, QC information is required. it can be managed in QC menu.

- ப **Exdio** TRF Plus aaaa Others I User ID Password I I Login 60 2019/06/20 14:41 5X 5 [][5] ሕ Ŷ -----
- **1.** Enter ID and the password and press the **[Login]** button.

2. Press the **B** button.

		Test		
Patient ID	search field			
Sample Type				
Whole Blood	Plasma / Serum	Others		
Incubation Mode				
Auto		Skip		
Test Name				
Cassette ID				
Expiration			Abort	Run
👤 aaaa			1 🕴 i 🖶 i 🖽	2019/06/20 14:41

3. Press the [Setting] button.



4. Press the [Quality Control] button.

← Settings				i
Date / Time / Language	Date Format	M-D-Y	Time Forma 12H	t 24н
Network / LIS	System Date	Syr	nc	Set
Printer / Sound	Y 🔇 2019	> M < 0	6 > D	< 20 >
Operators	System Time			
Advanced	h 🔇 15	> m < 1	7 >	AM PM
Service	Language	✓ 简体中文	√ it	aliano
Quality Control	українська	< español de	España	
🔹 aaaa	-		Ý I 🖶 I 🔤	2019/06/20 15:07

The Quality Control screen will appear.

\leftarrow	Se	ttings	i
Date / Time / Language	External Quality Contr		
Network / LIS	QC Materials	A	II 0/1 Single
Printer / Sound	Name	Brand	Lot
Operators	PB 3in1	РВ	PB-1234
Advanced			
Service			
Quality Control	Export	Add Mod	dify Delete
🗶 aaaa	6 23	a 4 🔹 👘	2019/06/20 15:07



A QC data file can be exported.

Connect a USB memory to the analyzer and select a QC data file.

\leftarrow Settings				i
Date / Time / Language	External Quality Contro	ol		
Network / LIS	QC Materials	•	All 🗸 1/1	Single
Printer / Sound	Name	Brand	Lot	
Operators	PB 3in1	РВ	PB-12	34
Advanced				
Service				
Quality Control	Export	Add	Modify [Delete
🕵 aaaa	50	2001 🖧 i 🖞 i	2019	/06/20 15:07

Press the [Export] button.

← Settings i				
Date / Time / Language	External Quality Contr			
Network / LIS	QC Materials		All 1/1 Single	
Printer / Sound	Name	Brand	Lot	
Operators	PB 3in1	РВ	PB-1234	
Advanced				
Service				
Quality Control	Export	Add Mo	dify Delete	
🗶 aaaa	59	満日品 (*) 🖷	2019/06/20 15:07	

A QC data file has been created in the USB memory. Press the **[OK]** button.

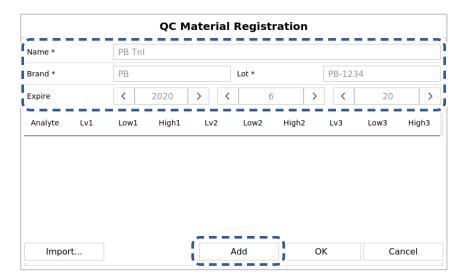
Date / Time	QC M	aterial Manag	er		
Language					
Network / LIS		\bigtriangledown		1/1	Single
Printer / Soun		\bigcirc		Lot	
Operators	QC Materia	al File Export is com	nplete.	PB-12	34
Advanced	17	ок	1		
Service		OK	1		
Quality Control	Export	Add	Modify		Delete

Add

Register new QC data. Press the [Add] button.

\leftarrow	Set	tings		i
Date / Time / Language	External Quality Contro	ol		
Network / LIS	QC Materials Filter Text Name	•	All 🗹 1/1	Single
Printer / Sound	Name	Brand	Lo	ot
Operators	PB 3in1	РВ	PB-1	234
Advanced				
Service				
Quality Control	Export	Add	Modify	Delete
, aaaa	C4D	йш 🕹 🖞	201	9/06/20 15:08

Enter information on Name, Brand, Lot and Expire and press the [Add] button.



Select an analyte and enter concentrations for three levels.

	Analyte Registration										
Analyte *	Tnl										
Level 1:	Value1	0.08	Low1	0.06	High1	0.1					
Level 2:	Value2	0.2	Low2	0.18	High2	0.22					
Level 3:	Value3	1	Low3	0.8	High3	1.2					

Click the **[OK]** button.

Analyte *	Tnl						
Level 1:	Value1	0.08	Low1	0.06	High1	0.1	
Level 2:	Value2	0.2	Low2	0.18	High2	0.22	
Level 3:	Value3	1	Low3	0.8	High3	1.2	

If there is QC data provided by a supplier, connect a USB memory and press the [Import] button.

lame *		PB Tnl							
Brand *		PB			Lot *		PB-123	34	
xpire		<	2020	> <	6	>	<	20	>
Analyte	Lv1	Lowl	High1	Lv2	Low2	High2	Lv3	Low3	High3
Tnl	0.080	0.060	0.100	0.200	0.180	0.220	1.000	0.800	1.200

QC Material Registration PB Tnl Name * PB-1234 Brand * PΒ Lot * < 2020 > < 6 > < 20 > Expire Analyte Lv1 Low1 High1 Lv2 Low2 High2 Lv3 Low3 High3 Tnl 0.080 0.060 0.100 0.200 0.180 0.220 1.000 0.800 1.200 Import... Add ΟК Cancel

Register the entered QC data by pressing the **[OK]** button.

When the **[OK]** button is pressed, a confirmation message window will be displayed. To register, press the **[OK]** button, or press the **[Cancel]** button if you wish to cancel registration.

Name *		Q	C Material Mana	ger		
Brand *			~		4	
Expire			(?)		20	>
Analyte	Lv1		\smile		Low3	High3
Tnl	0.080	Are ye	ou sure you want to reg material?	ister this	0.800	1.200
		(OK Ca	ncel		
Impo	rt		Add	ОК	C	ancel



You can select and modify QC data.

		Set	tings			i
Date / Time / Language		Quality Contro	I			
Network / LIS	QC Mater		.		All 🧹 0	/ 2 Single
Printer / Sound		Name		Brand		Lot
Operators	P	B 3in1		РВ		PB-1234
Advanced	F	PB Tnl		РВ		PB-1234
Service						
Quality Control	Ехро	rt	Add	М	lodify	Delete
aaaa		60	çx STUS I d	몸 (🖞) 🕴		2019/06/20 15:1

Press the [Modify] button.

\leftarrow		Set	tings			i
Date / Time / Language	External Quality	y Contro	I			
Network / LIS	QC Materials	5	•	All	√ 1/2	Single
Printer / Sound	Name		Brand		Lo	ot
Operators	PB 3in1		РВ		PB-1	234
Advanced	PB Tnl		РВ		PB-1	234
Service						
Quality Control	Export		Add	Modi	fy	Delete
, aaaa		DD ,	šia 🔒 🕴		201	9/06/20 15:14

Modify information on Name, Brand and Expire.

Name *		PB Tnl							
Brand *		PB			Lot *		PB-123	4	
Expire		<	2020	>	<	6	> <	20	>
Analyte	Lv1	Low1	High1	Lv2	Low2	High2	Lv3	Low3	High3
Tnl	0.080	0.060	0.100	0.200	0.180	0.220	1.000	0.800	1.200

To modify an analyte, select the analyte and press the [Modify] button.

rand *		РВ			Lot *		PB-123	4	
			2020			6			
xpire		<	2020	>	<	6	> <	20	>
Analyte	Lv1	Low1	High1	Lv2	Low2	High2	Lv3	Low3	High3
	0.080	0.060	0.100	0.200	0.180	0.220	1.000	0.800	1.200

Change the concentrations for Level 1, 2 and 3 and press the [Modify] button.

		Analyte Modification							
		Anary	e mourr	cation					
	-								
Analyte *	Tnl					_			
Level 1:	Value1	0.080	Low1	0.060	High1	0.100			
Level 2:	Value2	0.200	Low2	0.180	High2	0.220			
Level 2.	Valuez	0.200	20112	0.100	Ingitz	0.220			
Level 3:	Value3	1.000	Low3	0.800	High3	1.200			

QC Material Modification PB Tnl Name * PB-1234 Brand * PΒ Lot * < 2020 > < 6 > < 20 > Expire Analyte Lv1 Low1 High1 Lv2 Low2 High2 Lv3 Low3 High3 - ----. . 1 Ì Add Modify Delete ОΚ Cancel J

Select an analyte you wish to delete and press the [Delete] button.

After modification is complete, press the **[OK]** button.

Name *		PB Tnl							
Brand *		PB			Lot *		PB-123	4	
Expire		<	2020	>	<	6	> <	20)
Analyte	Lv1	Low1	High1	Lv2	Low2	High2	Lv3	Low3	High3
Tni	0.080	0.060	0.100	0.200	0.180	0.220	1.000	0.800	1.200
Tnl	0.080	0.060	0.100	0.200	0.180	0.220	1.000	0.800	1.200



QC data can be deleted. Select QC data.

\leftarrow		Setting	5		i
Date / Time / Language	External Quality (Control			
Network / LIS	QC Materials	Ŧ		All 🗹 0/2	Single
Printer / Sound	Name		Brand	Lo	t
Operators	PB 3in1		РВ	PB-1	234
Advanced	PB Tnl		РВ	PB-1	234
Service					
Quality Control	Export	Ad	ld N	lodify	Delete
🔉 aaaa	D	9 500	品 (🐑	201	9/06/20 15:15

Press the [Delete] button.

\leftarrow	← Settings i				i	
Date / Time / Language	External Qu	-	bl			
Network / LIS	QC Material	ame	•	AI	I 🗹 1/2	Single
Printer / Sound	Na	me	Brand	1	L	ot
Operators	PB 3	Bin1	РВ		PB-1	234
Advanced	PB	Tnl	РВ		PB-1	.234
Service						
Quality Control	Export		Add	Mod	ify	Delete
🔔 aaaa			sii A	¥ I 📼	20	19/06/20 15:16

Information

View and export program information and log information to a USB memory.

- ப **Exdio** TRF Plus aaaa Others I User ID Password I L Login I. 60 2019/06/20 14:41 5X 5 [][5] ሕ Ŷ -----
- **1.** Enter ID and the password and press the **[Login]** button.

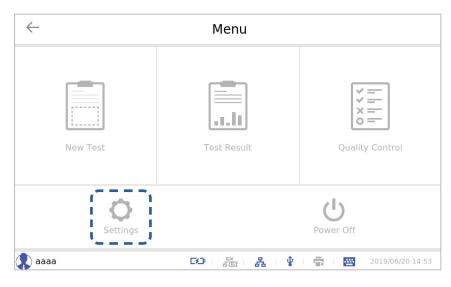
2. Press the **B** button.

		Test		
Patient ID	search field			
Sample Type				
Whole Blood	Plasma / Serum	Others		
Incubation Mode	2			
Auto		Skip		
Test Name				
Cassette ID				
Expiration			Abort	Run
👤 aaaa			& · • • 🔿 · 📾	2019/06/20 14:41

The analyzer to which this user manual refers may differ slightly from an actual analyzer according to the customer's requirements.

l

3. Press the [Setting] button.



4. Press the **i** button.

\leftarrow	Settings	[i]	
Date / Time / Language	Date Format Time Format	24H	
Network / LIS	System Date Sync	Set	
Printer / Sound	Y < 2019 > M < 6 > D <	20 >	
Operators	System Time		
· · · · · ·	h 🔇 15 > m < 16 > AM	РМ	
Advanced			
Service	Language ✓ English		
Quality Contro	V English У українська V español de España	0	
🔹 aaaa	Ge i 🚈 i 🗛 i 🛊 i 🖶 i 📟	2019/06/20 15:17	

5. Check the program information.

\leftarrow	Set	tings	i
Date / Time /	Ab	out	at
Language Network / LIS	Program Name	Exdia TRF Plus	24H
Printer / Sound	Version	1.1.8 Build 20190617	Set
Operators	Serial Number	NSL60-A00011	< 20 >
Advanced	Available Space	1229 MB	AM PM
Service	Export	OK	
	 English 	✓ 简体中文	✓ italiano
Quality Control	українська	< español de España	
💽 aaaa	D2	2001 R I 🛊 I 🖶	2019/06/20 15:17

6. To export log information to a USB memory, connect a USB memory to the analyzer and press the **[Export Log]** button.

	Set	tings	i
Date / Time /	Ab	out	at
Language	Program Name	Exdia TRF Plus	24H
Network / LIS	Version	1.1.8 Build 20190617	Set
Printer / Sound			< 20 >
Operators	Serial Number	NSL60-A00011	
Advanced	Available Space	1229 MB	AM PM
Service	Export	ОК	
Service	✓ English	✓ 简体中文	italiano
Quality Control	🗸 українська	🗸 español de España	



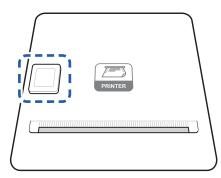
Please check the instruction to replace printing papers and the maintenance of the printer.

Replace Printing Paper

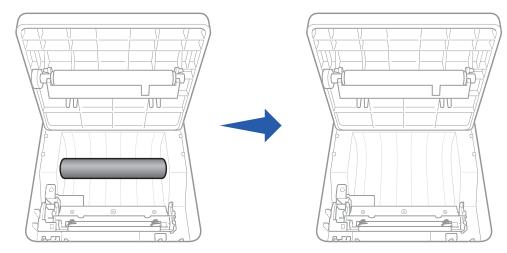
Print a test result using the thermal printer in the Exdia TRF Plus. A roll of printing paper is included in the printer when the analyzer is purchased. Replace it with a new roll of printing paper according to the following method.

Use a roll of thermal printing paper 57 mm in width and 30 mm in external diameter when replacing the roll of printing paper.

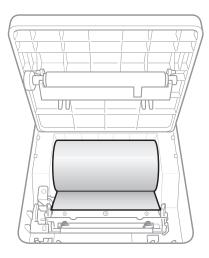
1. Open the printer cover by pressing the printer cover button located at the top of the analyzer.



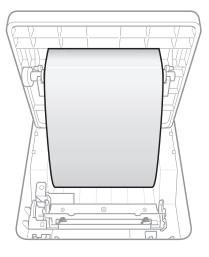
2. Remove the remaining roll.



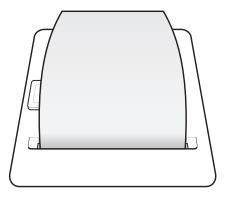
3. Fit a new roll of printing paper.



4. Position the end of the printing paper in the printing paper outlet.



5. Close the printer cover.



Maintenance

The maintenance schedule should be set according to the following schedule.

ltem	Everyday	Every week	Every month	Quarterly	As needed
Quality Control of the Analyzer					
Cleaning of the cassette slot		•			
Comparison with the previous IQC data			•		
Cleaning of the temperature sensor				•	
Replacement of the Li-Po battery					•
Surface cleaning of the analyzer					•
Data backup					

Cleaning

If the cassette slot is contaminated, wipe the contaminated area using a soft cloth or a cotton swab.

• Do not wipe using alkaline detergent or an organic solvent (thinner, acetone, etc.).

Caution • Turn off the analyzer and disconnect the external power supply before cleaning.

Disposal



The Exdia TRF Plus should be disposed of according to the regulations on the disposal of electronic and electrical equipment.



Send the Exdia TRF Plus to Precision Biosensor Inc. for proper disposal.

If you dispose the analyzer onsite, dispose it according to local regulations.

Transportation and Storage

• Transport the analyzer after removing the cassette or the QR card from the cassette slot.

• Store the analyzer in a dry place away from direct sunlight. Caution



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📕 Repair

The operator should not directly repair the Exdia TRF Plus. If you need technical repairs, be sure to contact the Customer Support Team (support@precision-bio.com).

Troubleshooting

Symptom	Cause	Solution
Nothing is displayed	Abnormal input power	Check if the external power supply is correct.
	Abnormal power cable connection	Separate the power cable from the electrical outlet and then connect it again.
on the screen. (The status indication	Abnormal AC adaptor	Contact the Customer Support Team.
LED is off.)	Abnormal power cable	Contact the Customer Support Team.
	Power button not pressed	Press the Power button to turn on the analyzer.
A specific screen is frozen.	Software failure	Press the Forced Termination button and reboot the computer.
(The status indication LED is on.)	Software damage	Contact the Customer Support Team.
No touch recognition	Abnormal touch recognition	Turn off the product, and then turn it on 10 seconds later. If the problem persists, contact the Customer Support Team.
USB memory cannot be recognized. (Abnormal recognition)	Abnormal USB port	Separate the USB memory from the port and connect it to another port. Reboot the analyzer and try again. If the problem persists, contact the Customer Support Team.
	Abnormal USB connection	Check if the USB memory is connected to the USB port.
	No printing paper	Check if there is any remaining printing paper. If no printing paper remains, replace the printing paper according to "Replace Printing Paper".
No built-in printer operation	Printing paper jam	Check if the printing paper is jammed. If it is jammed, replace the printing paper according to "Maintenance - Replace Printing Paper".
	Built-in printer failure	Contact the Customer Support Team.

Symptom	Cause	Solution
No external printer operation	Status of supported printer	Check Page 77 (Printer/Sound) and check if it is a supported printer.
	Printer setting	Go to Settings and check if Local is set for the printer setting.
	Power supply to the printer	Check if the power supply is connected to the printer normally.
	Abnormal USB port	Separate the USB memory from the port and connect it to another port. If the problem persists, contact the Customer Support Team.
	Abnormal USB connection	Check if the printer is connected to the USB port.
	Abnormal network settings	Check the network setting in Settings.
No email/LIS transmission	Abnormal network	Check the network system with the network administrator for the place of installation.
	Abnormal LAN cable connection	Check if the LAN cable is connected to the analyzer.
QR code cannot be read.	The QR card is inserted in reverse.	Checking the direction, insert the QR card into the cassette slot and test again. If the problem persists, contact the Customer Support Team.
The cassette barcode cannot be read.	Check the cassette position.	Check the cassette position and test again. If the problem persists, contact the Customer Support Team.
The cassette slot won't shut.	Check the cassette position.	Check the cassette position and close the cassette slot again. If the problem persists, contact the Customer Support Team.
The cassette slot won't open.	The cassette is jammed internally.	Contact the Customer Support Team.



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