

BioCheck
DxDATA[™]

Calibration and Quality Control Quick Start Guide



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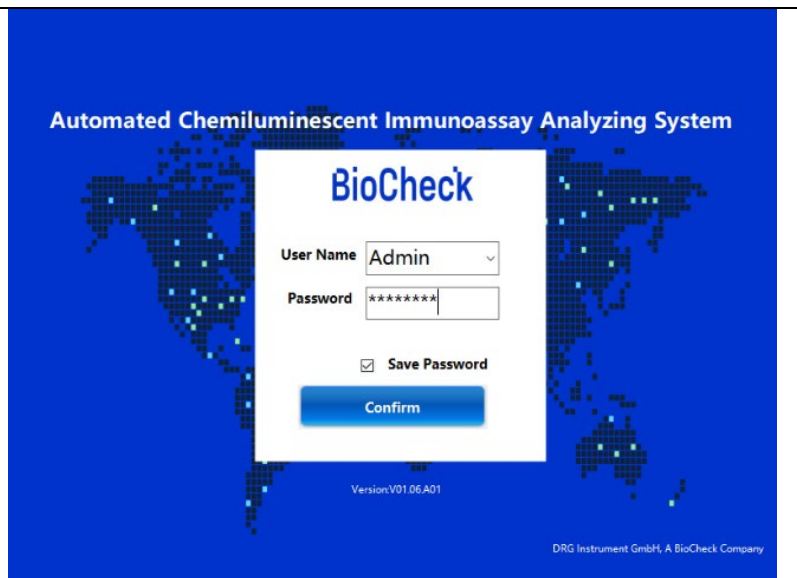
General Notes:

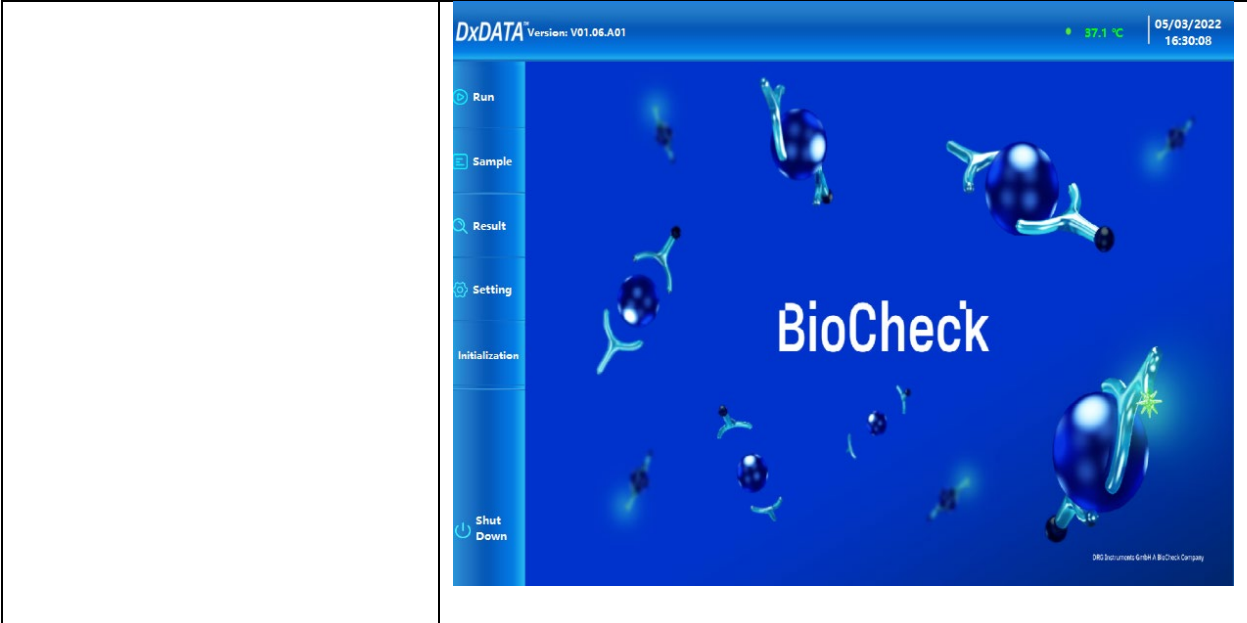
1. Procedure is intended for user: Admin
2. Use DxDATA™ kits provided with QR bar code on the side of kit box.
3. Resuspend lyophilized Calibrators and QC samples as described on kit's Instruction for Use.
4. Let kit equilibrate to room temperature for 30 min.
5. Run this procedure with new kit lot on each instrument.
6. New kit lot requires recalibration and QC test by the user.
7. Recalibration is done every 28 days.
8. One or two QC samples are provided with target concentration to ensure quality.

Procedure:

Turn on the DxDATA™ instrument (the switch is at the back of the unit).
Select your User Name and enter the password.
Click “Confirm” to proceed.

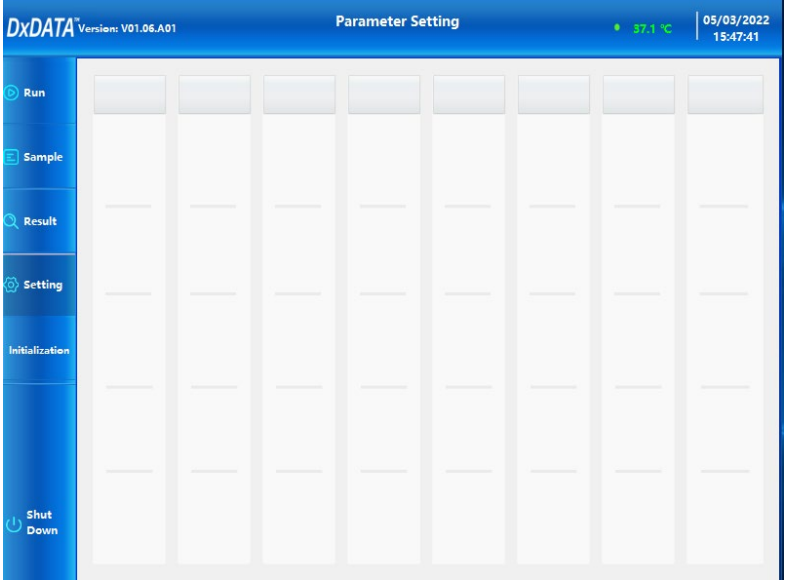
Wait for the instrument to reach a temperature of $37\pm 1^{\circ}\text{C}$, which is reflected at the top right corner of the screen.





In the Main menu click Setting, then select **Reagent management**.

Select kit's Target on the left bar and click **"Add New Batch"**. Make sure that the temperature reaches 37°C for 30 min.



In the Reagent Management window, select the assay you want to calibrate, then click, "Add New Batch"

DxDATA Version: V01.06.A01 Reagent Management 37.1 °C 05/03/2022 15:53:06

Run Sample Result Setting Initialization Shut Down

GFAP PGP9.5 S100-β NSE PTH 25-OH-V D CKMB cTnI D-Dimer Hs-CRP Lp-PLA2 Myo NT-proB

Project List Back Add New Batch Calibration History Re-Curve-fitting

Project Name: Glial fibrillary acid
Abbr.: GFAP
Sample Type: Serum
Project Code: 1101
Unit: pg/mL 1

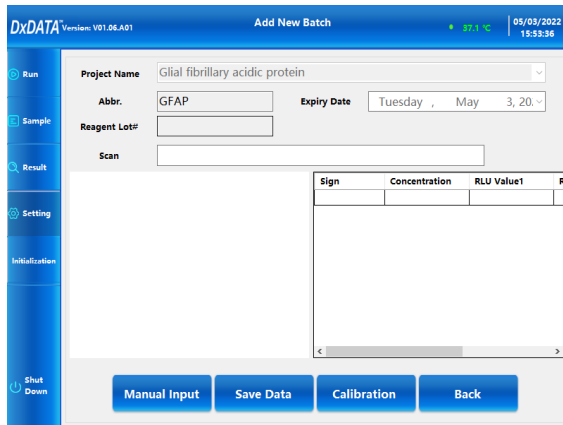
Reference Interval

Gender	Lower age limit
	0

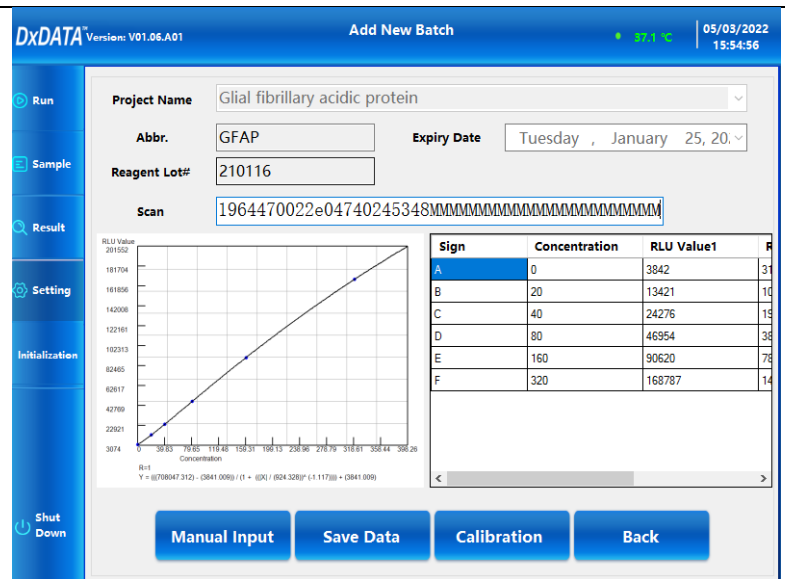
Reagent Lot#:
Expiry Date:
Calibration Date:
Next Calibration Time: days

Sign	Concentration
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Click **Scan QR** window and then scan DxDATA™ kit box barcode.



The Scan QR will populate and a plot with three standard curves' RLU values will show up. Click **“Save Data”**.



Three Calibration RLU data should popup. Confirm and Save Data. Click “Calibration”.

Sign	Concentration	RLU Value1	R
A	0	3842	31
B	20	13421	10
C	40	24276	15
D	80	46954	38
E	160	90620	75
F	320	168787	14

Load Calibrators 1 and 2 in duplicates, and QC 1 and 2. Then, click “Run”.

If successful, a “Calibration Success” message will appear. Click “**Confirm**”, then “Recalculation”.

Calibrator	Bottle Label Concentration	RLU	Position	Test Concentration
Cal1				171.534
Cal1				171.554
Cal2				1189.783
Cal2				1156.511

Record the concentrations.

Calibrator	Bottle Label Concentration	RLU	Position	Test Concentration
Cal1	160	6028	1	167.534
Cal1	160	6142	2	171.554
Cal2	1280	35953	3	1189.783
Cal2	1280	35002	4	1156.511

To view QC, go to Results in the main menu, and click **“Search QC”**.

Enter date (or range) and Project Name. Then click **“Search”**.

Double click on the Testing Date to populate the right window. Record values.

Click "Exit" to come back to the main menu.

Search Sample
Search Calibration
Search QC
Exit

Start Time
QC Batch

End Time
Project Name

Search
Print
Export
导出PDF
Save QC Chart

Testing Date	Project Name	QC Batch
20210607	PGP9.5	
20210901	PGP9.5	

QC Chart

Q1 AVERAGE: 567.897 SD: 607.448 CV (%): 106.96

Q2 AVERAGE: 654.957 SD: 523.387 CV (%): 79.91

Testing Date

QC Batch

TestID

RLU-1

RLU-2

RLU-3

Project Name

Reagent Batch

Concentration-1

Concentration-2

Concentration-3

Confirm
Recalculation
Cancel

Document Revision History		
Version #	Date	Description
1	May 17, 2022	Creation of Document