

BioCheck
DxDATA[™]

Assay Quick Start Guide



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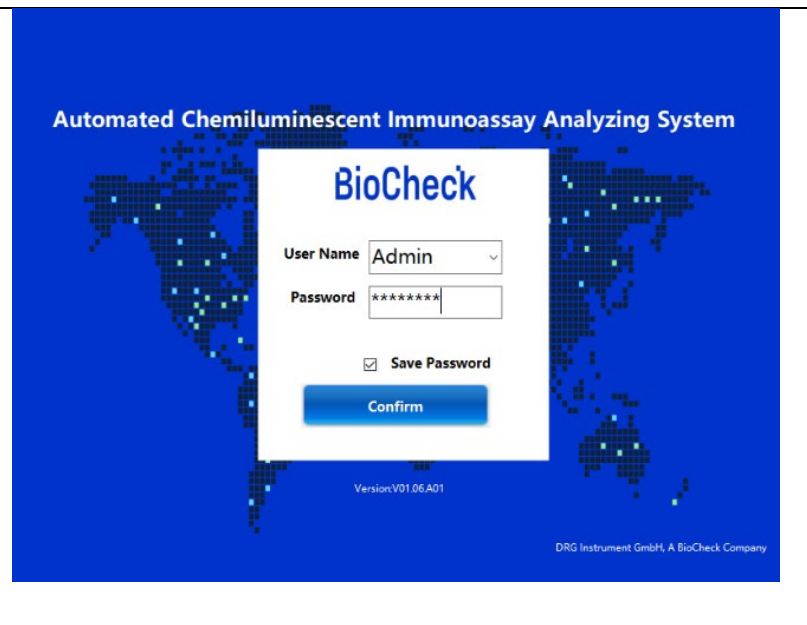
General Notes:

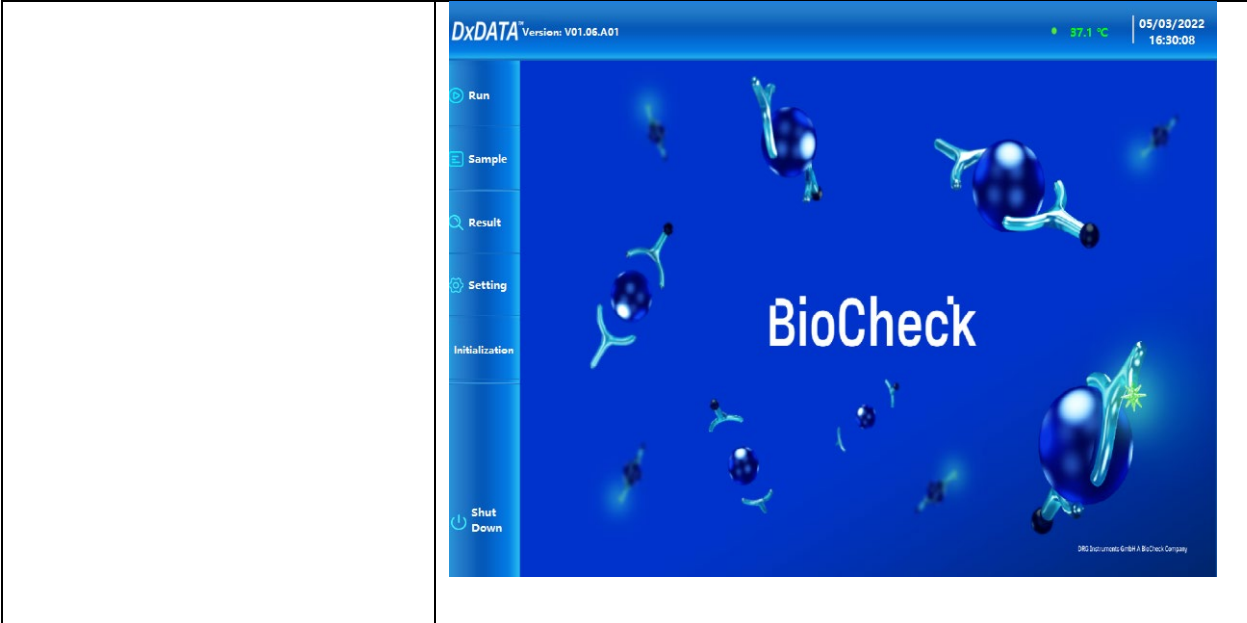
1. Procedure is intended for user: Admin
2. Use the DxDATA™ kit provided with a QR bar code on the side of the kit box.
3. Resuspend lyophilized Calibrators and QC samples as described on the kit's Instruction for Use.
4. Let kit equilibrate to room temperature for 30 min.
5. Run this procedure with the 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.
9. DxDATA™ Assay Group Compatibility:
 - a. Assays that share the same protocol can be grouped together in one run. (e.g. D-Dimer, Procalcitonin, Carbohydrate Antigen 125)
 - b. Up to 8 samples per run.

Procedure:

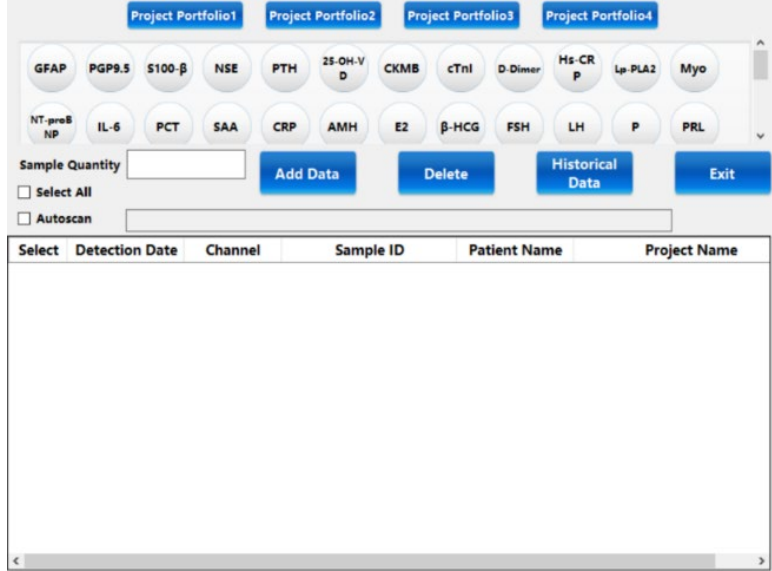
Turn on the DxDATA™ instrument (the switch is at the back of the unit). Select User Name and enter the password and Initialization.

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.





Select the sample reagents.
 Fill in the number of sample quantities, then click “Add Data”.



Double click on the sample to manually populate patient information.

The screenshot shows a software interface with a top navigation bar containing four 'Project Portfolio' buttons. Below this is a grid of assay tests including GFAP, PGP9.5, S100-β, NSE, PTH, 25-OH-Vit D, CKMB, cTnl, D-Dimer, Hs-CRP, Lp-PLA2, Myo, NT-proBNP, IL-6, PCT, SAA, CRP, AMH, E2, β-HCG, FSH, LH, P, and PRL. A 'Sample Quantity' field is set to 3. There are buttons for 'Add Data', 'Delete', 'Historical Data', and 'Exit'. Below the assay list is a table with columns: Select, Detection Date, Channel, Sample ID, Patient Name, and Project Name. The table contains six rows, with the fourth row (Sample ID 4, Project Name PGP9.5) selected.

Select	Detection Date	Channel	Sample ID	Patient Name	Project Name
<input type="checkbox"/>	20220321	1	1		GFAP
<input type="checkbox"/>	20220321	2	2		GFAP
<input type="checkbox"/>	20220321	3	3		GFAP
<input checked="" type="checkbox"/>	20220321	4	4		PGP9.5
<input type="checkbox"/>	20220321	5	5		PGP9.5
<input type="checkbox"/>	20220321	6	6		PGP9.5

Add the patient information manually or scan the patient information.

The screenshot shows a patient information form with the following fields:

- Detection Date: 20220321
- Sample ID: 1
- Patient Name: (empty)
- Gender: (dropdown)
- Age: (input) year(s) (dropdown)
- Hospitalization No.: (input)
- Hospital Bed#: (input)
- Examiner: (dropdown)
- Auditor: (dropdown)
- Serial Number: 107
- Submitting Doctor: (dropdown)
- Submission Date: 3/21/2022 3:03:38 PM
- Contact Number: (input)
- Submission: (dropdown)
- Patient Category: (dropdown)
- Clinical Diagnosis: (input)
- Received Date: Monday, March (dropdown)
- Remarks: (input)

At the bottom of the form are three buttons: 'Continue', 'Cancel', and 'Finish'.

Click “Continue” to add more than one assay or click “Finish”. Results will be printed automatically. Click “Exit”.

The screenshot shows the assay selection screen with four project portfolios at the top. Below are buttons for various assays: GFAP, PGP9.5, S100-β, NSE, PTH, 25-OH-Vit D, CKMB, cTnI, D-Dimer, Hs-CRP, Lp-PLA2, Myo, NT-proBNP, IL-6, PCT, SAA, CRP, AMH, E2, β-HCG, FSH, LH, P, and PRL. There is a 'Sample Quantity' input field with the value '3' and buttons for 'Add Data', 'Delete', 'Historical Data', and 'Exit'. There are also checkboxes for 'Select All' and 'Autoscan'.

Select	Detection Date	Channel	Sample ID	Patient Name	Project Name
<input type="checkbox"/>	20220321	1	1		GFAP
<input type="checkbox"/>	20220321	2	2		GFAP
<input type="checkbox"/>	20220321	3	3		GFAP
<input checked="" type="checkbox"/>	20220321	4	4		PGP9.5
<input type="checkbox"/>	20220321	5	5		PGP9.5
<input type="checkbox"/>	20220321	6	6		PGP9.5

On the Home screen task bar, click “Run”.

The screenshot shows the home screen of the DxDATA software. At the top, it displays 'DxDATA Version: V01.06.A01', 'Run', a temperature indicator '37.1 °C', and the date/time '05/03/2022 15:58:17'. On the left is a vertical task bar with icons for 'Run', 'Sample', 'Result', 'Setting', 'Initialization', and 'Shut Down'. The main area shows a grid of assay slots. The first six slots are labeled 'GFAP' and contain 'Calibrator' or 'QC product' samples. The last two slots are empty.

GFAP	GFAP	GFAP	GFAP	GFAP	GFAP		
Calibrator	Calibrator	Calibrator	Calibrator	QC product	QC product		
Cal1	Cal1	Cal2	Cal2	QC1	QC2		

Manage and search your test results after running the sample.

Search Sample Search Calibration Search QC Exit

Detection Date: Tuesday, June 1, -- Monday, March 21, ▾

Project Name: PGP9.5 ▾

Sample ID: Patient Name:

Search Upload to LIS Print Result Print List Export-TXT Export-PDF Export-EXL

Select All

Select	Detection Date	Submission Time	Detection Time	Channel	Concentration
<input checked="" type="checkbox"/>	20211028	10/28/2021 15:49:03	10/28/2021 16:06:03	1	199.972
<input checked="" type="checkbox"/>	20211028	10/28/2021 15:49:03	10/28/2021 16:06:03	2	164.184
<input checked="" type="checkbox"/>	20211028	10/28/2021 15:49:03	10/28/2021 16:06:03	3	180.692
<input checked="" type="checkbox"/>	20211028	10/28/2021 15:49:03	10/28/2021 16:06:03	4	189.255
<input checked="" type="checkbox"/>	20211028	10/28/2021 15:49:04	10/28/2021 16:06:04	5	189.024

Search other project portfolios to add data or look up historical data.

Project Portfolio1 Project Portfolio2 Project Portfolio3 Project Portfolio4

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

NT-proBNP IL-6 PCT SAA CRP AMH E2 β-HCG FSH LH P PRL

Sample Quantity:

Select All Add Data Delete Historical Data Exit

Autoscan

Select	Detection Date	Channel	Sample ID	Patient Name	Project Name
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Select the portfolio name and samples. Then, click “Confirm”.

Several different portfolios and samples can be selected for comparison.

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