


Assay Quick Start Guide



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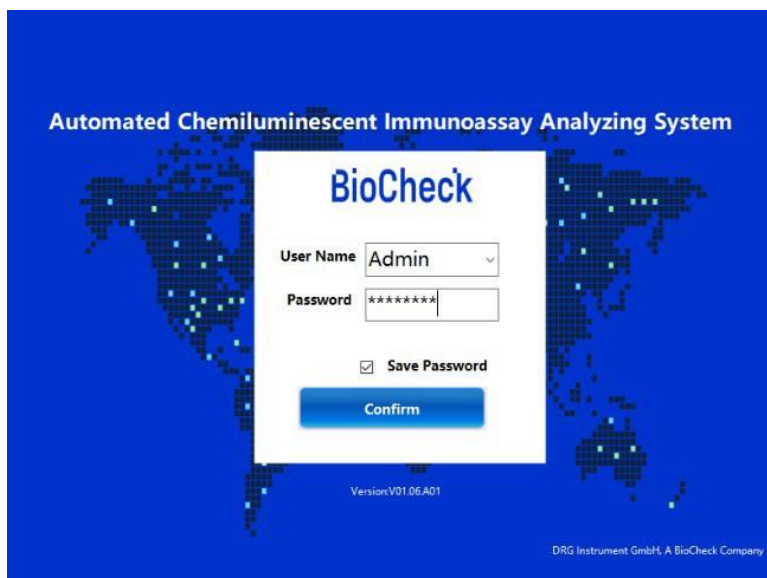
General Notes:

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. Follow the "DxDATA Assay Cartridge Inspection" to ensure the cartridges are in good condition
10. Attention: DO NOT expose the assay cartridge to light before using. 
11. 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.

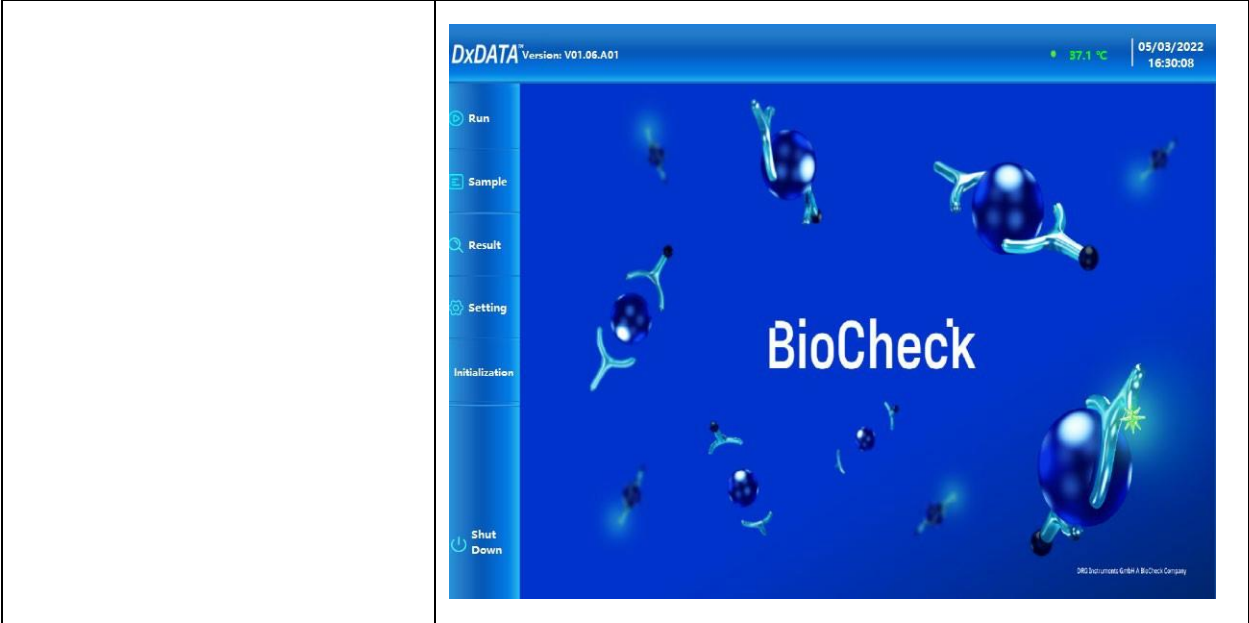
Procedure:

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

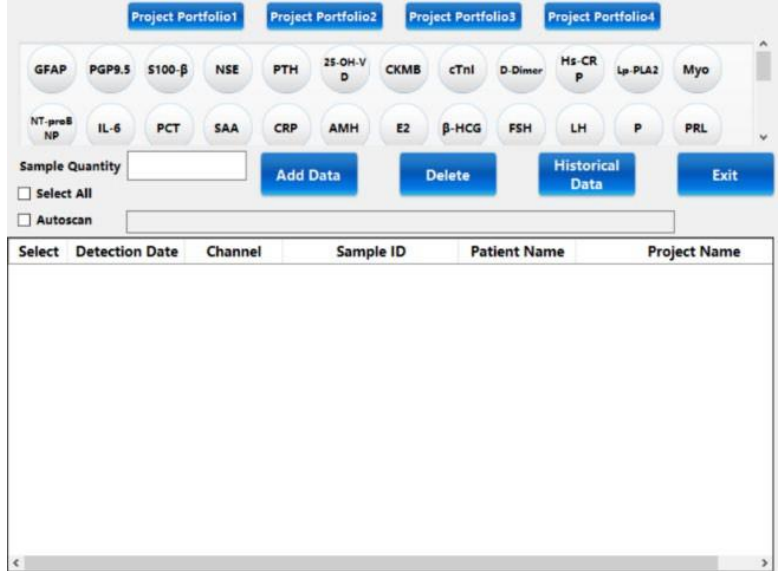
Wait for the instrument to reach a temperature of $37\pm 1^\circ\text{C}$, which is reflected at the top right corner of the screen.



BioCheck



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 the BioCheck DxDATA software interface. At the top, there are four tabs labeled 'Project Portfolio1', 'Project Portfolio2', 'Project Portfolio3', and 'Project Portfolio4'. Below the tabs is a grid of assay options 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 options is a table with columns: Select, Detection Date, Channel, Sample ID, Patient Name, and Project Name. The table contains six rows of data, with the fourth row (Sample ID 4, Project Name PGP9.5) selected. Below the table is an 'Autoscan' field.

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 the patient information form in the BioCheck DxDATA software. The form contains the following fields:

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

The screenshot shows the assay selection screen with four project portfolios. Assays include GFAP, PGP9.5, PTH, 25-OH-V D, CKMB, cTnI, D-Dimer, Hs-CRP, Myo, NT-proBNP, IL-6, PCT, SAA, CRP, AMH, E2, β-HCG, FSH, LH, P, PRL, T, and C-P. The 'Sample Quantity' is set to 3. Below the selection are buttons for 'Add Data', 'Delete', 'Historical Data', and 'Exit'. A table lists the selected assays:

Select	Detection Date	Channel	Sample ID	Patient Name	Project Name
<input checked="" type="checkbox"/>	20220616	1	1		GFAP
<input checked="" type="checkbox"/>	20220616	2	1		PGP9.5
<input checked="" type="checkbox"/>	20220616	3	2		GFAP
<input checked="" type="checkbox"/>	20220616	4	2		PGP9.5
<input checked="" type="checkbox"/>	20220616	5	3		GFAP
<input checked="" type="checkbox"/>	20220616	6	3		PGP9.5

Load your samples into cartridges in the instrument.

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

Your results will be printed out automatically after the run.

The screenshot shows the 'Run' screen of the DxDATA software. The top bar displays 'DxDATA Run' with a temperature of 37.1 °C and the date/time 06/16/2022 10:56:17. A task bar on the left includes 'Run', 'Samples', 'Results', 'Settings', 'Initialization', and 'Shut Down'. The main area shows six sample slots for GFAP and PGP9.5 assays, each with 'Samples' and 'Serum' labels and sample IDs 1, 2, and 3.

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	199.024

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 Add Data Delete Historical Data Exit

Select All

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	Name	Description
1	May 17, 2022	Marco Euler	Creation of Document
2	June 28, 2022	Marco Euler	Updated images on Page. 5
3	October 26, 2022	BC Team	Added revision status to front page; Added Cartridge Inspection reference on page 1.