DRG
A BioCheck COMPANY
Diagnostics that perform

BioCheck
DxDATA™

DxDATA General Product Presentation

Applications and Sales Training
Mon 28th – Thu 31st March 2022 Dubai, UAE

Contents

Highlights

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DxDATA™ Automated Chemiluminescence Immunoassay Analyzing System (CLIA)

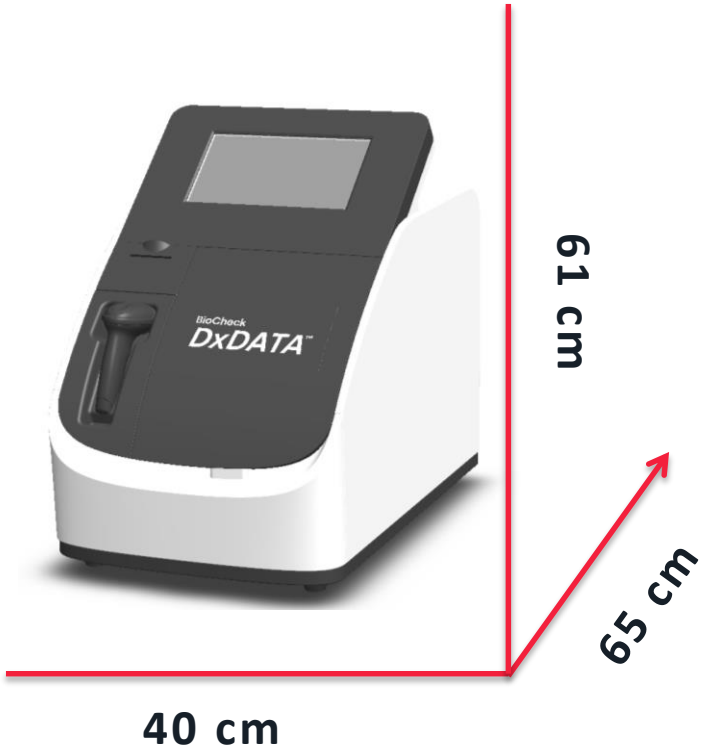
- **Small foot print - bench-top CLIA point of care analyzer**
- **Closed system** – proprietary line of assay kits
- **Cartridge based mono test** – one reagent cartridge for one test – all reagents are **ready-to-use** in a convenient reagent cartridge
- **Accurate and rapid** - get core-lab quality test results in **15 – 30 minutes**
- **Flexible –** run up to 8 cartridges simultaneously
- **No carry-over** - disposable pipette tips

Note: NO random and NO continuous access!

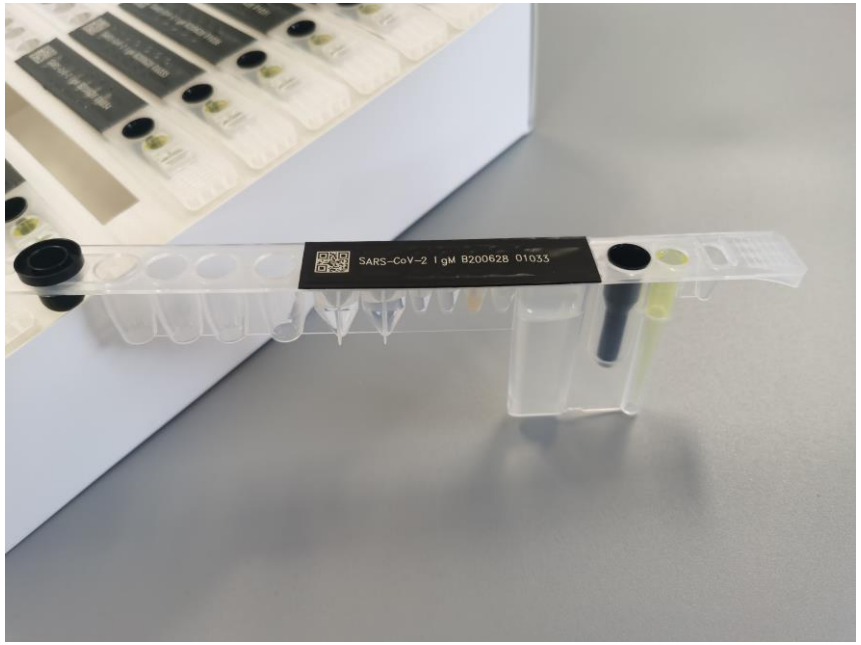
Highlights

- **No contamination** - all liquids contained in the cartridge **– no hydraulic system in the unit, user-friendly maintenance**
- Convenient for Calibration and Quality Control - All **Certified Reference Materials** needed for testing validation are included in every kit
- **On-board master curve** – no need to run a full standard curve each time – only two re-calibrators needed for re-calibration
- **LIS Interface** – Uni-directional, TCP/IP, RS-232.Bi-directional software update coming soon.
- Control history charts (L-J) are available

DxDATA™ space requirements



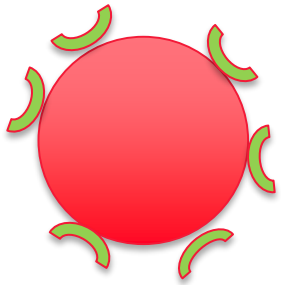
- The unit has a small footprint (40 x 61 x 65 cm)
- A thermal printer is included in the unit. External printers can be connected via USB/network.
- The depth of the bench should be min. 80 cm to ensure sufficient ventilation.

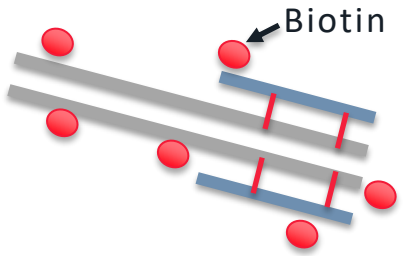


Test Menu and All-in-one Cartridges

Assay Configurations

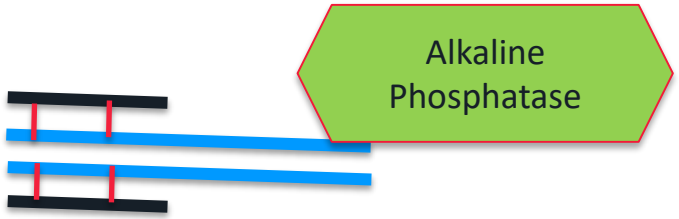
Format A

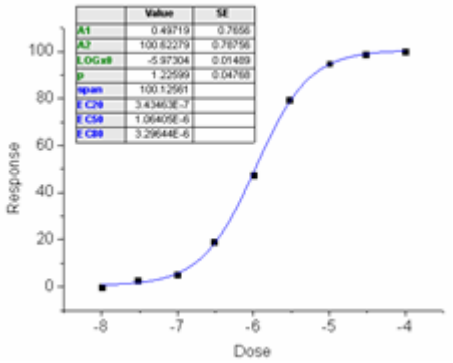




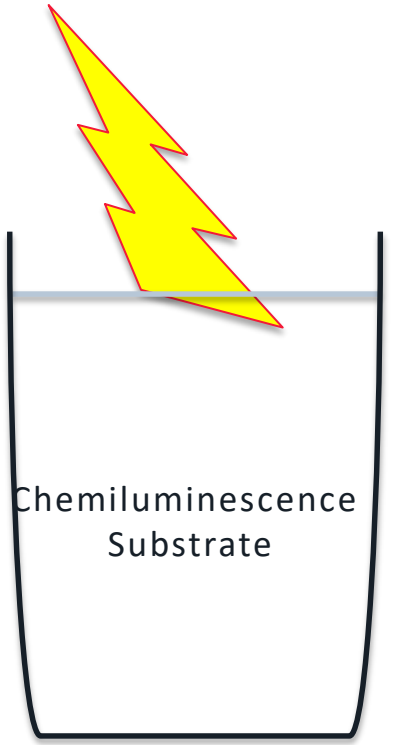
Streptavidin Magnetic beads

Protein

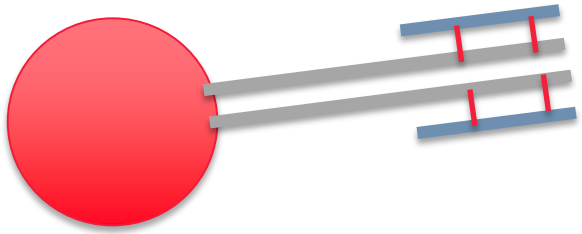




Photons (relative Light Units, RLU)



Format B



Magnetic beads coupled Ab

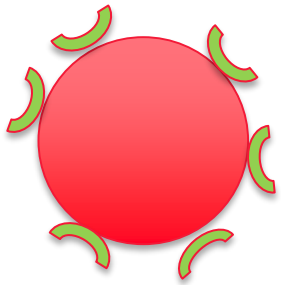
Assay characteristics

- Results output is short; 15-30min
- Better sensitivity

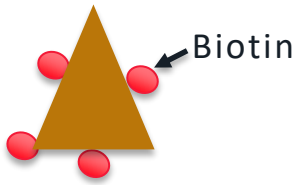
Covid-19 Assay Configurations

Format C

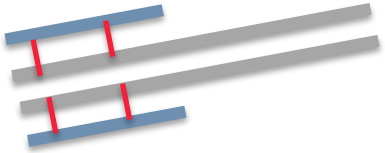
Format A



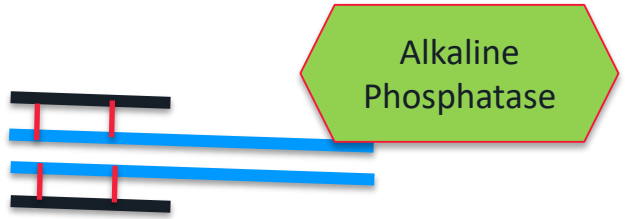
Streptavidin Magnetic beads



(S) protein or
(N) protein

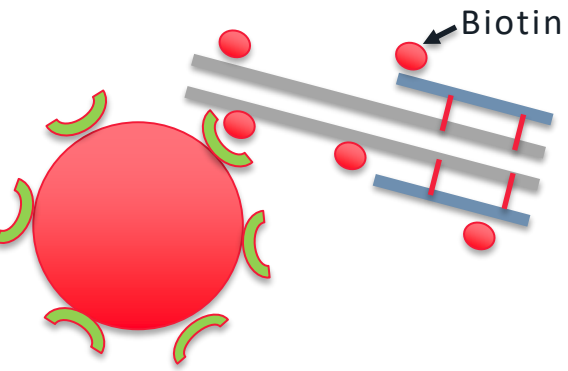


Patients anti-S
or anti-N antibody

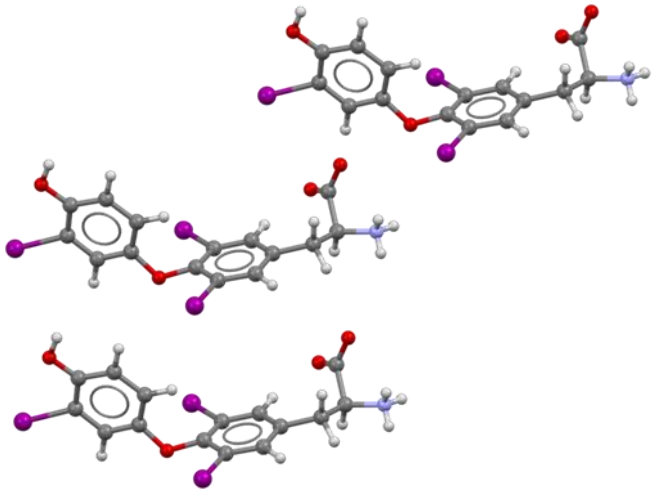


Anti-IgM
Anti-IgG

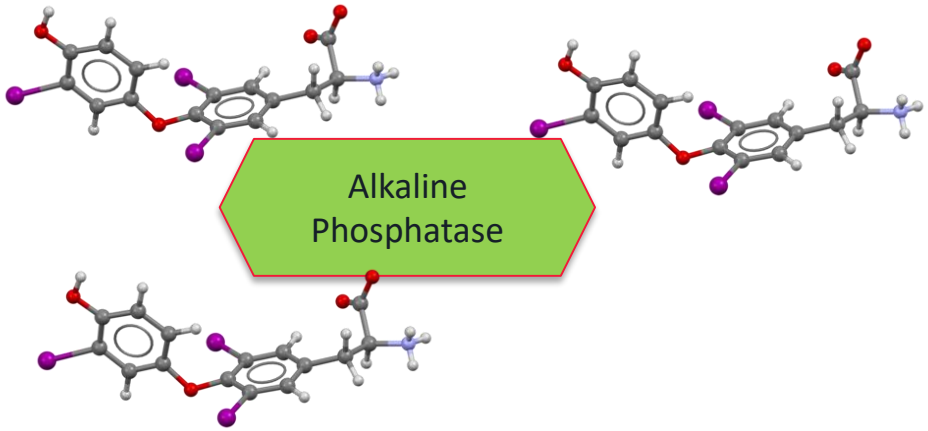
Cometition Assay: Total Triiodothyronine (TT3)

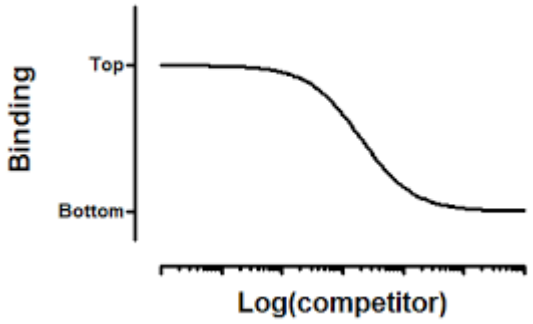


Streptavidin Magnetic beads

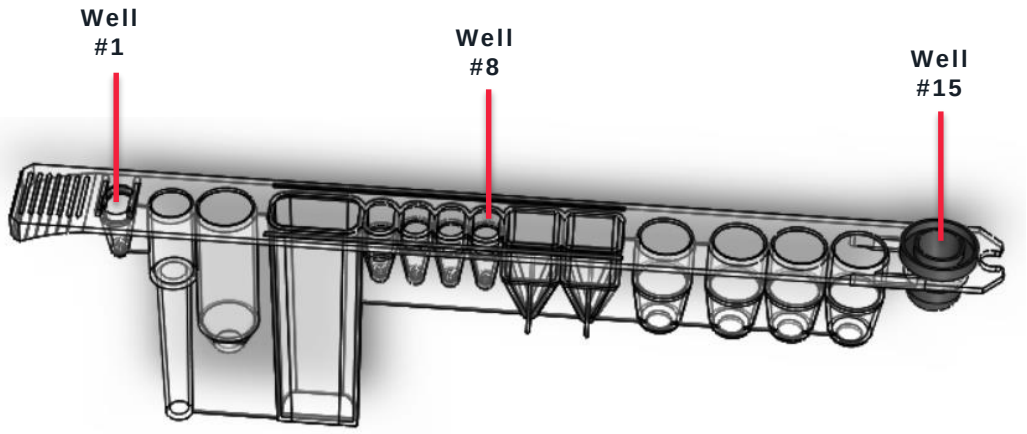


TT3 in sample





All-in-one reagent cartridge



Reagent cartridge

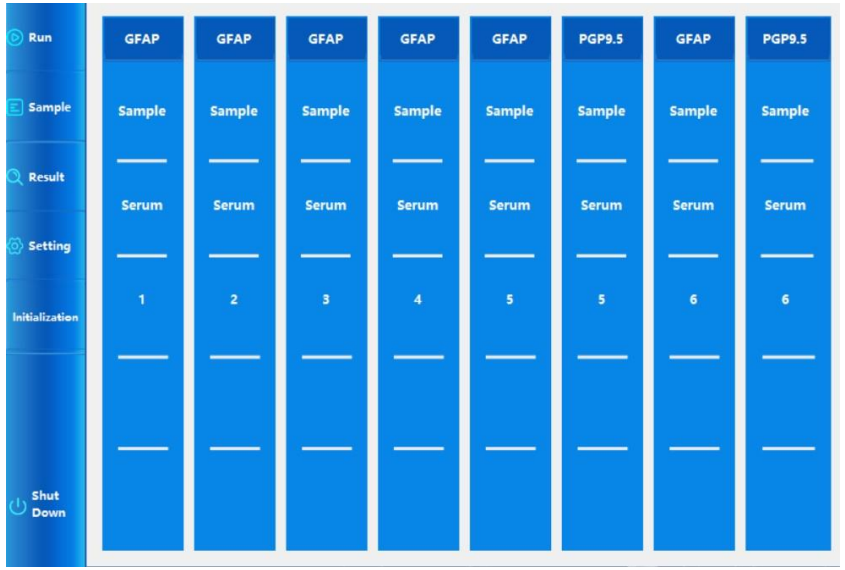
#	Test cartridge components	Quantity	Main composition
1	Sample Well	1	N/A
2	Pipette tip	1	N/A
3	Eluting sleeve	1	N/A
4	Wash buffer	2.0mL	0.95‰Tween-20, 0.17‰ Proclin300 in Tris buffer
5	Luminescent substrate	180μL	APCL-1 substrate
6	Magnetic separation reagent	60μL	PBS buffer containing streptavidin-labeled magnetic beads
7	Enzyme-labeled reagent	80μL	ALP-labeled mouse anti-human monoclonal antibody, 0.1% Proclin 300 in Tris buffer
8	Antibody reagent	80μL	Biotinylated mouse anti-human monoclonal antibody, 0.1% Proclin 300 in Tris buffer
9	Empty	N/A	Diluent Well
10	Empty	N/A	Diluent Well
11	Empty	N/A	Reaction Well
12	Empty	N/A	Wash Well
13	Empty	N/A	Wash Well
14	Empty	N/A	Wash Well
15	Reading aperture	1	N/A

All-in-one reagent cartridge

Barcode
(reagent info)

Reagent lot, item, S/N

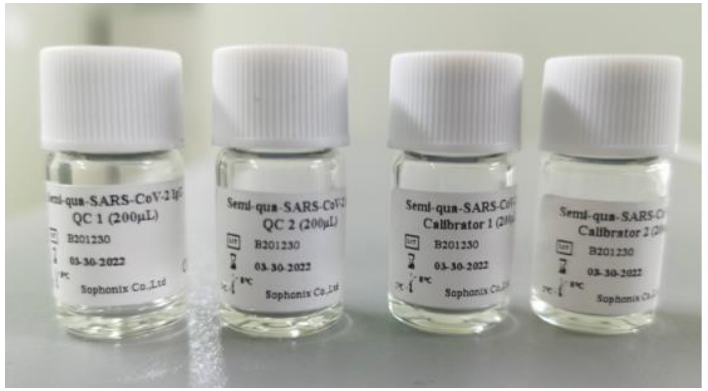
Graphic User Interface



Easy to operate
Operate with **touch screen**, or **mouse** and **keyboard**

Hierarchical structure
Main menu and respective sub-menus

Stable OS (Microsoft Windows 10 Enterprise)



Calibration and Controls

QR code system

Import the new reagent lot calibration information to the software by scanning QR code on the reagent kits

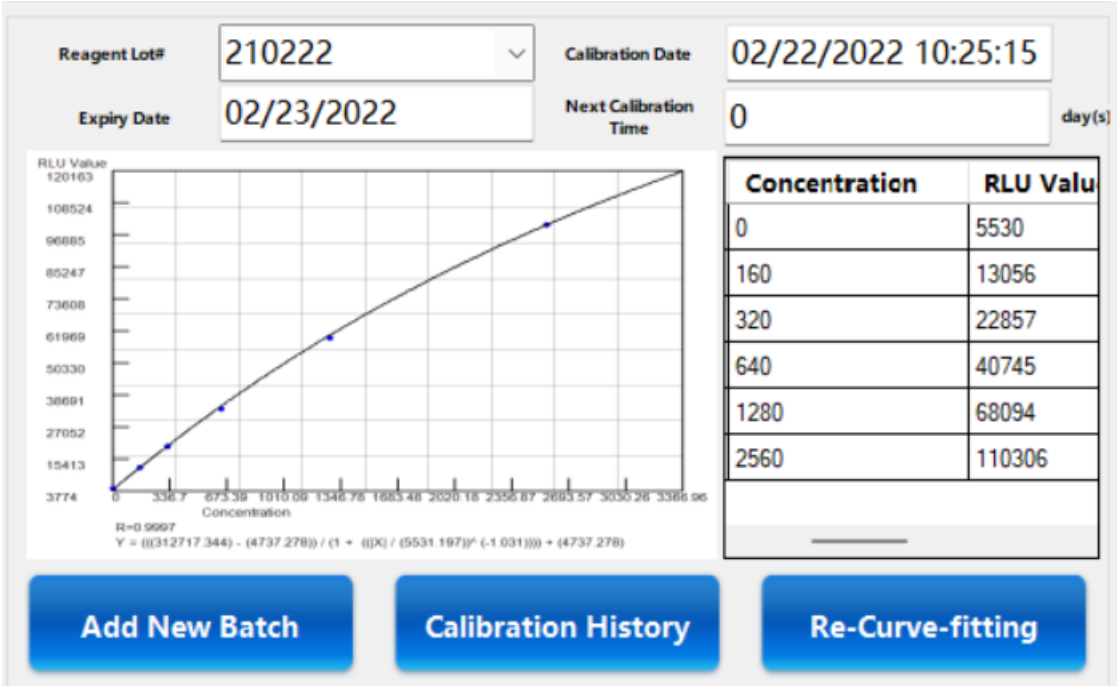
The QR code on the strip will be scanned by the internal scanner

Calibration and Controls

Multiple master curves (High, Medium, Low) on the reagent kits to adapt unit-to-unit variation.

QR code for master curves

Scan



Data for master curves

Calibration and Controls

On-board Master Curve

- No need to run a full standard curve each time (e.g., with 6 standards)
- The QR code is scanned by the user to store the master curve on the device

Easy to QC

- Only 2 cartridge is needed for QC

Long time calibration stability

- Calibration is stable for **28 days** of use of the same lot on the unit

Re-calibrators and controls delivered with each kit

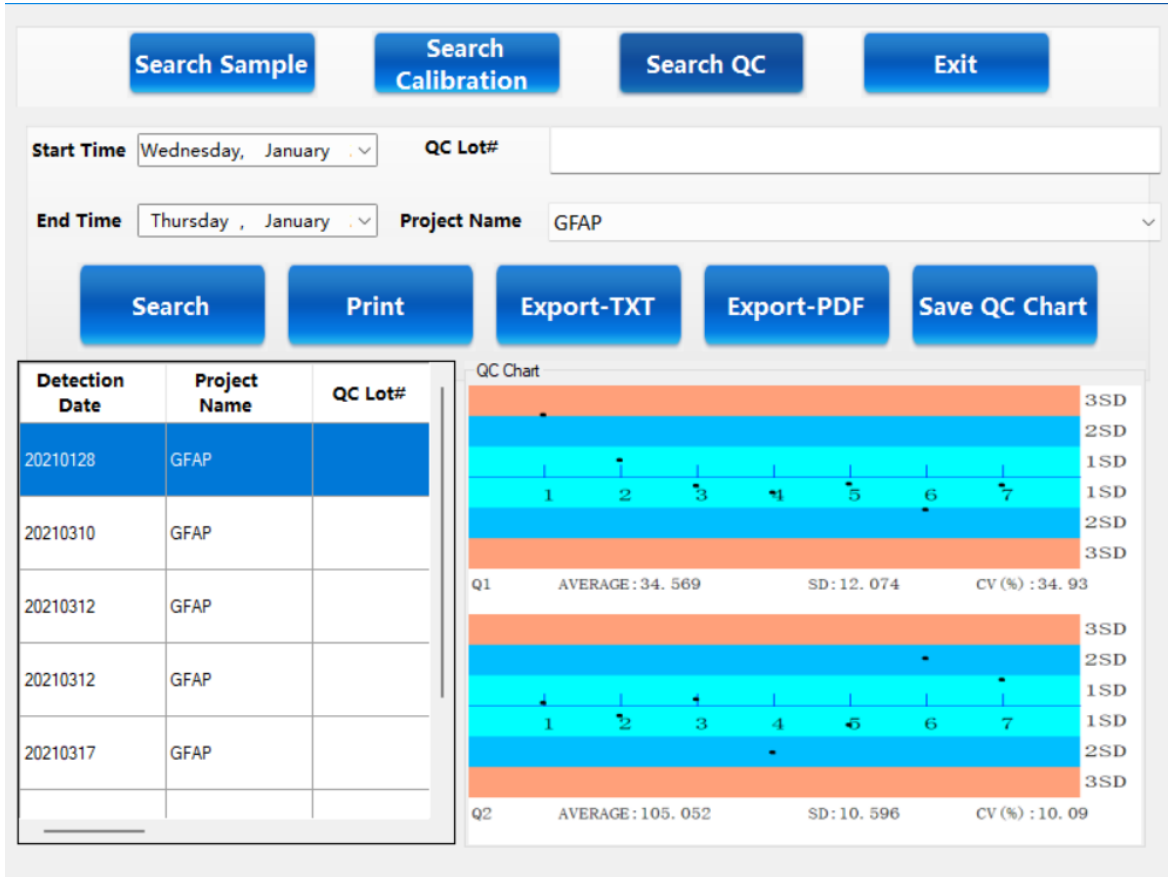
- Each new kit comes with 2 calibrators and 2 internal controls (High and Low)

Calibration, Controls and Rules

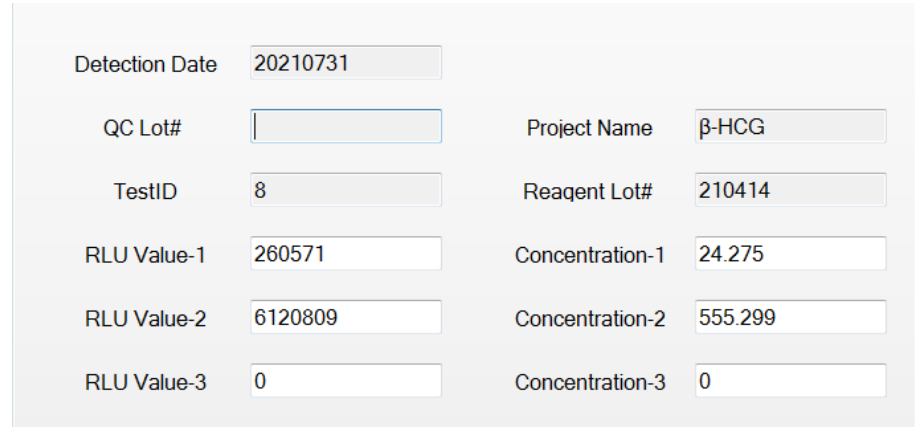
- QC can be done in 15 - 30 minutes. Easy for frequent QC or daily QC.

- The failed control results (which are outside the current dynamic range) will be stored flagged

Calibration and Control Rules



QC Record



- L-J chart
- Traceable Results
- Exportable txt, PDF and QC chart
- Printable

Assay Overview

Current Test Menu

TBI (Traumatic Brain Injury):
GFAP
PGP9.5

COVID-19:
SARS-CoV-2 IgM
SARS-CoV-2 IgG
SARS-CoV-2 N

Cardiovascular & Cerebrovascular Disease:
CKMB
cTnI
D-Dimer
Myo
NT-proBNP

Inflammation:
hs-CRP
CRP
PCT
SAA
IL-6

Cytokine Storm:
IL-6
IFN-γ

Gonadal Hormone:
AMH
E2*
β-HCG
FSH
LH*
Progesterone*
PRL
Testosterone

Diabetes:
HbA1c
C-Peptide*
Insulin

Thyroid Function:
TSH
T3*
fT3
T4*
fT4
Anti-TG
Anti-TPO

Tumor Marker:
AFP
CEA
CA125
CA19-9
CA15-3

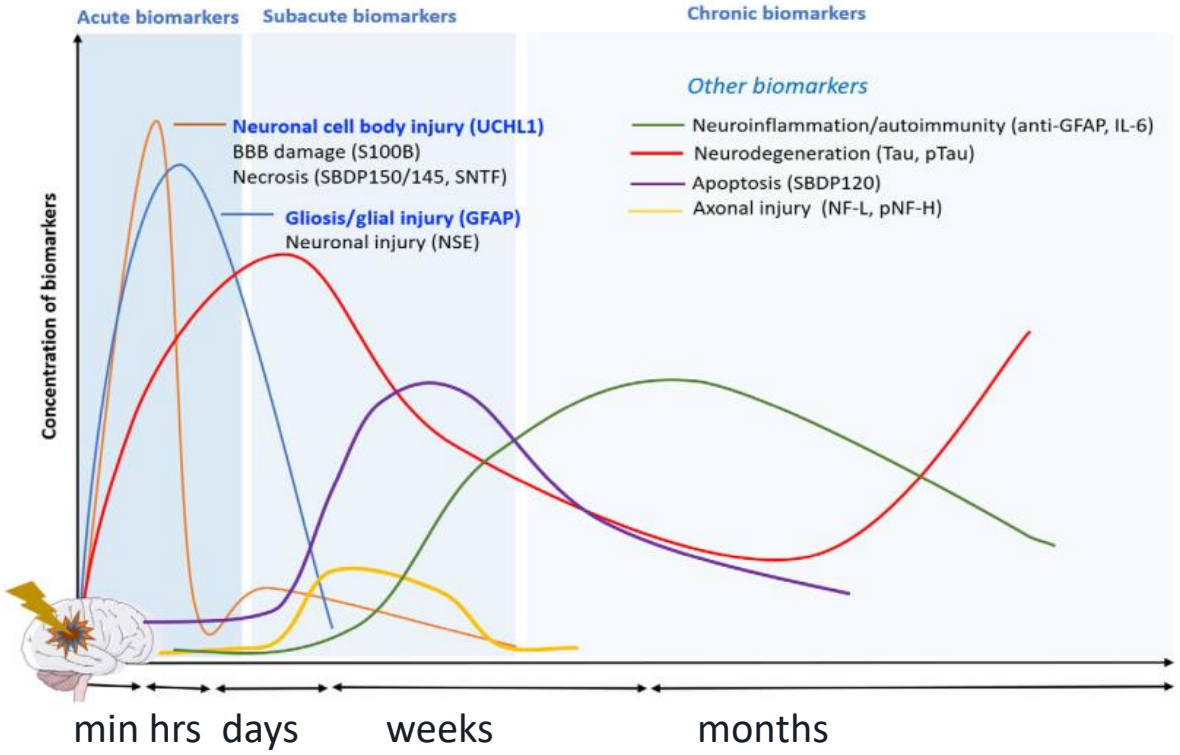
Bone Metabolism:
PTH
25-OH-Vitamin D

Maternal & Child Care:
25-OH-Vitamin D
Folic Acid
Vitamin B12
Ferritin

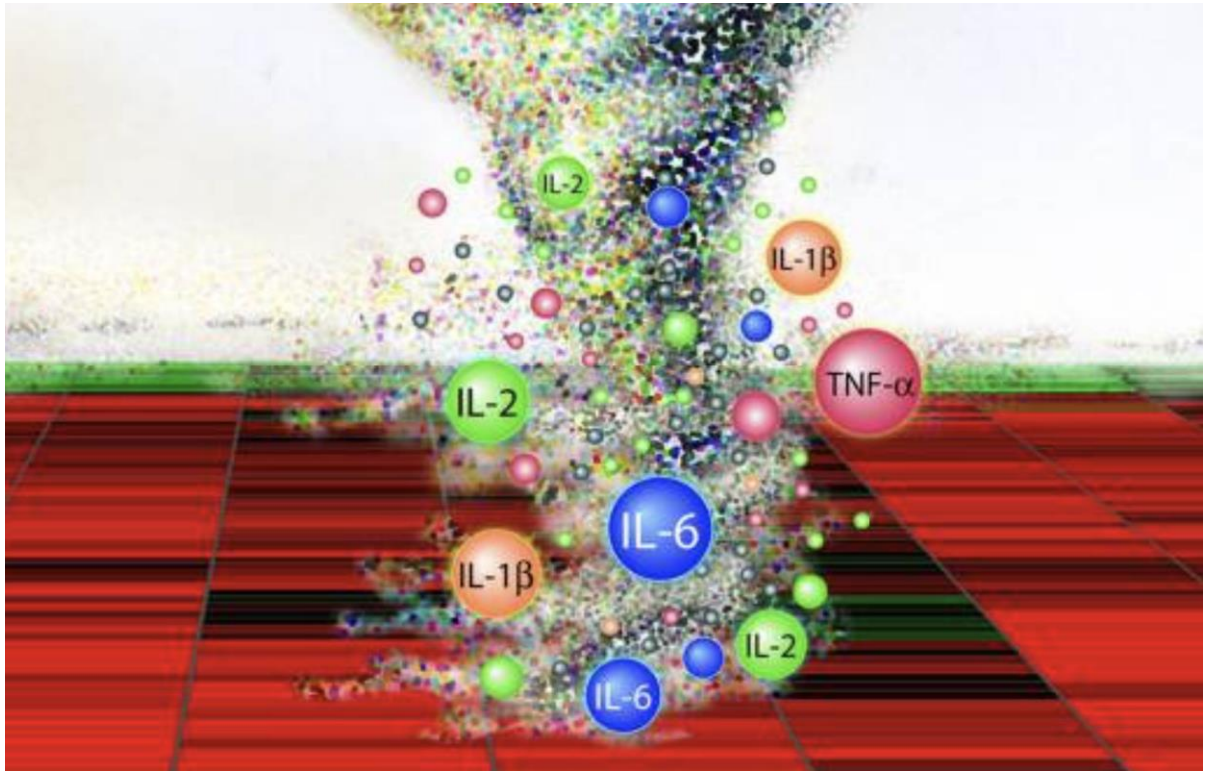
*510(K) exempt. All other test menu items are CE IVD

Traumatic Brain Injury Assays

- **UCH-L1** and **GFAP** assays available:
  The best TBI markers in the acute phase.
- Use venous blood samples:
  Convenient
- No CT scan is needed:
  Safe, Rapid, and Low Cost.
- CE Approved.



Cytokines Storm Assays



Ref: Tisoncik JR, Korth MJ, Simmons CP, Farrar J, Martin TR, Katze MG. Into the eye of the cytokine storm. *Microbiol Mol Biol Rev*. 2012;76(1):16-32. doi:10.1128/MMBR.05015-11

Assay	Availability
IL-6	CE
IFN-γ	CE

More Cytokines Storm Assays coming soon!

Assay	Availability
IL-2	Coming Soon
IL-8	Coming Soon
IL-10	Coming Soon
IL-18	Coming Soon
TNF-α	Coming Soon
MCP-1	Coming Soon

Gonadal Hormone Assays

Project Name	Function	Clinical Application	Best Detection Time	CE
FSH	Promote follicle development	↑ Ovarian insufficiency ↓ During estrogen and progesterone treatment	3-5 days after menstruation	√
LH	Promote ovulation	↑ Ovarian insufficiency, premature ovarian failure, etc ↓ Sheehan syndrome	3-5 days after menstruation	√
PRL	Promote breast hyperplasia	↑ Hyper prolactinosis, Premature ovarian failure etc ↓ Pituitary function decline	any day	√
E2	Promote transition of the endometrium into the proliferative phase	↓ Reduced ovarian function, premature failure, Sheehan syndrome, etc	3-5 days after menstruation, Pre-ovulation	√
Progesterone	Promote the transition of the endometrium into the secretory phase	↓ Reduced ovarian function, premature failure, Threatened abortion, etc	Luteal phase	√
Testosterone	Promote the development of clitoris, labia and testicles	↑ Polycystic Ovary Syndrome	any day	√
AMH	Ovarian function	↑ Polycystic Ovary Syndrome ↓ Premature ovarian failure	any day	√
β-HCG	Detection of human chorionic gonadotropin			√

AMH Assays

Anti-Müllerian hormone (AMH), also known as Müllerian-inhibiting hormone (MIH), is a glycoprotein hormone whose key roles are in growth differentiation and folliculogenesis.

AMH can quickly and reliably evaluate: 1)Assessing ovarian status, including ovarian reserve and ovarian responsiveness, as part of an evaluation for infertility and assisted reproduction protocol, 2)Assessment of menopausal status, including premature ovarian failure, 3)Evaluation of infants with ambiguous genitalia and other intersex conditions, 4) Evaluating testicular function in infants and children, and 5)Monitoring patients with AMH secreting ovarian granulosa cell tumors.

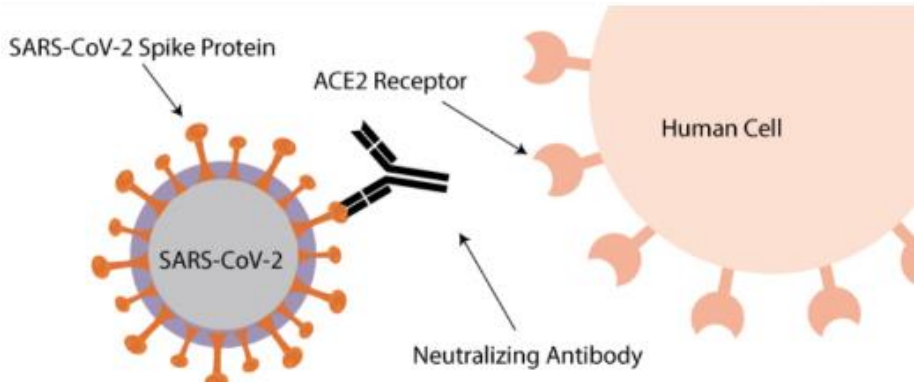
Unlike FSH and E2, AMH can quickly and reliably evaluate ovarian reserve function predicting fertility.

	AMH	FSH and E2
Time of Detection	Any time of menstrual cycle	The 3rd day of menstrual cycle
Affected by hormonal contraceptives	No	Yes
Affected by menstrual cycle	No	Yes
Sensitivity	High	Low

Covid-19 Assay Series

Combined detection:

1. Antigen N protein
2. Neutralizing Antibody
3. IgG
4. IgM



More Assays Coming Soon

HSV-I IgG
HSV-I IgM
HSV-II IgG
HSV-II IgM
ANA
dsDNA IgG
Anti-CCP
RF IgG
MPO IgG
Proteinase 3 IgG
GBM IgG
T-IgE
CA50
Cyfra21-1
CA242
CA72-4
HE4

Take-home messages

Take-Home Messages

- The DxDATA™ is a fully automated chemiluminescence immunoassay (CLIA) analyzing system using magnetic-particle technology.
- Operation of the system is simple and intuitive. The single cartridge-based reagents technology is stable and requires no onboard refrigeration, no preparation, and no pre-mixing. The reagent system saves time and cost by eliminating errors and waste.
- All components and reagents for routine analysis are contained in a single cartridge. The reagents are stable and can be directly loaded. The consistent use of barcoded reagents greatly reduces the need for time-consuming manual entries in the daily routine.
- Additional automation can be achieved by connecting to the laboratory LIMS (host) information system (Coming soon).
- All reference materials needed for testing and validation are delivered in every kit.

Questions?

THANK YOU!