Make sense of your research!

Explore The Biomarker Potential Of BDNF…

Our recent BDNF BioSpeak e-Bulletins have highlighted the need for validated ELISA assays that distinguish between the three BDNF isoforms, as well as the importance of correct sample preparation for blood specimens.

The Biosensis Mature BDNF Rapid™ ELISA (Catalog No: BEK-2211-2P) provides a solution for quantifying BDNF which is accurate and reproducible, as demonstrated by independent published data (Polacchini et al., 2015).

Today's newsletter focuses on the **NEW CE-Marked BDNF Rapid™ ELISA Kit** - a collaboration of Biosensis and the immunoassay manufacturer Calbiotech Inc. This new CE-Marked kit (Catalog No: BEK-2211-1P-CE) qualifies for the CE Mark and is approved for sale as an In-vitro Diagnostic Medical Device (IVD) in Europe.

WHY IS THERE A NEED FOR A CE MARKED KIT?

Changes in BDNF blood levels have been associated with a variety of disorders and thus been proposed to be useful to predict, diagnose and monitor the state of various medical conditions and their treatment. Table 1 represents a non-exhaustive summary of recent publications that highlight the biomarker potential of BDNF.

Table 1: Recently Published Evidence for BDNF as a Biomarker Candidate.

Medical Condition	Blood Levels of BDNF	Publication
Acute major depressive disorder (MDD), bipolar disorder (BD)	Decreased serum and plasma BDNF levels were observed in affected patients. Treatment with anti-depressive medication significantly increased serum BDNF levels in MDD in responders and remitters in comparison to non-responders.	Polyakova et al., 2015
Post Traumatic Stress Disorder (PTSD)	Patients diagnosed with full PTSD showed lower BDNF plasma levels than patients with partial PTSD and controls	Stratta et al., 2016
Cognitive impairment in Parkinson's Disease (PD)	Significantly decreased serum BDNF levels in PD patients than in healthy controls	Wang et al., 2016
Cognitive impairment in PD (PD)	Significant correlation of serum BDNF levels with cognitive function in PD. BDNF concentrations in serum were significantly lower in PD patients as compared to healthy controls.	Khalil et al., 2016
Major depression	Electroconvulsive Therapy (ECT) caused increase of serum BDNF in patients with major depression. Increase in blood BDNF levels was associated with seizure quality during ECT.	Bumb et al., 2015
Traumatic brain injury (TBI)	Clinical severity of TBI and decreased 6-month functional outcome scores were associated with decreased BDNF serum levels.	Korley et al., 2016
Traumatic brain injury (TBI)	The concentration of serum BDNF was decreased in TBI patients and correlated with injury severity.	Failla et al., 2016
Traumatic brain injury (TBI)	TBI patients that did not survive had significantly lowered BDNF plasma levels at 24 h after hospital admission as opposed to patients that survived TBI.	Di Battista et al., 2015
Gulf War Illness (GWI)	BDNF levels in blood were significantly elevated in patients suffering from GWI, among other blood proteins.	Johnson et al., 2016

While there is research-based evidence for the biomarker potential of BDNF, clinical trials are yet to be conducted, but require assays approved by regulatory bodies. Biosensis has responded to this need with the **NEW CE-Marked BDNF Rapid™ ELISA Kit.**

THE NEW CE-MARKED BDNF ELISA KIT

Biosensis has teamed up with the immunoassay manufacturer Calbiotech Inc. to transform the Mature BDNF *Rapid*™ ELISA Kit into a CE-Marked kit for diagnostic applications in Europe. This new kit (which will be released in November 2016) combines speed, accuracy, sensitivity and reproducibility with **regulatory approval!** This kit is validated for human serum and citrate-treated plasma samples.

Figure 1: The new CE-Marked BDNF ELISA Kit **- Fast and simple assay procedure!** Coloured kit reagents allow monitoring of assay steps.
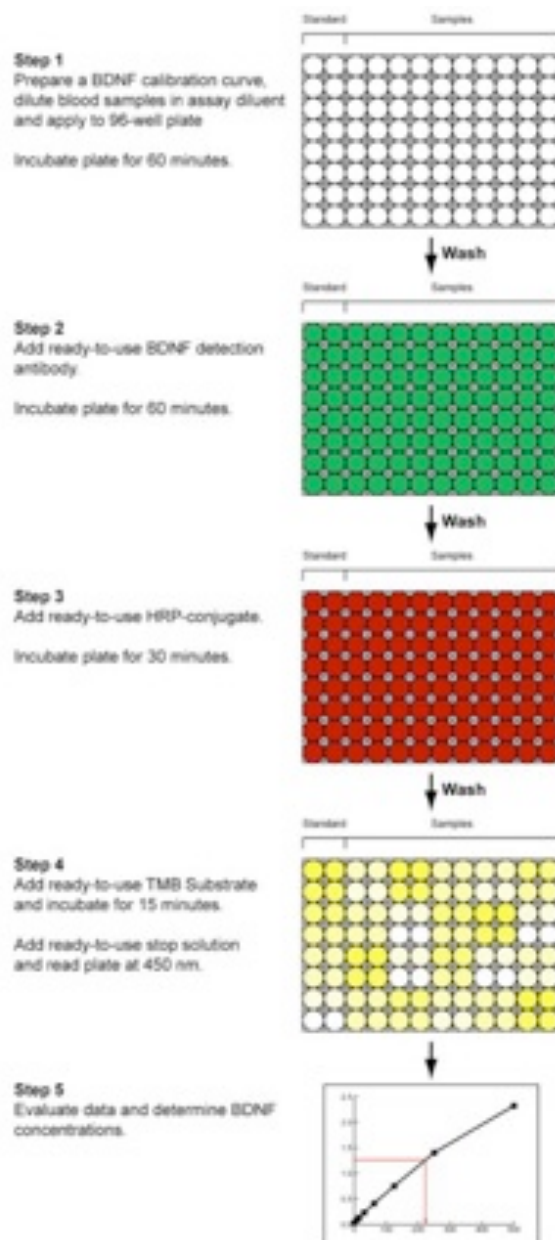
Table 2: Performance Characteristics of the New CE-Marked BDNF ELISA Kit. Data demonstrates excellent reproducibility and highest assay sensitivity.

Serum	No. of Replicates	Intra-Assay			Inter-Assay		
		Mean BDNF (pg/mL)	Standard Deviation	CV (%)	Mean BDNF (pg/mL)	Standard Deviation	CV (%)
1	16	8.6	0.71	8.26	8.7	0.73	8.4
2	16	60.2	3.00	4.98	59.7	2.98	5.0
3	16	215.9	8.44	3.91	217.1	10.52	4.8

	No. of Replicates	Sensitivity*					
		Mean BDNF (pg/mL)	Standard Deviation	Mean + 2SD (pg/mL)			
Zero Standard	20	1.11	0.745	2.6			

*Sensitivity was determined by calculating the mean + 2SD of the standard zero point tested 20 times in the same run

Table 3: Correlation with a Reference ELISA Kit. Data demonstrates excellent correlation ensuring accurate BDNF quantification.

Correlation	Slope	Intercept
0.99	0.93	11.2

Enquire now at biospeak@biosensis.com.

Sincerely,

The Biosensis Team