Diagnostic Kit for S100β protein（Immunochromatographic assay）

User manual

【Product Name】

Diagnostic Kit for S100β protein（Immunochromatographic assay）

【Packing Specification】

25 Tests/kit

【Intended Use】

The kit is used for quantitative determination of S100β in human whole blood, serum or plasma. Clinically, by detecting the expression of S100β protein, we can judge the degree of brain injury and evaluate the prognosis of patients.

【Test principle】

The Diagnostic Kit for S100β is a one-step chromatographic sandwich immunoassay designed for the quantitative measurement of S100β. The S100β antigen in the sample was first bound with the conjugated compound of fluorescent labeled S100β monoclonal antibody, then moved and combined with another S100β monoclonal antibody fixed on the nitrocellulose membrane, and the double antibody sandwich complex was formed at the detection line of the cellulose nitrate membrane. The quantitative detection results were obtained by NIR-1000 dry fluoroimmunoassay analyser.

【Components】

Name	Quantity	Component
Test cards	25	The product consists of fluorescent pat (coated with fluorescently-labeled S100β monoclonal antibody), nitrocellulose membrane (coated with S100β monoclonal antibody), absorbent paper and PVC soleplate.
Sample diluent	25 (200μL/ tube)	Tris-HCl buffer
ID card	1	With specific stand curve file

The components in different batches of kits cannot be used interchangeably.

【Storage Conditions and Validity】

The kit should be stored at 4℃~30℃, out of direct sunlight. It is valid for 18 months. The test card should be used within 15 minutes after unsealing under the environment of 15℃~30℃ and 20% ~ 90% relative humidity. The sample buffer is disposable and used immediately after opening the cap.
The production date, batch number and expiration date are shown in the outer package of the product.

【Applicable Instrument】

NIR-1000 dry fluoroimmunoassay analyser produced by WWHS Biotech. Inc.

【Sample Requirements】

1. Plasma, serum and whole blood can be used as samples. The whole blood should be collected in a tube containing citrate as the anticoagulant. If the serum procedure is used, collect blood in a tube without anticoagulant and allow clotting. Hemolyzed samples should not be used.
2. Venous blood was collected according to routine laboratory methods to avoid hemolysis.
3. It is highly recommended to use fresh samples instead of keeping the samples at room temperature for a long time. After samples were collected, the detection should be completed within 4 hours at room temperature (15℃~30℃). The whole blood sample can be stored at 2℃~8℃ for 48 hours. Plasma and serum samples can be stored at 2℃~ 8℃ for 7 days, -20℃for 30 days.
4. Before testing, the sample should return to room temperature (15℃~30℃). The frozen samples should be completely thawed, rewarming and mixed evenly before use. Repeated freeze-thaw cycles should be avoided.

【Test procedure】

1. Before the test, please read the instructions completely. If the test card and sample are stored in cold storage, they should be balanced at room temperature (15-30)℃ for not less than 30min before use.
2. Start NIR-1000 dry fluoroimmunoassay analyser and correctly select the corresponding sample type on the instrument.
3. Take out the ID card, make sure that the batch number of the ID card is consistent with that of the test card, and insert the ID card into the ID card port of the instrument.
4. Take out the test card from the aluminum foil bag and use it within 15 minutes.
5. Place the test card on a clean horizontal table and mark it horizontally.
6. Mix 100 μL of urine sample with 200μL of sample diluent. Apply 100 μL of diluted samples to the well of the test card.
7. Insert the test card into NIR-1000 dry fluoroimmunoassay analyser and click the “instant test” button to read the results at 10 minutes after addition of samples.

【Reference interval】

S100β normal reference value is less than 0.20ng/mL. It is strongly recommended that each laboratory should determine its own normal and abnormal values.

【Interpretation of test results】

1. The kit can be used for auxiliary test only. If test result is abnormal, retest timely and judge combined with clinical symptoms.
2. For samples whose S100β concentration is lower than 0.05ng/mL and higher than 10.00ng/mL,

test result is “＜0.05ng/mL” and “＞10.00ng/mL” respectively.

【Limitation of test method】

1. This kit is only used to detect human serum/plasma/whole blood samples
2. Due to the limitations of immunoassay methods of antigen and antibody reaction, the results cannot be used as the only basis for clinical diagnosis, but should be evaluated with all the existing clinical and experimental data.
3. The triglyceride content in the sample does not exceed 15mg/mL, the hemoglobin content does not exceed 5mg/mL, the bilirubin content does not exceed 0.5mg/mL, the content of neuron-specific enolase does not exceed 200ng/mL, the content of glial fibrillary acidic protein does not exceed 5ng/mL, the content of IL-6 does not exceed 200pg/mL, the content of tumor necrosis factor does not exceed 200pg/mL, the content of albumin does not exceed 60mg/mL, the content of fibroblast growth factor does not exceed 20ng/mL, the cholesterol does not exceed 10mg/mL, the content of total protein does not exceed 120mg/mL, and the relative deviation of the measurement results does not exceed ±15.0%.
4. When S100β concentration of samples reaches 40.00ng/mL, there is no hook effect.
5. HAMA effect was not produced when the concentration of human anti rat in the sample was less than 50ng/ml.
6. When RF concentration of samples is less than 2000IU/mL, relative deviation of test result is limited to ±15.0%.
7. For samples exceeding the linearity range, test cannot be conducted after dilution.

【Performance】

1. Limits of detection

No higher than 0.05ng/mL

2. Accuracy

The relative deviation to the target value is limited to ±15.0%.

3. Precision

The within and between assay coefficient of variations are within 15%.

4. Linear range

Within the linear range [0.05,10.00]ng/mL, the linear correlation coefficient R≥0.990.

【Note】

1. The kit can be used for in vitro diagnosis only.
2. Test card and buffer solution are single-use and they cannot be reused.
3. Please check the integrity and validity of the kit package before use, and then open the package. When it is stored at low temperature, it should be restored to room temperature (15℃ ～30℃) before opening the package for use. The reagents with damaged inner package and beyond the validity period cannot be used.
4. Take the test card out of the aluminum foil bag and carry out experiment in 15min. Do not place it in the air for a long time to avoid dampness.
5. It is required to strictly comply with the requirements for sample collection and storage. If the sample is turbid, please centrifuge and precipitate it before use.
6. The kit used should be disposed of as latent infective material, and all samples, reagents and latent contaminants should be disinfected and disposed of according to relevant local regulations.

【Interpretation of Signs】

	Storage temperature		Single-use
	Keep in dark place	IVD	IVD Reagents
	Dampproof		Refer to the specification

【Reference】

[1] TangFei, AnLiyun, JiaZhiran. Dynamic observation of serum S100B protein expression in patients with acute cerebral infarction and its relation with the degree of nervous function defect[J]. Laboratory Medicine and Clinic2014,11（16）：2216-2217.

[2] Foerch C, Otto B, Singer OC, et al. Serum S100B predicts a malignant course of infarction in patients with acute middle cerebral artery occlusion[J].Stroke,2004,35:2160-2164

【Essential information】

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