Nephstar
ASO Kit
For determination of Anti-Streptolysin O

Code	DK021

1. Intended Use
This product is used on Nephstar protein analysis system for quantitative determination of Anti-Streptolysin O (ASO) in human serum as an aid in determination of levels of streptococcal infection.

2. Summary
The group A β-hemolytic streptococci produces various toxins that can act as antigens, and one of these exotoxins is streptolysin O. The affected patient produces specific antibodies against streptolysin O. The concentration of ASO in the patient's serum will enable to establish the degree of infection due to β-hemolytic streptococci. Measuring the ASO antibodies is useful for the diagnosis of rheumatoid fever, acute glomerulonephritis and streptococcal infections.

3. Test Principle
Immunonephelometry is applied. This method measures the light scattered by the insoluble immune complexes formed between ASO in the sample and its specific ligands, and the amount of light scattered is directly proportional to the concentration of ASO when the ligand is in excess. The ASO concentration is automatically calculated by reference to a calibration curve stored in the instrument.

4. Kit Components

Nephstar ASO Kit				
Cat No.	**Package**	**Component Code**	**Component Name**	**Component Volume/Quantity**
NS21050	50T	DA021	ASO Antiserum	2 × 0.9 mL
		DB021	ASO Reaction Buffer	1 × 25.0 mL
		DC021	ASO Magnetic Card	1
		DM021	ASO Control	1 × 0.3 mL
			Manual	1

5. Materials Required But Not Supplied
5.1 NEPHSTAR Protein analysis system (NS100)
5.2 NEPHSTAR Accessory pack (NSAS200), the pack contains cuvettes, stirrers, and the diluent
5.3 Pipette 5 - 50 µL, 100 - 1000 µL
5.4 Equipment for collection of samples

6. Storage and Stability
Store the ASO Antiserum and the ASO Control at 2 - 8°C. The unopened antiserum and control are stable until the expiry date labeled on the vials. Once opened, they are stable for 30 days. Store the ASO Reaction Buffer at 2 - 30°C. The unopened buffer is stable until the expiry date labeled on the vial. Once opened, it is stable for 30 days.

7. Sample Collection and Preparation
Fresh serum samples can be used. Samples can be kept at 2 to 8°C for up to 72 hours. Samples can be kept longer at -20°C or below. Do not freeze and thaw samples more than once. Testing of the following types of samples may result in misleading values:
7.1 Highly lipemic, turbid and haemolyzed samples are not suitable for nephelometric assays and should not be used unless centrifuged or prepared in advance. If the background is too turbid to be cleared, please consider alternative measuring methods.
7.2 Testing of samples containing rheumatoid factors, paraproteins or circulating immunocomplexes may result in misleading values due to non-specific scattering light generated by these articles.

8. Test Procedure
Summary: Reagents added to the cuvette

Reagents	Volume
Diluted sample (1/11)	20 µL
ASO Reaction Buffer	400 µL
ASO Antiserum	30 µL

Note: All reagents should be equilibrated to room temperature before use.

8.1 Switch NEPHSTAR on, choose Manual mode.
8.2 Enter chemistry number. Enter the chemistry number of ASO Kit (ASO = 21). If ASO assay has never been performed on the instrument before, please swipe card when “please swipe card” is displayed.
8.3 The assay name and the lot of reagent will be displayed. Press ENTER if the lot number is identical to that printed on the card or the kit label, otherwise swipe card to update the curve data stored in Nephstar.
8.4 Enter sample ID. Press number keys to enter the sample ID; or press ENTER to accept the currently displayed sample ID.
8.5 Enter sample dilution: 11. Accept the default sample dilution factor by pressing ENTER, otherwise press number keys to alter the dilution factor.
8.6 Dilute samples or controls using the diluent supplied with NEPHSTAR accessory pack (Cat No.: NSAS200). The default dilution factor for ASO assay is 11 (e.g. 400 µL of diluent + 40 µL of sample or control).
8.7 Prepare one cuvette for each sample to be assayed. Place a stirring bar to the cuvette using forceps, then add 20 µL of diluted sample to the bottom of the cuvette.
8.8 Place the cuvette into the chamber and press it down slightly until it reaches the bottom of the chamber. The cuvette will be detected automatically.
8.9 Add 400 µL of ASO Reaction Buffer and then 30 µL of ASO Antiserum into the cuvette with common pipettes. Press "NUM LOCK" button. The reaction will be started immediately. The assay begins after blanking and the

result will be printed out automatically at the end of the assay.

8.10 On completion of the assay, remove the cuvette, press ENTER to perform the next assay. Sample ID will increase sequentially. To change the sample ID, press BACK twice and tap in the right number.

8.11 On completion of all assays of the same chemistry press ESC and return to step 8.2. Enter new chemistry number and begin another assay.

9. Quality Control

In accordance with good laboratory practice, users should run control with every batch of samples. Results of control should fall in the validity range provided along with the control.

10. Linear Range

The linear range for the assay is 41.00 – 607.00 IU/mL with the correlation coefficient ≥ 0.99.

11. Antigen Excess

Sample concentration of less than 3,000 IU/mL will not result in antigen excess. If the concentration is higher than 3,000 IU/mL, the results will be misleadingly low. If this is suspected, further dilute the sample to 1/121 (400 µL of diluent + 40 µL of 1/11 diluted sample), and reperform the assay.

12. Reference Range

12.1 The expected reference ranges of serum ASO are < 200 IU/mL in healthy adults and < 150 IU/mL in healthy children. The expected reference ranges may vary with age, gender, diet and geographical location. Each laboratory should determine its own expected values as dictated by good laboratory practice.

12.2 Diagnosis and treatment should not only depend on determination of ASO alone. The clinical symptoms and other laboratory findings of patients should always be taken into consideration.

13. Performance

13.1 Precision: CV ≤ 10%

13.2 Accuracy: Relative deviation within 20%

14. Caution and Warning

14.1 The reagents are only for *in vitro* diagnostic use.

14.2 The reagents can be used only by trained personnel with good laboratory practice and the stated procedure should be followed strictly.

14.3 All antiserums have been tested to be HBsAg negative HIV (1&2) antibody negative, HCV Ab negative. However, none of the testing methods can assure the absolute absence of infectious agents in blood products so please be sure to handle the blood products such as controls and antiserums as potentially infectious materials.

14.4 All reagents of the kit contain sodium azide as preservative. Take caution when handling them. Avoid ingesting or contacting of the reagents with skin or mucosa. If the contact occurs wash with large amount of water and seek medical advice. Azide may form explosive metal compounds in lead or copper plumbing. When disposing these reagents, be sure to flush with large amount of water to avoid accumulation of azide.

14.5 All components of this kit are exclusive for Nephstar. Reagents of different lots are not interchangeable. The results may not be reliable if reagents from different lots are mixed or used together.

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