



08186 Lliçà d'Amunt
Barcelona
Spain

Tel.:+ 34 93 860 90 00
Fax:+ 34 93 860 90 17
e-mail: biokit@biokit.com
www.biokit.com

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SUBJECT Rheumajet ASO
Implementation of special
procedure for preschool
children samples



Up to now, Biokit was offering two versions of the Rheumajet ASO, one for the USA market (w here we are market leaders) and a second one for the EU and Rest Of World (ROW).

Taking in to consideration that both reagents are exactly the same, we decided to unify these two presentations in only one to be used World Wide, that will be at the same time CE mark and FDA cleared.

The final codes and presentations will remain the same for EU and ROW:

COD. 3000-7007. Kit 50 tests, containing 1 x 2.5 mL Reagent, 1 mL Positive control, 1 mL Negative control and 9 x 6 disposable slides.

COD. 3000-7009. Kit 150 tests, containing 3 x 2.5 mL Reagent. (NOT AVAILABLE IN USA)

Differences

From the insert point of view there is only an importance difference for the EU/ROW users.

We are offering from now on, the possibility to work with paediatric samples (preschool children) using a different protocol and also a different “cut-off”.

Let us add here the most relevant parts of the insert that will be modified explaining this extra option:

Expected values

Although normal values can vary with age, season of the year and geographical area, the «upper limit of normal» antistreptolysin-O titers for preschool children is less than 100 IU/ml and in school age children or young adults is usually between 166 and 250 IU/ml. In any case, the average can be established at less than 200 IU/ml.

Because of this variation, titers above the upper limits may be indicative of a streptococcal infection, but only a two dilution rise in titer between acute and convalescent stage specimens should be considered significant.

Following acute streptococcal infection, the antistreptolysin-O titer will usually rise after one week, increasing to a maximum level within 3 to 5 weeks and usually returning to the preinfection levels in approximately 6 to 12 months.

QUALITATIVE TECHNIQUE

200 IU/ml detection level

- Allow reagents and samples to reach room temperature (20 to 30°C).
- Gently shake the reagent vial to disperse and suspend the latex particles in the buffer solution. Vigorous shaking should be avoided.
- Place 50 µl of the serum onto one section of the disposable slide.
- Place one drop of reagent next to the drop of serum.
- Mix both drops with a stirrer covering the whole surface of the slide section.
- Gently rotate the slide for 2 minutes manually or on a rotary shaker set at 80-100 rpm.
- Look for the presence or absence of agglutination after the aforementioned period of time.

100 IU/ml detection level

- Allow reagents and samples to reach room temperature (20 to 30°C).
- Gently shake the reagent vial to disperse and suspend the latex particles in the buffer solution. Vigorous shaking should be avoided.
- Place 100 µl of the serum onto one section of the disposable slide.
- Place one drop of reagent next to the drop of serum.
- Mix both drops with a stirrer covering the whole surface of the slide section.
- Gently rotate the slide for 4 minutes manually or on a rotary shaker set at 80-100 rpm.

- Look for the presence or absence of agglutination after the aforementioned period of time.

Interpretation of the results

200 IU/ml detection level

The presence of agglutination indicates a content of antistreptolysin-O in the serum equal to or greater than 200 IU/ml.

The absence of agglutination indicates a content of antistreptolysin-O in the serum of less than 200 IU/ml.

100 IU/ml detection level

The presence of agglutination indicates a content of antistreptolysin-O in the serum equal to or greater than 100 IU/ml.

The absence of agglutination indicates a content of antistreptolysin-O in the serum of less than 100 IU/ml.

Note: Some other sentences will be modified to uniform both versions.

The first kit lot containing this new insert version will be the **E-0706 (COD. 3000-7007)**, available in our stock from the end of May.

For more detailed technical information about the product, please contact with our Product Manager:

Mr. Ricard Forns (rforns@biokit.com)