



en

Intended use

The test reagents are intended for use in the serological detection and the determination of the serovar of *Shigella* strains isolated from test material of human or other origin using the slide agglutination test.

Principle of the test

If the *Shigella* strain possesses an antigen covered by the test reagent, this antigen becomes bound when mixed with the specific antibody. The antigen-antibody reaction results in clearly visible agglutination of the strain.

Composition

The test reagents are absorbed sera from immunised rabbits, a mixture of absorbed sera from immunised rabbits and contain only monoclonal antibodies.

Preservative: sodium azide (NaN₃) 0.9 mg/ml

Available polyspecific specificities

Name	contains antibodies against
Anti-Shigella I	<i>S. flexneri</i> type 1 to 6 and group 3,4 (y); 6 and 7,8 (x); <i>S. sonnei</i> S- and F-form (phase I and II)
Anti-Shigella II	<i>S. dysenteriae</i> types 1 to 10
Anti-Shigella III	<i>S. boydii</i> type 1 to 15
Anti-Shigella flexneri	<i>S. flexneri</i> type 1 to 6 and group 3,4 (y); 6 and 7,8 (x)

Available monospecific specificities

Name	Name	Name
Anti-Shigella dysenteriae type 1	Anti-Shigella flexneri type 4	Anti-Shigella flexneri group 7,8 (x)
Anti-Shigella dysenteriae type 2	Anti-Shigella flexneri type 5	Anti-Shigella sonnei S-form (phase I)
Anti-Shigella flexneri type 1	Anti-Shigella flexneri type 6	Anti-Shigella sonnei F-form (phase II)
Anti-Shigella flexneri type 2	Anti-Shigella flexneri group 3,4 (y)	Anti-Shigella sonnei S- and F-form (phase I and II)
Anti-Shigella flexneri type 3	Anti-Shigella flexneri group 6	

Form in which product is supplied, shelf life and storage

The test reagents which are **lyophilized** are ready for use once they have been rehydrated in 1 ml or 5 ml distilled water as stated on the label.

If stored unopened at 2...8 °C, they may be used up to the date given on the label. Once opened and rehydrated, they must be closed properly using the enclosed pipette. If stored at 2...8 °C, the polyspecific test reagent remain usable for at least 12 months, and the monospecific products for at least 18 months. However, they must not be used after the date given on the label.

Liquid test reagents may be used up to the date given on the label if stored at 2...8 °C both before and after opening. The reagents are ready to use.

The test reagent may sometimes show turbidity not caused by microbes. Such turbidity does not impair effectivity and the test reagents can be clarified by centrifugation or filtration. The test reagents must have their temperatures adjusted to room temperature (18...26 °C) before use.

Warnings and precautions

The biotechnological manufacture of the monoclonal antibodies means that the risk of contamination by infectious agents can be virtually excluded. Because they contain animal materials (fetal calf serum, stabilizer), they should be treated as potentially infectious and handled accordingly.

Test reagents containing biological material in the form of rabbit serum should be treated as potentially infectious and handled accordingly.

As these products contain sodium azide, contact with the skin and mucous membranes must be avoided! In case of contact, rinse with plenty of water.

Since the performance of the slide agglutination test involves working with native pathogenic materials, all necessary work protection procedures must be adhered to (risk of infection)!

Materials and equipment not supplied

Glass slides, stirring rods, distilled water, physiological saline (NaCl 9 g/l), disposal containers for infectious material, pipettes, pipette tips.

Test material and methodology

Transfer a small amount of bacterial mass from a suspicious colony onto a slide and mix with one drop of the test reagent (ca. 25 µl) so that a homogenous, slightly milky suspension results. Ensure that the slide is positioned on a dark surface.

The result is read with the naked eye by holding the slide in front of a light source against a black background and rocking it (tilting it back and forth).

In exceptional cases, selective culture media may impair the agglutinability of the bacteria. This factor can be eliminated by removing the bacteria from the nutrient or blood agar or from the Kligler medium. To exclude the possibility of spontaneous agglutinations, a negative control (NC) with physiological saline must be tested in parallel.

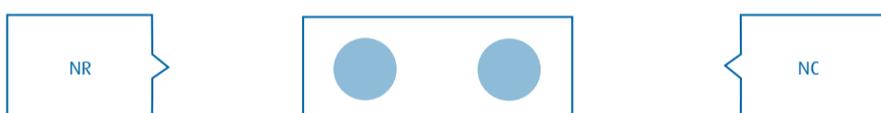
Evaluation

The test can only be evaluated if the negative control (NC) remains milky-opaque.

Positive: visible agglutination after the sample has been tilted back and forth less than 20 times. In a strongly positive reaction (PR), agglutination (coarsely or finely flocculent) appears as soon as the bacterial mass is mixed in. In a weakly positive result, agglutination only appears after the slide has been tilted back and forth 10-20 times.



Negative: If the suspension remains milky-opaque, or a reaction occurs only after the sample has been tilted back and forth more than 20 times, the reaction is negative (NR).



Quality assurance during the testing procedure

For the quality control of serological determination by slide agglutination test, the good expression of the strain's cell-surface antigen is important. The use of strains from interlaboratory tests, field strains of defined origin that have been characterised by an external laboratory, or sifin Shigella control antigens for the slide agglutination test is therefore recommended for quality control.

Limits of the procedure

The test reagents react with *Shigella* strains which contain antigens of the specificity declared on the label.

In exceptional cases, cross-reactions may occur with other genera of *Enterobacteriaceae* – especially with *E. coli* strains – due to antigen identities or related antigens.

Explanation of the symbols used

LOT	Batch code (Lot)		Use by YYYY-MM (MM = end of month)
REF	Catalogue number		Temperature limitation
IVD	In Vitro Diagnostic Medical Device		Consult instructions for use
TR	Test reagent		Slide agglutination
mTR	Monoclonal test reagent	LYO	lyophilized