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PUO SCREEN™

Screening test for Typhoid, Brucellosis and Scrub typhus fever

INTENDED USE

PUO SCREEN™ test can be used for screening of antibodies produced in febrile diseases such as Typhoid, Brucellosis and Scrub Typhus. The screening helps in detection or ruling out the presence of any or all of these febrile diseases.

SUMMARY

Pyrexia of unknown origin (PUO) refers to a condition in which the patient has elevated temperature but despite of investigations by the physician no proper explanation can be found. PUO SCREEN™ is a rapid slide screening test especially useful when large numbers of sera must be examined. Positive test results obtained by the slide test should be confirmed by tube test.

PRESENTATION

REF		105910032
Σ		3 x 2 ml
Reagents		*S.typhi 'O', Brucella abortus , Proteus OXK*
Control	+	1 ml
PACKAGE INSERT		1

REAGENT

PUO SCREEN™ reagent set consist of ready to use standardized, killed, stained, smooth antigen suspensions of the *Salmonella* bacilli; *S. typhi O, Brucella abortus* and *Proteus OXK* antigen along with a Polyspecific positive control which is reactive with these antigens.
Each batch of reagents undergoes rigorous quality control at various stages of manufacture for its specificity and performance.

REAGENT STORAGE AND STABILITY

(1). Store the reagent at 2-8^{0}C. DO NOT FREEZE.(2). The shelf life of reagent is as per the expiry date mentioned on the reagent vial label. Keep the reagents away from direct sunlight.

PRINCIPLE

When the coloured, smooth attenuated PUO SCREEN™ antigen suspension is mixed / incubated with patient's serum, antibodies to the corresponding PUO SCREEN™ antigen if present in the patient's serum reacts with the antigen suspension to produce an agglutination. Agglutination is a positive test result, indicating presence of specific antibodies to the PUO SCREEN™ antigen in the patient's sample. No agglutination is a negative test result indicating absence of specific antibodies to the PUO SCREEN™ antigen.

NOTE

(1). In vitro diagnostic reagent for laboratory and professional use only. Not for medicinal use. Keep the reagents away from direct sunlight. (2). The *S. typhi* 'O' reagent contains 0.5% Phenol as preservative. *Proteus OXK* reagent contains 0.1% Sodium azide as preservative and *Brucella abortus* reagent contains 0.01% Thimerosal as preservative. Polyspecific positive control contains 0.1% Sodium azide as preservative. Avoid contact with skin and mucosa. On disposal flush with large quantities of water. (3). The reagent can be damaged due to microbial contamination or on exposure to extreme temperatures. It is recommended that the performance of the reagent be verified with positive and negative controls. (4). Shake the reagent vials well before use to disperse the antigen suspension uniformly and improve test performance. (5). Only clean and dry glass slides/tubes must be used. Clean the glass slide /tube with distilled water and dry. (6). It is necessary to use the calibrated dropper provided in the reagent vial to dispense a reagent drop. (7).PUO SCREEN™ reagent antigens are not from human source hence contamination due to HBsAg and HIV is practically excluded. (8). Do not use damaged or leaking reagents.

SAMPLE COLLECTION AND STORAGE

(1). No special preparation of the patient is required prior to sample collection by approved techniques. Do not use hemolysed samples. (2). Clean and dry glassware free from detergents must be used for sample collection. (3).Do not heat inactivate the serum. (4).Though freshly collected serum is preferable, store samples at 2-8^{0}C in case of delay in testing.

MATERIAL PROVIDED WITH THE KIT

Reagent pack

1. *S.typhi* 'O' antigen
2. *Brucella abortus* antigen
3. *Proteus OXK* antigen
4. Polyspecific positive control

ADDITIONAL MATERIAL REQUIRED

Slide Test Method: Stopwatch, appropriate pipettes/micropipettes, 0.9% physiological saline as negative control and high intensity direct light source, slides, mixing sticks.

TEST PROCEDURE

1. Bring all reagents to room temperature before testing.
2. Shake and mix antigens well before dispensing.

Rapid Slide screening method

1. Place one drop of polyspecific positive control onto the reaction circle of the glass slide.

2. Place one drop of negative control (0.9% physiological saline) onto the next reaction circle of the glass slide.
3. Place one drop of patient serum (50 µl) to be tested onto each of the required number of reaction circles.
4. Add one drop of the appropriate PUO SCREEN™ antigen suspension to each circle using the reagent dropper.
5. Mix contents of each circle uniformly over the entire circle with separate mixing sticks.
6. Rock the slide gently, back and forth, and observe for agglutination macroscopically **at one minute.**

INTERPRETATION OF RESULTS

Rapid Slide screening method

Agglutination obtained within one minute is a positive reaction and indicates the presence of the corresponding antibody in the patient serum. No agglutination is a negative test result and indicates the absence of the corresponding antibody in the patient's serum.

REMARKS

(1). Sera from normal patients may show positive agglutination with PUO SCREEN™ antigens due to previous immunization, past infection or the presence of antibodies to related antigens. In general the titres found in these cases will be lower and remain at a constant level. (2). Positive results obtained in the slide test should be confirmed with the tube test to establish whether the titres are diagnostically significant or not. (3). Cross reactions, previous vaccinations, amnestic responses, antibiotic therapy, other diseases known or unknown, prozones and autoagglutinations, as well as other factors, may affect results. (4). In certain geographic regions and occupations, Typhoid fever, Brucellosis and Scrub typhus are endemic and high level of natural agglutinins may be present. (5). 'O' being a somatic antigen brings about coarse, compact, granular agglutination. (6). Turbid and contaminated sera should not be used for testing. (7). Generally antibody titres of 1:80 or more are considered clinically and diagnostically significant. However the significant titre may vary from population to population and needs to be established for each area. (8). It is recommended that results of the tests should be correlated with clinical findings to arrive at the final diagnosis. (9). False positive reactions may occur with *Brucella* antigen in sera of patient's infected with *Pasteurella tularensis* or vaccinated with *Vibrio cholerae*. (10). Serological findings are not intended as a substitute for culture. An appropriate attempt should be made to recover and identify the etiologic organisms through various culture and biochemical tests. (11). A great number of false positive reaction have been reported in healthy individuals with *Proteus* antigens especially in slide agglutination testing. A titre of less than 1:160 should not be considered significant. (12). A rising or falling titre is more useful than a single elevated titre. (13).The test is not a substitute for culture. An appropriate attempt should be made to recover and identify the etiologic organism.

PERFORMANCE CHARACTERISTICS

1. The positive control antisera should produce 1+ or greater agglutination in the slide when tested with the PUO SCREEN™ antigen suspensions.
2. The negative control should show no agglutination with any of the PUO SCREEN™ antigen suspensions.
3. Generally accepted performance characteristic of this type of test is 70% specificity and sensitivity.
4. Reproducibility of PUO SCREEN™ antigen suspensions is 100% (+/- one double dilution).

WARRANTY

This product is designed to perform as described on the label and package insert. The manufacturer disclaims any implied warranty of use and sale for any other purpose.

BIBLIOGRAPHY

(1).Cruickshank R. (1982), Medical Microbiology, 12th Ed.; 403. (2). Felix A., (1942), Brit. Med. J., 11, 597-600. (3). J. G. Collee, J. P. Duguid, A. G. Fraser, Practical Medical Microbiology, 14th Ed.: 473-478 & 573-588. (4). G. Galton, L. M. Jones, R. D. Angus, J. M. Verger, Techniques for the brucellosis laboratory, INRA, Paris, 1988. (5). Data on file: Tulip Diagnostics (P) Ltd.

SYMBOL KEYS

Temperature limitation	Manufacturer	Contains sufficient for <n> tests
Use by	Consult Instructions for use	This way up
Date of Manufacture	REF Catalogue Number	PS Production Site
LOT Batch Number/ Lot Number	IVD *In vitro* Diagnostic Medical Device	CONTROL + Positive control
EC REP Authorised Representative in the European Community		

Manufactured by

TULIP DIAGNOSTICS (P) LTD.

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