



POLYSPECIFIC POSITIVE CONTROL

INTENDED USE

PROGEN™ Polyspecific Positive Control can be used for validating the performance of PROGEN™ OX19, PROGEN™ OX2 and PROGEN™ OXK antigen suspensions.

SUMMARY

Rickettsiae is an arthropod associated infection of ticks, mites, lice, or fleas. The disease is frequently associated with vertebrates; including humans as accidental hosts. *Rickettsia conorii* causes Mediterranean Spotted Fever in humans and is contracted by contact with infected brown dog ticks. Other Rickettsia include *Rickettsia prowazekii*, which causes typhus, *Rickettsia rickettsii*, which causes Rocky Mountain Spotted Fever and *Rickettsia akari*, which causes rickettsialpox. PROGEN™ OX19, PROGEN™ OX2, PROGEN™ OXK antigen suspensions are employed for the Weil-Felix test. The Weil-Felix test is based on the principle that some strains of *Proteus* share common somatic constituents with certain species of *Rickettsia*. Sera from patients infected with *Rickettsia* will therefore produce agglutination with *Proteus* antigen suspensions. The performance of PROGEN™ OX19, PROGEN™ OX2, PROGEN™ OXK can be validated with the help of PROGEN™ Polyspecific Positive Control.

REAGENT

The PROGEN™ Polyspecific Positive Control contains ready to use standardized Goat antiserum with polyspecific antibodies having specific reactivity towards PROGEN™ OX19, PROGEN™ OX2, PROGEN™ OXK antigens and is useful in the validation of the performance of PROGEN™ OX19, PROGEN™ OX2, PROGEN™ OXK reagents.

Each batch of controls undergoes rigorous quality control at various stages of manufacture for its specificity, sensitivity, and performance.

REAGENT STORAGE AND STABILITY

1. Store the control reagent at 2-8°C. DO NOT FREEZE. Keep the control reagent away from sunlight.
2. The shelf life of the control reagent is as per the expiry date mentioned on its vial labels. Do not use beyond expiry date.
3. Once opened the shelf life of the control reagent is as described on its vial label provided it is not contaminated.

PRESENTATION

		1 ml
		105840001
Control	+	1 ml
PACKAGE INSERT		1 No.

PRINCIPLE

The PROGEN™ Polyspecific Positive Control is mixed with the *Proteus* antigen suspensions to be tested and allowed to react. Specific reactivity of *Proteus* antigens if present in the antigen suspensions will produce an agglutination reaction. No agglutination indicates the deterioration of the performance of antigen suspensions.

NOTE

1. *In vitro* diagnostic reagent for laboratory and professional use only. Not for medicinal use.
2. The control reagent contains 0.1% sodium azide as preservative. Avoid contact with skin and mucosa. Sodium azide may react with lead and copper in plumbing and form highly explosive metal oxides, on disposal flush with large quantities of water.

ADDITIONAL MATERIAL REQUIRED

Stop watch, Physiological saline, glass slide with clean/white background, appropriate pipettes/micropipettes, mixing sticks & a high intensity direct light source.

TEST PROCEDURE

1. Bring all reagents to room temperature.
2. Shake and mix the PROGEN™ Polyspecific Positive Control well before dispensing.

Slide Test Method

1. Place one drop of PROGEN™ Polyspecific Positive Control onto the reaction circle of glass slide.
2. Place ~ 50 µl of saline onto the next reaction circle of the glass slide.
3. Add one drop of test reagent (*Proteus* antigen suspensions) in each of the above circles.
4. Mix contents of each circle uniformly over the entire circle with separate mixing sticks.
5. Gently rock the slide back and forth, observe for agglutination macroscopically **at one minute**.

INTERPRETATION OF RESULTS

Slide test method

Agglutination is a positive test result and indicates that the *Proteus* antigen reagents are performing satisfactorily.
No agglutination is a negative test result and indicates the deterioration of *Proteus* antigen reagents.

PERFORMANCE CHARACTERISTICS

1. The positive control antisera should produce 1+ or greater agglutination in the slide at one minute when tested with the PROGEN™ OX19, PROGEN™ OX2 and PROGEN™ OXK antigen suspensions.
2. Reproducibility of PROGEN™ POSITIVE CONTROL is 100% (+/- one double dilution).














WARRANTY

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

BIBLIOGRAPHY

(1). Felix, A.(1942). Brit. Med.J., 11, 597-600. (2) J. G. Collee, J. P. Duguid, A. G. Fraser, Practical Medical Microbiology, 14th Ed. 573-588. (3). Date 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	 Catalogue Number	 Production Site
 Batch Number/ Lot Number	 <i>In vitro</i> Diagnostic Medical Device	 Positive control
 Authorised Representative in the European Community		



Manufactured by

TULIP DIAGNOSTICS (P) LTD.

PGN/0917/VER-02



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Manufacturing Unit

PLOT NO. UTILITY VIII, PHASE III B, VERNA IND.
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