NOVACLONE™ DILUENT CONTROL
For NOVACLONE™ BLOOD GROUPING REAGENTS
(For Slide, Tube and Microplate Test)

IVD In Vitro Diagnostic Medical Device

CONTROL Control

CE 0197

Harmful – Contains 0.1% Sodium azide
Components contain natural rubber latex

Consult Instructions for Use

Temperature Limitation - Store at 1-10°C.

EC REP
IMMUCOR Medizinische Diagnostik GmbH
Robert-Bosch-Strasse 32
63303 Dreieich, GERMANY
AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMMUNITY

Manufacturer:
Dominion Biologicals Limited
5 Isnor Drive, Dartmouth, Nova Scotia CANADA B3B 1M1
Tel: 902-468-3992 Fax: 902-468-3599

	Use By (expiration)		Harmful
LOT	Batch Code	REF	Catalogue Number

RECOMMENDED DIRECTIONS FOR USE

SUMMARY
NOVACLONE™ DILUENT CONTROL is intended for use as a control test for NOVACLONE™ Blood Grouping Reagents.
On rare occasion false positive results may occur in any serological test procedure[1, 2]. False positive results in blood grouping tests may be associated with a number of different factors including *in vivo* sensitization of red cells with immunoglobulin or as a result of serum protein abnormalities (when unwashed cells are used for testing)[3]. False positive results in ABO Blood Grouping Tests may often be recognized by observed discrepancies between the forward (cell) and reverse (serum) grouping tests. False positive results in Rh (D) and Rh-Hr typing tests may not easily be recognized since no analogous reverse grouping confirmation test exists. False positive results, such as these, are most likely to occur with traditional Rh (D) and Rh-Hr slide and rapid tube reagents that contain high protein levels and macromolecular potentiators. Examples of similar false positive results with Monoclonal Blood Grouping Reagents that contain low protein levels are very rare[3]. In addition, the routine use of washed red cells for rapid tube tests can reduce the incidence of some types of false positive reactions.
In some cases, the use of a specific control test may be indicated to detect and allow the recognition of possible false positive results [2, 3, 4]. Furthermore, some standards and regulations require the inclusion of a control test in routine testing. Although, several types of control tests may be performed, a specific Manufacturer's Control Reagent (such as NOVACLONE™ DILUENT CONTROL) is recommended as an optimal control test for this purpose [3].

PRINCIPLE
NOVACLONE™ DILUENT CONTROL for NOVACLONE™ Blood Grouping Reagents contains the same diluent components as NOVACLONE™ Blood Grouping Reagents but does not contain any key antibody component. This control reagent is intended to provide a specific negative control test and may be used for simultaneous, parallel control tests in all procedures recommended for use for NOVACLONE™ Blood Grouping Reagents. No agglutination with the specific NOVACLONE™ DILUENT CONTROL indicates an expected control test result, and within the limitations of the test procedure, confirms the validity of a positive test result with NOVACLONE™ Blood Grouping Reagents. If positive results are observed with NOVACLONE™ DILUENT CONTROL, then concurrent positive test results with NOVACLONE™ Blood Grouping Reagents should not be interpreted as valid without further investigation and confirmatory testing.

REAGENT
FOR *IN VITRO* PROFESSIONAL DIAGNOSTIC USE ONLY
NOVACLONE™ DILUENT CONTROL is prepared using the same proprietary diluent components that comprise NOVACLONE™ Blood Grouping Reagents. This Control Reagent contains no antibody component.

This Control Reagent is intended for use by slide, tube and microplate test and provides a qualitative control test when used in parallel with NOVACLONE™ Blood Grouping Reagents. The diluent used for this low protein control reagent contains sodium chloride, bovine serum albumin, pH buffers and other selected components. Sodium azide, at a final concentration of 0.1%, is added as an antimicrobial agent. Do not dilute - Use as supplied.

PRECAUTIONS
Marked turbidity may indicate bacterial contamination or reagent deterioration. Do not use contaminated reagents or unlabeled vials. Do not use beyond expiration date. Store at 1-10°C when not in use. Do not freeze. Do not ingest.

Allow reagent to equilibrate to ambient room temperature (~18-25°C) prior to use.

SODIUM AZIDE IS TOXIC. DO NOT INGEST. SODIUM AZIDE MAY REACT WITH COPPER AND LEAD PLUMBING TO FORM EXPLOSIVE METAL AZIDES. ON DISPOSAL, FLUSH WITH LARGE VOLUMES OF WATER TO PREVENT AZIDE BUILD UP.

THIS PRODUCT HAS COMPONENTS (DROPPER BULBS) THAT CONTAIN NATURAL RUBBER LATEX, WHICH IS KNOWN TO CAUSE ALLERGIC REACTIONS IN SOME INDIVIDUALS.

ALL BLOOD PRODUCTS SHOULD BE TREATED AS POTENTIALLY INFECTIOUS. THIS PRODUCT DOES NOT CONTAIN HUMAN SOURCE MATERIAL.

THESE PRODUCTS SHOULD BE CONSIDERED BIOHAZARDOUS AND DISPOSAL SHOULD CONFORM TO APPLICABLE REQUIREMENTS FOR DISPOSAL OF BIOHAZARDOUS WASTE MATERIAL.

ANY BOVINE SOURCE MATERIAL, USED IN THE MANUFACTURE OF THIS PRODUCT, IS SOURCED FROM DONOR ANIMALS THAT HAVE BEEN INSPECTED AND CERTIFIED BY VETERINARY SERVICE INSPECTORS TO BE DISEASE-FREE. THIS RUMINANT-BASED PRODUCT IS DEEMED TO HAVE LOW TSE (TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHY) RISK.

NOVACLONE™ DILUENT CONTROL

For Use with

NOVACLONE™ Blood Grouping Reagents

(FOR SLIDE, TUBE AND MICROPLATE TEST)

IMMUCOR

SPECIMEN COLLECTION
Refer to **Specimen Collection** outlined in the Manufacturer's specific Directions for Use for NOVACLONE™ Blood Grouping Reagent(s) for which the control test is intended.

For Microplate testing with automated instrumentation, refer to instructions provided in the instrument operator manual.

PROCEDURES
Reagents Supplied: NOVACLONE™ DILUENT CONTROL (For Slide, Tube and Microplate Test).

Materials and Equipment Not Supplied: Transfer pipettes, isotonic saline (Phosphate Buffered Saline at a pH of 6.5-7.5 is recommended).
SLIDE TEST: Glass slides or plastic TP-12 plates, applicator sticks.
TUBE TEST: 12 x 75 mm or 10 x 75 mm glass or plastic (polystyrene) test tubes, test tube racks, serological centrifuge (900-1000rcf).
MICROPLATE METHOD: Rigid U-bottom microplates, calibrated centrifuge with microplate carriers, microplate shaker (optional, but recommended).

For Microplate testing with automated instrumentation, refer to instructions provided in the instrument operator manual.

Users are responsible for validation of an accessory device for its intended use.

TEST PROCEDURES

Slide Test Method; Tube Test Method; Microplate Method:
Control tests using NOVACLONE™ DILUENT CONTROL should be performed in an identical manner as the specific NOVACLONE™ Blood Grouping Reagent for which the control test is intended. NOVACLONE™ DILUENT CONTROL may be used in any of the procedures recommended for use for NOVACLONE™ Blood Grouping Reagents. Refer to the specific Manufacturer's Directions for Use for NOVACLONE™ Blood Grouping Reagents.

For Microplate testing with automated instrumentation, refer to instructions provided in the instrument operator manual.

CONTROL TESTS
Appropriate control tests are essential for all laboratory test procedures.

1. It is strongly recommended that the reactivity of Blood Grouping Reagents be confirmed each day of use by control tests with antigen positive and antigen negative red cells. For NOVACLONE™ DILUENT CONTROL it is recommended that a negative control test be performed using an unsensitized, normal donor cell.
2. For Microplate testing with automated instrumentation, refer to instructions provided in the instrument operator manual.

INTERPRETATION OF TEST RESULTS
Slide and Tube and Microplate Test:
NEGATIVE (-): Within the accepted limitations of the test procedure, no agglutination of test red cells with NOVACLONE™ DILUENT CONTROL provides the expected control test result that supports the validity of positive test results obtained with concurrent typing tests using NOVACLONE™ Blood Grouping Reagents.

POSITIVE (+): Within the accepted limitations of the test procedure, agglutination of test cells with NOVACLONE™ DILUENT CONTROL indicates "non-specific" agglutination. Positive results obtained in concurrent typing tests with NOVACLONE™ Blood Grouping Reagents may therefore be invalid and should not be interpreted without further investigation and studies.

LIMITATIONS OF THE TEST PROCEDURE
1. NOVACLONE™ DILUENT CONTROL is applicable only for use as a control for NOVACLONE™ Blood Grouping Reagents. This control reagent is not appropriate for use as a negative control test for other types of Blood Grouping Reagents or reagents from other manufacturers.
   NOVACLONE™ DILUENT CONTROL is not an appropriate control for NOVACLONE™ Anti-Human Globulin reagents.
2. Control tests using NOVACLONE™ DILUENT CONTROL are valid only if the reagent is used in a procedure identical to that of the specific NOVACLONE™ Blood Grouping Reagent for which the control test is intended. Parallel testing of the control reagent is recommended to ensure test conditions are identical.
3. The use of unwashed test cells may promote false positive reactions such as those associated with rouleaux or autoantibodies. The routine use of washed, saline suspended red cells for tube tests may reduce the risk of such false positive reactions.
4. NOVACLONE™ DILUENT CONTROL may not detect all types of false positive results that could occur with NOVACLONE™ Blood Grouping Reagents.
5. NOVACLONE™ DILUENT CONTROL contains no EDTA and will not detect potential false positives that may occur in ABO forward grouping tests performed in the presence of plasma or serum (unwashed test cells) when rare examples of antibodies to EDTA are encountered.
6. NOVACLONE™ DILUENT CONTROL *must not* be used in tests with enzyme treated red cells.
7. Other variables such as improper technique, inappropriate centrifugation or incubation, improperly cleaned glassware, incorrect saline pH and/or contaminated materials or reagent may cause false negative or false positive results.

SPECIFIC PERFORMANCE CHARACTERISTICS

When used in accordance with the recommended Directions for Use, NOVACLONE™ DILUENT CONTROL provides an appropriate control test to detect false positive reactions associated with non-specific agglutination. Each lot of NOVACLONE™ DILUENT CONTROL has been tested to confirm the lack of reactivity with a panel of normal human red cells by the recommended tube, and microplate test methods.

Deviation from the recommended Directions for Use may result in less than optimal product performance. User-defined modifications to test procedures may require validation.

REFERENCES

1. Mollison PL. Blood transfusion in clinical medicine. 7th edition. Oxford: Blackwell Scientific, 1993
2. Issitt PD, Anstee DJ. Applied Blood Group Serology. 4th edition. Montgomery Scientific. Durham, SC. 1998.
3. Garratty G. et al. Spontaneous agglutination of red cells with a positive direct antiglobulin test in various media. Transfusion 1984; 24:214-217
4. Brecher, m. Ed. Technical manual 15th edition. American association of blood banks. Bethesda, MD. 2005.

PRODUCT	ITEM CODE	
	1 x 10 mL	10 x 10 mL
NOVACLONE™ DILUENT CONTROL	5100012	5100022
NOVACLONE™ DILUENT CONTROL (Galileo)	5100011	5100021

NOVACLONE™ is a registered trademark of Dominion Biologicals Limited.

Additional information may be provided on request from:
Dominion Biologicals Limited
5 Isnor Drive,
Dartmouth, Nova Scotia CANADA B3B 1M1
Tel: 902-468-3992; Fax: 902-468-3599

Technical Support :
Immucor Technical Service (+49) 6074 8420-10
Email:-tech.support.eu@immucor.com

[NC18A – Revised 09/2019]