



P0263
Negative human serum

RUO

REF P0263



The kit insert contains a detailed protocol and should be read carefully before testing the run control to ensure optimal performance



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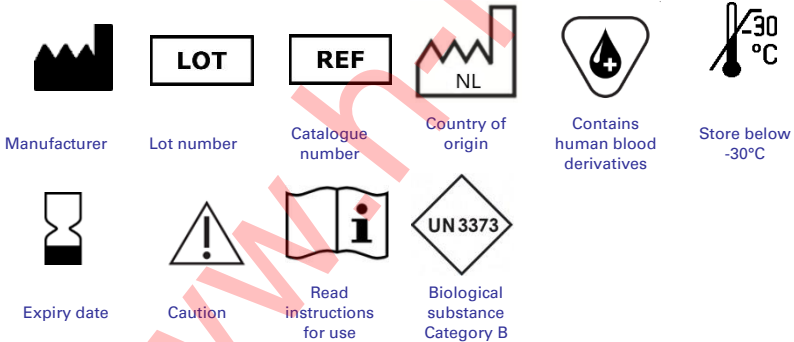
Intended use

P0263 normal human serum intended to be used as dilution matrix for preparation of dilutions in normal human serum. P0263 normal human serum is prepared from pooled human plasma, converted to serum by adding thrombine and stabilised using a proprietary matrix. Table 1 present the marker tested negative in P0165 Normal human serum. P0263 normal human serum is not a negative control to be used in blood screening tests. P0263 normal human serum preparation can be lyophilised.

Table 1. Assays and platforms covered by P0263 Normal human serum run control

Marker	Platform	Test result
HBsAg	Abbott Alinity	Negative
a-HCV	Abbott Alinity	Negative
a-HIV-1/2	Abbott Alinity	Negative
a-HBc	Abbott Alinity	Negative
a-HBs	Abbott Alinity	<1.0 mIU/ml
a-HTLV-I/II	Abbott Alinity	Negative
a-Trep.p	Abbott Alinity	Negative
HBV-DNA, HCV-RNA and HIV-RNA	Roche 6800/8800	Negative

Key to symbols used



Principle of method

P0263 Normal human serum has been formulated to mimic natural serum plasma specimens. P0263 Normal human serum can be used to dilute serum samples for testing on markers listed in table 1. P0263 Normal human serum is made from a pool of plasma units; 16 litres or about 70 plasma units. All plasma units were tested negative in the blood bank and released for transfusion or manufacturing of plasma products.

Table 2. Description of kit formats and contents

Cat. Code	Quantity
P0263	1 x 225 mL

Storage instructions

P0263 Normal human serum should be stored at or below -30°C. After thawing, store P0263 Normal human serum at 2-8°C for maximum one month. After thawing a clear solution should be found. Do not refreeze P0263 Normal human serum after thawing to prevent formation of cryoprecipitates.

Warning and precautions

P0263 Normal human serum is prepared from human blood plasma that tested negative for blood borne viruses (HBV-DNA, HCV-RNA, HIV-RNA, HBsAg, anti-HBc, anti-HBs, anti-HIV, anti-HCV and anti-Treponema *pallidum*) and after pooling, manufacturing retested negative. No test method can offer complete assurance that products derived from human blood cannot transmit (unknown) infectious agents. P0263 normal human serum should only be used by trained laboratory workers who are aware of the potential risk of infectious agents in human plasma samples and take the necessary precautions. Observe the universal precautions for prevention of transmission of infectious agents when handling these materials^{1,2}.

- Do not pipette by mouth.
- Use personal protective equipment, including lab coats, gloves and safety glasses.
- Do not eat, drink or smoke in areas where the serum is handled.
- Disinfect spills using a 0.5% hypochlorite solution (1:10 v/v household bleach) or equivalent disinfectant.
- Dispose unused or spilled materials according to the normal practices for biological waste disposal in your institution.
- If precipitates are visible, mix the run controls for 2 minutes thoroughly.
- Once thawed, do not re-freeze and thaw the run control samples to avoid formation of cryoprecipitates that could alter reactivity or cause pipetting errors in the automated sampling systems.
- Store run controls in an upright position

Reagent preparation

- Thaw the P0263 normal human serum quickly in a water bath at 37°C.
- Mix gently during thawing until contents are just thawed.
- Immediately after thawing remove the bottle from the water bath.
- Mix the content gently.
- Use within one month after thawing
- After thawing when not in use: store at 2-8°C

Limitations

- P0263 is a dilution matrix, and not a run control.
- P0263 Normal human serum must not be substituted for the mandatory (negative) controls or calibrators provided with NAT test kits for calculating the cut-off and/or criteria for releasing test results.

References

1. Centers for Disease Control (CDC). Update: Universal precautions for prevention of transmission of human immunodeficiency virus, hepatitis B virus, and other blood borne pathogens in health-care settings. MMWR 1988; 37:377-388.
2. Centers for Disease Control (CDC). Guidelines for prevention of transmission of human immunodeficiency virus and hepatitis B virus to health-care and public-safety workers. MMWR 1989; 38(S-6): 1-36.

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Biologicals Quality Control B.V.
De Droogmakerij 31h
1851 LX, Heiloo
The Netherlands

Telephone : +31-72-2020730
E-mail: info@bioQControl.com
Internet: www.bioQControl.com

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CERTIFICATE OF ANALYSIS

Dilution matrix

IDENTIFICATION

Article nr.	Product name	Lot nr.	Number tested	Quality control nr.
P0263	P0263 Negative human serum class 1	B4243-010	2 samples	OCF4010-023

PROCEDURE

Sources material was tested negative on blood borne viruses. In release testing this is verified for all specifications of the dilution matrix

SUMMARY OF TEST RESULTS

Test	Requirement	Actual result
Gravimetical records	All additions are within +/- 0.5 % of the target value	Confirmed
Batch release testing	The test results fulfil the release criteria	Confirmed

CONCLUSION

We hereby certify that this batch in compliance with the product specifications.

Production Manager K Zwaan

23-05-2024 (date)  (signature)

Quality Assurance Manager RR Werkman

27-05-2024 (date)  (signature)