Blood Culture GN Verification Kit (RUO)

STRECK

INSTRUCTIONS FOR USE

This product has not been cleared by the U.S. Food and Drug Administration for In Vitro Diagnostic Use. The product is for Research Use Only. Not for use in diagnostic procedures. Patents Pending.

INTENDED USE

Blood Culture GN (BCN) Verification Kit (RUO) can be used to develop procedures for performance verification of sample-to-answer molecular panels that detect nucleic acids from sepsis-causing gram-negative bacteria and associated antimicrobial resistance genes listed in Table 1. Blood Culture GN Verification Kit (RUO) contains two tubes that are composed of a buffered solution with stabilized erythrocytes and leukocytes in a matrix of blood culture media components. Vial 1: gram-negative bacteria: *Acinetobacter baumannii, Haemophilus influenzae, Neisseria meningitidis, Pseudomonas aeruginosa, Stenotrophomonas maltophilia*; genus: *Acinetobacter* spp., *Pseudomonas* spp.; antimicrobial resistance genes: KPC, NDM, and VIM. Vial 2: gram-negative bacteria: *Escherichia coli, Klebsiella oxytoca, Klebsiella pneumoniae, Klebsiella variicola, Morganella morganii, Serratia marcescens*; family/genus: *Enterobacteriaceae/Morganellaceae, Citrobacter* spp., *Enterobacter* spp., *Proteus* spp., *Salmonella* spp.; antimicrobial resistance genes: CTX-M, IMP, MCR, OXA, and SME. This product is not intended to replace manufacturer controls provided.

SUMMARY AND PRINCIPLES

Sepsis (defined as system inflammatory response syndrome in response to infection) is the 11th leading cause of death in the United States[1]. Life-threatening bacterial and fungal sepsis currently strikes approximately 240 out of 100,000 people per year in the U.S. (750,000 total cases), with severe sepsis (associated with acute organ dysfunction) in 95 out of 100,000 people[2]. Timely diagnosis and administration of effective treatment can significantly reduce mortality, duration of hospital stays, and costs due to sepsis.

Blood Culture GN Verification Kit (RUO) is designed to assist with the development of procedures used to verify performance of molecular testing processes that detect the presence of nucleic acids from various bacteria, train personnel, and evaluate operator proficiency.

REAGENTS

Blood Culture GN Verification Kit (RUO) contains stabilized human leukocytes and erythrocytes, and the following inactivated bacteria and bacteria components (see Table 1) in simulated blood culture media. Each verification kit is supplied with 10 pink-capped 0.5mL microtubes, each containing 300µL of the Vial 1 formulation, and 10 black-capped 0.5mL microtubes, each containing 300µL of the Vial 2 formulation.

PRECAUTIONS

1. Blood Culture GN Verification Kit (RUO) is for Research Use Only. Not for use in diagnostic procedures.
2. **CAUTION**: All blood products should be treated as potentially infectious. All human source material used to manufacture this product was previously established to be negative for the target analytes by a third party; non-reactive for antigens to Hepatitis B (HBsAg), negative by tests for antibodies to HIV (HIV-1/HIV-2) and Hepatitis C (HCV), non-reactive for HIV-1 RNA, and HCV RNA by licensed NAT, and non-reactive to Serological Test for Syphilis (STS), West Nile Virus and Chagas disease. Because no known test method can assure complete absence of human pathogens, this product should be handled with appropriate precautions.
3. **CAUTION**: All bacterial products should be treated as potentially infectious. Source material from which this product was derived was inactivated and tested in accordance with CDC/USDA "Guidance on the Inactivation or Removal of Select Agents and Toxins for Future Use." These procedures cannot offer assurance that products containing bacteria are non-infectious.
4. These RUO lots should not be disposed of in general waste but should be disposed of with infectious medical waste. Disposal by incineration is recommended.
5. These RUO lots are intended for use as supplied. Adulteration by dilution or addition of any materials to the vials invalidates the use of the product.

STORAGE

Blood Culture GN Verification Kit (RUO) is stored at 2 °C to 25 °C.

INDICATION OF PRODUCT DETERIORATION

Discoloration of the product may be caused by overheating or freezing during shipping or storage. Dark colored (gross hemolysis) supernatant may be indicative of product deterioration. However, light colored (moderate hemolysis) or cloudy supernatant is normal and should not be confused with deterioration of the product.

INSTRUCTIONS FOR USE

Adding Verification Sample

1. **Verification samples should be processed in control mode when required per manufacturer's instructions or when given as an option for sample-to-results tests.**
2. If refrigerated, remove verification tubes from the refrigerator and allow to sit at room temperature to acclimate for 15 minutes before use. Vortex Vial 1 and Vial 2 tubes at a high speed for 30 seconds. **Note: Always use aseptic technique when handling verification tubes to prevent cross-contamination or environmental contamination**.
   a. Verify Vial 1 has been adequately mixed by inverting the tube and examining the bottom for the absence of cellular material.
   b. Flash spin the tube to remove material from cap.
   c. Open the tube and mix the sample via pipet by repeatedly pipetting up and down 5-10 times.
3. Remove 300µL of sample and process according to the manufacturer's instructions for sample-to-results tests.
   a. Each sample tube has sufficient volume for one test and can be discarded after use.
4. Repeat Steps 1-3 with Vial 2.

LIMITATIONS

Blood Culture GN Verification Kit (RUO) should be used in accordance with local, state, federal regulations, and accreditation requirements.

EXPECTED RESULTS

All organisms and resistance genes stated in the control should be "Detected," "Not Detected," or "Not Reviewed," as indicated (see Table 1).

REFERENCES

1. National Vital Statistics Reports, Deaths: Preliminary Data for 2010. Available from: http://www.cdc.gov/nchs/data/nvsr/nvsr60/nvsr60_04.pdf.
2. Angus, D.C., et al., Epidemiology of severe sepsis in the United States: analysis of incidence, outcome, and associated costs of care. Crit Care Med, 2001. 29(7): p. 1303-10.

Table 1: Blood Culture GN Verification Kit (RUO) Vial 1 and Vial 2 Results Summary

Gram-Negative Bacteria		
Target	**Vial 1**	**Vial 2**
Enterobacteriaceae/Morganellaceae	Not Detected	Detected
Acinteobacter spp.	Detected	Not Detected
Acinteobacter baumannii	Detected	Not Detected
Citrobacter spp.	Not Detected	Detected
Enterobacter spp.	Not Detected	Detected
Escherichia coli	Not Detected	Detected
Haemophilus influenzae	Detected	Not Detected
Klebsiella oxytoca	Not Detected	Detected
Klebsiella pneumoniae	Not Detected	Detected
Klebsiella variicola	Not Detected	Detected
Morganella morganii	Not Detected	Detected
Neisseria meningitidis	Detected	Not Detected
Proteus spp.	Not Detected	Detected
Pseudomonas spp.	Detected	Not Detected
Pseudomonas aeruginosa	Detected	Not Detected
Salmonella spp.	Not Detected	Detected
Serratia marcescens	Not Detected	Detected
Stenotrophomonas maltophilia	Detected	Not Detected
Antimicrobial Resistance Genes		
Gene	**Vial 1**	**Vial 2**
CTX-M	Not Detected	Detected
IMP	Not Detected	Detected
KPC	Detected	Not Detected
MCR	Not Detected	Detected
NDM	Detected	Not Detected
OXA	Not Detected	Detected
SME	Not Reviewed	Detected
VIM	Detected	Not Detected

ORDERING INFORMATION

Please call our Customer Service Department 800-228-6090 for assistance. Additional information can be found online at streck.com.

TECHNICAL SUPPORT

Please call Streck Technical Services at 800-843-0912 for assistance. Additional information can be found online at streck.com.

See the Instructions (IFU) tab under Resources on the product page at streck.com.

See streck.com/patents for patents that may be applicable to this product.

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350848-1
Date of Issuance: 2025-09