MDx-Chex® for BC-GP

IVD

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INSTRUCTIONS FOR USE

INTENDED USE

MDx-Chex® for BC-GP is intended for use as an external positive and negative assayed control to monitor the performance of the qualitative detection of Gram-positive bacteria and associated antimicrobial resistance genes, by the Luminex VERIGENE® Gram-Positive Blood Culture Nucleic Acid Test (BC-GP) on Luminex VERIGENE® systems. The MDx-Chex® for BC-GP Positive and Negative Controls are composed of a buffered solution with stabilized erythrocytes and leukocytes in a matrix of blood culture media components. Positive Control: Gram-positive bacteria: *Staphylococcus aureus*, *Staphylococcus epidermidis*, *Staphylococcus lugdunensis*, *Streptococcus agalactiae*, *Streptococcus pneumoniae, Streptococcus pyogenes*, *Enterococcus faecalis, Enterococcus faecium*, *Streptococcus anginosus group*; Species: *Staphylococcus* spp., *Streptococcus* spp., *Listeria* spp.; antimicrobial resistance genes: *mecA*, *vanA* and *vanB*. Negative Control: buffered solution only. This product is not intended to replace manufacturer controls provided with the device.

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. The VERIGENE Gram-Positive Blood Culture Nucleic Acid Test simultaneously tests a single positive blood culture sample to provide results for 12 different organisms and species that cause bloodstream infections and 3 genes that are known to confer antimicrobial resistance. The test can be performed on blood culture bottles that are flagged as positive by a continuously monitoring blood culture instrument. Luminex BC-GP test results are available within approximately two hours. Rapid identification of the organism(s) in the blood culture, along with information about antimicrobial resistance gene status for select microorganisms, may aid the physician in making appropriate treatment decisions.

MDx-Chex® for BC-GP is a quality control containing stabilized blood components, blood culture media components, and inactivated microorganisms resulting in a full-process, cellular-based control for the Luminex BC-GP Panel. Use of full-process cellular controls are necessary to evaluate the entire analytical process, including sample lysis, nucleic acid isolation and purification, hybridization, detection, and analysis, as well as the impact of inhibitors and preanalytical variables. Routine use of full process quality controls can help identify variations in the test system that can lead to incorrect results.

REAGENTS

MDx-Chex® for BC-GP contains stabilized human leukocytes and erythrocytes, and the following inactivated bacteria (see Table 1) in a simulated blood culture media. Each Control tube contains enough reagent for 1 test.

PRECAUTIONS

1. MDx-Chex® for BC-GP is for *In Vitro* Diagnostic Use.
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. This product should not be disposed in general waste but should be disposed with infectious medical waste. Disposal by incineration is recommended.
5. This product is intended for use as supplied. Adulteration by dilution or addition of any materials to the product vial invalidates the use of the product.

STORAGE

MDx-Chex® for BC-GP is stored at 2 °C to 25 °C. The product may be used until the expiration date.

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

1. If refrigerated, remove vials of control from the refrigerator and allow to sit at room temperature to acclimate for 15 minutes before use.
   Note: Always use aseptic technique when handling control tubes to prevent cross-contamination or environmental contamination.
2. Prepare a VERIGENE BC-GP Cartridge according to the VERIGENE BC-GP Test Procedure, Steps 1–6a, package insert[3].
3. Immediately prior to use, vortex the control sample for 30 seconds to mix.
   Note: Verify the product has been adequately mixed by inverting the vial and examining the bottom for the absence of cellular material.
4. Flash spin the control to remove material from cap.
5. Enter the Sample ID of the control by scanning or manually enter the Sample ID using the VERIGENE Reader's touch-screen keyboard. Press Yes to confirm the Sample ID.
6. Select QC Mode prior to initiating the control run.
7. Mix the control via pipet (or transfer pipet) by repeatedly pipetting up and down 5-10 times.
8. Withdraw 350µL from the control vial and load the sample into the bottom of the Sample Loading Well in the Extraction Tray. Discard used control vial.
9. Close the Drawer Assembly by pressing the OPEN/CLOSE button on the Processor SP and wait for the processor to automatically verify that each consumable is properly loaded.
10. Confirm that the test countdown has started on the Processor SP display screen before leaving the test area.
11. Upon completion of a test run, follow Steps 9–10 of the BC-GP Test Procedure in the package insert.

Table 1: MDx-Chex® for BC-GP Positive Control (BC-GP Pos) and Negative Control (BC-GP Neg) Result Summary

Gram-Positive Bacteria and Species		
Pathogen/Species	**Control BC-GP Pos**	**Control BC-GP Neg**
Staphylococcus aureus	Detected	Not Detected
Staphylococcus epidermidis	Detected	Not Detected
Staphylococcus lugdunensis	Detected	Not Detected
Streptococcus agalactiae	Detected	Not Detected
Streptococcus pneumoniae	Detected	Not Detected
Streptococcus pyogenes	Detected	Not Detected
Enterococcus faecalis	Detected	Not Detected
Enterococcus faecium	Detected	Not Detected
Streptococcus anginosus group	Detected	Not Detected
Staphylococcus spp.	Detected	Not Detected
Streptococcus spp.	Detected	Not Detected
Listeria spp.	Detected	Not Detected
Antimicrobial Resistance Genes		
Gene	**Control BC-GP Pos**	**Control BC-GP Neg**
mecA (methicillin)	Detected	Not Detected
vanA (vancomycin)	Detected	Not Detected
vanB (vancomycin)	Detected	Not Detected

LIMITATIONS

MDx-Chex® for BC-GP is to be used for the Luminex BC-GP Test, on the Luminex VERIGENE System only. It is not intended for controlling other tests or procedures. Quality control materials should be used in accordance with local, state, federal regulations, and accreditation requirements.

EXPECTED RESULTS

When analyzed by the VERIGENE BC-GP Test, all organisms and resistance genes stated in the control should be "Detected" or "Not Detected," as indicated (see Table 1).

PERFORMANCE CHARACTERISTICS

1. Repeatability (precision)
   Evaluation of repeatability (precision) of MDx-Chex® for BC-GP was performed using three separately manufactured lots. Twenty samples per control type (positive and negative control tubes) for 40 samples per lot were tested over 20 days for a total of 120 runs (60 Positive Control, 60 Negative Control). Samples were prepared according to the MDx-Chex® for BC-GP IFU and analyzed on the Luminex VERIGENE system per the IFU for the BC-GP panel. All MDx-Chex® for BC-GP Positive and Negative Control lots passed with >90% agreement with expected results.

Table 1: Repeatability of MDx-Chex® for BC-GP Positive Control: Positive Percent Agreement

Category	# Observed Results/ # Expected Results *	Positive Percent Agreement	95% Confidence Interval
MDx-Chex® for BC-GP, Positive Control	60/60	100%	94% - 100%

*Expected result for the Positive Control is Detected.

Table 2: Repeatability of MDx-Chex® for BC-GP Negative Control: Negative Percent Agreement

Category	# Observed Results/ # Expected Results *	Negative Percent Agreement	95% Confidence Interval
MDx-Chex® for BC-GP, Negative Control	60/60	100%	94% - 100%

*Expected result for the Negative Control is Not Detected.

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2. Reproducibility
   Evaluation of reproducibility of MDx-Chex® for BC-GP was performed using three separately manufactured lots. Testing was completed at three sites and consisted of 10 Positive Control samples and 10 Negative Control samples resulting in 30 samples per control type (positive and negative control tubes) per lot on 10 different days for a total of 180 runs (90 Positive Control, 90 Negative Control). Samples were prepared according to the MDx-Chex® for BC-GP IFU and analyzed on the Luminex VERIGENE system per the IFU for the BC-GP panel. All MDx-Chex® for BC-GP Positive and Negative Control lots passed with >90% agreement with expected results.

Table 1: Reproducibility of MDx-Chex® for BC-GP Positive Control: Positive Percent Agreement

Category	Site #1		Site #2		Site #3		Percent Agreement (all sites combined)	95% Confidence Interval
	# Observed Results/ # Expected Results*	Positive Percent Agreement	# Observed Results/ # Expected Results*	Positive Percent Agreement	# Observed Results/ # Expected Results*	Positive Percent Agreement		
MDx-Chex® for BC-GP Positive Control	30/30	100%	30/30	100%	30/30	100%	100% (90/90)	96% - 100%

*Expected result for the Positive Control is Detected.

Table 2: Reproducibility of MDx-Chex® for BC-GP Negative Control: Negative Percent Agreement

Category	Site #1		Site #2		Site #3		Percent Agreement (all sites combined)	95% Confidence Interval
	# Observed Results/ # Expected Results*	Negative Percent Agreement	# Observed Results/ # Expected Results*	Negative Percent Agreement	# Observed Results/ # Expected Results*	Negative Percent Agreement		
MDx-Chex® for BC-GP Negative Control	30/30	100%	30/30	100%	30/30	100%	100% (90/90)	96% - 100%

*Expected result for the Negative Control is Not Detected.

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.
3. Luminex VERIGENE Gram-Positive Blood Culture Nucleic Acid Test (BC-GP) Package Insert – 89-30000-00-782 Rev. B.

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.

Rx Only

GLOSSARY OF SYMBOLS

IVD	LOT			
In Vitro Diagnostic Medical Device	Batch Code	Use By	Manufacturer	Do Not Re-use
REF				
Catalog Number	Temperature Limitation	Biological Risk	Consult Instructions For Use	

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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