

INSTRUCTIONS FOR USE

INTENDED USE

MDx-Chex® for BCN is intended for use as an external positive and negative assayed control to monitor the performance of the qualitative detection of Gram-negative bacteria and associated antimicrobial resistance genes, by the Diasorin LIAISON PLEX® Gram-Negative Blood Culture assay on the LIAISON PLEX System. MDx-Chex for BCN Control 1 and Control 2 are composed of a buffered solution with stabilized erythrocytes and leukocytes in a matrix of blood culture media components. Control 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. Control 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 with the device.

SUMMARY AND PRINCIPLES

Sepsis is the third leading cause of death in U.S. hospitals¹. 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 people². Timely diagnosis and administration of effective treatment can significantly reduce mortality, duration of hospital stays, and costs due to sepsis.

MDx-Chex for BCN is an external quality control containing stabilized blood and blood culture media components, and inactivated microorganisms (11 organisms and 7 species that can cause bloodstream infection, as well as 8 genes known to confer antimicrobial resistance) resulting in a full-process, cellular-based control that simulates positive and negative blood culture samples. Use of full-process cellular controls are necessary to evaluate the entire analytical process for sample-to-results tests, including sample lysis, nucleic acid isolation and purification, hybridization, detection, and analysis, as well as impact of inhibitors and pre-analytical 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 BCN contains stabilized human leukocytes and erythrocytes, and the following inactivated bacteria and bacteria components (see Table 1) in simulated blood culture media.

Catalog Number	Product Name	Application	Kit Configuration	Reagent Volume
250085	MDx-Chex for BCN	Routine QC	5 tubes of Control 1 pink-capped vials and 5 tubes of Control 2 black-capped vials	300µL per vial (sufficient volume for one test)
250088	MDx-Chex for BCN Verification Kit	Equipment installation, development of workflow processes, operator proficiency	10 tubes of Control 1 pink-capped vials and 10 tubes of Control 2 black-capped vials	300µL per vial (sufficient volume for one test)

PRECAUTIONS

- For In Vitro Diagnostic Use.
- 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.
- 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.
- This product should not be disposed of in general waste but should be disposed of with infectious medical waste. Disposal by incineration is recommended.
- This product is intended for use as supplied. Adulteration by dilution or addition of any materials to the tubes invalidates the use of the product.

STORAGE

MDx-Chex for BCN 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

Adding Sample

- Control samples must be processed in control mode per manufacturer's instructions.**
- If refrigerated, remove product from the refrigerator and allow to sit at room temperature to acclimate for 15 minutes before use.
Note: Always use aseptic technique when handling samples to prevent cross-contamination or environmental contamination.
- Immediately prior to use, vortex the sample for 30 seconds to mix.
Note: Verify the product has been adequately mixed by inverting the tube and examining the bottom for the absence of cellular material.
- Flash spin the sample to remove material from cap.

Table 1: MDx-Chex for BCN Control 1 and Control 2 Results Summary

Gram-Negative Bacteria		
Target	Control 1	Control 2
<i>Enterobacteriaceae/Morganellaceae</i>	Not Detected	Detected
<i>Acinetobacter</i> spp.	Detected	Not Detected
<i>Acinetobacter baumannii</i>	Detected	Not Detected
<i>Citrobacter</i> spp.	Not Detected	Detected
<i>Enterobacter</i> spp.	Not Detected	Detected
<i>Escherichia coli</i>	Not Detected	Detected
<i>Haemophilus influenzae</i>	Detected	Not Detected
<i>Klebsiella oxytoca</i>	Not Detected	Detected
<i>Klebsiella pneumoniae</i>	Not Detected	Detected
<i>Klebsiella variicola</i>	Not Detected	Detected
<i>Morganella morganii</i>	Not Detected	Detected
<i>Neisseria meningitidis</i>	Detected	Not Detected
<i>Proteus</i> spp.	Not Detected	Detected
<i>Pseudomonas</i> spp.	Detected	Not Detected
<i>Pseudomonas aeruginosa</i>	Detected	Not Detected
<i>Salmonella</i> spp.	Not Detected	Detected
<i>Serratia marcescens</i>	Not Detected	Detected
<i>Stenotrophomonas maltophilia</i>	Detected	Not Detected
Antimicrobial Resistance Genes		
Gene	Control 1	Control 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

- Mix the sample via pipet (or transfer pipet) by repeatedly pipetting up and down 5-10 times.
- Withdraw 300µL from the sample and process according to the LIAISON PLEX Gram-Negative Blood Culture Assay instructions for use.

LIMITATIONS

MDx-Chex for BCN 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).

PERFORMANCE CHARACTERISTICS

- Repeatability (precision)

Evaluation of repeatability (precision) of MDx-Chex for BCN was performed using three separately manufactured lots. Twenty samples per control type (Control 1 and Control 2) for 40 samples per lot were tested over 20 days for a total of 120 runs (60 Control 1, 60 Control 2). Samples were prepared according to the MDx-Chex for BCN IFU and analyzed on the Diasorin LIAISON PLEX system per the IFU for the BCN panel. All MDx-Chex for BCN Control 1 and Control 2 lots passed with >90% agreement with expected results.

Repeatability of MDx-Chex for BCN: Positive Percent Agreement

Category	#Observed Results/ #Expected Results *	Positive Percent Agreement	95% Confidence Interval	PPA ≥ 90% Acceptance
MDx-Chex for BCN (Control 1 and Control 2 Combined)	118/120**	98%	94%-100%	Pass

*Expected result for the positive targets in Control 1 and Control 2 is detected. Denominator = total number of expected positive results combined from MDx-Chex for BCN Control 1 and Control 2.

**One positive target in Control 1 and one positive target in Control 2 produced unexpected results.

Repeatability of MDx-Chex for BCN: Negative Percent Agreement

Category	#Observed Results/ #Expected Results *	Negative Percent Agreement	95% Confidence Interval	PPA ≥ 90% Acceptance
MDx-Chex for BCN (Control 1 and Control 2 Combined)	120/120	100%	97%-100%	Pass

*Expected result for the negative targets in Control 1 and Control 2 is not detected. Denominator = total number of expected negative results combined from MDx-Chex for BCN Control 1 and Control 2.

2. Reproducibility

Evaluation of reproducibility of MDx-Chex for BCN was performed using three separately manufactured lots. Testing was completed at three sites and consisted of 10 Control 1 samples and 10 Control 2 samples resulting in 30 samples per control type (Control 1 and Control 2) per lot on 10 different days for a total of 180 runs (90 Control 1 and 90 Control 2). Samples were prepared according to the MDx-Chex for BCN IFU and analyzed on the Diasorin LIAISON PLEX system per the IFU for the BCN panel. All MDx-Chex for BCN Control 1 and Control 2 lots passed with >90% agreement with expected results.

Reproducibility of MDx-Chex for BCN: 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 BCN (Control 1 and Control 2 combined)	58/60**	97%	60/60	100%	60/60	100%	99% (178/180 total runs)	96% - 100%

*Expected result for the positive targets in Control 1 and Control 2 is detected. Denominator = total number of expected positive results combined from MDx-Chex for BCN Control 1 and Control 2.

**One positive target in Control 1 and one positive target in Control 2 produced unexpected results.

Reproducibility of MDx-Chex for BCN: 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 BCN (Control 1 and Control 2 combined)	60/60	100%	60/60	100%	60/60	100%	100% (180/180 total runs)	98% - 100%

*Expected result for the negative targets in Control 1 and Control 2 is not detected. Denominator = total number of expected negative results combined from MDx-Chex for BCN Control 1 and Control 2.

REFERENCES

1. The Association of American Medical Colleges AAMC.org: <https://www.aamc.org/news/sepsis-third-leading-cause-death-us-hospitals-quick-action-can-save-lives>.
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.

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

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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