

INSTRUCTIONS FOR USE

INTENDED USE

MDx-Chex® for BCP 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 Diasorin LIAISON PLEX® Gram-Positive Blood Culture assay on the LIAISON PLEX System. The MDx-Chex BCP 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 anginosus* group, *Streptococcus pneumoniae*, *Streptococcus pyogenes*, *Enterococcus faecalis*, *Enterococcus faecium*; genus: *Bacillus* spp., *Listeria* spp., *Staphylococcus* spp., *Streptococcus* spp.; antimicrobial resistance genes: *mecA/mecC*, *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 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 BCP is an external quality control containing stabilized blood and blood culture media components, and inactivated microorganisms (9 organisms and 4 species that can cause bloodstream infection, as well as 3 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 BCP 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	Kit Configuration	Reagent Volume
250084	MDx-Chex for BCP	5 tubes of Positive Control violet-capped vials and 5 tubes of Negative Control white-capped vials	300µL per vial (sufficient volume for one test)
250087	MDx-Chex for BCP Verification Kit	10 tubes of Positive Control violet -capped vials and 10 tubes of Negative Control white-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 BCP 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.
- 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-Positive Blood Culture Assay instructions for use.

Table 1: MDx-Chex for BCP Positive Control and Negative Control Results Summary

Gram-Positive Bacteria		
Pathogen/Species	Positive Control	Negative Control
<i>Bacillus</i> spp.	Detected	Not Detected
<i>Listeria</i> spp.	Detected	Not Detected
<i>Staphylococcus</i> spp.	Detected	Not Detected
<i>Staphylococcus aureus</i>	Detected	Not Detected
<i>Staphylococcus epidermidis</i>	Detected	Not Detected
<i>Staphylococcus lugdunensis</i>	Detected	Not Detected
<i>Streptococcus</i> spp.	Detected	Not Detected
<i>Streptococcus agalactiae</i>	Detected	Not Detected
<i>Streptococcus anginosus</i> group	Detected	Not Detected
<i>Streptococcus pneumoniae</i>	Detected	Not Detected
<i>Streptococcus pyogenes</i>	Detected	Not Detected
<i>Enterococcus faecalis</i>	Detected	Not Detected
<i>Enterococcus faecium</i>	Detected	Not Detected
Antimicrobial Resistance Genes		
Gene	Positive Control	Negative Control
<i>mecA/mecC</i>	Detected	Not Reviewed
<i>vanA</i>	Detected	Not Reviewed
<i>vanB</i>	Detected	Not Reviewed

LIMITATIONS

MDx-Chex for BCP is to be used for the Diasorin Liaison Plex Gram-Positive Blood Culture Assay, on the Diasorin LIAISON PLEX 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 LIAISON PLEX Gram-Positive Blood Culture Assay, all organisms and resistance genes stated in the control should be "Detected," "Not Detected," or "Not Reviewed," as indicated (see Table 1).

PERFORMANCE CHARACTERISTICS

1. Repeatability (precision)

Evaluation of repeatability (precision) of MDx-Chex for BCP 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 BCP IFU and analyzed on the Diasorin LIAISON PLEX system per the IFU for the BCP panel. All MDx-Chex for BCP Positive and Negative Control lots passed with >90% agreement with expected results.

Repeatability of MDx-Chex for BCP Positive Control: Positive Percent Agreement

Category	#Observed Results/ #Expected Results *	Positive Percent Agreement	95% Confidence Interval	PPA ≥ 90% Acceptance
MDx-Chex for BCP Positive Control	59/60**	98%	91%-100%	Pass

*Expected result for the Positive Control is Detected.

**One Positive Control produced an unexpected result.

Repeatability of MDx-Chex for BCP Negative Control: Negative Percent Agreement

Category	#Observed Results/ #Expected Results*	Positive Percent Agreement	95% Confidence Interval	NPA ≥ 90% Acceptance
MDx-Chex for BCP Negative Control	60/60	100%	94%-100%	Pass

*Expected result for the Negative Control is Not Detected.

2. Reproducibility

Evaluation of reproducibility of MDx-Chex for BCP 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 BCP IFU and analyzed on the Diasorin LIAISON PLEX system per the IFU for the BCP panel. All MDx-Chex for BCP Positive and Negative Control lots passed with >90% agreement with expected results.

Reproducibility of MDx-Chex for BCP 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 BCP Positive Control	29/30**	97%	30/30	100%	30/30	100%	99% (89/90 total runs)	94% - 100%

*Expected result for the Positive Control is Detected.

**One Positive Control produced an unexpected result.

Reproducibility of MDx-Chex for BCP 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 BCP Negative Control	30/30	100%	29/30**	97%	29/30**	97%	98% (88/90 total runs)	92% - 100%

*Expected result for the Negative Control is Not Detected.

**Two Negative Controls produced unexpected results.

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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