

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

The MDx-Chex® for CT/NG/TV Positive and Negative Quality Control Kit is designed to support research, development, optimization, verification, and analytical performance assessment of laboratory assays targeting *Chlamydia trachomatis* (CT), *Neisseria gonorrhoeae* (NG), and *Trichomonas vaginalis* (TV).

The Positive Control contains material formulated to simulate specimens with detectable CT, NG, and/or TV nucleic acid targets. The Negative Control contains material that does not include these targets and is used to confirm assay specificity and evaluate potential cross-reactivity or contamination within a workflow.

These controls may be used to assess assay workflow consistency, monitor reagent or instrument performance, support method development or analytical studies, and evaluate assay robustness, inclusivity/exclusivity, or contamination control within a laboratory environment.

SUMMARY AND PRINCIPLES

Sexually Transmitted Infections (STIs) represent a major global health challenge, with over 1 million curable infections acquired daily worldwide among individuals aged 15-49. These infections include bacterial, viral, and parasitic pathogens transmitted primarily through sexual contact.¹

STIs can lead to severe complications such as pelvic inflammatory disease, infertility, ectopic pregnancy, congenital deformities, and increased HIV susceptibility. Mother-to-child transmission can result in stillbirth, neonatal death, and other adverse outcomes. Many infections remain asymptomatic, complicating detection and control efforts.¹

MDx-Chex for CT/NG/TV is an external quality control containing stabilized cells in a patient-like matrix and inactivated microorganisms that can cause sexually transmitted infection, resulting in a full-process, cellular-based control that simulates positive and negative STI culture samples. Use of full-process cellular controls is necessary to evaluate the entire analytical process for sample-to-results tests, including sample lysis, nucleic acid isolation and purification, amplification/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 CT/NG/TV contains stabilized human blood and cellular components, and the following inactivated microorganisms (see Table 1). Each control kit is supplied with 5 black capped 2mL microtubes, each containing 1mL of the Positive Control formulation, and 5 white capped 2mL microtubes, each containing 1mL of the Negative Control formulation.

PRECAUTIONS

- MDx-Chex for CT/NG/TV is for Research Use Only. Not for use in diagnostic procedures
- 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 CT/NG/TV 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 Control Sample**

- Control samples must be processed in control mode per manufacturer's instructions or when given as an option for sample-to-results tests.**
- 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 the required volume of sample and process according to the manufacturer's instructions for sample-to-results tests.

LIMITATIONS

MDx-Chex for CT/NG/TV 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" or "Not Detected," as indicated (see Table 1).

Table 1: MDx-Chex for CT/NG/TV Positive Control and Negative Control Results Summary

Gram-Negative Bacteria		
Target	Positive Control	Negative Control
<i>Neisseria gonorrhoeae</i>	Detected	Not Detected
<i>Chlamydia Trachomatis</i>	Detected	Not Detected
Parasites		
Target	Positive Control	Negative Control
<i>Trichomonas vaginalis</i>	Detected	Not Detected

REFERENCES

- World Health Organization: [https://www.who.int/news-room/fact-sheets/detail/sexually-transmitted-infections-\(stis\)](https://www.who.int/news-room/fact-sheets/detail/sexually-transmitted-infections-(stis))

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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