MDx-Chex® for RSP

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 RSP Positive and Negative Quality Control Kit is designed to support research, development, optimization, verification, and analytical performance assessment of laboratory assays targeting Adenovirus (A / B / C / D / E / F), *Bordetella holmesii, Bordetella parapertussis*, *Bordetella pertussis*, *Chlamydia pneumoniae*, SARS-CoV-2, Coronavirus (HKU1 / 229E / NL63 / OC43), Enterovirus/Rhinovirus, Influenza A (subtype H1), Influenza A (subtype H3), Influenza A, Influenza B, Human Metapneumovirus, *Mycoplasma pneumoniae*, Parainfluenza 1, Parainfluenza 2, Parainfluenza 3, Parainfluenza 4, and Respiratory Syncytial Virus (RSV A and RSV B).

The Positive Control contains material formulated to detect RSP 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

Respiratory infections pose a significant global health burden, affecting millions of individuals annually. Respiratory multiplex molecular panels are essential diagnostic tools that detect multiple respiratory pathogens, including viruses and bacteria, in a single test. These panels enable rapid and accurate identification of infections such as Influenza, Respiratory Syncytial Virus (RSV), and various coronaviruses as examples. Early and precise diagnosis is crucial for effective patient management, reducing the spread of infections, and guiding appropriate treatment strategies. The use of molecular panels can also help in monitoring outbreaks and informing public health interventions. As respiratory infections can lead to severe complications, including pneumonia, bronchitis, and exacerbation of chronic respiratory conditions, timely diagnosis and intervention are vital for improving patient outcomes and preventing further transmission.

MDx-Chex for RSP is an external quality control containing stabilized human erythrocytes, lung epithelial cells, and inactivated microorganisms that can cause respiratory infections in a simulated patient matrix, resulting in a full-process, cellular-based control that simulates positive and negative respiratory specimens/samples. Use of full-process cellular controls is necessary to evaluate the entire analytical process for sample-to-result tests, including sample lysis, nucleic acid isolation and purification, amplification/hybridization, detection, and analysis, as well as impacts 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 RSP contains stabilized human erythrocytes and lung epithelial cells, and the following bacterial and viral targets (see Table 1) in a simulated patient matrix. Each control kit is supplied with 5 blue capped 0.5mL microtubes, each containing 0.3mL of the Positive Control formulation, and 5 white capped 0.5mL microtubes, each containing 0.3mL of the Negative Control formulation.

PRECAUTIONS

1. MDx-Chex for RSP 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. This product should not be disposed of in general waste but should be disposed of 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 tubes invalidates the use of the product.

STORAGE

MDx-Chex for RSP 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

1. **Control samples must be processed in control mode per manufacturer's instructions or when given as an option for sample-to-result tests.**
2. 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.
3. 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.
4. Flash spin the sample to remove material from cap.
5. Mix the sample via pipet (or transfer pipet) by repeatedly pipetting up and down 5-10 times.
6. Withdraw the required volume of sample and process according to the manufacturer's instructions for sample-to-result tests.

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

Control Kit Targets		
Target	**Positive Control**	**Negative Control**
Adenovirus (A / B / C / D / E / F)	Detected	Not Detected
Bordetella holmesii	Detected	Not Detected
Bordetella parapertussis	Detected	Not Detected
Bordetella pertussis	Detected	Not Detected
Chlamydia pneumoniae	Detected	Not Detected
SARS-CoV-2	Detected	Not Detected
Coronavirus (HKU1 / 229E / NL63 / OC43)	Detected	Not Detected
Enterovirus/Rhinovirus	Detected	Not Detected
Influenza A (subtype H1)	Detected	Not Detected
Influenza A (subtype H3)	Detected	Not Detected
Influenza A	Detected	Not Detected
Influenza B	Detected	Not Detected
Human Metapneumovirus	Detected	Not Detected
Mycoplasma pneumoniae	Detected	Not Detected
Parainfluenza 1	Detected	Not Detected
Parainfluenza 2	Detected	Not Detected
Parainfluenza 3	Detected	Not Detected
Parainfluenza 4	Detected	Not Detected
Respiratory Syncytial Virus (RSV A and RSV B)	Detected	Not Detected

LIMITATIONS

MDx-Chex for RSP should be used in accordance with local, state, federal regulations, and accreditation requirements.

EXPECTED RESULTS

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

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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