

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 RP Positive and Negative Quality Control Kit is designed to support research, development, optimization, verification, and analytical performance assessment of laboratory assays targeting Adenovirus, Coronavirus 229E, Coronavirus HKU1, Coronavirus NL63, Coronavirus OC43, Human Metapneumovirus, Human Rhinovirus/Enterovirus, Influenza A, Influenza A/H1, Influenza A/H1-2009, Influenza A/H3, Influenza B, Parainfluenza Virus 1, Parainfluenza Virus 2, Parainfluenza Virus 3, Parainfluenza Virus 4, Respiratory Syncytial Virus (RSV), *Bordetella parapertussis*, *Bordetella pertussis*, *Chlamydia pneumoniae*, *Mycoplasma pneumoniae*, SARS-CoV-2, *Streptococcus dysgalactiae* (Group C/G Strep), *Streptococcus pyogenes* (Group A Strep).

The Positive Control contains material formulated to simulate specimens with detectable 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 high-plex 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, 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 RP is an external quality control containing human erythrocytes, lung epithelial cells, and inactivated microorganisms that can cause respiratory infections, resulting in a full-process, cellular-based control that simulates positive and negative respiratory culture 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 RP contains stabilized human erythrocytes and lung epithelial cells, and the following bacterial and viral targets (see Table 1) in simulated patient-like media.

Catalog Number	Product Name	Configuration	Reagent Volume
250101	MDx-Chex for RP	5 tubes of blue-capped Positive Control, 5 tubes of white-capped Negative Control	300µL per vial (sufficient volume for one test)

PRECAUTIONS

- MDx-Chex for RP 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 RP 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**

- If refrigerated, remove tubes of control from the refrigerator and allow to sit at room temperature to acclimate for 15 minutes before use. Vortex the Positive Control tube at a high speed for 30 seconds. **Note: Always use aseptic technique when handling control tubes to prevent cross-contamination or environmental contamination.**
 - Verify the control tube has been adequately mixed by inverting the tube and examining the bottom for the absence of cellular material.
 - Flash spin the Control to remove material from cap.
 - Open the tube and mix the control sample via pipet by repeatedly pipetting up and down 5-10 times.
- Remove the required volume of sample and process according to the manufacturer's instructions for sample-to-result tests.
 - Each control tube has sufficient volume for one test and can be discarded after use.

- Samples should be processed in control mode when given as an option for sample-to-result systems.
- Repeat Steps 1-4 for Negative Control.

LIMITATIONS

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

EXPECTED RESULTS

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

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

Control Kit Targets		
Target	Positive Control	Negative Control
Adenovirus	Detected	Not Detected
Coronavirus (Seasonal): HKU1, NL63, OC43, 229E	Detected	Not Detected
Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2)	Detected	Not Detected
Human Metapneumovirus	Detected	Not Detected
Human Rhinovirus/Enterovirus	Detected	Not Detected
Influenza A	Detected	Not Detected
Influenza A H1-2009	Detected	Not Detected
Influenza A H3	Detected	Not Detected
Influenza B	Detected	Not Detected
Parainfluenza Virus 1	Detected	Not Detected
Parainfluenza Virus 2	Detected	Not Detected
Parainfluenza Virus 3	Detected	Not Detected
Parainfluenza Virus 4	Detected	Not Detected
Respiratory Syncytial Virus	Detected	Not Detected
Bacteria		
<i>Bordetella parapertussis</i> (IS1001)	Detected	Not Detected
<i>Bordetella pertussis</i> (ptxP)	Detected	Not Detected
<i>Chlamydia pneumoniae</i>	Detected	Not Detected
<i>Mycoplasma pneumoniae</i>	Detected	Not Detected
<i>Streptococcus dysgalactiae</i> (Group C/G Strep)	Detected	Not Detected
<i>Streptococcus pyogenes</i> (Group A Strep)	Detected	Not Detected

Note: Different instrumentation and assays use different language. Streck verbiage of Detected and Not Detected should be considered synonymous with Positive and Negative or Yes and No, respectively.

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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