RSV + hMPV Assay

Frequently Asked Questions

General

How can I cut down on the chances of contamination in the lab?
Our assays are very sensitive and each lab needs to take all precautions to avoid carry-over and residual contamination. Be sure to clean well with 10% bleach, use UV light, work in a uni-directional manner, change tips between each sample, use barrier tips and change gloves often.

What is the precision of the Lyra RSV + hMPV Assay?
The reproducibility of the Lyra RSV + hMPV Assay was evaluated at three laboratory sites. The panels and controls that were extracted using the bioMerieux easyMAG system and tested on Cepheid SmartCycler® II and ABI® 7500 Fast Dx were found to be reproducible. Additional information regarding the performance characteristics for the reproducibility study can be found in the Lyra RSV + hMPV Assay Package Insert.

How accurate is the Lyra RSV + hMPV Assay?
In a recent clinical study using ABI 7500 Fast Dx, the sensitivity with fresh and frozen nasal/nasopharyngeal swab samples was approximately 99% for RSV and the positive percent agreement was 98% for hMPV. The specificity was approximately 97% for RSV and the negative percent agreement 99% for hMPV. These results were in comparison with a DSFA and Cell Culture with DFA for RSV and a FDA-cleared Molecular test for hMPV. Additional clinical performance characteristics can be found in the Lyra RSV + hMPV Assay Package Insert.

What is the limit of detection (LOD) for RSV and hMPV using this kit?
The LOD varies by strain but is generally in the range of 0.6 to 2 $TCID_{50}$/mL for RSV and 1 to 26 $TCID_{50}$/mL for hMPV.

Refer to our website at quidel.com for additional performance claims.

Is the Lyra RSV + hMPV Assay FDA cleared?
Yes. It has been 510k-cleared.

What are the targets for the Lyra RSV + hMPV Assay?
They are conserved regions of the RSV and hMPV genomes.

What detection technology does Quidel use?

The Lyra RSV + hMPV Assay is based on TaqMan® chemistry, and uses an enzyme with reverse transcriptase, DNA polymerase, and 5'-3' exonuclease activities.

Specimen Collection, Storage and Handling

What sample types can I use with the Lyra RSV + hMPV Assay?

Each Package Insert describes the sample types that were used in validation of the product. The RSV + hMPV Assay can be used for nasal swabs and nasopharyngeal swab specimens.

Can the Eswab be used with the Lyra RSV + hMPV Assay?

The Eswab is a bacterial collection swab and should not be used for collection of samples for viral detection.

What types of transport media are acceptable for use with the Lyra RSV + hMPV Assay?

Quidel has validated the following media types for use with the Lyra RSV + hMPV Assay: Universal Transport Media (UTM), M4, M4-RT, M5 and M6. Any other media types not listed here have not been validated and validation would be the responsibility of the end user**.**

How should specimens be handled and stored prior to the extraction process?

Specimens should be transported refrigerated at 2°C to 8°C and stored refrigerated (2°C to 8°C) for up to 72 hours before processing**.** Any additional leftover specimen should be stored at ≤–70°C.

What are the storage conditions for specimen eluates?

The user is responsible for validation of the storage procedures and conditions used in their own laboratory. Eluates can be stored at room temperature (20°C to 25°C) for up to 4 hours, at 2°C to 8°C for 6 hours, and 1 month at –20°C. The extracted RNA is stable for up to 3 freeze thaw cycles when stored at –20°C.

Kit Formats

What kit formats are available and what does the kit include?

The kit comes in one format which allows you to run as few as 3 (1 patient, 2 controls) but up to 96 reactions. The kit includes:

Rehydration Solution – 1 vial/kit 1.9 mL
Lyra RSV + hMPV Master Mix – 12 vials/kit, 8 reactions/vial
Process Control – 1 vial/kit 2.0 mL

Kit Storage

What are the storage conditions for the kit and reconstituted components?

The kit is stored at 2°C to 8°C until expiration; the rehydrated Master Mix can be stored at room temperature for up to 24 hours or at 2°C to 8°C or ≤–20°C for up to 2 days. The rehydrated Master Mix should be recapped, sealed with parafilm, and stored in an upright position. **Protect the Master Mix from light during storage.**

What is the shelf life of the kit?
The kit shelf life is 24 months from the date of manufacture.

Master Mix

Which enzyme is used in the Master Mix?
The master mix is a proprietary mix with excipients chosen to enhance shelf life.

Quality Control (External Control)

What is Quidel's quality control recommendation for these tests?
Quidel recommends that each thermocycler run includes a reaction tube or well for an extracted RSV + hMPV External Positive control (i.e., Quidel Molecular RSV + hMPV Control Set #M107 or previously characterized positive RSV or hMPV specimen) and Negative Control (this can be transport media or a previously identified negative sample). Controls should be run and interpreted in accordance with your lab practices and policies.

I would like to run Limits of Detection. Are your controls quantified?
No. The controls are provided in a qualitative format. Quantification of controls is the responsibility of the end user.

How many tests can be performed with the RSV + hMPV Control Set #M107 when used with the Lyra RSV + hMPV Assay?
There is enough material in the control set for approximately 10 runs.

Process Control (PRC)

What is the PRC in the kit?
The RNA bacteriophage MS2.

What is the concentration of the PRC?
That is proprietary information.

Can I use a process control (internal control) other than what is provided in the kit?
No. We do not recommend deviating from the Package Insert.

Can a sample extracted with another manufacturer's process control be used in your assays?
No. The sample must have Quidel's PRC in it, therefore, you should not use a sample extracted using another kit (another MS2 could have a different concentration).

Can I add the PRC to the Master Mix instead of adding it to the samples prior to extraction?
No. We do not recommend deviating from the Package Insert. The PRC acts as a control for the extraction process as well.

How long can I leave my sample and the PRC mixed together before adding it to the easyMAG?
The samples should be processed on the easyMAG as soon as possible after mixing the PRC and sample. The Package Insert does not state that it is acceptable to allow samples to sit after they are mixed.

My PRC did not show up. What should I do?
If the specimen is positive, the PRC does not need to be detected for the specimen to be called a positive. If the specimen is negative and the PRC is not detected, it is considered an invalid result.

Reagents

My kit was placed in the freezer (–20°C or –80°C) upon arrival can I still use it?
It is recommended that the kit not be used. The proper storage conditions of the kit are 2°C to 8°C.

Can I purchase the reagents individually?
The reagents are produced in a kit format. Individual reagents are not available for purchase. If a vial is damaged upon receipt, please contact Quidel Technical Support for replacement arrangements.

Extraction

What extraction system can I use to run this assay?
The bioMérieux NucliSENS easyMAG is the only extraction system that has been validated for this assay.

How long does it take to extract the nucleic acid on the bioMérieux NucliSENS easyMAG?
The extraction time is dependent on the number of samples. A full 24 samples would take approximately 40 minutes.

Thermocycler

What thermocycler can I use to run this assay?
The Applied Biosystems® 7500 Fast Dx, Life Technologies QuantStudio™ Dx and the Cepheid SmartCycler® II have been validated for this assay. Use of other PCR systems is under investigation. Contact Quidel for a list of upcoming thermocycler validations.

Which 7500 Fast Dx software version is compatible with the templates provided?
SDS version 1.4. The template cannot be used with other software versions.

Which SmartCycler II software version is compatible with the templates provided?
SmartCyclerII Dx 3.0b.

Does the 7500 Fast Dx, QuantStudio Dx or SmartCycler II need to be calibrated in a certain manner to perform appropriately with the dye sets used in the assay?
The user should ensure that the following dyes were calibrated during regular maintenance: FAM, Texas Red, and CY5.

Can you send me the supplemental instructions for the thermocyclers?
The 7500 Fast Dx, QuantStudio Dx and SmartCycler II are incorporated into the Package Insert which is available on our website.

On the SmartCycler II what does it mean when my channel result says Fail, Pass, NA or ND?
For interpretation of the results on the SmartCycler, refer to the Lyra RSV + hMPV Assay Package Insert.

What is the approximate test time for the thermocyclers?
The 7500 Fast Dx, QuantStudio Dx and SmartCycler II take approximately 70-75 minutes.

Reporting

Can I use the results if I forgot to centrifuge my plate/tubes?
Failure to centrifuge the plate/tube is a major deviation from the PI. It is recommended the run be repeated.

What does the amplification curve tell me?
In general it allows you to visualize the PCR reaction. If the amplification of DNA crosses over the specified threshold during the appropriate cycling time, then the sample is positive for that virus.

What do I do if I get an invalid result for the positive control?
We suggest that the run be repeated. Controls should be run and interpreted in accordance with your lab practices and policies.

What can cause a false positive with a negative control?
This could be caused by contamination from the target virus. Controls should be run and interpreted in accordance with your lab practices and policies.

What can cause a false positive with a patient sample?
This could be caused by a cross contamination from another sample.

What can cause a false negative with a patient sample?
Some suggested causes are the presence of sequence variants in the viral target, improper collection, storage, or transport of the specimen, inhibitors present in the specimen or not following the assay procedure correctly.

Additional Information

Does the Lyra RSV + hMPV Assay detect both hMPV subtypes A and B?
The Lyra RSV + hMPV Assay has been shown to detect both subtypes, but will not differentiate between the hMPV A and hMPV B.

Does the Lyra RSV + hMPV Assay detect both RSV subtypes A and B?
The Lyra RSV + hMPV Assay has been shown to detect both subtypes and various strains, but will not differentiate between the RSV-A and RSV-B or strains.

Where can I find up-to-date news and information on human Metapneumovirus and Respiratory Syncytial Virus?
The World Health Organization (WHO) and the Centers for Disease Control and Prevention (CDC) post information on their websites:
http://www.who.int/en/ and http://www.cdc.gov