Parainfluenza Virus Assay

Frequently Asked Questions

General

Do you have a proficiency recommendation to validate the Lyra Parainfluenza Virus Assay?
Check with your Local and State regulation for proficiency requirements. If you are using the CAP proficiency, ID-1 Virus survey is for nucleic acid testing of viruses and the VR1 survey is for Virus Culture. Both of these surveys have been tested with this assay and performed satisfactorily. However, the only survey that reports results by molecular method is the ID-1.

What is the CMS suggested CPT code and National Limit amount for the Lyra Parainfluenza Virus Assay?
The suggested CPT code is 87631* – Respiratory Virus (e.g., Adenovirus, Influenza Virus, Coronavirus, Metapneumovirus, Parainfluenza Virus, Respiratory Syncytial Virus, Rhinovirus) multiplex reverse transcription and amplified probe technique, multiple types or subtypes, 3-5 targets. For the current Medicare National Limit amount** click here. For additional reimbursement information and support, please visit our website at **quidel.com** or contact Quidel directly at **800.874.1517 Option 2**, or via e-mail at technicalsupport@quidel.com.

Is the Lyra Parainfluenza Virus Assay FDA cleared?
Yes. It has been FDA cleared. K141927.

I would like to run Limits of Detection. Are your controls quantified?
No. Quidel Molecular Control Sets are unassayed controls. Quantification of controls is the responsibility of the end user.

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**.**

What thermocycler can I use to run this assay?
The Applied Biosystems® (ABI) 7500 Fast Dx is the only thermocycler that has been validated for this assay. Use of other PCR systems are under investigation. Contact Quidel for a list of upcoming thermocycler validations.

Does the ABI 7500 Fast Dx 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, JOE, Texas Red, and CY5.

What is the approximate test time for the thermocycler?
The ABI 7500 Fast Dx takes approximately 70-75 minutes.

When using the ABI 7500 Fast Dx, I had very weak or no amplification of any of my targets. What should I do?
Ensure that the passive reference dye was changed to "none," as it states on page 8 in the Package Insert. If the reference dye is still set to ROX, then this is likely the cause of the weak amplification. This change can be made after the run is complete so the run does not have to be repeated. Change the reference dye to "none" on the template to enable all future runs to be analyzed properly.

What is the shelf life of the kit?
The kit shelf life is 12 months from the date of manufacture. Actual expiration date of product shipped will vary depending on lot availability.

If my kit was placed in a freezer upon arrival, can I still use it?
It is recommended that the kit not be used. The proper storage condition of the unopened kit is 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 at **800.874.1517 Option 2,** or via e-mail at technicalsupport@quidel.com for replacement arrangements.

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

How many tests can be performed with the Lyra Parainfluenza Virus Control Set #M115 when used with the Lyra Parainfluenza Virus Assay?
There is enough material in the control set for approximately 10 runs.

What is the PRC and what is its concentration in the kit?
The internal process control is MS2 Bacteriophage. The concentration is proprietary.

Can I use a process control (internal control) other than what is provided in the kit?
Using another process control would be a major deviation from the Package Insert and we would not recommend it.

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.

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.

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 target DNA.

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

What is the target for the Lyra Parainfluenza Virus Assay?
The PCR primers are developed to bind to the Parainfluenza Type 1 nuclear protein gene, Parainfluenza Type 2 phosphate protein gene, and Parainfluenza Type 3 phosphate protein gene.

Frequently Asked Questions

What is the sensitivity/specificity of the Lyra Parainfluenza Virus Assay?
Performance characteristics of the Lyra Parainfluenza Virus Assay extracted by bioMérieux NucliSENS easyMag System and run on the ABI 7500 Fast Dx were established at three sites across the United States. A description of this trial and the results can be found on pages 14-16 of the Lyra Parainfluenza Virus Assay Package Insert:
https://www.quidel.com/molecular-diagnostics/lyra-parainfluenza-virus-assay

What is the precision of the Lyra Parainfluenza Virus Assay?
The precision of the Lyra Parainfluenza Virus Assay was demonstrated in a separate study. Data for this study can be found on pages 17 and 18 of the Lyra Parainfluenza Virus Assay Package Insert: https://www.quidel.com/molecular-diagnostics/lyra-parainfluenza-virus-assay

What is the limit of detection (LOD) for Parainfluenza Virus using this kit?
The analytical LOD of the Lyra Parainfluenza Virus Assay was demonstrated with Parainfluenza Virus types 1, 2, and 3. Data for these types can be found on page 16 of the Lyra Parainfluenza Virus Assay Package Insert:
https://www.quidel.com/molecular-diagnostics/lyra-parainfluenza-virus-assay

What detection technology does the Lyra Parainfluenza Virus Assay use?
The Lyra Parainfluenza Virus Assay is a real-time polymerase chain reaction (PCR) *in vitro* diagnostic test based on TaqMan® chemistry. An expanded description of the principle of Lyra Parainfluenza Virus Assay can be found on page 3 of the Lyra Parainfluenza Virus Assay Package Insert:
https://www.quidel.com/molecular-diagnostics/lyra-parainfluenza-virus-assay

What does the Lyra Parainfluenza Virus Assay kit contain?
The materials provided in each kit are listed on page 3 of the Lyra Parainfluenza Virus Assay Package Insert:

What sample types can I use with the Lyra Parainfluenza Virus Assay?
How should specimens be handled and stored prior to the extraction process?

What media is acceptable to be used with the assay?
The specimen collection, storage, and handling requirements for the Lyra Parainfluenza Virus Assay can be found on page 5 of the Lyra Parainfluenza Virus Assay Package Insert:
https://www.quidel.com/molecular-diagnostics/lyra-parainfluenza-virus-assay

Can I use the results if I forgot to centrifuge my plate?
The PCR Set-Up Procedure is described on page 12 of the Lyra Parainfluenza Virus Assay Package Insert:
https://www.quidel.com/molecular-diagnostics/lyra-parainfluenza-virus-assay
Failure to follow this protocol invalidates the test result.

What are the storage conditions for nucleic acid extracts?
The user is responsible for validation of the storage procedures and conditions used in their own laboratory. Nucleic acid extract storage guidelines can be found on page 5 of the Lyra Parainfluenza Virus Assay Package Insert:
https://www.quidel.com/molecular-diagnostics/lyra-parainfluenza-virus-assay

What are the storage conditions for the kit and the components?
The storage conditions for the Lyra Parainfluenza Virus Assay kit and components can be found on page 5 of the Lyra Parainfluenza Virus Assay kit Package Insert:
https://www.quidel.com/molecular-diagnostics/lyra-parainfluenza-virus-assay

What is Quidel's quality control recommendation for these tests?
Quidel's quality control recommendations are provided on page 13 of the Lyra Parainfluenza Virus Assay Package Insert:
https://www.quidel.com/molecular-diagnostics/lyra-parainfluenza-virus-assay

Does Quidel provide an external quality control for the Lyra Parainfluenza Virus Assay?
The Lyra Parainfluenza Virus Assay does not include an External Control as part of the kit. A suggested External Control is listed on page 4 of the Lyra Parainfluenza Virus Assay kit Package Insert:
https://www.quidel.com/molecular-diagnostics/lyra-parainfluenza-virus-assay
A full description of External Control use is provided on page 13 of the Lyra Parainfluenza Virus Assay Package Insert:
https://www.quidel.com/molecular-diagnostics/lyra-parainfluenza-virus-assay

What do I do if I get a negative result for the Positive Control or an invalid result for the Negative Control?
A full description of External Control use is provided on page 13 of the Lyra Parainfluenza Virus Assay Package Insert:
https://www.quidel.com/molecular-diagnostics/lyra-parainfluenza-virus-assay

What should I do if my PRC does not show up?
An interpretation table of results is provided on page 13 of the Lyra Parainfluenza Virus Assay Package Insert:
https://www.quidel.com/molecular-diagnostics/lyra-parainfluenza-virus-assay

Can you send me the supplemental instructions for the thermocycler?
The ABI 7500 Fast Dx instructions are incorporated starting on page 7 in the Lyra Parainfluenza Virus Assay Package Insert:
https://www.quidel.com/molecular-diagnostics/lyra-parainfluenza-virus-assay

Which software versions have been validated for the bioMérieux NucliSENS easyMAG and ABI 7500 Fast Dx instruments?
The software versions that have been validated are listed on pages 4 and 8 of the Lyra Parainfluenza Virus Assay Package Insert:
https://www.quidel.com/molecular-diagnostics/lyra-parainfluenza-virus-assay
Please contact Quidel Technical Support prior to modifying or upgrading beyond these versions of software.

What can cause a false positive with a Negative Control or patient sample?
A list of warnings and precautions are provided on page 4 of the Lyra Parainfluenza Virus Assay Package Insert:
https://www.quidel.com/molecular-diagnostics/lyra-parainfluenza-virus-assay

This list covers many of the identified causes of false positive results seen with many molecular test systems.

What can cause a false negative with a Positive control or patient sample?
A list of warnings and precautions are provided on page 13 of the Lyra Parainfluenza Virus Assay Package Insert:
https://www.quidel.com/molecular-diagnostics/lyra-parainfluenza-virus-assay

This list covers many of the identified causes of false negative results seen with many molecular test systems.

Refer to the Package Insert on our website at **quidel.com** for additional performance claims.

Customer support and technical assistance information is provided on page 20 of the Lyra Parainfluenza virus Assay Package Insert:
https://www.quidel.com/molecular-diagnostics/lyra-parainfluenza-virus-assay

*This information is being provided as a reference, for informational purposes only, with no express or implied warranty and does not purport to provide legal or certified coding advice. **Under Federal and State law, it is the individual provider's responsibility to determine appropriate coding, charges and claims for a particular service.** Policies regarding appropriate coding and payment levels can vary greatly from payer to payer and change over time. Quidel Corporation strongly recommends that providers contact their contracted payers to determine appropriate coding and charge or payment levels prior to submitting claims.

**For state by state fee schedule go to www.cms.gov.

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