Influenza A+B Assay

Frequently Asked Questions

General

Do you have a proficiency recommendation to validate the Lyra Influenza A+B 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. If you are using API proficiency you may use Virology package 322.

What are the CMS suggested CPT codes and National Limit amounts for the Lyra Influenza A+B Assay?
The suggested CPT code is 87502.* The 2015 Medicare National Limit amount** is $115.80. For 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 Influenza A+B Assay FDA cleared?
Yes. It has been 510k-cleared. K131728.

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® 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.

Does the 7500 Fast Dx, SmartCycler II, or QuantStudio 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 dyes used for testing with each thermocycler were calibrated during regular maintenance.

What is the approximate test time for the thermocyclers?
The cycling program takes approximately 70-75 minutes.

When using the 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 24 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 Quidel Molecular Influenza A+B Control Set (Cat. #M106) when used with the Lyra Influenza A+B Assay?
There is enough material in the control set for approximately 10 runs.

What do I do if I get a negative result for the Positive Control or an invalid result for the Negative Control?
We suggest that the run be repeated. Controls should be run and interpreted in accordance with your lab practices and policies.

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.

What are the targets for the Lyra Influenza A+B Assay?
The conserved regions of the Influenza A matrix protein gene and Influenza B neuraminidase gene.

Where can I find up-to-date news and information on Influenza A+B?
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/

Frequently Asked Questions

What is the sensitivity/specificity of the Lyra Influenza A+B Assay?
Performance characteristics of the Lyra Influenza A+B Assay extracted by bioMérieux NucliSENS easyMag System and run on each of the three thermocyclers were verified by testing with a comparator method (FDA-cleared Influenza A and B molecular test). A description of this trial and the results can be found on pages 18-23 of the Lyra Influenza A+B Assay Package Insert:
http://www.quidel.com/sites/quidel.com/files/product/documents/m100en_lyra_influenza_a%2Bb_pi.pdf

What is the precision of the Lyra Influenza A+B Assay?
The precision of the Lyra Influenza A+B Assay was demonstrated in a separate study. Data for this study can be found on pages 26-29 of the Lyra Influenza A+B Assay Package Insert:
http://www.quidel.com/sites/quidel.com/files/product/documents/m100en_lyra_influenza_a%2Bb_pi.pdf

What is the limit of detection (LOD) for Influenza A+B using this kit?
The analytical LOD of the Lyra Influenza A+B Assay was determined using quntified cultures of five influenza A strains and three Influenza B strains, serially diluted in negative nasopharyngeal matrix. Data can be found on pages 23-24 of the Lyra Influenza A+B Assay Package Insert:
http://www.quidel.com/sites/quidel.com/files/product/documents/m100en_lyra_influenza_a%2Bb_pi.pdf

What detection technology does the Lyra Influenza A+B Assay use?
The Lyra Influenza A+B 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 Influenza A+B Assay can be found on pages 2 and 3 of the Lyra Influenza A+B Assay Package Insert:
http://www.quidel.com/sites/quidel.com/files/product/documents/m100en_lyra_influenza_a%2Bb_pi.pdf

What does the Lyra Influenza A+B Assay kit contain?
The materials provided in each kit are listed on page 4 of the Lyra Influenza A+B Assay Package Insert:
http://www.quidel.com/sites/quidel.com/files/product/documents/m100en_lyra_influenza_a%2Bb_pi.pdf

What sample types can I use with the Lyra Influenza A+B 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 Influenza A+B Assay can be found on page 5 of the Lyra Influenza A+B Assay Package Insert:
http://www.quidel.com/sites/quidel.com/files/product/documents/m100en_lyra_influenza_a%2Bb_pi.pdf

Can I use the results if I forgot to centrifuge my plate or reaction tubes?
The PCR Set-up Procedure is described on page 14 of the Lyra Influenza A+B Assay Package Insert:
http://www.quidel.com/sites/quidel.com/files/product/documents/m100en_lyra_influenza_a%2Bb_pi.pdf

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 Influenza A+B Assay Package Insert:
http://www.quidel.com/sites/quidel.com/files/product/documents/m100en_lyra_influenza_a%2Bb_pi.pdf

What are the storage conditions for the kit and the components?
The storage conditions for the Lyra Influenza A+B Assay kit and components can be found on page 5 of the Lyra Influenza A+B Assay kit Package Insert:
http://www.quidel.com/sites/quidel.com/files/product/documents/m100en_lyra_influenza_a%2Bb_pi.pdf

What is Quidel's quality control recommendation for this assay?
Quidel's quality control recommendations are provided on page 17 of the Lyra Influenza A+B Assay Package Insert:
http://www.quidel.com/sites/quidel.com/files/product/documents/m100en_lyra_influenza_a%2Bb_pi.pdf

Does Quidel provide an external quality control for the Lyra Influenza A+B Assay?
The Lyra Influenza A+B Assay does not include an external control as part of the kit. A suggested external control is listed on page 4 of the Lyra Influenza A+B Assay kit Package Insert:
http://www.quidel.com/sites/quidel.com/files/product/documents/m100en_lyra_influenza_a%2Bb_pi.pdf

What should I do if my PRC does not show up?
An interpretation table of results is provided on pages 16-17 of the Lyra Influenza A+B Assay Package Insert:
http://www.quidel.com/sites/quidel.com/files/product/documents/m100en_lyra_influenza_a%2Bb_pi.pdf

Can you send me the supplemental instructions for the thermocyclers?
The thermocycler instructions are incorporated starting on page 8 in the Lyra Influenza A+B Assay Package Insert:
http://www.quidel.com/sites/quidel.com/files/product/documents/m100en_lyra_influenza_a%2Bb_pi.pdf

Which software versions have been validated for the bioMérieux NucliSENS easyMAG and for the thermocycler instruments?
The software versions that have been validated are listed on page 4 of the Lyra Influenza A+B Assay Package Insert:
http://www.quidel.com/sites/quidel.com/files/product/documents/m100en_lyra_influenza_a%2Bb_pi.pdf

Please contact Quidel Technical Support prior to modifying 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 pages 4-5 of the Lyra Influenza A+B Assay Package Insert:
http://www.quidel.com/sites/quidel.com/files/product/documents/m100en_lyra_influenza_a%2Bb_pi.pdf

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 limitations is provided on pages 17-18 of the Lyra Influenza A+B Assay Package Insert:
http://www.quidel.com/sites/quidel.com/files/product/documents/m100en_lyra_influenza_a%2Bb_pi.pdf

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 31 of the Lyra Influenza A+B Assay Package Insert:
http://www.quidel.com/sites/quidel.com/files/product/documents/m100en_lyra_influenza_a%2Bb_pi.pdf

*This information is being provided as a reference, for informational purposes only, with no expressed 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.