



# Lyra™

## Adenovirus Assay

### Supplemental Information and Frequently Asked Questions

#### **Supplemental Information**

#### **Do you have a proficiency recommendation to validate the Lyra Adenovirus 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 are the CMS suggested CPT codes and National Limit Amounts for the Lyra Adenovirus Assay?**

The Medicare National Limit Amount\* is \$47.87. The suggested\*\* CPT Code 87798 – Infectious Agent detection by nucleic acid – not otherwise specified – amplified probe technique. For reimbursement information and support, please visit our website at [quidel.com](http://quidel.com) or contact Quidel directly at 800.874.1517 Option 2, or via e-mail at [technicalsupport@quidel.com](mailto:technicalsupport@quidel.com).

#### **Is the Lyra Adenovirus Assay FDA cleared?**

Yes. It has been FDA cleared. K141931.

#### **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, 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 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 and CY5.

**What is the approximate test time for the thermocycler?**

The 7500 Fast Dx 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, 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](mailto: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 Adenovirus Control Set #M110 when used with the Lyra Adenovirus 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 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 Adenovirus?**

The World Health Organization (WHO) and the Centers for Disease Control and Prevention (CDC) post information on their websites:

<http://www.who.int>

<http://www.cdc.gov>

**What is the target for the Lyra Adenovirus Assay?**

The PCR primers are developed to bind to the penton base gene.

**Frequently Asked Questions****What is the sensitivity/specificity of the Lyra Adenovirus Assay?**

Performance characteristics of the Lyra Adenovirus Assay extracted by bioMérieux NucliSENS easyMag System and run on the Applied Biosystems® 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 and 15 of the Lyra Adenovirus Assay Package Insert:

[http://www.quidel.com/sites/quidel.com/files/product/documents/lyra\\_adenovirus\\_pi.pdf](http://www.quidel.com/sites/quidel.com/files/product/documents/lyra_adenovirus_pi.pdf)

**What is the precision of the Lyra Adenovirus Assay?**

The precision of the Lyra Adenovirus Assay was demonstrated in a separate study. Data for this study can be found on pages 17 and 18 of the Lyra Adenovirus Assay Package Insert:

[http://www.quidel.com/sites/quidel.com/files/product/documents/lyra\\_adenovirus\\_pi.pdf](http://www.quidel.com/sites/quidel.com/files/product/documents/lyra_adenovirus_pi.pdf)

**What is the limit of detection (LOD) for Adenovirus using this kit?**

The analytical LOD of the Lyra Adenovirus Assay was demonstrated with six species of Human Adenovirus. Data for these species can be found on page 15 of the Lyra Adenovirus Assay Package Insert:

[http://www.quidel.com/sites/quidel.com/files/product/documents/lyra\\_adenovirus\\_pi.pdf](http://www.quidel.com/sites/quidel.com/files/product/documents/lyra_adenovirus_pi.pdf)

**What detection technology does the Lyra Adenovirus Assay use?**

The Lyra Adenovirus 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 Adenovirus Assay can be found on pages 2 and 3 of the Lyra Adenovirus Assay Package Insert:

[http://www.quidel.com/sites/quidel.com/files/product/documents/lyra\\_adenovirus\\_pi.pdf](http://www.quidel.com/sites/quidel.com/files/product/documents/lyra_adenovirus_pi.pdf)

**What does the Lyra Adenovirus Assay kit contain?**

The materials provided in each kit are listed on page 3 of the Lyra Adenovirus Assay Package Insert:

[http://www.quidel.com/sites/quidel.com/files/product/documents/lyra\\_adenovirus\\_pi.pdf](http://www.quidel.com/sites/quidel.com/files/product/documents/lyra_adenovirus_pi.pdf)

**What sample types can I use with the Lyra Adenovirus 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 Adenovirus Assay can be found on pages 4 and 5 of the Lyra Adenovirus Assay Package Insert:

[http://www.quidel.com/sites/quidel.com/files/product/documents/lyra\\_adenovirus\\_pi.pdf](http://www.quidel.com/sites/quidel.com/files/product/documents/lyra_adenovirus_pi.pdf)

**Can I use the results if I forgot to centrifuge my plate?**

The PCR Set-up Procedure is described on page 11 of the Lyra Adenovirus Assay Package Insert:  
[http://www.quidel.com/sites/quidel.com/files/product/documents/lyra\\_adenovirus\\_pi.pdf](http://www.quidel.com/sites/quidel.com/files/product/documents/lyra_adenovirus_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 Adenovirus Assay Package Insert:

[http://www.quidel.com/sites/quidel.com/files/product/documents/lyra\\_adenovirus\\_pi.pdf](http://www.quidel.com/sites/quidel.com/files/product/documents/lyra_adenovirus_pi.pdf)

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

The storage conditions for the Lyra Adenovirus Assay kit and components can be found on page 4 of the Lyra Adenovirus Assay kit Package Insert:

[http://www.quidel.com/sites/quidel.com/files/product/documents/lyra\\_adenovirus\\_pi.pdf](http://www.quidel.com/sites/quidel.com/files/product/documents/lyra_adenovirus_pi.pdf)

**What is Quidel's quality control recommendation for these tests?**

Quidel's quality control recommendations are provided on page 12 of the Lyra Adenovirus Assay Package Insert:

[http://www.quidel.com/sites/quidel.com/files/product/documents/lyra\\_adenovirus\\_pi.pdf](http://www.quidel.com/sites/quidel.com/files/product/documents/lyra_adenovirus_pi.pdf)

**Does Quidel provide an external quality control for the Lyra Adenovirus Assay?**

The Lyra Adenovirus Assay does not include an External Control as part of the kit. A suggested External Control is listed on page 3 of the Lyra Adenovirus Assay kit Package Insert:

[http://www.quidel.com/sites/quidel.com/files/product/documents/lyra\\_adenovirus\\_pi.pdf](http://www.quidel.com/sites/quidel.com/files/product/documents/lyra_adenovirus_pi.pdf)

A full description of External Control use is provided on page 12 of the Lyra Adenovirus Assay Package Insert: [http://www.quidel.com/sites/quidel.com/files/product/documents/lyra\\_adenovirus\\_pi.pdf](http://www.quidel.com/sites/quidel.com/files/product/documents/lyra_adenovirus_pi.pdf)

**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 12 of the Lyra Adenovirus Assay Package Insert: [http://www.quidel.com/sites/quidel.com/files/product/documents/lyra\\_adenovirus\\_pi.pdf](http://www.quidel.com/sites/quidel.com/files/product/documents/lyra_adenovirus_pi.pdf)

**What should I do if my PRC does not show up?**

An interpretation table of results is provided on page 12 of the Lyra Adenovirus Assay Package Insert: [http://www.quidel.com/sites/quidel.com/files/product/documents/lyra\\_adenovirus\\_pi.pdf](http://www.quidel.com/sites/quidel.com/files/product/documents/lyra_adenovirus_pi.pdf)

**Can you send me the supplemental instructions for the thermocycler?**

The ABI 7500 Fast Dx instructions are incorporated starting on page 11 in the Lyra Adenovirus Assay Package Insert:

[http://www.quidel.com/sites/quidel.com/files/product/documents/lyra\\_adenovirus\\_pi.pdf](http://www.quidel.com/sites/quidel.com/files/product/documents/lyra_adenovirus_pi.pdf)

**Which software versions have been validated for the bioMerieux NucliSENS easyMAG and ABI 7500 Fast Dx instruments?**

The software versions that have been validated are listed on page 4 of the Lyra Adenovirus Assay Package Insert:

[http://www.quidel.com/sites/quidel.com/files/product/documents/lyra\\_adenovirus\\_pi.pdf](http://www.quidel.com/sites/quidel.com/files/product/documents/lyra_adenovirus_pi.pdf)

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 13 of the Lyra Adenovirus Assay Package Insert: [http://www.quidel.com/sites/quidel.com/files/product/documents/lyra\\_adenovirus\\_pi.pdf](http://www.quidel.com/sites/quidel.com/files/product/documents/lyra_adenovirus_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 warnings and precautions are provided on page 4 of the Lyra Adenovirus Assay Package Insert: [http://www.quidel.com/sites/quidel.com/files/product/documents/lyra\\_adenovirus\\_pi.pdf](http://www.quidel.com/sites/quidel.com/files/product/documents/lyra_adenovirus_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](http://www.quidel.com) for additional performance claims.

Customer support and technical assistance information is provided on page 20 of the Lyra Adenovirus Assay Package Insert: [http://www.quidel.com/sites/quidel.com/files/product/documents/lyra\\_adenovirus\\_pi.pdf](http://www.quidel.com/sites/quidel.com/files/product/documents/lyra_adenovirus_pi.pdf)

\*For state by state fee schedule go to [www.cms.gov](http://www.cms.gov).

\*\*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.

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