



## Strep Assay

### Frequently Asked Questions

#### **General**

##### **Do you have a proficiency recommendation to validate the Lyra Direct Strep Assay?**

Check with your local and state regulation for proficiency requirements. If you are using the CAP proficiency, D6 is the evaluation. For the API proficiency, Group A Strep Antigen 312 may be used.

##### **What is the CMS suggested CPT code and National Limit amount for the Lyra Direct Strep Assay?**

The suggested CPT codes are 87651\* and 87798\* – Infectious Agent detection by nucleic acid – Streptococcus, group A – amplified probe technique and “amplified probe technique, each organism,” respectively. For the current Medicare National Limit amount\* for each code, [click here](#). For additional 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 Direct Strep Assay FDA cleared?**

Yes. It has been FDA cleared via the De Novo Request process. K133883.

##### **What are the targets for the Lyra Direct Strep Assay?**

They are conserved regions in the genomes of group A Streptococci and pyogenic group C and G Streptococci.

##### **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 thermocycler can I use to run this assay?**

The Applied Biosystems<sup>®</sup> (ABI) 7500 Fast Dx is the only thermocycler that has been validated for this assay. The 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, ROX, and CY5.

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

The ABI 7500 Fast Dx takes less than 1 hour after the samples are prepared.

**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 5 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](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 Quidel Molecular Strep A+G Control Set (Cat. #M111 when used with the Lyra Direct Strep Assay?**

There is enough material in the control set for approximately 20 runs.

**What is the PRC and what is its concentration in the kit?**

This is proprietary information.

**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 I use a process control or a purified sample processed from another kit?**

No. We do not recommend deviating from the Package Insert. The PRC is prefilled in the Process Buffer. The Process Buffer should be used during sample processing and amplification in the assay.

**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 and should be repeated.

**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 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.

### **Does the Lyra Direct Strep Assay distinguish between Group A, Group G, and Group C Streptococcus?**

The Lyra Direct Strep Assay will differentiate between a Group A and Group G/C but will not differentiate between Group G and Group C positive specimen.

### **Where can I find up-to-date news and information on Group A $\beta$ -hemolytic Streptococcus, pyogenic Group C and G $\beta$ -hemolytic Streptococcus?**

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 Direct Strep Assay?**

Performance characteristics of the Lyra Direct Strep Assay using the ABI 7500 Fast Dx was established during a prospective study. One thousand two hundred ninety-three (1293) fresh throat specimens were included in this study at three sites across the United States. Descriptions of the data and the results can be found on pages 11-13 of the Lyra Direct Strep Assay Package Insert:

<https://www.quidel.com/molecular-diagnostics/lyra-direct-strep-assay>

### **What is the precision of the Lyra Direct Strep Assay?**

The precision of the Lyra Direct Strep Assay was demonstrated in a separate study. Data for this study can be found on pages 15-16 of the Lyra Direct Strep Assay Package Insert:

<https://www.quidel.com/molecular-diagnostics/lyra-direct-strep-assay>

### **What is the limit of detection (LOD) for Group A Strep, Pyogenic Group C Strep, and Pyogenic Group G Strep using this kit?**

Data can be found on pages 13-14 of the Lyra Direct Strep Assay Package Insert:

<https://www.quidel.com/molecular-diagnostics/lyra-direct-strep-assay>

### **What detection technology does the Lyra Direct Strep Assay use?**

The Lyra Direct Strep Assay is a real-time polymerase chain reaction (PCR) *in vitro* diagnostic test based on TaqMan<sup>®</sup> chemistry. An expanded description of the Lyra Direct Strep Assay technology can be found on pages 2-3 of the Lyra Direct Strep Assay Package Insert:

<https://www.quidel.com/molecular-diagnostics/lyra-direct-strep-assay>

### **What does the Lyra Direct Strep Assay kit contain?**

The materials provided in each kit are listed on page 4 of the Lyra Direct Strep Assay Package Insert:

<https://www.quidel.com/molecular-diagnostics/lyra-direct-strep-assay>

### **What sample types can I use with the Lyra Direct Strep Assay?**

#### **What media is acceptable to be used with the assay?**

#### **How long and at what temperature can specimens diluted in Process Buffer be stored?**

The specimen collection, storage and handling requirements and processed specimen storage for the Lyra Direct Strep Assay can be found on page 5 of the Lyra Direct Strep Assay Package Insert:

<https://www.quidel.com/molecular-diagnostics/lyra-direct-strep-assay>

### **Can I use the results if I forgot to centrifuge my plate or reaction tubes?**

The PCR Set-up Procedure is described on page 8 of the Lyra Direct Strep Assay Package Insert:

<https://www.quidel.com/molecular-diagnostics/lyra-direct-strep-assay>

Failure to follow this protocol invalidates the test result.

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

The storage conditions for the Lyra Direct Strep Assay kit and components can be found on page 5 of the Lyra Direct Strep Assay Package Insert:

<https://www.quidel.com/molecular-diagnostics/lyra-direct-strep-assay>

### **What are Quidel's quality control recommendations for this test?**

Quidel's quality control recommendations are provided on page 10 of the Lyra Direct Strep Assay Package Insert:

<https://www.quidel.com/molecular-diagnostics/lyra-direct-strep-assay>

### **Does Quidel provide an external quality control for the Lyra Direct Strep Assay?**

The Lyra Direct Strep Assay does not include an external control as part of the kit. A suggested external control manufactured by Quidel is listed on page 4 of the Lyra Direct Strep Assay kit Package Insert:

<https://www.quidel.com/molecular-diagnostics/lyra-direct-strep-assay>

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

An interpretation table of results is provided on page 10 of the Lyra Direct Strep Assay Package Insert:

<https://www.quidel.com/molecular-diagnostics/lyra-direct-strep-assay>

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

The ABI 7500 Fast Dx instructions are incorporated starting on page 5 in the Lyra Direct Strep Assay Package Insert:

<https://www.quidel.com/molecular-diagnostics/lyra-direct-strep-assay>

### **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 Direct Strep Assay Package Insert:

<https://www.quidel.com/molecular-diagnostics/lyra-direct-strep-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 limitations is provided on page 10 of the Lyra Direct Strep Assay Package Insert:

<https://www.quidel.com/molecular-diagnostics/lyra-direct-strep-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](https://www.quidel.com) for additional performance claims.

Customer support and technical assistance information is provided on page 19 of the Lyra Direct Strep Assay Package Insert:

<https://www.quidel.com/molecular-diagnostics/lyra-direct-strep-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](http://www.cms.gov).

FQM112000EN00 (09/21)