C. difficile Assay

Frequently Asked Questions

General

Do you have a proficiency recommendation to validate the Lyra Direct C. difficile Assay?
Check with your local and state regulation for proficiency requirements. If you are using the CAP proficiency, Stool Pathogens (SP) is the evaluation. For the API proficiency, 347 or 350 C. difficile toxin or antigen.

What is the CMS suggested CPT code and National Limit amount for the Lyra Direct C. difficile Assay?
The suggested CPT Code is 87493.* The 2015 Medicare National Limit amount** is $47.76. 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 Direct C. difficile Assay FDA cleared?
Yes. It has been FDA cleared. K123998.

What are the targets for the Lyra Direct C. difficile Assay?
They are conserved regions of the *C. difficile* toxin A and toxin B genes.

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® 7500 Fast Dx, the 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 following dyes were calibrated during regular maintenance:
7500 Fast Dx: JOE, CY5
SmartCycler II: Alx532, Alx647
QuantStudio Dx: VIC, CY5

What is the approximate test time for the thermocyclers?
The 7500 Fast Dx, SmartCycler II, and QuantStudio Dx take less than 1 hour after the sample process procedure.

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 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 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 C. difficile Control Set (Cat. #M108) when used with the Lyra Direct C. difficile Assay?
There is enough material in the control set for approximately 40 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 Process Buffer 2. All specimens must first be processed using the Quidel Rapid DNA Stool Sample Prep Kit.

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.

Where can I find up-to-date news and information on C. difficile?
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 C. difficile Assay?
The performance of the Lyra Direct C. difficile Assay was evaluated with specimens collected at four geographically diverse locations within the United States. Descriptions of the data and the results can be found on pages 15-19 of the Lyra Direct C. difficile Assay Package Insert:
http://www.quidel.com/sites/quidel.com/files/product/documents/M105en_Lyra%20Direct%20C%20diff%20Assay%20PI%202643ID0414D%20%280614%29.pdf

What is the precision of the Lyra Direct C. difficile Assay?
The precision of the Lyra Direct C. difficile Assay was demonstrated in a separate study. Data for this study can be found on page 23 of the Lyra Direct C. difficile Assay Package Insert:
http://www.quidel.com/sites/quidel.com/files/product/documents/M105en_Lyra%20Direct%20C%20diff%20Assay%20PI%202643ID0414D%20%280614%29.pdf

What is the limit of detection (LOD) for C. difficile using this kit?
The analytical limit of detection of the Lyra Direct C. difficile Assay was determined using quantified cultures of two *C. difficile* strains serially diluted in a negative fecal matrix. Data can be found on page 19 of the Lyra C. difficile Assay Package Insert:
http://www.quidel.com/sites/quidel.com/files/product/documents/M105en_Lyra%20Direct%20C%20diff%20Assay%20PI%202643ID0414D%20%280614%29.pdf

What detection technology does the Lyra Direct C. difficile Assay use?
The Lyra Direct C. difficile Assay is a real-time polymerase chain reaction (PCR) *in vitro* diagnostic test based on TaqMan® chemistry. An expanded description of the Lyra Direct C. difficile Assay technology can be found on page 2 of the Lyra Direct C. difficile Assay Package Insert:
http://www.quidel.com/sites/quidel.com/files/product/documents/M105en_Lyra%20Direct%20C%20diff%20Assay%20PI%202643ID0414D%20%280614%29.pdf

What does the Lyra Direct C. difficile Assay kit contain?
The materials provided in each kit are listed on page 3 of the Lyra Direct C. difficile Assay Package Insert:
http://www.quidel.com/sites/quidel.com/files/product/documents/M105en_Lyra%20Direct%20C%20diff%20Assay%20PI%202643ID0414D%20%280614%29.pdf

What sample types can I use with the Lyra Direct C. difficile 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 C. difficile Assay can be found on page 5 of the Lyra Direct C. difficile Assay Package Insert:
http://www.quidel.com/sites/quidel.com/files/product/documents/M105en_Lyra%20Direct%20C%20diff%20Assay%20PI%202643ID0414D%20%280614%29.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 11 of the Lyra Direct C. difficile Assay Package Insert:
http://www.quidel.com/sites/quidel.com/files/product/documents/M105en_Lyra%20Direct%20C%20diff%20Assay%20PI%202643ID0414D%20%280614%29.pdf

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 C. difficile Assay kit and components can be found on page 4 of the Lyra Direct C. difficile Assay Package Insert:
http://www.quidel.com/sites/quidel.com/files/product/documents/M105en_Lyra%20Direct%20C%20diff%20Assay%20PI%202643ID0414D%20%280614%29.pdf

What are Quidel's quality control recommendations for this test?
Quidel's quality control recommendations are provided on page 15 of the Lyra Direct C. difficile Assay Package Insert:
http://www.quidel.com/sites/quidel.com/files/product/documents/M105en_Lyra%20Direct%20C%20diff%20Assay%20PI%202643ID0414D%20%280614%29.pdf

Does Quidel provide an external quality control for the Lyra Direct C. difficile Assay?
The Lyra Direct C. difficile Assay does not include an external control as part of the kit. A suggested external control manufactured by Quidel is listed on page 3 of the Lyra Direct C. difficile Assay kit Package Insert:
http://www.quidel.com/sites/quidel.com/files/product/documents/M105en_Lyra%20Direct%20C%20diff%20Assay%20PI%202643ID0414D%20%280614%29.pdf

What should I do if my PRC does not show up?
An interpretation table of results is provided on page 14 of the Lyra Direct C. difficile Assay Package Insert:
http://www.quidel.com/sites/quidel.com/files/product/documents/M105en_Lyra%20Direct%20C%20diff%20Assay%20PI%202643ID0414D%20%280614%29.pdf

Can you send me the supplemental instructions for the thermocycler?
The ABI 7500 Fast Dx, SmartCycler II, and Quant Studio DX instructions are incorporated starting on page 11 in the Lyra Direct C. difficile Assay Package Insert:
http://www.quidel.com/sites/quidel.com/files/product/documents/M105en_Lyra%20Direct%20C%20diff%20Assay%20PI%202643ID0414D%20%280614%29.pdf

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 C. difficile Assay Package Insert:
http://www.quidel.com/sites/quidel.com/files/product/documents/M105en_Lyra%20Direct%20C%20diff%20Assay%20PI%202643ID0414D%20%280614%29.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 page 15 of the Lyra Direct C. difficile Assay Package Insert:
http://www.quidel.com/sites/quidel.com/files/product/documents/M105en_Lyra%20Direct%20C%20diff%20Assay%20PI%202643ID0414D%20%280614%29.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 24 of the Lyra Direct C. difficile Assay Package Insert:
http://www.quidel.com/sites/quidel.com/files/product/documents/M105en_Lyra%20Direct%20C%20diff%20Assay%20PI%202643ID0414D%20%280614%29.pdf

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

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