



HSV 1+2/VZV Assay

Frequently Asked Questions

General

Do you have a proficiency recommendation to validate the Lyra Direct HSV 1+2/VZV 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 HC-4 survey is for Herpes Culture. Both of these surveys have been tested with this assay and performed satisfactorily. For API proficiency, Virology package 322 is the evaluation that we suggest.

What are the CMS suggested CPT codes and National Limit Amounts for the Lyra Direct HSV 1+2/VZV Assay?

The suggested CPT code for HSV 1+2 is 87529 x 2* – Herpes Simplex Virus amplified probe technique. The suggested CPT code for VZV is 87798* – amplified probe technique, each organism, not otherwise specified. The 2015 National Limit amounts** are \$47.76 for 87529 (HSV 1+2) and \$47.76 for 87798 (VZV). 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 HSV 1+2/VZV Assay FDA cleared?

Yes. It has been FDA-cleared via the De Novo Request process. K133448.

What are the targets for the Lyra Direct HSV 1+2/VZV Assay?

They are conserved regions in the genomes of HSV-1, HSV-2, and VZV.

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 or SmartCycler II 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: for 7500 Fast Dx: FAM, VIC, Texas Red, and CY5. For SmartCycler II: FAM, CY3, Texas Red, and 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 7 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 HSV 1+2/VZV Control Set (Cat. #M121) when used with the Lyra Direct HSV 1+2/VZV 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?

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 preparation 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 HSV 1+2/VZV Assay distinguish between HSV-1 and HSV-2?

Yes. The Lyra Direct HSV 1+2/VZV Assay will differentiate between an HSV-1, HSV-2, and VZV positive specimen.

Where can I find up-to-date news and information on HSV 1+2 and VZV?

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 HSV 1+2/VZV Assay?

A multi-center study was performed to evaluate the Lyra Direct HSV 1+2/VZV Assay using lesion swab specimens obtained from cutaneous or mucocutaneous lesions and submitted for HSV and/or VZV culture. Descriptions of the data and the results can be found on pages 32-39 of the Lyra Direct HSV 1+2/VZV Assay Package Insert:

<http://www.quidel.com/sites/quidel.com/files/product/documents/Lyra%20Direct%20HSV%20VZV%20PI.pdf>

What is the precision of the Lyra Direct HSV 1+2/VZV Assay?

The precision of the Lyra Direct HSV 1+2/VZV Assay was demonstrated in a separate study. Data for this study can be found on pages 40-41 of the Lyra Direct HSV 1+2/VZV Assay Package Insert:

<http://www.quidel.com/sites/quidel.com/files/product/documents/Lyra%20Direct%20HSV%20VZV%20PI.pdf>

What is the limit of detection (LOD) for HSV 1+2/VZV using this kit?

The analytical limit of detection of the Lyra Direct HSV 1+2/VZV Assay was determined using quantified stocks of two strains of HSV-1, two strains of HSV-2, and two strains of VZV serially diluted in a negative matrix. Data can be found on pages 39-40 of the Lyra HSV 1+2/VZV Assay Package Insert:

<http://www.quidel.com/sites/quidel.com/files/product/documents/Lyra%20Direct%20HSV%20VZV%20PI.pdf>

What detection technology does the Lyra Direct HSV 1+2/VZV Assay use?

The Lyra Direct HSV 1+2/VZV Assay is a real-time polymerase chain reaction (PCR) *in vitro* diagnostic test based on TaqMan[®] chemistry. An expanded description of the Lyra Direct HSV 1+2/VZV Assay technology can be found on pages 3-4 of the Lyra Direct HSV 1+2/VZV Assay Package Insert:

<http://www.quidel.com/sites/quidel.com/files/product/documents/Lyra%20Direct%20HSV%20VZV%20PI.pdf>

What does the Lyra Direct HSV 1+2/VZV Assay kit contain?

The materials provided in each kit are listed on page 5 of the Lyra Direct HSV 1+2/VZV Assay Package Insert:

<http://www.quidel.com/sites/quidel.com/files/product/documents/Lyra%20Direct%20HSV%20VZV%20PI.pdf>

What sample types can I use with the Lyra Direct HSV 1+2/VZV Assay?

What media is acceptable to be used with the assay?

How long and at what temperature can prepared samples be stored?

The specimen collection, storage and handling requirements and processed specimen storage for the Lyra Direct HSV 1+2/VZV Assay can be found on page 6 of the Lyra Direct HSV 1+2/VZV Assay Package Insert:

<http://www.quidel.com/sites/quidel.com/files/product/documents/Lyra%20Direct%20HSV%20VZV%20PI.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 21 of the Lyra Direct HSV 1+2/VZV Assay Package Insert:
<http://www.quidel.com/sites/quidel.com/files/product/documents/Lyra%20Direct%20HSV1VZV%20PI.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 HSV 1+2/VZV Assay kit and components can be found on page 6 of the Lyra Direct HSV 1+2/VZV Assay Package Insert:
<http://www.quidel.com/sites/quidel.com/files/product/documents/Lyra%20Direct%20HSV1VZV%20PI.pdf>

What is Quidel's quality control recommendation for this test?

Quidel's quality control recommendations are provided on page 29 of the Lyra Direct HSV 1+2/VZV Assay Package Insert:
<http://www.quidel.com/sites/quidel.com/files/product/documents/Lyra%20Direct%20HSV1VZV%20PI.pdf>

Does Quidel provide an external quality control for the Lyra Direct HSV 1+2/VZV Assay?

The Lyra Direct HSV 1+2/VZV Assay does not include an external control as part of the kit. A suggested external control manufactured by Quidel is listed on page 5 of the Lyra Direct HSV 1+2/VZV Assay kit Package Insert:
<http://www.quidel.com/sites/quidel.com/files/product/documents/Lyra%20Direct%20HSV1VZV%20PI.pdf>

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

An interpretation table of results is provided on pages 27-29 of the Lyra Direct HSV 1+2/VZV Assay Package Insert:
<http://www.quidel.com/sites/quidel.com/files/product/documents/Lyra%20Direct%20HSV1VZV%20PI.pdf>

Can you send me the supplemental instructions for the thermocyclers?

The ABI 7500 Fast Dx, SmartCycler II, and Quant Studio Dx instructions are incorporated starting on page 6 in the Lyra Direct HSV 1+2/VZV Assay Package Insert:
<http://www.quidel.com/sites/quidel.com/files/product/documents/Lyra%20Direct%20HSV1VZV%20PI.pdf>

What can cause a false positive with a Negative Control or patient sample?

A list of warnings and precautions is provided on pages 5-6 of the Lyra Direct HSV 1+2/VZV Assay Package Insert:
<http://www.quidel.com/sites/quidel.com/files/product/documents/Lyra%20Direct%20HSV1VZV%20PI.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 29 of the Lyra Direct HSV 1+2/VZV Assay Package Insert:
<http://www.quidel.com/sites/quidel.com/files/product/documents/Lyra%20Direct%20HSV1VZV%20PI.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 48 of the Lyra Direct HSV 1+2/VZV Assay Package Insert:

<http://www.quidel.com/sites/quidel.com/files/product/documents/Lyra%20Direct%20HSV%20VZV%20PI.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.

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