QUIDEL | AmpliVue®

Anytime, Anywhere Molecular Assays

HSV 1+2 Assay

Frequently Asked Questions

General

Do you have a proficiency recommendation to validate the AmpliVue HSV 1+2 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.

What is the CMS suggested CPT code and National Limit amount for the AmpliVue HSV 1+2 Assay?
The suggested CPT Code is 87529* x 2. The Medicare National Limit amount** is $47.80 x 2. 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 AmpliVue HSV 1+2 Assay FDA cleared?
Yes. It has been FDA cleared. K140029.

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.

Are there any special licensing or certifications required to run the AmpliVue HSV 1+2 Assay?
The qualifications for laboratories performing a moderately complex test can be found on the CDC website at **cdc.gov**. For additional information you should contact your State Agency CLIA Contact.

What are the requirements for setting up a correlation study?
The assay should be treated in the same way any other FDA-cleared moderate complexity test brought into the laboratory is treated. There is nothing written in the regulations, that we are aware of, that identifies an assay like AmpliVue requiring anything additional.

Can I use any heat block for the amplification step?
The 64°C amplification block is available from Quidel. The catalog number for this heat block is M215. The 64°C amplification block is designed specifically with holes to fit the reaction tubes, maintains a temperature of 64°C ± 2°C and has a heated lid. The heat block that is used for the amplification process must have a heated lid.

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.

What is the concentration of the process control?
That is proprietary information.

Can a sample with another manufacturer's process control be used in your assays?
No. The sample must have a Quidel process control in it; therefore, you should not use a sample lysed using another kit.

Why is the C line not necessary to call a positive result?
The process control is intended to show any inhibition during the assay. A positive result tells you that no inhibition has taken place, the sample has been processed correctly, and the integrity of the reagents and Cassette detection has been confirmed. This occurs because of an overabundance of amplicons which generate competition with the test targets.

What if I can't see the fluid flowing up the detection strip in the Cassette?
If liquid is not flowing in the Cassette then it is recommended that the assay be repeated.

What are the targets for the AmpliVue HSV 1+2 Assay?
A conserved fragment of HSV-1 and HSV-2 DNA. A different target is used for each virus.

What is the CLIA quality control policy for these tests?
Based on the Memorandum the Office of Clinical Standards and Quality/Survey Certification Group there are two mechanisms for meeting the federal guidelines:

- The default mechanism is to follow 42 CFR 493.1256(d)(3) – which states that two levels of external quality control per day of patient testing will be performed. All manufacturer's instructions must be followed, per 42 CFR 493.1256(d)(2);

- A new program (Individualized Quality Control Plan (IQCP)) has been launched. The Centers for Medicare & Medicaid Services (CMS) is incorporating into the Interpretive Guidelines (IG), based on 42 CFR 493.1250, key concepts and graphics from Clinical and Laboratory Standards Institute (CLSI) Evaluation Protocol-23 (EP-23), 'Laboratory Quality Control Based on Risk Management,' as alternative Clinical Laboratory Improvement Amendment (CLIA) Quality Control (QC) policy.

For more information please request the Quidel Technical Bulletin for AmpliVue Assay External Quality Control.

What is the CAP quality control requirement for these tests?
CAP Molecular MOL.34220 or MIC.63262: Validation studies must include daily comparisons of external controls to built-in controls for at least 20 consecutive days. Then external controls are run for each new lot number and new shipment and before use or every 30 days whichever is more frequent.

How many tests can I get out of the Quidel Molecular HSV 1+2 Control Set (Cat. #M109)?
Approximately 50 AmpliVue Cassettes can be run from each control set.

What is the approximate test time for the AmpliVue assay?
The total assay time is approximately 60 minutes.

Where can I find up-to-date news and information on HSV 1+2?
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 AmpliVue HSV 1+2 Assay?
The performance of the AmpliVue HSV 1+2 Assay was evaluated at five geographically diverse locations within the United States. A description of this trial and the results can be found on page 9 of the AmpliVue HSV 1+2 Assay Package Insert:
http://www.quidel.com/sites/quidel.com/files/product/documents/AmpliVue%20HSV%201%2B2%20PI_Updated%2040114.pdf

What is the precision of the AmpliVue HSV 1+2 Assay?
The precision of the AmpliVue HSV 1+2 Assay was demonstrated in a separate study. Data for this study can be found on pages 10-11 of the AmpliVue HSV 1+2 Assay Package Insert:
http://www.quidel.com/sites/quidel.com/files/product/documents/AmpliVue%20HSV%201%2B2%20PI_Updated%2040114.pdf

What is the limit of detection (LOD) for HSV 1+2 using this kit?
The analytical limit of detection of the AmpliVue HSV 1+2 Assay can be found on pages 16-17 of the AmpliVue HSV 1+2 Assay Package Insert:
http://www.quidel.com/sites/quidel.com/files/product/documents/AmpliVue%20HSV%201%2B2%20PI_Updated%2040114.pdf

What detection technology does the AmpliVue HSV 1+2 Assay use?
The AmpliVue HSV 1+2 Assay detects and differentiates HSV-1 and HSV-2 DNA by a HDA reaction which simultaneously amplifies a HSV-1 specific sequence and a HSV-2 specific sequence in the presence of an internal control sequence. An expanded description of the principle of AmpliVue HSV 1+2 Assay can be found on pages 2-3 of the AmpliVue HSV 1+2 Assay Package Insert:
http://www.quidel.com/sites/quidel.com/files/product/documents/AmpliVue%20HSV%201%2B2%20PI_Updated%2040114.pdf

What does the AmpliVue HSV 1+2 Assay kit contain?
The materials provided in each kit are listed on page 3 of AmpliVue HSV 1+2 Assay Package Insert:
http://www.quidel.com/sites/quidel.com/files/product/documents/AmpliVue%20HSV%201%2B2%20PI_Updated%2040114.pdf

What sample types can I use with the AmpliVue HSV 1+2 Assay?
How should specimens be handled and stored prior to the amplification process?
What swabs and media are acceptable to be used with the assay?
The specimen collection, storage and handling requirements for the AmpliVue HSV 1+2 Assay can be found on page 4 of the AmpliVue HSV 1+2 Assay Package Insert:
http://www.quidel.com/sites/quidel.com/files/product/documents/AmpliVue%20HSV%201%2B2%20PI_Updated%2040114.pdf

What are the storage conditions for the kit and the components?
The storage conditions for the AmpliVue HSV 1+2 Assay kit and components can be found on page 3 of the AmpliVue HSV 1+2 Assay kit Package Insert:
http://www.quidel.com/sites/quidel.com/files/product/documents/AmpliVue%20HSV%201%2B2%20PI_Updated%2040114.pdf

What are Quidel's quality control recommendations for this test?
Quidel's quality control recommendations are provided on page 7 of the AmpliVue HSV 1+2 Assay Package Insert:
http://www.quidel.com/sites/quidel.com/files/product/documents/AmpliVue%20HSV%201%2B2%20PI_Updated%2040114.pdf

Does Quidel provide an external quality control for the AmpliVue HSV 1+2 Assay?
The AmpliVue HSV 1+2 Assay does not include an external control as part of the kit. A suggested external control is listed on page 4 of the AmpliVue HSV 1+2 Assay Package Insert:
http://www.quidel.com/sites/quidel.com/files/product/documents/AmpliVue%20HSV%201%2B2%20PI_Updated%2040114.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 7 of the AmpliVue HSV 1+2 Assay Package Insert:
http://www.quidel.com/sites/quidel.com/files/product/documents/AmpliVue%20HSV%201%2B2%20PI_Updated%2040114.pdf

What should I do if my process control line (C line) does not show up?
An interpretation table of results is provided on pages 6-7of the AmpliVue HSV 1+2 Assay Package Insert:
http://www.quidel.com/sites/quidel.com/files/product/documents/AmpliVue%20HSV%201%2B2%20PI_Updated%2040114.pdf

What can cause a false positive with a Negative Control or patient sample?
A list of warnings and precautions is provided on page 4 of the AmpliVue HSV 1+2 Assay Package Insert:
http://www.quidel.com/sites/quidel.com/files/product/documents/AmpliVue%20HSV%201%2B2%20PI_Updated%2040114.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 7 of the AmpliVue HSV 1+2 Assay Package Insert:
http://www.quidel.com/sites/quidel.com/files/product/documents/AmpliVue%20HSV%201%2B2%20PI_Updated%2040114.pdf

This list covers many of the identified causes of false negative results seen with many molecular test systems.

How long are samples stable in the Dilution Tube?
Stability is listed in the Note section in the Specimen Preparation Procedure. This information can be found on page 5 of the AmpliVue HSV 1+2 Assay Package Insert:
http://www.quidel.com/sites/quidel.com/files/product/documents/AmpliVue%20HSV%201%2B2%20PI_Updated%2040114.pdf

What temperature do the samples need to be amplified at?
This information is supplied in the Amplification Procedure found on page 5 of the AmpliVue HSV 1+2 Package Insert:
http://www.quidel.com/sites/quidel.com/files/product/documents/AmpliVue%20HSV%201%2B2%20PI_Updated%2040114.pdf

How long after the 15-minute read time are results valid?
This information is supplied in the Detection Procedure found on page 5 of the AmpliVue HSV 1+2 Assay Package Insert:
http://www.quidel.com/sites/quidel.com/files/product/documents/AmpliVue%20HSV%201%2B2%20PI_Updated%2040114.pdf

Can I use the results if I forgot to mix my Dilution Tubes?
Failure to mix the tubes is a major deviation from the Package Insert. It is recommended that the assay be repeated. The complete Assay Procedure can be found on pages 5-6 of the AmpliVue HSV 1+2 Assay Package Insert:
http://www.quidel.com/sites/quidel.com/files/product/documents/AmpliVue%20HSV%201%2B2%20PI_Updated%2040114.pdf

What do the T1 line and T2 line tell me?
Interpretation of Results can be found on pages 6-7 of the AmpliVue HSV 1+2 Assay Package Insert:
http://www.quidel.com/sites/quidel.com/files/product/documents/AmpliVue%20HSV%201%2B2%20PI_Updated%2040114.pdf

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 17 of the AmpliVue HSV 1+2 Assay Package Insert:
http://www.quidel.com/sites/quidel.com/files/product/documents/AmpliVue%20HSV%201%2B2%20PI_Updated%2040114.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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