Influenza A+B Assay

Frequently Asked Questions

General

Do you have a proficiency recommendation to validate the Solana Influenza A+B Assay?
Check with your local and state regulation for proficiency requirements. All recommended surveys have been tested with this assay and performed satisfactorily.

If you are using the CAP proficiency, VR1 survey Virology Culture, ID-2 Respiratory by Nucleic Acid testing, ID-3 survey Influenza A, Influenza B, and RSV by Nucleic Acid testing and IDR survey for Infectious Disease Respiratory Panel testing on Molecular Multiplex Testing.

If you are using API proficiency you may use Virology package 322.

If you are using WSLH Proficiency Testing, you may use Viral Antigens package 6150 or Respiratory Multiplex package 6240.

What are the CMS suggested CPT codes and National Limit amounts for the Solana Influenza A+B Assay?
The suggested CPT code is 87502.* For reimbursement information and support, please visit our website at quidel.com or contact Quidel directly at 800.874.1517 Option 2, then option 2, or via e-mail at technicalsupport@quidel.com.

Is the Solana Influenza A+B Assay FDA cleared?
Yes. It has been FDA cleared. K161814

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 Solana Influenza A+B 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 Solana requiring anything additional.

Does each Solana Instrument need to be validated before use?
No. Quidel has, through the 510(k) process demonstrated that the Solana instrument to be substantially equivalent across the device platform. Instruments are interchangeable and each will yield qualitatively equivalent results. The validation process is independent from the instrument and should be used to demonstrate that the end-user can perform the assay in a manner consistent with FDA-cleared labeling and to generate data using the end-users patient population.

Does the Solana Instrument need to be calibrated?
No, Solana does not need to be calibrated. Solana will perform an internal check upon start-up or after it has been asleep for a period of time. Solana will not let the "New Test" button appear if the internal check does not pass.

Can I use any heat block for the lysis and amplification steps?
The 95°C Lysis Block is available from Quidel. The 95°C Lysis Block is designed specifically with holes to fit the Buffer Tubes and maintains a temperature of 95°C ±2°C. If using an alternate 95°C lysis block, please ensure that the lysis block maintains the specified temperature for the entire heating period.

The Solana instrument is designed to maintain the correct temperature for the Solana Influenza A+B Assay. The temperature is monitored by the instrument.

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, then 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.

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 is the target for the Solana Influenza A+B Assay?
The Solana Influenza A+B Assay amplifies and detects viral RNA present in viral transport media containing nasopharyngeal or nasal swab specimens obtained from symptomatic patients.

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 announced. 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 Solana 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 Influenza A+B Assay Control Kit (Cat. #106)?
Approximately 40 Solana reactions can be run from each control set.

What is the approximate test time for the Solana assay?
The total assay time is approximately 40 minutes.

Where can I find up-to-date news and information on Influenza A+B?
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 Solana Influenza A+B Assay?
Performance characteristics of the Solana Influenza A+B Assay were verified in a multi-center study at four locations in the United States and one location in Canada. A description of this trial and the results can be found in the Solana Influenza A+B Assay Package Insert:
https://www.quidel.com/molecular-diagnostics/solana-influenza-assay**

What is the precision of the Solana Influenza A+B Assay?
The precision of the Solana Influenza A+B Assay was demonstrated in a separate study. Data for this study can be found in the Solana Influenza A+B Assay Package Insert:
https://www.quidel.com/molecular-diagnostics/solana-influenza-assay**

What is the limit of detection (LOD) for Influenza A+B using this kit?
The analytical limit of detection information can be found in the Solana Influenza A+B Assay Package Insert:
https://www.quidel.com/molecular-diagnostics/solana-influenza-assay**

What detection technology does the Solana Influenza A+B Assay use?
The Solana Influenza A+B Assay is a nucleic acid amplification test based on Helicase-Dependent Amplification (HDA) technology and a disposable lateral-flow detection device. An expanded description of the principle of the Solana Influenza A+B Assay can be found in the Solana Influenza A+B Assay Package Insert:
https://www.quidel.com/molecular-diagnostics/solana-influenza-assay**

What does the Solana Influenza A+B Assay kit contain?
The materials provided in each kit are listed in the Solana Influenza A+B Assay Package Insert:
https://www.quidel.com/molecular-diagnostics/solana-influenza-assay**

What sample types can I use with the Solana Influenza A+B Assay?
How should specimens be handled and stored prior to the heat lysis process?
What swabs and media are acceptable to be used with the assay?
The specimen collection, storage and handling requirements for the Solana Influenza A+B Assay can be found in the Solana Influenza A+B Assay Package Insert:
https://www.quidel.com/molecular-diagnostics/solana-influenza-assay**

What are the storage conditions for the kit and the components?
The storage conditions for the Solana Influenza A+B Assay kit and components can be found in the Solana Influenza A+B Assay Package Insert:
https://www.quidel.com/molecular-diagnostics/solana-influenza-assay**

Does Quidel provide an external quality control for the Solana Influenza A+B Assay?
The Solana Influenza A+B Assay does not include an external control as part of the kit. A suggested external control is listed in the Solana Influenza A+B Assay Package Insert:
https://www.quidel.com/molecular-diagnostics/solana-influenza-assay**

A full description of External Control use is provided in the Solana Influenza A+B Assay Package Insert:
https://www.quidel.com/molecular-diagnostics/solana-influenza-assay**

What can cause a false negative with a Positive control or patient sample?
A list of limitations is provided in the Solana Influenza A+B Assay Package Insert:
https://www.quidel.com/molecular-diagnostics/solana-influenza-assay**

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

How long are samples stable in Process Buffer Tubes?
Stabilities are listed in the Note sections in the Assay Procedure. This information can be found in the Solana Influenza A+B Assay Package Insert:
https://www.quidel.com/molecular-diagnostics/solana-influenza-assay**

What temperature do the samples need to be lysed at?
This information is contained in the Assay Procedure found in the Solana Influenza A+B Assay Package Insert:
https://www.quidel.com/molecular-diagnostics/solana-influenza-assay**

What if I forgot to heat lyse my samples?
The Assay Procedure is described in the Solana Influenza A+B Assay Package Insert:
https://www.quidel.com/molecular-diagnostics/solana-influenza-assay**
Failure to follow this protocol invalidates the test result.

What temperature do the samples need to be amplified at?
This information is supplied in the Assay Procedure found in the Solana Influenza A+B Package Insert:
https://www.quidel.com/molecular-diagnostics/solana-influenza-assay**

Can I use the results if I forgot to vortex my tubes?
Failure to vortex 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 in the Solana Influenza A+B Assay Package Insert:
https://www.quidel.com/molecular-diagnostics/solana-influenza-assay**
Refer to the Package Insert on our website at **quidel.com** for additional performance claims.

Customer support and technical assistance information is provided in the Solana Influenza A+B Assay Package Insert:
https://www.quidel.com/molecular-diagnostics/solana-influenza-assay**

*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.

**-To view the Package Insert, select Product Documentation from the menu.

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