Strep Complete Assay

Frequently Asked Questions

General

Do you have a proficiency recommendation to validate the Solana Strep Complete Assay?
Check with your Local and State regulation for proficiency requirements.

If you are using the CAP proficiency, D1-Throat Culture is the evaluation we would recommend.

If you are using the API proficiency, Strep pyogenes Molecular catalog number 364 is the evaluation that we would recommend. This API survey includes a Strep C/G challenge.

WSLH offers proficiency 5410, Group A Strep Molecular.

What are the CMS suggested CPT codes and National Limit Amounts for the Solana Strep Complete 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 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 Strep Complete Assay FDA cleared?
Yes. It has been FDA cleared. K162274.

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 Strep Complete 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 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-user's patient population.

Can I use any heat block for the lysis 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 heat block, please ensure that the heat block maintains the specified temperature for the entire heating period.

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.

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 is the target for the Solana Strep Complete Assay?
The Solana Strep Complete Assay amplifies, detects and differentiates *Streptococcus pyogenes* DNA and *Streptococcus dysgalactiae* DNA nucleic acids isolated from throat swab specimens obtained from patients with signs and symptoms of pharyngitis, such as sore throat.

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 Strep A+G Control Set (Cat. #M111)?
Approximately 20 Solana Strep Complete Assays can be run from each control set.

What is the approximate test time for the Solana Complete Strep Assay?
The total assay time is approximately 25 minutes.

Where can I find up-to-date news and information on Strep?
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 Strep Complete Assay?
Performance characteristics of the Solana Strep Complete Assay were established at five sites across the United States. A description of this trial and the results can be found in the Solana Strep Complete Assay Package Insert:
https://www.quidel.com/molecular-diagnostics/solana-strep-complete-assay**

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

What is the limit of detection (LOD) for *Streptococcus pyogenes* (Group A β-hemolytic Streptococcus) and *Streptococcus dysgalactiae* (pyogenic Group C and G β-hemolytic Streptococcus) using this kit?
The analytical limit of detection of the Solana Strep Complete Assay can be found in the Solana Strep Complete Assay Package Insert:
https://www.quidel.com/molecular-diagnostics/solana-strep-complete-assay**

What detection technology does the Solana Strep Complete Assay use?
The assay utilizes helicase-dependent amplification (HDA) of the target sequences and fluorescent probe-based detection in the Solana instrument to determine assay results. An expanded description of the principle of Solana Strep Complete Assay can be found in the Solana Strep Complete Assay Package Insert:
https://www.quidel.com/molecular-diagnostics/solana-strep-complete-assay**

What does the Solana Strep Complete Assay kit contain?
The materials provided in each kit are listed in the Solana Strep Complete Assay Package Insert: https://www.quidel.com/molecular-diagnostics/solana-strep-complete-assay**

What sample types can I use with the Solana Strep Complete 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 Strep Complete Assay can be found in the Solana Strep Complete Assay Package Insert:
https://www.quidel.com/molecular-diagnostics/solana-strep-complete-assay**

What are the storage conditions for the kit and the components?
The storage conditions for the Solana Strep Complete Assay kit and components can be found in the Solana Strep Complete Assay Package Insert:
https://www.quidel.com/molecular-diagnostics/solana-strep-complete-assay**

What is Quidel's quality control recommendation for this test?
Quidel's quality control recommendations are provided in the Solana Strep Complete Assay Package Insert: https://www.quidel.com/molecular-diagnostics/solana-strep-complete-assay**

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

A full description of External Control use is provided in the Solana Strep Complete Assay Package Insert:
https://www.quidel.com/molecular-diagnostics/solana-strep-complete-assay**

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 in the Solana Strep Complete Assay Package Insert:
https://www.quidel.com/molecular-diagnostics/solana-strep-complete-assay**

What should I do if my result is invalid does not show up?
An interpretation table of results is provided in the Solana Strep Complete Assay Package Insert:
https://www.quidel.com/molecular-diagnostics/solana-strep-complete-assay**

What can cause a false positive with a Negative Control or patient sample?
A list of limitations is provided ~~on pages 3 to 4 of~~ in the Solana Strep Complete Assay Package Insert:
https://www.quidel.com/molecular-diagnostics/solana-strep-complete-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 warnings and precautions are provided in the Solana Strep Complete Assay Package Insert:
https://www.quidel.com/molecular-diagnostics/solana-strep-complete-assay**

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

How long are samples stable in Lysis Tubes?
Stabilities are listed in the Note sections in the Assay Procedure. This information can be found in the Solana Strep Complete Assay Package Insert:
https://www.quidel.com/molecular-diagnostics/solana-strep-complete-assay**

What temperature do the samples need to be lysed at?
This information is contained in the Assay Procedure found in the Solana Strep Complete Assay Package Insert: https://www.quidel.com/molecular-diagnostics/solana-strep-complete-assay**

What if I forgot to heat lyse my samples?
The Assay Procedure is described in the Solana Strep Complete Assay Package Insert:
https://www.quidel.com/molecular-diagnostics/solana-strep-complete-assay**

Failure to follow this protocol invalidates the test result.

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 Strep Complete Assay Package Insert: https://www.quidel.com/molecular-diagnostics/solana-strep-complete-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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