C. difficile Assay

Frequently Asked Questions

Do you have a proficiency recommendation to validate the Solana C. difficile Assay?
Check your local and state regulations for proficiency requirements. If you are using the CAP proficiency, we recommend the C. difficile, 5 Challenge, CDF5. For the API proficiency, number 350 *C. difficile* Toxin / Antigen is the evaluations we suggest. If testing with WSLH, we recommend the 5060, *Clostridium difficile* survey.

What is the CMS suggested CPT code and National Limit amount for the Solana C. difficile Assay?
The suggested CPT code is 87493.* 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 C. difficile Assay FDA-cleared?
Yes. Both the Solana instrument and the Solana C. difficile Assay are FDA-cleared. Information on their clearance can be found on the FDA website. The submission number is K170491.

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 C. difficile 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 FDA 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-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.

The Solana instrument is designed to maintain the correct temperature for the Solana C. difficile Assay. The temperature is monitored by the instrument.

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 C. difficile Assay?
A highly-conserved fragment of the Toxin A gene sequence. Both toxin genes (*tcdA* and *tcdB,* respectively) are located within a 19.6 Kb pathogenicity locus (PaLoc) found within the genome of all known toxogenic *C. difficile* strains. The Solana C. difficile Assay targets a highly conserved region of the PaLoc, which is intact in all known A+B+ and A-B+ toxinotypes of *C. difficile*.

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.

How many tests can I get out of the Quidel Molecular C. difficile Control Set (Cat. #M108)?
Approximately 40 Solana tests can be run from each control set.

What is the approximate test time for the Solana assay?
The total assay time is approximately 30 minutes.

Does the Solana C. difficile Assay detect hypervirulent strains?
The Solana C. difficile Assay has been shown to detect hypervirulent strains, but will not differentiate them from other toxigenic genotypes.

Is it relevant which toxins are recognized for the clinical management of patients?
No. There is no relevance in what toxins are actually produced. As long as it's toxigenic *C. difficile*, then the patient is considered *C. difficile* positive and treated with the same drugs according to standard clinical practices.

Is it important to identify the toxins to determine the bacteria toxigenicity?
No, because the toxins degrade quite rapidly at room temperature and the toxin A or B Enzyme Immunoassays (EIA) have differing sensitivities to different strains of *C. difficile*. The EIA's have a very low sensitivity (approximately 50%), which makes them very unreliable in terms of being able to detect the toxins. Molecular assays (whether they target *tcdA* or *tcdB*) generally detect toxigenic *C. difficile* and do not detect non-toxigenic *C. difficile*. The genes are far more stable than the proteins and they end up being a much more reliable test for the presence of toxigenic *C. difficile* than the EIA's.[1]

Presence of the *C. difficile* bacteria but without toxins, is this important from a clinical point of view?
There is no diagnostic need to determine if someone is an asymptomatic carrier of toxigenic *C. difficile* in stool as this is still considered to be quite rare (2-3% of the population) based on standard clinical practices. Molecular tests are sensitive enough to pick up carriers; however, because they all specify that loose or unformed stool be the specimen tested (rather than solid stool), it is highly unlikely that you would pick up a carrier. If a hospital would like to use an assay to detect carriers, then they could use a molecular test but it would need to be validated for this use.[2]

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 Solana C. difficile Assay?
Performance characteristics of the Solana C. difficile Assay were established at three sites across the United States. A description of this trial and the results can be found in the Solana C. difficile Assay Package Insert:
https://www.quidel.com/molecular-diagnostics/solana-c-difficile-assay**

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

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

What detection technology does the Solana C. difficile Assay use?
The Solana C. difficile Assay utilizes helicase-dependent amplification (HDA) for the amplification of a highly conserved fragment of the Toxin A gene sequence and fluorescent probe-based detection in the Solana instrument to determine assay results. An expanded description of the principle of Solana C. difficile Assay can be found in the Solana C. difficile Assay Package Insert:
https://www.quidel.com/molecular-diagnostics/solana-c-difficile-assay**

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

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

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

What are Quidel's quality control recommendations for this test?
Quidel's quality control recommendations are provided in the Solana C. difficile Assay Package Insert:
https://www.quidel.com/molecular-diagnostics/solana-c-difficile-assay**

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

What should I do if my result is invalid?
An interpretation table of results is provided in the Solana C. difficile Assay Package Insert:
https://www.quidel.com/molecular-diagnostics/solana-c-difficile-assay**

What can cause a false positive with a Negative Control or patient sample?
A list of warnings and precautions is provided in the Solana C. difficile Assay Package Insert:
https://www.quidel.com/molecular-diagnostics/solana-c-difficile-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 limitations is provided in the Solana C. difficile Assay Package Insert:
https://www.quidel.com/molecular-diagnostics/solana-c-difficile-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 Lysis Buffer Tubes?
Stabilities are listed in the Note sections in the Assay Procedure. This information can be found in the Solana C. difficile Assay Package Insert:
https://www.quidel.com/molecular-diagnostics/solana-c-difficile-assay**

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

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

References:

1. Miyajima F., Roberts P., Swale A., Price V., Jones M., Horan M., et al. Characterisation and carriage ratio of *Clostridium difficile* strains isolated from a community-dwelling elderly population in the United Kingdom. *PLoS One*. 2011;6(8):e22804. doi: 10.1371/journal.pone .0022804. Epub 2011 Aug 23.
2. Niyogi S.K., Dutta D., Bhattacharya M.K., Bhattacharya S.K. Frequency of isolation of toxigenic *Clostridium difficile* from healthy adults. *Indian J. Med. Res*. 1997 Dec;106:497-9.

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

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