Xpert® Xpress Strep A*

Frequently Asked Questions

Q1: What targets are detected by Xpert Xpress Strep A?

The Xpert **Xpress** Strep A detects Streptococcus pyogenes (Group A β-hemolytic Streptococcus, Strep A) - which are gram-positive beta-hemolytic bacterial pathogens that commonly cause infections in the throat, otherwise known as pharyngitis or “strep throat”.

Q2: Does Xpert Xpress Strep A detect Strep C and Strep G types?

Unlike Group A, the group C and group G have not been studied extensively. The diseases due to groups C and G are much less common; and, diseases caused are less well-recognised. Although Group A lives in people’s throats and can spread in the community from person to person, groups C and G most commonly live in animals, such as horses and cattle, and can spread to humans through raw milk or contact with animals. It is uncertain whether Group C or Group G causes endemic or sporadic pharyngitis and even rheumatic fever. There is limited information in the literature regarding the clinical impact and antibiotic therapy.

Q3: Which collection device is compatible with Xpert Xpress Strep A?

Cepheid recommends using the ESwab Collection and Transport System (Copan 480CE or Copan 480C) to collect a throat swab specimen.

Q4: What is the smallest sample size I can use with Xpert Xpress Strep A?

The transfer pipette provided in the Xpert **Xpress** Strep A kit will allow collection of a 300ul sample.

Q5: Will Xpert Xpress Strep A work with skin lesion samples?

No. Xpert **Xpress** Strep A is validated to detect bacteria from throat swab specimens obtained from patients with symptoms of pharyngitis.

Q6: Are there any external positive control materials for validation purposes?

Yes. The Xpert **Xpress** Strep A StartPAK is available to help speed test implementation. The convenient bundled approach provides reagents, external controls, and panels. Speak to your Cepheid representative for more information.

Q7: What is the test time for Xpert Xpress Strep A?

The Xpert **Xpress** Strep A overall time to result is 24 minutes. A strongly positive sample will have a time to result as early as 18 minutes.

* CE-IVD. *In Vitro* Diagnostic Medical Device. Product distribution outside the United States. Product may not be available in all countries.

Frequently Asked Questions *(continued)*

Q8: Which GeneXpert® system/software is compatible with Xpert® Xpress Strep A?

Xpert **Xpress** Strep A is a complex test and requires functionality that is only available in later software releases. The GeneXpert must be running software version 4.7b and above, and the Infinity system must be running software version 6.4b and above.

Q9: Will Xpert Xpress Strep A be available on Omni system?

Yes. Xpert **Xpress** Strep A will be available on the GeneXpert Omni system; anticipated availability is late 2018.

Q10: Does the test have an Early Assay Termination (EAT)?

Yes. A strongly positive sample will have a time to result as early as 18 minutes.

Q11: What quality controls are included in the Xpert Xpress Strep A test?

Each cartridge includes a Sample Processing Control (SPC) and a Probe Check Control (PCC).

The Sample Processing Control (SPC) ensures the sample was processed correctly and verifies that sample processing is adequate. Additionally, this control detects sample-associated inhibition of the real-time PCR test, ensures the PCR reaction conditions (temperature and time) are appropriate for the amplification reaction, and that the PCR reagents are functional.

Probe Check Control (PCC): before the start of the PCR reaction, the GeneXpert System measures the fluorescence signal from the probes to monitor bead rehydration, reaction tube filling, probe integrity, and dye stability.

Q12: What are the recommended storage conditions for the kits?

Kits should be stored at room temperature at 2-28 °C until the expiration date provided per the Package Insert.

Q13: Does the test have potentially interfering substances?

Please refer to the Xpert **Xpress** Strep A Package Insert (CE IVD 301-6569 Rev. A) section 19.5 which describes the substances listed in the table below. There was no test interference in the presence of the substances at the concentrations tested. All positive and negative samples were correctly identified using the test.

Potential Interfering Substances Tested

Substance/Class	Description/Active Ingredient	Concentration Tested
Saliva	100% Human saliva	6.5% (v/v)
Mucin	Bound sialic acid, 0.5-1.5%	2.5% (w/v)
Blood	Whole human blood	5.0% (v/v)
Antiseptic	0.092% Eucalyptol, 0.042% menthol, 0.060% methyl salicylate, 0.064% thymol	6.5% (v/v)
Cough medicine	Dextromethorphan HBr USP 10 mg, Guaifenesin USP 200 mg	5 mg/mL
Sugar-containing cold and flu remedies	Acetaminophen 650 mg, Dextromethorphan HBr 20 mg, Doxylamine Succinate 12.5 mg, Phenylephrine HCl 10 mg	6.5% (v/v)
Salt-modifying remedies	Sodium chloride (0.65%)	6.5% (v/v)
Foods/drinks that increase salivary viscosity	Milk	6.5% (v/v)
pH modifying remedies	100% Orange juice	6.5% (v/v)

Frequently Asked Questions *(continued)*

Q14: Does the test have any limitations?

In the Package Insert of Xpert® **Xpress** Strep A (PN 301-6569 Rev A) section 17, the following limitations have been described:

- Mutations or nucleotide polymorphisms in primer or probe binding regions may affect detection of new or unknown Streptococcus pyogenes strains resulting in a false negative result.
- The results from the Xpert **Xpress** Strep A test should be interpreted in conjunction with other laboratory and clinical data available to the clinician.
- This test has not been evaluated for patients without signs and symptoms of pharyngitis.
- This test cannot rule out pharyngitis caused by other bacterial or viral pathogens besides Group A streptococci.

Q15: Can I re-use the same sample with a new Xpert Xpress Strep A cartridge?

If an “invalid”, “error”, or a “no result”, is obtained, the sample may be retested following the instructions in section 16.2 Retest Procedure of Xpert **Xpress** Strep A Package Insert (CE IVD 301-6569 Rev. A):

To retest an INVALID, NO RESULT, or ERROR result (non-determinate result), use a new cartridge.

Use the leftover sample from the original ESwab transport medium tube.

1. Mix the leftover patient specimen by vigorously shaking the specimen transport tube for 5 seconds.
2. Open the cartridge by lifting the cartridge lid.
3. Remove the transfer pipette from the wrapper by opening the end next to the bulb.
4. Squeeze the bulb of the transfer pipette completely and place the pipette tip in the transport medium tube containing the patient specimen.
5. Release the bulb of the pipette to fill the pipette with the patient specimen.
6. To transfer the patient specimen to the cartridge, squeeze the bulb of the transfer pipette completely to empty the contents of the pipette into the large opening (Sample Chamber).
7. Close the cartridge lid.
8. Dispose of the used pipette in an appropriate waste container.

Q16: How do I have to store the sample?

Specimen Transport and Storage Conditions are showed in Table 1 of Section 11.2: Specimen Transport and Storage in Xpert **Xpress** Strep A Package Insert (CE IVD 301-6569 Rev. A), and shown below:

Specimen Transport and Storage Conditions

Specimen Collection Device	Specimen Transport and Storage Temperature (°C)	Specimen Storage Time
ESwab (Copan 480CE; Copan 480C)	15–30 °C	Up to 48 hours
	2–8 °C	Up to 6 days

Q17: Can I purchase ESwabs from Cepheid?

No, ESwabs can only be purchased via Copan; product numbers 480C and 480CE based on a customer’s geographical location.