Presage® ST2 Assay

Test Number: **19750** CPT Code: **83006**

Synonyms	Soluble ST2 (sST2, ST2S) Suppression of Tumorigenicity 2 IL33 Receptor Heart Failure
Use	The Presage® ST2 Assay is indicated to be used in conjunction with clinical evaluation as an aid in assessing the prognosis of patients diagnosed with chronic heart failure. The Presage ST2 Assay is intended to be used only in patients with chronic heart failure and should not be used for diagnosis of heart failure.
Turnaround Time	2-14 days (depending on volume)
Specimen Requirements	
Specimen	Serum, Plasma (K3-EDTA or Lithium heparin)
Minimum volume	0.2 mL for Serum, Plasma (K3-EDTA or Lithium heparin)
Collection	1. Collect and label sample according to standard protocols. 2. Gently invert tube 5 times immediately after draw. DO NOT SHAKE. 3. For serum collection allow blood to clot 30 minutes, no more than 2 hours, for plasma no more than 2 hours 4. Centrifuge for 10 minutes. 5. Aliquot serum or plasma into a labeled transport tube and cap tightly.
Transport and Storage Instructions	Specimen may be transferred to transport tube after collection processing as above. Store processed specimen at 2°C to 8°C and ship the same day or next day, using overnight or 2-day shipping on ice*.

	Storage Limits - per 510k information [1] Room Temperature Storage: 2 days Refrigerated Storage: 7 days Frozen Storage: 18 months For Serum, Plasma (K3-EDTA or Lithium heparin), do not freeze samples in original collection tubes. Tubes including separator gel can be shipped cold (4-8 °C) after centrifugation without any additional processing. If tubes without the separator gel are used for collection, the serum or plasma must be transferred to a transport tube after centrifugation and shipped either frozen or on ice. ** Larger sized shipping containers (more ice) may be required for samples shipped during summer months. Please contact us regarding summer shipping from your region.*
Causes for Rejection	Gross hemolysis for plasma and serum samples Insufficient sample (< 0.2mL of venous blood) Citrate or NaF plasma Frozen whole blood, including frozen treated whole blood Improper labeling Samples not stored properly, or transport tubes are damaged Samples older than stability limits
Limitations	The sST2 Presage Assay Kit is 510k cleared for the stated intended use – see the sST2 Presage Assay 510k [1]. Results should be interpreted in the context of the individual patient presentation. Elevated ST2 results indicate an increased risk for adverse outcomes. Knowledge of ST2 results in a heart failure patient may assist in cardiovascular risk stratification. There are no specific ST2 inhibitors available at this time and heart failure patients with elevated ST2 concentrations should be treated and monitored according to established guidelines.

ST2 has not been shown to be useful in the acute diagnosis of heart failure; natriuretic peptides (BNP or NT-proBNP) should be utilized for this purpose in the context of appropriate clinical suspicion of acute heart failure. ST2 and natriuretic peptides are measures of separate and distinct biological processes.

There are no significant analytical interferences reported for ST2 from bilirubin, hemoglobin, triglycerides, cholesterol, or total protein. Forty-nine therapeutic substances were tested for analytical interference, and none had significant interference with the ST2 assay [1].

Testing is performed at ProterixBio, 1 Fortune Drive, Billerica, MA 01821 under CLIA certificate #22D2189261; Laboratory Director Mark D. Kellogg, PhD, MT(ASCP), DABCC

Additional Information	The Critical Diagnostics Presage® ST2 Assay kit is an in vitro diagnostic device that quantitatively measures ST2 in serum or plasma by enzyme-linked immunosorbent assay (ELISA) in a microtiter plate format. The established Presage Assay sST2 reference cut off level is 35 ng/mL for all ages, as an aid in assessing the prognosis of patients diagnosed with chronic heart failure. The level is between the 90th and 95th percentile of a measured self-declared healthy cohort that were without evidence of heart disease [1-3].

References

1. sST2 Presage Assay Kit 510k - https://www.accessdata.fda.gov/cdrh_docs/reviews/K111452.pdf
2. Whellan DJ, O'Connor CM, Lee, KL, et al: HF-ACTION Trial Investigators. Heart failure and a controlled trial investigating outcomes of exercise training (HF-ACTION): design and rationale. Am Heart J. 2007;153(2):201-211
3. Lu J, Snider JV, Grenache DG: Establishment of reference intervals for soluble ST2 from a United States population. Clinica Chemica Acta Volume 411, Issues 21–22, 11 November 2010, Pages 1825-1826