TEG® 6s

Hemostasis System

Instructions for Use Addendum

Using the TEG 6s Hemostasis System for Hospitalized Patients Suspected of a COVID-19 Associated Coagulopathy

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Reader comments

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Introduction

What is the Purpose of this Addendum?

The *Instructions for Use Addendum* provides information that highlights changes to the TEG® 6s Hemostasis System to allow use with hospitalized patients suspected of a COVID-19 associated coagulopathy. It is intended as a supplement to the following TEG 6s manuals and package inserts:

- TEG® 6s User Manual (115191-US)
- TEG® 6s Citrated: K, KH, RT, FF insert (115873-US)
- TEG® 6s Citrated: K, RT, FF insert (121239-US)
- TEG® 6s PlateletMapping® ADP & AA insert (115874-US)
- TEG® 6s PlateletMapping® ADP insert (120334-US)

The information in this addendum is based on the FDA guidance document, *Coagulation Systems for Measurement of Viscoelastic Properties: Enforcement Policy During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency* (“Coagulation Systems”).

For questions regarding testing and COVID-19, contact HaemoneticsMedInfo@Haemonetics.com.

Attention: *This addendum is valid only for the duration of the COVID-19 public health emergency as declared by the Secretary of Health and Human Services.*

Attention: *Use this addendum in conjunction with the TEG 6s User Manual (115191-US).*

Precautions

- **All test results generated by the TEG 6s Hemostasis System are adjunctive (supporting) and should not be solely or primarily relied upon to diagnose or treat COVID-19 associated bleeding disorders.**
- **Use universal precautions for handling potentially biohazardous material when using the TEG 6s device.** All parts of the TEG analyzer system should be considered potentially infectious and are capable of transmitting blood-borne pathogens between patients and healthcare professionals. Although the TEG analyzer does not present a significant biohazard risk in itself, the unit is used to analyze human blood, so care must be taken to properly handle, clean, and disinfect the equipment as appropriate. Haemonetics recommends that institutions follow CDC guidance to protect against COVID-19 infection.
- The TEG 6s Hemostasis System is not indicated for the diagnosis of COVID-19.
- All results from the TEG 6s Hemostasis System are intended to be interpreted by a licensed healthcare provider with appropriate training.

Interfering Substances

The TEG 6s system has been evaluated for interfering substances according to CLSI EP7-A2. Refer to the applicable cartridge assay package inserts for specific interfering substances.

Specific to the extended intended population described in this addendum, the TEG 6s Hemostasis System has not been evaluated for interference from substances such as, but not limited to, the following:

- Antiphospholipid antibodies
- Bamlanivimab
- Baricitinib and remdesivir, separately or in combination
- Casirivimab and imdevimab, separately or in combination
- Convalescent plasma

Additional Labeling for Modified Devices

Device Modifications

There are **no** changes to the functionality of the TEG 6s Hemostasis system, which is made up of the following components:

- TEG 6s Hemostasis Analyzer
- Disposable assay cartridges with preloaded dried reagents
- Service-Maintenance-Settings (SMS) software interface
- TEG Manager software interface

Installation and Qualification Testing

There are **no** changes to the recommended installation and qualification testing for the TEG 6s system. Refer to the *TEG 6s User Manual* (115191-US) and *TEG 6s Validation Guide* (118597-US) for installation and qualification instructions.

Post-Installation Activities

There are **no** changes to the recommended post-installation, calibration, testing, and maintenance activities for the TEG 6s system. Refer to the *TEG 6s User Manual* (115191-US) for post-installation activities.

Indications for Use

As supported by the FDA *Coagulations Systems* guidance document, the indications for use for the TEG 6s Hemostasis System is expanded beyond the cleared indications to provide supporting and adjunctive diagnostic information to facilitate patient management recommendations to the healthcare professional for the treatment of COVID-19 or co-existing conditions in hospitalized patients suspected of a COVID-19 associated coagulopathy.

The following section outlines the FDA-cleared indications for use and the allowed use for the applicable components of the TEG 6s Hemostasis System.

TEG 6s Hemostasis System

FDA-Cleared Indications for Use

The TEG® 6s Hemostasis System consists of the TEG 6s Hemostasis Analyzer, TEG 6s PlateletMapping Assay Cartridge, TEG 6s Citrated Multichannel Cartridge, and TEG 6s Citrated: K, RT, FF Assay Cartridge. The TEG 6s Hemostasis System is intended for in vitro diagnostic use to provide qualitative assessment of platelet function and semi-quantitative indications of the hemostasis state of a blood sample. The TEG 6s Hemostasis System records the kinetic changes in a sample of heparinized or 3.2% citrated whole blood as the sample clots.

The PlateletMapping Assay Cartridge provides four channels of dried-in-place reagents, HKH (Kaolin with Heparinase), Activator F, AA, and ADP (one reagent in each channel). In combination, MA parameter results from these four reagents are used to calculate the parameters platelet % Inhibition and % Aggregation for AA and ADP. A PlateletMapping ADP Assay Cartridge is available without the AA reagent.

The Citrated Multichannel Cartridge contains four independent assays (CK, CRT, CKH and CFF) and the system output consists of a table of numerical values for parameters R, K, Angle, MA, and FLEV.

The Citrated: K, RT, FF Assay Cartridge contains three independent assays (CK, CRT and CFF) and the system output consists of a table of numerical values for parameters R, LY30, and MA.

The CK assay monitors the hemostasis process via the intrinsic pathway in 3.2% citrated whole blood specimens on the TEG 6s Hemostasis System. Clotting characteristics are described by the functional parameters R (clotting time) and LY30 (fibrinolysis after 30 minutes of reaching maximum clot strength).

The CRT assay monitors the hemostasis process via both the intrinsic and extrinsic pathways in 3.2% citrated whole blood specimens on the TEG 6s Hemostasis System. Clotting characteristics are described by the functional parameter MA (maximum clot strength).

The CKH assay monitors the effects of heparin in 3.2% citrated whole blood specimens on the TEG 6s System. CKH is used in conjunction with CK, and heparin influence is determined by comparing clotting times (R) between the two tests.

The CFF assay monitors hemostasis of 3.2% citrated whole blood specimens in the TEG 6s Hemostasis System after blocking platelet contributions to clot strength. Clotting characteristics are described by the functional parameter MA (maximum clot strength).

Results from the TEG 6s analysis should not be the sole basis for a patient diagnosis, but should be evaluated together with the patient's medical history, the clinical picture and, if necessary, further hemostasis tests. The indication for TEG 6s Hemostasis System use is with adult patients (18 years and older) where an evaluation of their blood hemostasis properties is desired. Hemostasis evaluation with the TEG 6s Hemostasis System using the PlateletMapping Assay Cartridge and Citrated Multichannel

Cartridge is used to assess clinical conditions in cardiovascular surgery and cardiology procedures to assess hemorrhage or thrombosis conditions. Hemostasis evaluation with the TEG 6s Hemostasis System using the Citrated: K, RT, FF Assay Cartridge is used to assess clinical conditions in a trauma setting to assess hemorrhage or thrombosis conditions. For professional use only.

Allowed Use

The TEG® 6s Hemostasis System is intended to provide supporting and adjunctive diagnostic information to facilitate patient management recommendations to the healthcare professional for the treatment of COVID-19 or co-existing conditions in hospitalized patients suspected of a COVID-19 associated coagulopathy.

TEG 6s Citrated Multichannel Assay Cartridge

FDA-Cleared Indications for Use

The TEG 6s Hemostasis System is intended for in vitro diagnostic use to provide semi-quantitative indications of the hemostasis state of a venous blood sample. The Citrated Multichannel Cartridge, to be used with the TEG 6s analyzer, contains four independent assays (CK, CRT, CKH and CFF), described below.

The CK assay monitors the hemostasis process via the intrinsic pathway in 3.2% citrated whole blood specimens on the TEG 6s System. Clotting characteristics are described by the functional parameters Clotting Time (R), Speed of Clot Formation (K and Alpha angle) and Maximum Clot Strength (MA).

The CRT assay monitors the hemostasis process via both the intrinsic and extrinsic pathways in 3.2% citrated whole blood specimens on the TEG 6s System. Clotting characteristics are described by the functional parameter Maximum Clot Strength (MA). The CRT MA parameter is equivalent to the CK MA parameter but the final MA value is reached more quickly using the CRT assay.

The CKH assay monitors the effects of heparin in 3.2% citrated whole blood specimens on the TEG 6s System. CKH is used in conjunction with CK, and heparin influence is determined by comparing Clotting Times (R) between the two tests.

The CFF assay monitors hemostasis of 3.2% citrated whole blood specimens in the TEG 6s System after blocking platelet contributions to clot strength. Clotting characteristics are described by the functional parameters Maximum Clot Strength (MA) and the Estimated Functional Fibrinogen Level (FLEV).

Results from the TEG 6s analysis should not be the sole basis for a patient diagnosis, but should be evaluated together with the patient’s medical history, the clinical picture and, if necessary, further hemostasis tests. The indication for TEG 6s System use is with adult patients where an evaluation of their blood hemostasis properties is desired. Hemostasis evaluations are commonly used to assess clinical conditions in cardiovascular surgery and cardiology procedures to assess hemorrhage or thrombosis conditions before, during and following the procedure.

Allowed Use

The TEG 6s Citrated Multichannel Assay Cartridge, used with the TEG 6s analyzer, is intended to provide supporting and adjunctive diagnostic information to facilitate patient management recommendations to the healthcare professional for the treatment of COVID-19 or co-existing conditions in hospitalized patients suspected of a COVID-19 associated coagulopathy.

TEG 6s Citrated: K, RT, FF Assay Cartridge

FDA-Cleared Indications for Use

The TEG 6s Hemostasis System consists of the TEG 6s Hemostasis Analyzer and TEG 6s Citrated: K, RT, FF Assay Cartridge. The TEG 6s Hemostasis System is intended for in vitro diagnostic use to provide semi-quantitative indications of the hemostasis state of a venous blood sample. The TEG 6s Hemostasis System records the kinetic changes in a sample of 3.2% citrated whole blood as the sample clots.

The Citrated: K, RT, FF Assay Cartridge contains three independent assays (CK, CRT and CFF) and the system output consists of a table of numerical values for parameters R, LY30, and MA.

The CK assay monitors the hemostasis process via the intrinsic pathway in 3.2% citrated whole blood specimens on the TEG 6s Hemostasis System. Clotting characteristics are described by the functional parameters R (clotting time) and LY30 (fibrinolysis after 30 minutes of reaching maximum clot strength).

The CRT assay monitors the hemostasis process via both the intrinsic and extrinsic pathways in 3.2% citrated whole blood specimens on the TEG 6s Hemostasis System. Clotting characteristics are described by the functional parameter MA (maximum clot strength).

The CFF assay monitors hemostasis of 3.2% citrated whole blood specimens on the TEG 6s Hemostasis System after blocking platelet contributions to clot strength. Clotting characteristics are described by the functional parameter MA (maximum clot strength).

Results from the TEG 6s analysis should not be the sole basis for a patient diagnosis, but should be evaluated together with the patient's medical history, the clinical picture and, if necessary, further hemostasis tests. The indication for TEG 6s Hemostasis System use is with adult patients (18 years and older) where an evaluation of their blood hemostasis properties is desired. Hemostasis evaluation with the TEG 6s Hemostasis System using the Citrated: K, RT, FF Assay Cartridge is used to assess clinical conditions in a trauma setting to assess hemorrhage or thrombosis conditions.

Allowed Use

The TEG 6s Citrated: K, RT, FF Assay Cartridge, used with the TEG 6s analyzer, is intended to provide supporting and adjunctive diagnostic information to facilitate patient management recommendations to the healthcare professional for the treatment of COVID-19 or co-existing conditions in hospitalized patients suspected of a COVID-19 associated coagulopathy.

TEG 6s PlateletMapping ADP & AA Assay Cartridge

FDA-Cleared Indications for Use

The TEG 6s System is intended for in vitro diagnostic use to provide qualitative assessment of platelet function. The system records the kinetic changes in a sample of heparinized whole blood as the sample clots.

The PlateletMapping Cartridge, to be used with the TEG 6s analyzer, provides four channels of dried-in-place reagents: HKH (Kaolin with Heparinase), Activator F, AA and ADP (one reagent in each channel). In combination, MA parameter results from these four reagents are used to calculate the parameters platelet % Inhibition and % Aggregation for AA and ADP.

Results from the TEG 6s analysis should not be the sole basis for a patient diagnosis, but should be evaluated together with the patient's medical history, the clinical picture and, if necessary, further hemostasis tests.

The TEG 6s System is indicated for use with adult patients where an evaluation of their blood hemostasis properties is desired. Hemostasis evaluation with the TEG 6s System is commonly used to assess clinical conditions in cardiovascular surgery and cardiology procedures to assess hemorrhage or thrombosis conditions.

Allowed Use

The TEG 6s PlateletMapping ADP & AA Assay Cartridge, used with the TEG 6s analyzer, is intended to provide supporting and adjunctive diagnostic information to facilitate patient management recommendations to the healthcare professional for the treatment of COVID-19 or co-existing conditions in hospitalized patients suspected of a COVID-19 associated coagulopathy.

TEG 6s PlateletMapping ADP Assay Cartridge

FDA-Cleared Indications for Use

The TEG 6s System is intended for in vitro diagnostic use to provide qualitative assessment of platelet function. The system records the kinetic changes in a sample of heparinized whole blood as the sample clots.

The PlateletMapping ADP Cartridge, to be used with the TEG 6s analyzer, provides three channels of dried-in-place reagents: HKH (Kaolin with Heparinase), Activator F, and ADP (one reagent in each channel). In combination, MA parameter results from these three reagents are used to calculate the parameters platelet % Inhibition and % Aggregation for ADP.

Results from the TEG 6s analysis should not be the sole basis for a patient diagnosis, but should be evaluated together with the patient’s medical history, the clinical picture and, if necessary, further hemostasis tests.

The TEG 6s System is indicated for use with adult patients where an evaluation of their blood hemostasis properties is desired. Hemostasis evaluation with the TEG 6s System is commonly used to assess clinical conditions in cardiovascular surgery and cardiology procedures to assess hemorrhage or thrombosis conditions.

Allowed Use

The TEG 6s PlateletMapping ADP Assay Cartridge, used with the TEG 6s analyzer, is intended to provide supporting and adjunctive diagnostic information to facilitate patient management recommendations to the healthcare professional for the treatment of COVID-19 or co-existing conditions in hospitalized patients suspected of a COVID-19 associated coagulopathy.