

Heska Element COAG™ Veterinary Analyzer

Operator's Guide



November 8, 2017



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About this Guide

This Operator's Guide is written for Heska Element COAG™ Analyzers with software newer than version 03102017_0848. Please refer to [Section 3.2.2](#) for information regarding finding the version of the software currently installed on the analyzer and instructions to upgrade to the newest version.

The following symbols and convention are used in this guide:

Bold Used for menu, command and keyboard selections and screens you will see.

Italics Used for emphasis.



Helpful information about a particular topic.



Important information to prevent problems and ensure that you are successful in using the instrument.

Technical Support

For any inquiries about the instrument or use of the test cartridges, contact your Distributor or Heska Corporation Customer Support.

See contact information below:

Heska Corporation

3760 Rocky Mountain Avenue
Loveland, Colorado 80538
USA

☎ 800-464-3752

🌐 www.heska.com

Part I.

**The Heska Element COAG™
Veterinary Analyzer**

1. Introduction

1.1. General Information

The Heska Element COAG™ Analyzer is an innovative specialty Analyzer developed and used *exclusively* for veterinary diagnostics.

The Heska Element COAG™ Analyzer enables veterinarians to perform automated in-clinic specialty testing using disposable cartridges. The Heska Element COAG™ Analyzer's operation is based on light absorption.

The Heska Element COAG™ Analyzer contains microprocessors and LED optical elements to control all testing and analytical functionalities. The operator controls the Analyzer's functions through a 7-inch color touch screen. An open slot in the front of the Analyzer allows the insertion of a cartridge, and guides the test cartridge into place for analysis.

The Heska Element COAG™ Analyzer test cartridge has two optical detection windows and is preloaded with dry reagents specific to the tests. All blood clot formations or reactions occur within the test cartridge.

Test results are displayed on screen, and are automatically stored in the instrument's memory database for later retrieval. The results can be printed to an optional USB printer or exported to a central Laboratory Information System (LIS). An external keyboard can also be connected to USB ports at the back of the instrument, if so desired.

1.2. Intended Use of the Heska Element COAG™ Analyzer

The Heska Element COAG™ Analyzer provides quantitative in-vitro determination of:

- Fibrinogen
- PT (Prothrombin Time)
- aPTT (activated Partial Thromboplastin Time)
- DEA 1 Canine Blood Typing
- Feline A & B Blood Typing

1. Introduction



If the Heska Element COAG™ Analyzer is used in any way other than that described in this manual, the Analyzer may not operate as intended, may produce inaccurate or no results, and may pose a safety hazard. Only use approved Heska Element COAG™ cartridges with the Analyzer.

1.3. Basic Operating Principles

The Heska Element COAG™ Analyzer's operation is based on one-time-use test cartridges containing micro channels and test-specific reagents. Samples added to the Heska Element COAG™ cartridges flow through micro channels in the cartridge where it reacts with test-specific reagents. Light passing through the optical detection window on the cartridge is absorbed by the sample in the channels. The Analyzer measures how much light is absorbed and automatically calculates the test results, which are displayed on screen and stored in the Analyzer's database. No interaction is needed or required by the user during the analysis.

1.4. Features of the Heska Element COAG™ Analyzer

- Large, 7-inch color touchscreen
- Easy-to-use touchscreen controls
- Small sample size (100 µL or less)
- Fast and accurate point-of-care results
- Simple and user-friendly operation
- Continuous internal self-test monitoring during operation
- Small footprint
- Up to 1000 test results can be stored and retrieved from the instrument's results database
- Allows Patient and Sample ID input (optional)
- LIS-interface

1.4.1. Symbols Used in Labeling



Caution, risk of danger
(see accompanying warning text)



Alternating Current



Direct Current



Caution, risk of electric shock



USB Connection

1.4.2. Intended Use of the Heska Element COAG™ Cartridges

The Heska Element COAG™ cartridges are *exclusively* intended for use with the Heska Element COAG™ Analyzer. Utilizing it with other instruments is not advisable.

- Each Heska Element COAG™ cartridge is clearly labeled with test type and individually packed in a sealed pouch with a desiccant bag to protect it from moisture.
- Once the pouch has been opened, the Heska Element COAG™ cartridge must be used within the time limit stated on the package insert.
- Do not use the cartridge after its expiration date since it is only stable until the date stamped on the pouch. Using it after the duration date can result in inaccurate test results.
- Do not store the Heska Element COAG™ cartridge outside the temperature range stated on the package insert:
 - Fibrinogen Test (36 °F to 46 °F) / (2 °C to 8 °C)
 - PT/aPTT Combination Test (36 °F to 46 °F) / (2 °C to 8 °C)
 - DEA 1 Canine Blood Typing Test (36 °F to 77 °F) / (2 °C to 25 °C)
 - Feline A & B Blood Typing Test (36 °F to 77 °F) / (2 °C to 25 °C)
- The Heska Element COAG™ cartridges should be at room temperature before use, i.e., between 59 °F to 86 °F (15 °C to 30 °C). Exposing the cartridge to extreme temperatures impairs its accuracy.
- Used cartridges, pipettes and collection tubes are considered potentially infectious. Dispose them off properly in accordance with the policies and regulations practiced at the place of operation.

1. Introduction

- When using the Heska Element COAG™ cartridges, all biohazard safety guidelines pertaining to handling and disposal of animal blood samples must be strictly followed.



Do not reuse cartridges. All Heska Element COAG™ cartridges are for single use only. Once used, the cartridge should be disposed of in accordance with the safety guidelines at the place of operation.

2. System Description and Setup

2.1. User Information and Precautions

Please read the instructions in this Operator's Guide carefully before using the Heska Element COAG™ Analyzer, and follow all instructions and warnings and keep it handy for future references.

The Heska Element COAG™ Analyzer and its cartridges are *exclusively* intended for veterinary use. If the Heska Element COAG™ Analyzer is used in a manner not specified by the manufacturer, the protection provided by the instrument may be impaired.

Observe the following:

- Attempting to open or dismantle the instrument can cause electric shock and will void the warranty.
- Protect the instrument from being wet, whether it is exposure to wet locations or to rain or snow.
- Use only the power supply that is provided together with the instrument. Use of any other power supply will damage the instrument, thus, voiding the warranty.
- It is highly recommended that the power supply be disconnected or the instrument turned off when not in use.
- The power supply must be connected to a main power outlet that is grounded and of a quality normally found in hospitals, domestic and commercial environments.
- Do not expose the Heska Element COAG™ Analyzer to extreme temperatures: below 59 °F (15 °C) and above 86 °F (30 °C). Never expose the Heska Element COAG™ Analyzer near a heat source nor expose it to direct sunlight.
- It is strongly recommended to inspect the Heska Element COAG™ Analyzer regularly for damages. If damaged, disconnect instantly and contact Technical Support for assistance.
- If the Heska Element COAG™ Analyzer is accidentally dropped, immediately contact Technical Support. In this case, no test should be performed until it has been serviced by authorized personnel.

2. System Description and Setup

- Do not use non-Heska Element COAG™ cartridges with the Heska Element COAG™ Analyzer. A non-Heska Element COAG™ cartridge will not operate in the instrument and will only generate an error message when used.
- Before inserting the cartridge, make sure that there are no foreign objects in the cartridge slot. Test cartridges should slide in easily into the cartridge slot. No force is needed in the insertion.
- Do not use excessive force or sharp objects on the Analyzer's sensitive touch screen. A light tap is sufficient.
- The detachable power supply cord set and appliance inlet of the external power supply are considered as the disconnecting device.
- The USB interface connector of the Heska Element COAG™ Analyzer must only be connected to SELV circuits.
- The LAN connector must only be connected to 10Base-T/100Base-TX circuits. External computing devices connected to the USB and LAN interface connectors have to comply with the standard UL60950 for US and Canada, and IEC60950 for other countries.
- Network/USB cables connected to Heska Element COAG™ Analyzer should not be more than 3 meters long.

2.2. Unpacking

When unpacking the instrument, be sure that the following guidelines are followed:

- Remove the Heska Element COAG™ Analyzer from the shipping carton.
- Place the Analyzer on a leveled surface relatively free of animal hair, dust and other contaminants.
- Do not place near a window or a heat source.

Make sure that you received the following components:

- Heska Element COAG™ Analyzer
- Sealing Cartridge
- Power supply with cord
- Power cord
- Heska Element COAG™ Diagnostic System Operator's Guide.
- Quick Guide for each of the tests in the Heska Element COAG™ test portfolio, see [Part II](#).

2.3. Main Components

2.3.1. The Heska Element COAG™ Analyzer

The main components of the Heska Element COAG™ Analyzer are shown in [Figure 2.1](#) and an overview of the Analyzer's technical specifications is given in [Table 2.1](#).

The Heska Element COAG™ Analyzer has a 7-inch touch screen which serves as the main interaction point between the operator and the instrument itself. The instrument has a cartridge slot located on the front where the Heska Element COAG™ test cartridges are inserted. The power supply connector is located at the back of the instrument together with the LAN port and two USB 2.0 ports. An on/off button is located at the rear of the instrument as well.

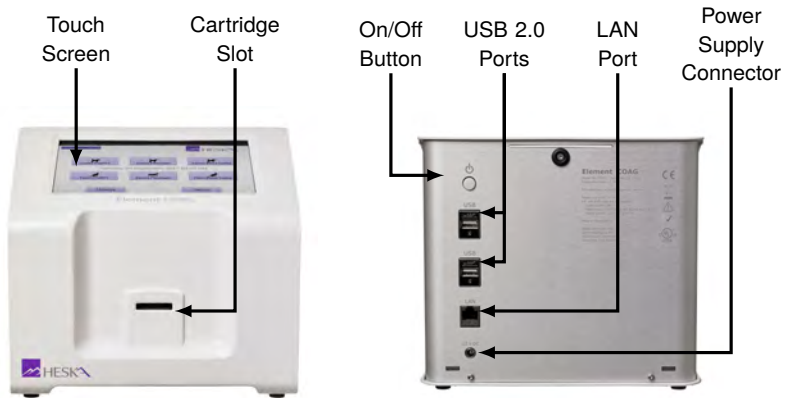


FIGURE 2.1: Front (left) and back (right) view of the Heska Element COAG™ Analyzer.

2. System Description and Setup

TABLE 2.1: Technical Specifications for the Heska Element COAG™ Analyzer.

Operating Environment	Indoor use only
Temperature	59 °F to 86 °F (15 °C to 30 °C)
Max. Relative Humidity	80 %
Max. Altitude	9843 ft (3000 m)
Pollution Degree	2
Others	
Mode of Operation	Continuous
Instrument's placement minimum distance from the nearest object	15 cm/6 in
Power Supply	
Input	100 V AC to 240 V AC (fluctuations < 10 % of nominal voltage) 1.5 A
Output	50 Hz to 60 Hz 12 V DC 6.67 A
Instrument	
Input	12 V DC 2.7 A
Power Consumption	32.4 W
Transient Overvoltage	Category II of IEC 60364-4-443
Instrument Input Connections	12 V DC Power Supply
Instrument Input and Output Connections	LAN and USB 2.0

2.3.2. The Heska Element COAG™ Cartridge

Figure 2.2 shows a typical Heska Element COAG™ test cartridge. The Heska Element COAG™ cartridge has a label that indicates the kind of test the cartridge performs. It has a sample well where the sample is being added or placed.

Sample added to the Heska Element COAG™ cartridge is drawn by capillary force into the cartridge where it is mixed with reagents. The microfluidic based design makes it possible to have two independent detection windows on the cartridge with a sample volume below 100 μL . Light passing through the two optical detection windows is absorbed by the sample. Test results are determined by using the measurement technology of light absorbance.

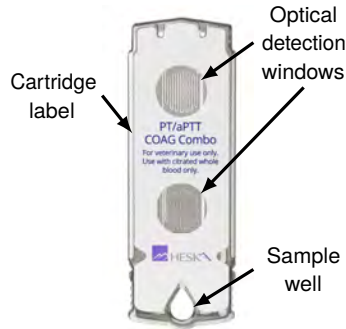


FIGURE 2.2: Heska Element COAG™ cartridge.

The cartridge contains the reagents necessary to perform the tests. The user only needs to insert the cartridge in the instrument's cartridge slot and follow the on-screen instructions. A small sample volume is enough to carry out the tests. Just add an adequate amount of sample and see the results after a few minutes.

2.4. Setup

Before setting up the Heska Element COAG™ Analyzer:

- Make sure that the room temperature is between 59 °F to 86 °F (15 °C to 30 °C).
- If the instrument has been stored outside the aforementioned temperature range, let the instrument reach room temperature prior to use.
- When the abovementioned factors have been met, place the Heska Element COAG™ Analyzer on a clean, flat, and stable vibration free surface at least 15 cm (6 in) from the nearest object.
- Plug the Heska Element COAG™ Analyzer into the power supply.
- Turn on the instrument by touching the power button at the back of the instrument.

2. System Description and Setup

The Heska Element COAG™ Analyzer is now ready for configuration. See [Chapter 3](#) for a detailed description of the Analyzer software and configuration options.

3. Configuring the Heska Element COAG™ Analyzer

3.1. The Home Screen

The Home Screen is the instrument's main menu screen, see [Figure 3.1](#). This screen is the first screen visible after the instrument has been turned on and serves as the main access point for operating the Analyzer and modifying the settings of the instrument.

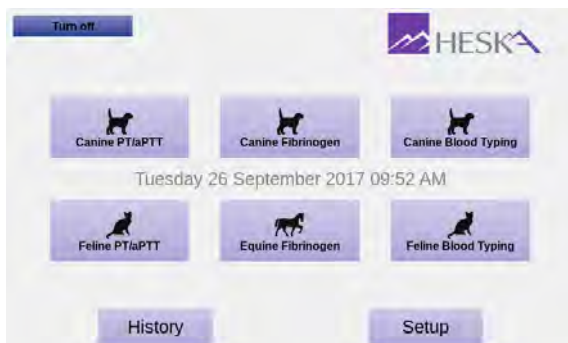


FIGURE 3.1: Home Screen. The main screen holds buttons for starting a new analysis, review the results history, and modify the instruments settings as well as turning off the instrument.

Make sure that the date and time shown on the screen are correct; otherwise, refer to Change the Date/Time under [Section 3.2.5](#) for resetting directions. The instrument is ready for use at this point. The following features are available at the Home Screen:

Turn Off an on-screen touch button situated at the upper left corner of the screen, used to turn the instrument off. It is also possible to turn off the instrument using the power button located at the back of the instrument.

Start Test on-screen touch buttons used to initiate the tests. Currently, canine and feline PT/aPTT coagulation tests, canine and feline blood typing, and canine and equine fibrinogen testing are available. See [Chapter 7](#) to [Chapter 10](#) for instructions about the specific tests.

History on-screen touch button for search and retrieval of measurement data gathered from previous testing. The results database is described in [Chapter 4](#).

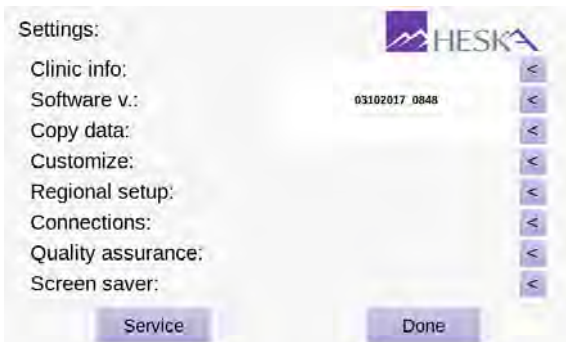
3. Configuring the Heska Element COAG™ Analyzer

Setup on-screen touch button for instrument configuration. This opens the Settings Menu for configuration. The instrument configuration is described in [Section 3.2](#).

3.2. Configuration of the Heska Element COAG™ Analyzer


Configuration of the Heska Element COAG™ Analyzer is performed from the Settings Menu which is accessed by touching the **Setup** button at the Home Screen. The Settings Menu can be seen in [Figure 3.2](#).

FIGURE 3.2: Settings Menu. From the Settings Menu it is possible to change and review the Analyzer configuration. The configuration options are organized in categories which can be accessed by touching the purple arrow button to the right of the category title.



The configuration options are divided into categories. The settings for a category can be accessed by touching the purple arrow button to the right of the category title. The categories are:

Clinic Info Edit your clinic information (name, contact information, etc.), see [Section 3.2.1](#). The information is not required, but if present it will appear on the result printouts and blood typing certificates.

Software V. View and update software version. The currently installed software version is printed in the text field next to the category title. Touch the  to install a different software version, see [Section 3.2.2](#) for detailed instructions.

Copy data Copy test data and results to a USB stick or an external hard drive, see [Section 3.2.3](#). The exported data can be sent to Customer Support for analysis in case of unexpected results or problems with the Analyzer.

Customize Modify the Analyzer's default settings, see [Section 3.2.4](#).

Regional Setup Change time, date and time format, see [Section 3.2.5](#). The current time and date are always displayed on the Analyzer's Home Screen and will be printed on the results printouts and logged in the results database.

Connections Use this menu to install an external printer or connect the instrument to a Laboratory Information System (LIS), see [Section 3.2.6](#) for a detailed discussion of the connectivity options.

Quality assurance From this menu, it is possible to calibrate the instrument for the Fibrinogen Test, see [Section 3.2.7.1](#), or to perform a self test of the Analyzer, see [Section 3.2.7.2](#).


Screen saver Turn the screen saver on/off and change the images shown on the screen when the screen saver is running, see [Section 3.2.8](#).



*The **Service** button is only used by Authorized Service Personnel to access internal system functions and requires a password.*

When the instrument is configured, touch **Done** to return to the Analyzer's Home Screen.

3.2.1. Clinic Info

The Clinic Info screen is shown in [Figure 3.3](#). The menu has data fields for entering the clinic's contact information. To enter the Clinic Info screen touch the **Setup** button on the Analyzer's Home Screen and touch the  to the right of the Clinic Info category in the Settings Menu.



All information in the Clinic Info screen is optional but will, if present, appear on the result printouts. Further, when connecting to a data exchange or computer network, the clinic information will also be transferred to any connected Laboratory Information System (LIS). Refer to [Section 3.2.6.2](#) for details regarding how to setup the Analyzer with a LIS.

The screenshot shows a 'Clinic info:' screen with the HESKA logo in the top right corner. On the left side, there are labels for various fields: Veterinarian, Clinic name, Address 1, Address 2, City, State, Zip, Phone number, Fax, Email, and Web. To the right of each label is a corresponding input field. On the far right of each input field, there is a small blue arrow pointing left. At the bottom of the screen, there are two buttons: 'Cancel' on the left and 'Done' on the right.

FIGURE 3.3: Clinic Info. In the Clinic Info menu the user can optionally supply name and contact information for the clinic. If entered, the information will be printed on result printouts and be exported if the Analyzer is connected to a LIS.

To enter your clinic information:

3. Configuring the Heska Element COAG™ Analyzer

1. Touch the purple arrow button  across the Clinic Info field on the Settings Menu. This opens the Clinic Info screen shown in [Figure 3.3](#).
2. Edit each field by touching  across each field.
3. Use the on-screen keyboard to type in relevant information.
4. When finished, touch **Done**. To clear any undesired changes and to start anew, touch **Cancel**.
5. Repeat [item 2](#) to [4](#) for each field that needs changing.
6. When all changes are applied, touch **Done** to return to the Settings Menu.



*Touching **Cancel** clears any undesired change(s) and touching **Done** confirms the change(s).*

3.2.2. Software Version/Upgrade


The Software screen is shown in [Figure 3.4](#). To enter the Software screen touch the **Setup** button on the Analyzer's Home Screen and touch the  to the right of the Software v. category in the Settings Menu. The current version of the software installed on the instrument is indicated on the Settings Menu screen and is also printed in the *Current software version* text field on the Software screen.

FIGURE 3.4: Software Version Screen. The currently installed software version is printed in the *Current software version* text field. A software upgrade can be applied by touching the **Upgrade** button.



To upgrade the Analyzer software:


1. Unplug any device that may be plugged into the USB port at the back of the Analyzer.
2. Insert the installer USB memory stick into the USB port at the back of the instrument and wait 10 seconds for the Analyzer to register the memory stick.
3. Touch **Upgrade** on the lower right hand side of the screen of the Software screen.

4. Touch **Yes** in the dialog box when asked to confirm that you want to upgrade, otherwise, touch **No**.
5. Wait for the Analyzer to apply the upgrade and reboot. When the instrument starts up anew, the upgrade has been applied and the new software version will be printed in the *Current Software version* text field.



Software upgrade requires that you obtain a USB memory stick containing an installer for the new software from Heska Corporation or from your Distributor.

3.2.3. Copy Data from the Analyzer

All test data and results stored in the Analyzer can be copied to a USB memory stick by touching the  to the right of the *Copy data* category in the Settings Menu, see Figure 3.5.

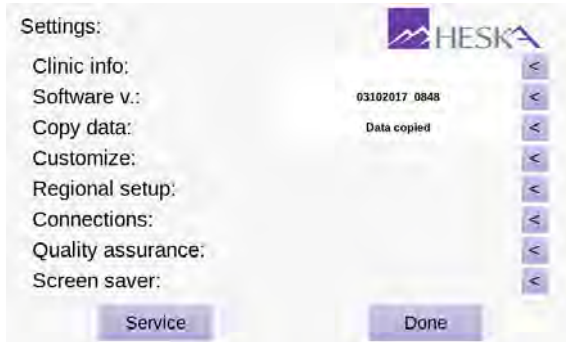




FIGURE 3.5: Measurement data can be copied from the instrument by touching  to the right of the *Copy data* category in the Settings Menu. When the data transfer is complete, *Data copied* will be printed in the text field next to the *Copy data* category.

To copy data from the Analyzer to a USB stick:

1. Unplug any device that may be plugged into the USB port at the back of the Analyzer.
2. Insert a USB memory stick into the USB port and wait 10 seconds for the Analyzer to register the memory stick.
3. From the Settings Menu touch the purple  to the right of the *Copy data* category. The data transfer will begin and *Copying data...* will appear in the status text field.
4. When the data transfer is complete *Data copied* will appear in the status text field.
5. Remove the USB stick and reconnect any device that was unplugged.



If a USB error message appears, check if the USB memory stick is properly inserted into the USB port and assure that the USB stick is not defective.

3.2.4. Customize


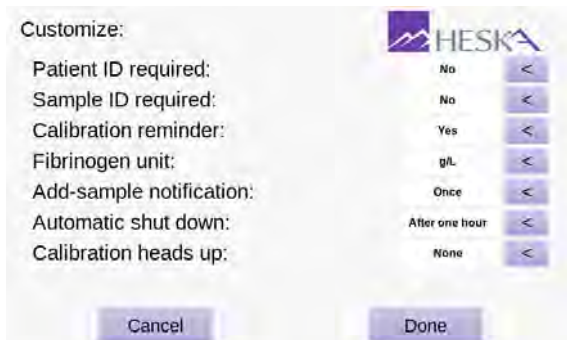
The Customize screen is shown in Figure 3.6. To enter the Customize screen touch the **Setup** button on the Analyzer's Home Screen and touch the  to the right of the Customize category in the Settings Menu.

FIGURE 3.6: Customize. From the Customize screen it is possible to customize whether or not Patient and Sample ID must be supplied during the test sequence, the unit for test results and frequency between notifications.



In the Customize menu, you can change the defaults for the following settings in the Heska Element COAG™ Analyzer:

Patient ID Required By default, this feature is deactivated but should be activated when used together with LIS as this field is used by many LIS systems to identify the test result for a particular patient. When Patient ID required is set to Yes, it is not possible to continue a test sequence without supplying information about the Patient ID.



Requiring Patient ID is highly recommended when using Heska Element COAG™ with a LIS, since editing the Patient ID is no longer possible after testing. For LIS users, please note that the Patient ID field is used as a unique identifier denoted as Practice Assigned ID (See Section 3.2.6.2).

Sample ID Required By default, this feature is deactivated but can be activated if the clinic wishes to have information in the Sample ID field in the results history (can be used to search for a particular result). When Sample ID required is set to Yes it is not possible to continue a test sequence without supplying information about the Sample ID.


Calibration Reminder By default is set to no, and does not remind you when the next Fibrinogen calibration is due. Should an analyzer require fibrinogen calibration, please contact Heska Technical Services.

Fibrinogen Unit Includes a selection of available units that is used for the Fibrinogen Test results. Possible choices are: grams per liter (g/L), milligrams per deciliter

(mg/dL) and grams per deciliter (g/dL). By default, the fibrinogen results are reported in grams per liter.

Add-sample notification Change the frequency of beeps when a test is ready for the sample. Possible choices are: once, every 10 seconds, every 30 seconds and every minute. By default, the user is notified only once when the test is ready for the sample.


To customize the above settings:

1. Toggle between the available options by touching the purple arrow button  to the right of the relevant menu point.
2. When finished, touch **Done** to confirm the new settings. To cancel any modifications, touch **Cancel**.



*Touching **Cancel** clears any undesired change(s) and touching **Done** confirms the change(s).*

3.2.5. Regional Setup

The Regional Setup screen is shown in [Figure 3.7](#). To enter the Regional Setup screen touch the **Setup** button on the Analyzer's Home Screen and touch the  to the right of the Regional Setup category in the Settings Menu.

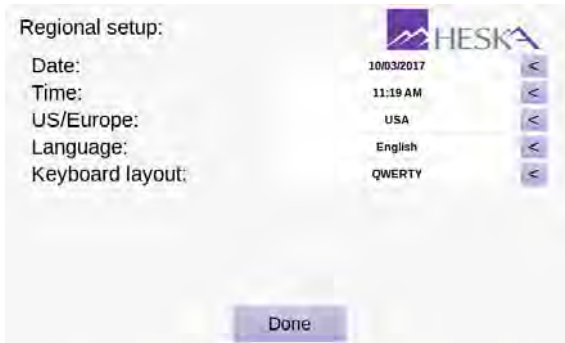


FIGURE 3.7: Regional Setup. In the Regional Setup menu, it is possible to adjust the date and time, modify the date/time format and change the language and keyboard layout used by the Analyzer.

From the Regional Setup screen it is possible to adjust the settings listed below:

Date Use this menu to set the current date, see [Section 3.2.5.1](#).


Time Use this menu to set the current time, see [Section 3.2.5.2](#).

US/Europe Use this menu to set the desired date and time format, see [Section 3.2.5.3](#).

3. Configuring the Heska Element COAG™ Analyzer

Language Use this menu to select the language used by the instrument, see [Section 3.2.5.4](#).

Keyboard layout Use this menu to change the keyboard layout, see [Section 3.2.5.5](#).

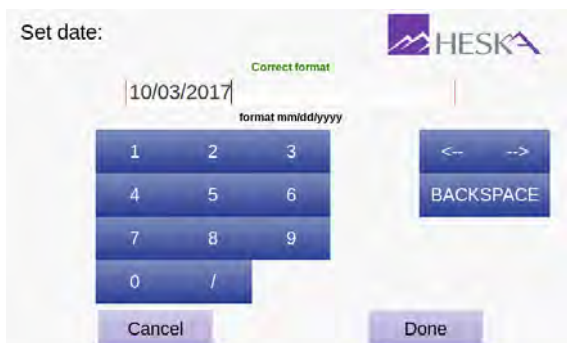
To change any of the above settings, touch the  to the right of the relevant settings field. When done modifying the regional settings, touch the **Done** button to return to the Settings Menu.

3.2.5.1. Set Date



The screen for setting or displaying the current date is shown in [Figure 3.8](#).

FIGURE 3.8: Date menu.

The current date is displayed in the text field at the top of the page. To change the current date use the on-screen keyboard. The date must be specified using mm/dd/yyyy format. When the complete entry complies with this format, **Correct Format** is displayed above the text field. Otherwise, **Incorrect Format** is displayed.



To set the current date:

1. From the Home Screen, touch **Setup** (this opens the Settings Menu).
2. From the Settings Menu, touch  to the right of the Regional Setup category (this opens the Regional Setup Menu).
3. From the Regional Setup page, touch  to the right of the Date entry field. [Figure 3.8](#) shows the Set Date screen.
4. Use the on-screen keyboard to enter the date.
5. Confirm by touching **Done**.

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The Date Format is shown below the Entry Box. **Incorrect Format** message is displayed above the entry box until the complete entry has been made. When the entry has been completed with the correct format, **Correct Format** message is displayed.



Touching **Cancel** clears any undesired change(s) and touching **Done** confirms the change(s).



3.2.5.2. Set Time

The screen for setting or displaying the current time is shown in Figure 3.9.

FIGURE 3.9: Time menu.
The current time is displayed in the text field at the top of the page. To change the current time use the on-screen keyboard. The time must be specified using the format shown below the entry field. When the complete entry complies with this format, **Correct Format** is displayed above the text field. Otherwise, **Incorrect Format** is displayed.



To set the current time:

1. From the Home Screen, touch **Setup** (this opens the Settings Menu).
2. From the Settings Menu, touch  to the right of the Regional Setup category (this opens the Regional Setup Menu).
3. From the Regional Setup page, touch  to the right of the Time entry field. [Figure 3.9](#) shows the Set Time screen.
4. Use the on-screen keyboard to enter the time.
5. Confirm by touching **Done**.



*The Time Format is shown below the Entry Box. **Incorrect Format** message is displayed above the entry box until the complete entry has been made. When the entry has been completed with the correct format, **Correct Format** message is displayed. The time and date format can be changed in the US/Europe Menu, see [Section 3.2.5.3](#).*



*Touching **Cancel** clears any undesired change(s) and touching **Done** confirms the change(s).*


3.2.5.3. Set the Date Format

The screen for setting or displaying the current date and time format is shown in Figure 3.10. Two formats are available:




USA When this date/time format is active, the date is shown as mm/dd/yy and the time is displayed using the 12-hour system followed by AM or PM.

Europe When this date/time format is active, the date is shown as dd/mm/yy and the time is displayed using the 24-hour system.



FIGURE 3.10: Date format. The currently active date and time format is indicated with a dark purple arrow button to the right. To select a different format, touch the  to the right of the desired format.

To set the current time and date format:

1. From the Home Screen, touch **Setup** (this opens the Settings Menu).
2. From the Settings Menu, touch  to the right of the Regional Setup category (this opens the Regional Setup Menu).
3. From the Regional Setup page, touch  to the right of the US/Europe entry field. Figure 3.10 shows the Date Format screen.
4. Activate the desired date and time format by touching  to the right of the preferred menu item. The active format is indicated by a dark purple button.
5. Touch **Done** to confirm the change.




Touching **Cancel** clears any undesired change(s) and touching **Done** confirms the change(s).




3.2.5.4. Set the Language

The screen for selecting or displaying the language used by the graphical user interface is shown in [Figure 3.11](#). The currently active language is indicated by a dark purple arrow button to the right of the language name. Currently, English (the default language) and Spanish, are supported.



FIGURE 3.11: Language Menu. The currently active language is indicated by a dark purple arrow button to the right of the language name. Touch the purple  to the right of another language option to change the language of the user interface.

To select a different language for the graphical user interface:

1. From the Home Screen, touch **Setup** (this opens the Settings Menu).
2. From the Settings Menu, touch  to the right of the Regional Setup category (this opens the Regional Setup Menu).
3. From the Regional Setup page, touch  to the right of the Language entry field. [Figure 3.11](#) shows the Language screen.
4. To change the language, touch the  to the right of the desired language so that it changes from purple to dark purple.
5. Touch **Done** to accept the change and return to the Regional Setup screen.



The purple arrow button to the right of the language options turns dark purple when the designated language is selected.



*Touching **Cancel** clears any undesired change(s) and touching **Done** confirms the change(s).*

3.2.5.5. Set the Keyboard Layout

The screen for selecting or displaying the keyboard layout used by the graphical user interface is shown in [Figure 3.12](#). The currently active keyboard layout is indicated by a dark purple arrow button to the right of the keyboard layout name.

The keyboard layout refers to the visual and functional arrangement of the keys and legends associated with the arrangement of buttons on the on-screen keyboards. Currently, five commonly used keyboard layouts are available:

QWERTY This keyboard layout is the most widespread layout in use and is the default layout used by the Heska Element COAG™ Analyzer. In this layout Q-W-E-R-T-Y are the first six letters in the upper row of letters on the keyboard.

AZERTY This keyboard layout is commonly used in French speaking countries. In this layout A-Z-E-R-T-Y are the first six letters in the upper row of letters on the keyboard.

QWERTZ This keyboard layout is commonly used in Germany. In this layout Q-W-E-R-T-Z are the first six letters in the upper row of letters on the keyboard.

Dvorak This keyboard layout is frequently used as an alternative for the QWERTY keyboard layout. In this keyboard layout most of the English characters are concentrated in the middle row of letters.

Blickensderfer This keyboard layout, for some people, provides better typing efficiency. The bottom row of characters in this layout is D-H-I-A-T-E-N-S-O-R.

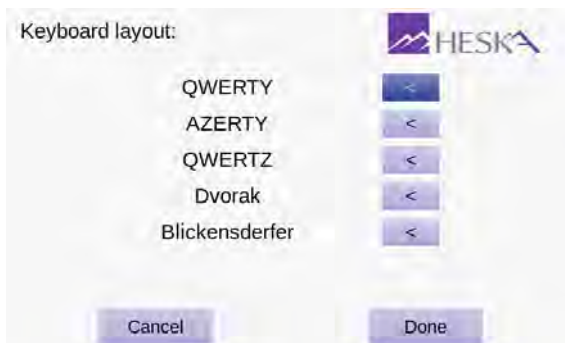






FIGURE 3.12: Keyboard Layout. The currently selected keyboard layout is indicated by a dark purple arrow button to the right of the keyboard layout name. Touch the purple  to the right of another layout option to change the layout of the graphical user interface.

By default, the Heska Element COAG™ Analyzer displays the QWERTY Keyboard Layout. To change to a different layout:


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1. From the Home Screen, touch **Setup** (this opens the Settings Menu).
2. From the Settings Menu, touch  to the right of the Regional Setup category (this opens the Regional Setup Menu).
3. From the Regional Setup, touch  to the right of the Keyboard Layout entry field.
4. To change to a different keyboard layout, touch the  button to the right of the desired layout. A dark purple button indicates the layout chosen. [Figure 3.12](#) shows the Keyboard Layout screen.
5. To apply the new setting, touch **Done**.



*Touching **Cancel** clears any undesired change(s) and touching **Done** confirms the change(s).*

3.2.6. Connections

The Connections screen is shown in [Figure 3.13](#). To enter the Connections menu, touch **Setup** on the Analyzer's Home Screen and the  across the Connections category in the Settings Menu.

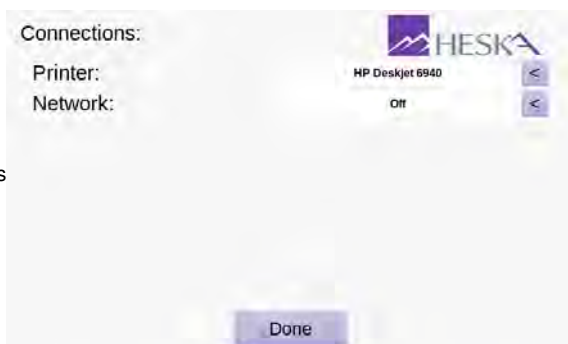



FIGURE 3.13: Connections Menu. The currently selected printer and the status for the LIS system is shown in the text fields in the connection menu.

Two external connections are available from the Connections screen:

Printer The name of the currently selected printer is shown in the text field to the right of the Printer category. Refer to [Section 3.2.6.1](#) for details regarding how to change to a different printer.

Network The network text field shows the status of the build in Laboratory Information System (LIS). By default, data export to a LIS is disabled. Refer to [Section 3.2.6.2](#) for details regarding how to configure the Heska Element COAG™ Analyzer for use with a LIS.

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To configure the Heska Element COAG™ Analyzer's connections to an external printer or an external network, touch the  to the right of the preferred category.



Touching **Done** returns to the Settings Menu.

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3.2.6.1. Printer



The Heska Element COAG™ Analyzer is programmed to run with specific printer models that are currently available in the market. This section covers the necessary information regarding printer compatibility and suggestions regarding other options, if these printers are not available at your convenience.

The Heska Element COAG™ Analyzer only functions properly if connected to a printer approved by the manufacturer and compatible with the Heska Element COAG™ Analyzer.

FIGURE 3.14: Printer Selection Menu. The Printer Menu shows a list of printers that are compatible with the Heska Element COAG™ Analyzer. The currently selected printer is indicated by a dark purple arrow button to the right of the printer name.



To change the printer or to view a list of printer models compatible with the Heska Element COAG™ Analyzer, follow these steps:

1. From the Home Screen, touch **Setup** (this opens the Settings Menu).
2. From the Settings Menu, touch  to the right of the Connections category (this opens the Connections Menu).
3. From the Connections screen, touch  to the right of the Printer entry field. This will display a list of printers compatible with the Heska Element COAG™ Analyzer.



Connected printers are indicated with black text, offline printers with red. The currently selected printer is indicated by a dark purple arrow button to the right of the name of the printer.

4. To select a different printer for use with the Heska Element COAG™ Analyzer, set the printer up according to the manufacturer's instructions and connect it to the Heska Element COAG™ Analyzer using a USB cable. The USB port is located on the back of the instrument, see [Figure 2.1](#).
5. Select your connected printer by touching the corresponding arrow key on the right-hand side of the screen.

6. Touch **Done** to confirm and return to the Settings Menu.



*Touching **Cancel** clears any undesired change(s) and touching **Done** confirms the change(s).*



As the instrument uses an embedded operating system, it has no physical means of adding new custom printers. If the available printers do not match your preference, it is recommended to use Heska Element COAG™ Auto-printer instead. Heska Element COAG™ Auto-printer is a free, standalone network based utility program, supplied by Heska Corporation that enables the Analyzer to print to any printer, connected directly or indirectly to a local network. Contact your Distributor regarding Auto-printer.

3.2.6.2. Network

This section discusses prerequisites and guidelines relevant to LIS technicians and the options that are available regarding data transmission from the Heska Element COAG™ Analyzer to a media within your data exchange network.



If your laboratory does not have a Laboratory Information System setup, leave the Data Export setting at off (the default) and disregard the remainder of this section.

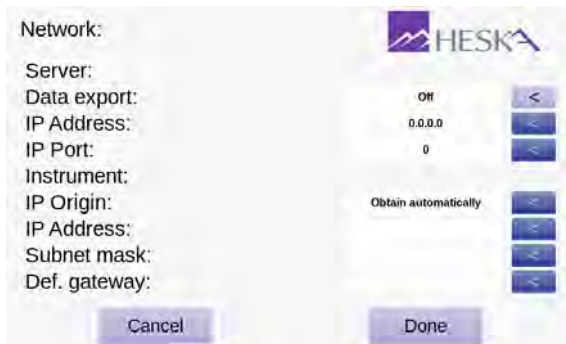


FIGURE 3.15: Network Screen. From the Network Screen it is possible to configure the Heska Element COAG™ Analyzer for use with a LIS.

Prerequisites The Heska Element COAG™ Analyzer transmits data via TCP/IP, hence an IP address and port number of your LIS are required in order to set up the data export.

The Heska Element COAG™ Analyzer should be connected to the network where a connection to your LIS can be achieved through an Ethernet port located at the back of your Heska Element COAG™ Analyzer.

3. Configuring the Heska Element COAG™ Analyzer


Note that the information is transmitted in the language chosen on the Heska Element COAG™ Analyzer.

Contact Heska Corporation for an updated list of applied LIS tags, enabling your LIS operator to set a viable connection up to your Heska Element COAG™ Analyzer. With regard to any LIS system, Heska Corporation does not deliver any specification files, drivers or middleware applications.



Industrial standard NCCLS LIS protocols, NCCLS LIS01-A2, Vol. 28, No. 13 and NCCLS LIS02-A2, Vol. 24, No. 33, have been implemented.

Guidelines To configure your Heska Element COAG™ Analyzer with a LIS, information must be provided by the user.

Edit each field in the Network Screen (see [Figure 3.15](#)) by touching the purple arrow button  to the right of the corresponding entry box.

Server The following fields apply to the identification of your LIS server:

Data Export Enables/disables data export to a LIS on the Analyzer. With data export activated the following fields become editable.

Note that when enabling data export from the Heska Element COAG™ Analyzer it will still function as a stand-alone instrument saving all measurements on disk, but will additionally transfer measurement results to your LIS.

Results measured when the connection to the LIS is offline are queued and transmitted when a connection has been established. This queue does not survive a power cycle (switching the instrument off/on).

With data export enabled a **Resend** button appears on the history pages for the test results of the Heska Element COAG™ Analyzer. This enables the operator to retransmit all or individually selected measurements stored on the Heska Element COAG™ Analyzer. Touching **Resend** when the connection to the server is offline will queue the measurement results for retransmission upon a reconnection. This queue does not survive a power cycle (switching the instrument off/on).

With data export enabled, the LIS can query the Heska Element COAG™ Analyzer to resend individual or all results. If communication is lost in the process, the Heska Element COAG™ Analyzer will queue the intended measurements for retransmission upon reconnection. This queue does not survive a power cycle (switching the instrument off/on).

On the Home Screen of the Heska Element COAG™ Analyzer, LIS connection problems are indicated, notifying the user to check connectivity.

- A small 'N' flashes on the lower right-hand corner, when no LIS connection can be established.
- A small 'T' flashes on the lower right-hand corner, when the LIS is not responding.

If the connection is lost or offline, reconnection is attempted at pre-defined time intervals.

IP Address Type your LIS server application's IP Address here. This field is forced editable, if data export has been enabled.

IP Port Type your LIS server application's IP port number. This field is forced editable, if data export has been enabled.

Instrument The instrument section in the screen specifies whether to obtain an IP address automatically from the network or to specify one manually.

IP Origin By default the IP origin is set to *Obtain automatically*. It is *strongly* recommended to leave this setting at the default value. As the Heska Element COAG™ Analyzer is equipped with Automatic Private IP Addressing (APIPA), it is not necessary to alter the remaining settings in the Instrument section (the Heska Element COAG™ Analyzer will work on networks without a DNS server).



Note that setting a fixed IP address as IP Origin will produce error messages if the instrument cannot connect to the network. If you set the IP Origin to a fixed value, you must contact your local IT administrator to obtain the values for the IP Address, Subnet mask and Default gateway.

If you have a strict IT setup at your facility, and need to white-list your Heska Element COAG™ Analyzer, the DNS or APIPA automatically obtained IP address for the Heska Element COAG™ Analyzer will be listed in the field Instrument IP Address. The MAC address of your Heska Element COAG™ Analyzer can be found on the Service page.



An important note on Practice Assigned ID: The LIS field, Practice Assigned ID, is a unique identifier (key) for any LIS to handle exported data. For this field, the Heska Element COAG™ Analyzer uses the Patient ID the operator entered. Therefore, when using the Analyzer in a data export setup, it is highly recommended to apply the user option to require Patient ID (See [Section 3.2.4](#)).

3. Configuring the Heska Element COAG™ Analyzer



A Note on the Communications Log: In the service page of the Heska Element COAG™ Analyzer, a log of the data export communication can be found (the last 1000 messages are shown).

The log page is intended for LIS service technicians to find transmission problems when integrating the Heska Element COAG™ Analyzer into their LIS system.

The transmitted data is shown at protocol layer with a primary column indicating direction to and from the instrument.

In addition to the transmitted data, the Heska Element COAG™ Analyzer will log messages when the communication with the server is established or lost. Also, miscellaneous error messages will appear here.

3.2.7. Quality Assurance

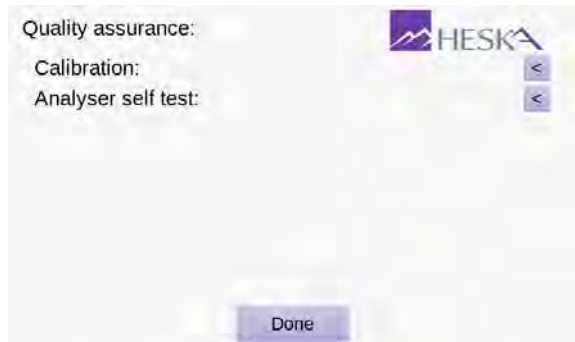



FIGURE 3.16: Quality assurance menu.

3.2.7.1. Calibration

The Calibration menu is shown in [Figure 3.18](#). The Calibration menu gives an overview over date(s) and time(s) for when calibration for the Fibrinogen Test has been performed. The currently active calibration is indicated with a dark purple button to the right of the row with the calibration information.



FIGURE 3.17: Calibration Overview. The Calibration overview shows details regarding date(s) and time(s) for when calibration for the Fibrinogen Test has been performed.

To access the Calibration overview, touch the **Setup** button on the Home Screen and then touch the  to the right of the Calibration category in the Settings Menu.

The Calibration page has three buttons:

Done Touching the **Done** button returns to the Settings Menu without making changes to the Fibrinogen Calibration settings.

Save If more than one calibration has been carried out, you can choose which calibration the Analyzer should use when performing a Fibrinogen Test. If the calibration is changed, you must touch **Save** to store the new selection and return the Settings Menu.

Calibrate To perform a new calibration of the Heska Element COAG™ Analyzer for use with the Fibrinogen Test, touch the **Calibrate** button. This will start a calibration sequence.



Note that performing a calibration of the Heska Element COAG™ Analyzer requires an Fibrinogen Calibration Kit. Please contact Technical Support Services for details regarding this procedure.

3.2.7.2. Analyzer Self Test

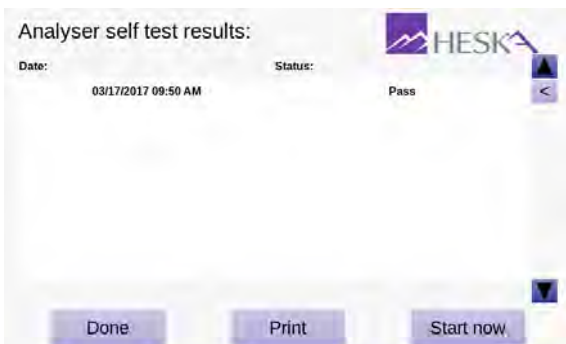


FIGURE 3.18: Analyzer self test results. This menu provides an overview of the details regarding date(s) and time(s) for when an Analyzer self test has been performed.

3.2.8. Screen Saver


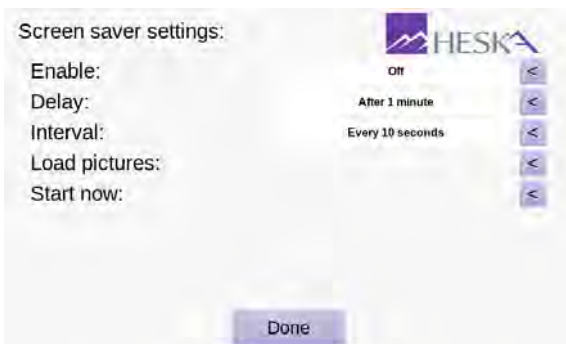


The Screen Saver Settings screen is shown in Figure 3.19. To enter the Screen Saver Settings screen, touch **Setup** on the Analyzer's Home Screen and touch the  to the right of the Screen Saver category in the Settings Menu. The Heska Element COAG™ Analyzer's screen saver consists of user-selected pictures shuffled randomly.


FIGURE 3.19: Screen saver settings. From the screen saver settings menu, it is possible to enable/disable the screen saver. If the screen saver is enabled, the delay for starting the screen saver and the interval between the exchanging the displayed images can be configured.





Five options are available to configure the Heska Element COAG™ Analyzer's screen saver:

Enable Touch the  to the right to turn the screen saver on/off. If the screen saver is turned off, the remaining settings have no effect.

Delay Touch the  to the right to change the delay before the screen saver is started. Possible choices are 1 minute, 5 minutes, 10 minutes, and 30 minutes.

Interval Touch the  to the right to change the interval between exchanging the displayed images when the screen saver is running. Possible choices are every 10 seconds, every minute, and every 5 minutes.

Load pictures To select pictures to be displayed when the screen saver is running, touch the  to the right. See [Section 3.2.8.1](#) for details regarding supported image formats and how to load the pictures.

Start now Touch the  to the right to test the screen saver. Touch anywhere on the screen to return to the Screen Saver Settings menu after testing.




*Touching **Done** in the Screen Saver Settings menu returns to the Settings Menu.*

3.2.8.1. Load Pictures


Pictures for display when the Heska Element COAG™ Analyzer's screen saver is running can be loaded from the Screen Saver Pictures menu, see [Figure 3.20](#). Up to eight pictures can be loaded and displayed at random when the screen saver is running.




FIGURE 3.20: Load Pictures.

Up to eight screen saver pictures can be loaded at a time for use by the Heska Element COAG™ Analyzer's screen saver. To load a picture, touch the  to the right of the desired picture number and select the image file. To delete a picture touch the purple cross next to the image.

To add a new picture for use by the screen saver:


1. From the Home Screen, touch **Setup** (this opens the Settings Menu).
2. From the Settings Menu, touch  to the right of the Screen Saver category (this opens the Screen Saver Settings page).

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3. From the Screen Saver Settings page, touch  to the right of the Load pictures entry (this opens the Screen Saver Pictures page, see [Figure 3.20](#)).
4. Insert a USB stick with the desired pictures in the USB port on the back of the Analyzer, see [Figure 2.1](#) for the location of the USB port.



The pictures must be in JPEG format with extension “.jpg” and be smaller than 1 MB.

5. Touch the  to the right of the desired picture number. This will open a list of JPEG images located at the root of the USB stick. If no images are found an error message will be displayed.
6. Select the image to load and touch **Done**.
7. Repeat [item 5](#) and [item 6](#) for all pictures you want to appear when the screen saver is running.
8. When all images are loaded, touch **Done** to return to the Screen Saver Settings menu, see [Section 3.2.8](#) for options in this menu.



*Touching **Done** in the Screen Saver Pictures menu returns to the Screen Saver Settings menu.*

4. Memory Database

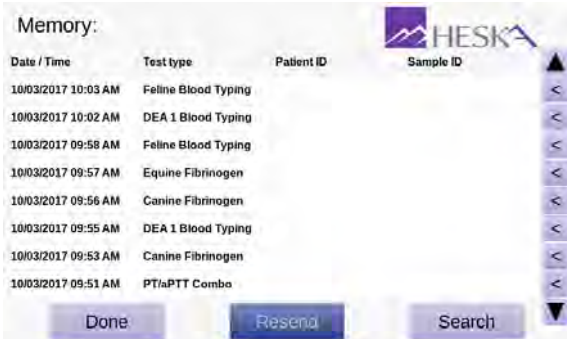
Up to a 1000 test results are automatically stored in the Heska Element COAG™ Analyzer's memory database. The files in the database are sorted by date, with the most recent first. Each file is stored with Patient ID, Sample ID, Test Date and Time, and test results. There is a built-in search function to retrieve test results by Test Type, Patient or Sample ID or by Date. Test results can be printed if a printer is connected to the Analyzer.

4.1. Viewing Test Results

To view the results database, touch the **History** button on the Analyzer's Home Screen. This will open the results database view shown in [Figure 4.1](#). This view shows the last 1000 results obtained on the Analyzer sorted by date (newest first).

For each result the following are listed: Date and time of test, Test Type, Patient ID and Sample ID. Patient and Sample ID are supplied by the operator when running the test. The test date/time and test type are automatically logged by the Analyzer when running a test.

Results can be retrieved from the database by performing a search based on the above meta-data. To access the Search Menu, touch the **Search** button at the bottom of the screen and follow the directions given in [Section 4.2](#).



Date / Time	Test type	Patient ID	Sample ID
10/03/2017 10:03 AM	Feline Blood Typing		
10/03/2017 10:02 AM	DEA 1 Blood Typing		
10/03/2017 09:58 AM	Feline Blood Typing		
10/03/2017 09:57 AM	Equine Fibrinogen		
10/03/2017 09:56 AM	Canine Fibrinogen		
10/03/2017 09:55 AM	DEA 1 Blood Typing		
10/03/2017 09:53 AM	Canine Fibrinogen		
10/03/2017 09:51 AM	PT/aPTT Combo		


FIGURE 4.1: Results history. Up to 1000 test results are stored in the internal results database on the Heska Element COAG™ Analyzer.

4. Memory Database

The **Resend** button is only visible if the Analyzer is connected to a LIS. Use the **Resend** button to synchronize the results in the LIS if you have changed the Analyzer configuration (language, time format, etc.) or if the connection to the LIS has been corrupted. All test results will remain in the Analyzer's database and only a copy will be transmitted to the LIS.

Touch the **Done** button to return to the Analyzer's Home Screen.

To view details for a particular test, follow the steps below:

1. From the Home Screen, touch **History** (this opens the Memory database).
2. Touch the ▼ and ▲ buttons to scroll through the files in the database.
3. Touch the  on the right hand side of the screen corresponding to each file or the result line to review the detailed test results. The test result is retrieved in the same format as it was originally obtained.



*If a printer is connected to the Analyzer, the test result can be printed by touching the on-screen **Print** button.*

4.2. Performing a Database Search

It is possible to search the results database for a particular result based on a number of search criteria. To access the Search menu, touch the **Search** button on the Memory screen, see [Figure 4.1](#). [Figure 4.2](#) shows the results history search interface.

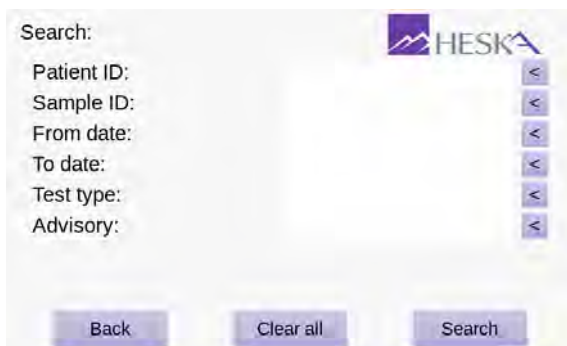



FIGURE 4.2: Results Search. A search for a particular result can be carried out using the Patient ID, Sample ID or test date and type as search criteria.

The available filters for a database search are listed below. It is possible to combine one or more search criteria when performing a database search.

Patient ID Supply a text string for filtering the results based on the user-supplied Patient IDs. See [Section 4.2.1](#) for details.

Sample ID Supply a text string for filtering the results based on the user-supplied Sample IDs. See [Section 4.2.2](#) for details.

From date & To date Supply dates for filtering the results based on the test dates when the analyses were performed. See [Section 4.2.3](#) for details.

Test type Use the  to the right of the text field to toggle which test types to show in a results search. See [Section 4.2.4](#) for details.

4.2.1. Search by Patient ID

1. Touch **History** on the Home screen, and then touch **Search** on the lower right hand side of the Memory screen to access the Search Menu.
2. On the Search Menu, touch the purple arrow button across the Patient ID field to access the on-screen keyboard to type in the designated information required to retrieve the corresponding measurement data for a specific patient.
3. Touch **Done** when finished registering the search entry.
4. To begin the search, touch **Search** on the lower right hand side of the screen. To restart the search process touch **Clear All**.
5. If the Search-button was previously touched, the results gathered will be shown.
6. To start anew, touch **Back**.



Writing the whole Patient ID info is not necessary. You can write the word or just part of the word as the search phrase.

4.2.2. Search by Sample ID



1. Touch **History** on the Home Screen, and then touch **Search** on the lower right hand side of the Memory screen to access the Search Menu.
2. On the Search Menu, touch the purple arrow button across the Sample ID field to access the on-screen keyboard to type in the designated information required to retrieve the corresponding measurement data for a specific patient.
3. Touch **Done** when finished registering the search entry.
4. To begin the search, touch **Search** on the lower right hand side of the screen. To restart the search process touch **Clear All**.
5. If the Search-button was previously touched, the results gathered will be shown.
6. To start anew, touch **Back**.

4. Memory Database




Writing the whole Sample ID info is not necessary. You can write the word or just part of the word as the search phrase.

4.2.3. Search by Date

1. Touch **History** on the Home Screen, and then touch **Search** on the lower right hand side of the Memory screen to access the Search Menu.
2. On the Search Menu, touch the  across the From Date field to access the on-screen keyboard to type in the start date wherein the test took place or touch the  across To Date field, if the end date is desired.
3. Touch Done when finished registering the search entry, or touch **Cancel** to clear the entry and return to the Search menu.
4. To begin the search, touch **Search** on the lower right hand side of the screen. To restart the search process touch **Clear All**.
5. If the Search-button was previously touched, the results gathered will be shown.
6. To start anew, touch **Back**.

4.2.4. Search by Test Type

1. Touch **History** on the Home Screen, and then touch **Search** on the lower right hand side of the Memory screen to access the Search menu.
2. On the Search Menu, touch the  across the Test Type field until the desired test type is accessed. These test types are as follows:
 - DEA 1 Canine Blood Typing
 - PT/aPTT Combo
 - Equine Fibrinogen
 - Feline A & B Blood Typing
 - Canine Fibrinogen
3. Touch **Done** when finished registering the search entry, or touch **Cancel** to clear the entry and return to the Search Menu.
4. To begin the search, touch **Search** on the lower right hand side of the screen. To restart the search process touch **Clear All**.
5. If the Search-button was previously touched, the results gathered will be shown.
6. To start anew, touch **Back**.

5. Maintenance and Support

5.1. Routine Maintenance

The Heska Element COAG™ Analyzer only requires cleaning on a regular basis as maintenance. A visual inspection of the instrument for damage and a regular cleaning of the surface are strongly recommended.



Do not use the Heska Element COAG™ Analyzer if it appears to be damaged. Disconnect the power, and contact your Distributor for technical support.

5.2. Cleaning the Outer Shell

Visually inspect the instrument and clean if necessary. Pay special attention to the cartridge slot opening. Removal of dried blood, dirt or other foreign matters is done by using a water-moistened cotton swab or a damp cloth. Make sure to remove residual water with a dry cotton swab or a dry cloth. If a disinfectant is needed, use Virkon (1 % solution). After disinfection of the instrument, wipe it with a damp water-moistened cloth or cotton swab to remove any residual disinfectant.

- Use of solvents or strong cleaning agents is inadvisable, as they may damage the instrument's surface and the LCD touch screen.
- Use of aerosols or pouring detergents, solutions or any other liquid directly onto the instrument is likewise not recommended.



We strongly suggest that you follow the instructions to avoid damaging the instrument. Damages incurred due to improper maintenance are not covered by the warranty.

5.3. Cleaning the Cartridge Slot and Air Filter

Cleaning of the cartridge slot and air filter should be done by lightly vacuuming their openings. The air filter is located on the right side (as seen from the front) of the instrument and the cartridge slot in front.

5. Maintenance and Support



Do not vacuum the fan opening as this may cause damage to the fan. The fan opening is located on the left-hand side (as seen from the front) of the instrument. Damage caused by non-recommended cleaning methods is not covered by the product warranty.

5.4. Service

The instrument monitors its internal hardware and software and reports problems to the display screen (see Troubleshooting Section). If the instrument, for some reason, does not work properly and needs to be serviced, please contact your Distributor or Heska Corporation Customer Support for technical assistance at 1-800-464-3752.

- The Heska Element COAG™ Analyzer has no user-serviceable parts.
- There is a battery on the computer board inside the instrument. Replacement of this battery must be carried out by an authorized service provider.
- The Heska Element COAG™ Analyzer has an anti-tampering device. The warranty is voided if the instrument is opened by a non-authorized service provider.

5.5. Disposal of the Heska Element COAG™ Analyzer

The Heska Element COAG™ Analyzer contains electronic circuits and battery, therefore, local regulations for electric equipment disposal should be followed in disposing of the instrument.

6. Troubleshooting

6.1. Technical Support

Contact Heska's Technical Support Services for assistance at 1-800-464-3752.

6.2. Problems That Give No Advisory Messages

Problems that may occur but will not give an error message on the screen are tabulated in [Table 6.1](#).

TABLE 6.1: List of problems that give no error messages.

Problem	Corrective Action
Nothing happens when the instrument is turned on	Make sure that the instrument is connected to the power supply and that the power supply is connected to a power outlet. Check that the LED on the power supply is lit.
The Heska Element COAG™ cartridge cannot be inserted in the cartridge slot of the Heska Element COAG™ Analyzer	Make sure that there are no foreign objects in the cartridge slot.
The message Please insert new cartridge is still shown on the screen even after the cartridge has been inserted.	Make sure that the cartridge is fully inserted in the cartridge slot.
Nothing happens when a button is touched or there is a misalignment between the point of touch and the action carried out by the Analyzer.	Make sure that the Analyzer's touch screen is properly calibrated. See Section 6.4 for information regarding how to perform a screen calibration.

6.3. List of Advisories

In case a problem occurs during a test, the Heska Element COAG™ Analyzer will in most instances report an Advisory Number. For a list of possible advisories and corresponding corrective actions, please refer to [Table 6.2](#).

6. Troubleshooting

If the problem persists after trying the corrective action listed for the relevant advisory number in [Table 6.2](#), please contact technical support.

TABLE 6.2: List of Advisories.

No.	Cause	Corrective Action
2	Blood sample not detected due to inadequate amount of blood used	Repeat the test with a new cartridge. Be sure to follow the on-screen instructions
6	No clot detected. Can be due to a very sick animal or the tube not filled correctly	Repeat the test with a new cartridge. Be sure to follow the on-screen instructions
7	Flow too fast in the cartridge	Repeat the test with a new cartridge. Be sure to follow the on-screen instructions
8	Flow too slow in the cartridge	Repeat the test with a new cartridge. Be sure to follow the on-screen instructions
9	Sample added too early	Wait for the message Add sample and wait before adding sample to the cartridge. Be sure to follow the on-screen instructions
10	Malfunction of instrument components	Turn off and restart the instrument
11	On-going test terminated by the user	Repeat the test with a new cartridge
12	Ambient temperature too low	Restore recommended ambient conditions for the instrument
13	Ambient temperature too high	Restore recommended ambient conditions for the instrument
14–19	Light detection issue	Repeat the test with a new cartridge and ensure that no foreign objects are in the cartridge slot
20	No cartridge detected	Make sure that the cartridge is fully inserted in the cartridge slot
22–23	Light detection issue	Repeat the test with a new cartridge and ensure that no foreign objects are in the cartridge slot
24	LIS is not responding	Check LIS and Ethernet cable

Continued on next page

No.	Cause	Corrective Action
25	Test error	Repeat the test with a new cartridge. Be sure to follow the on-screen instructions
26	Autoagglutination detected	Please check the sample quality and repeat the test with a new cartridge
27	Flow too slow in cartridge	Please ensure proper dilution of the sample and repeat test
29	Wrong calibration code	Ensure that the 11-digit code is correct and that the calibration kit has not expired
30–33	Incorrect cartridge code	Retype code from pouch
34	Incorrect cartridge code	Check date setting on instrument and retype code from pouch
35	Incorrect cartridge code	Check expiry date from pouch
36	Internal error	Contact technical service
37–38	Signal distortion	Repeat the test with a new cartridge. Be sure to follow the on-screen instructions
39	Poor sample quality due to hemolysis, RBCs or lipemia	Check sample quality and if needed take new sample

6.4. Screen Calibration

A screen calibration can be initiated by touching the touch screen (anywhere) during start-up of the Heska Element COAG™ Analyzer. Figure 6.1 shows the Screen Calibration initiation.



FIGURE 6.1: Screen Calibration. A screen calibration can be initiated by touching the Heska Element COAG™ Analyzer's touch screen during start-up.

6. Troubleshooting

Once the screen calibration has been initiated, a progress-bar will appear. Upon progress bar time-out, the screen calibration program will start automatically. Otherwise, touch **Start Now** on the touch screen to initialize the program immediately. To cancel the screen calibration, touch the **Cancel** button. Follow the on-screen instructions to perform the calibration. You will need a small and pointy – *but not sharp* – piece of plastic to perform the screen calibration.

Part II.

**The Heska Element COAG™ Test
Portfolio**

7. PT/aPTT Combination Test

The PT/aPTT Coag Combo cartridge used with the Heska Element COAG™ Analyzer is designed to detect and diagnose abnormalities in Prothrombin Time (PT) and Activated Partial Thromboplastin Time (aPTT).

Each PT/aPTT Coag Combo cartridge contains dual optical detection windows filled with micro-channels: one for detecting PT clotting time, another for aPTT clot detection.

The PT/aPTT Coag Combo test cartridge can simultaneously measure PT and aPTT from a single drop of citrated whole blood with nominal test duration of 10 minutes including warm-up time.



FIGURE 7.1: The Heska Element COAG™ PT/aPTT COAG Combo test kit.

7.1. Blood Coagulation

Blood coagulation is the process by which blood forms clots [1–4]. Disorders in the coagulation process can lead to an increased risk of bleeding and/or clotting. Events that lead to the formation of a blood clot are simplified in coagulation theory into two coagulation cascades that are referred to as the intrinsic pathway and the extrinsic pathway, both leading to the common pathway and the formation of a stable fibrin clot. The analysis of blood coagulation can be a guide in determining a large number of existing or potential disorders that can seriously affect the health of the patient, see Figure 7.2 and [4].

The extrinsic pathway is initiated through the interaction of tissue factor with factor VII. Tissue factor is released from or exposed on the damaged tissue, disrupted cells, or cells such as macrophages, monocytes, or activated endothelial cells. In-vivo platelets, the essential cofactors in this reaction, provide the platelet phospholipid surface on which the

7. PT/aPTT Combination Test

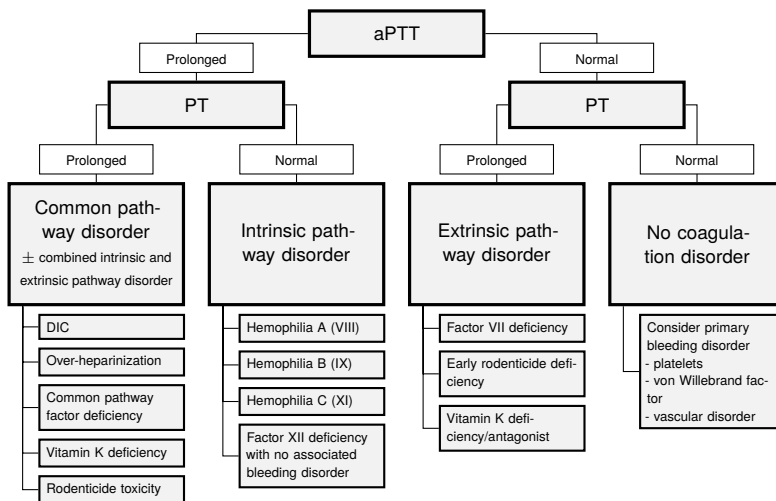


FIGURE 7.2: Guide to possible diagnosis based on PT and aPTT clot time.

coagulation occurs. The test reagents include phospholipid, therefore thrombocytopenia does not affect this test.

The intrinsic pathway is started through contact activation of factor XII. The pathway goes through several reactions that result in the formation of activated factor X. The common pathway uses factor X, factor V, and free calcium to create enzymatic conversion of prothrombin to thrombin, which is then used in creating fibrin from fibrinogen. Activated Partial Thromboplastin Time (aPTT) and Prothrombin Time (PT) tests are general coagulation tests used for screening and measuring the functionality of the blood coagulation cascade. PT is used to assess the extrinsic and common pathway and aPTT to assess the intrinsic and common pathway.

7.2. Test Specifications

An overview of the PT/aPTT COAG Combo test specifications is given in [Table 7.1](#). The test has been validated for use with feline (cat) and canine (dog) citrate-stabilized whole blood. Under normal operating conditions, test results have a Coefficient of Variation (CV) of 7% or better.

A PT/aPTT COAG Combo test takes less than 15 minutes to perform. The actual time depends on the blood sample and test environment. At room temperature, it takes about

90 seconds for the instrument to warm up the test cartridge to the operating temperature of 99 °F/37 °C. Lower and higher temperatures may change the warm up time. Once the procedure of the assay begins, the result is reported as soon as a clot is identified in either of the measuring channels. Typically, this occurs within approximately 10 minutes.

Each test cartridge is individually packed in a sealed pouch with a desiccant bag and a disposable pipette. The pouch should be stored at refrigerated temperatures (36 °F to 46 °F/2 °C to 8 °C). Remove the pouch from the refrigerator and allow the cartridge to reach room temperature prior to running the test. The pouch should not be exposed to direct sunlight. Once the pouch has been opened, the cartridge should be used within 10 minutes. A cartridge must be used within that day. Do not return a warmed cartridge to the refrigerator. If stored in accordance with these guidelines, the test cartridges are stable until the expiration date printed on the pouch label.

The test cartridge can be used only once and only in combination with the Heska Element COAG™ Analyzer. Once used, the cartridge, pipette and sample collection tube should be considered as potentially infectious. Dispose of them properly in accordance with the policies and regulations at the place of operation.



Always strictly adhere to all biohazard safety guidelines pertaining to handling and disposing of animal blood samples.

7. PT/aPTT Combination Test

TABLE 7.1: Specifications for the PT/aPTT COAG Combo Test.

Measurement Technology	Clot time, light absorbance		
Result Units	Second		
Reference Ranges	Species	PT	aPTT
	Feline (Cat)	15 s to 21 s	90 s to 130 s
	Canine (Dog)	14 s to 19 s	75 s to 105 s
Dynamic Range		PT	aPTT
		11 s to 35 s	30 s to 200 s
Sample Type	Whole blood		
Sample Volume	60 μ L		
Sample Collection	3.2 % concentration sodium citrate tube		
Sample Stability	2 hours of room temperature (59 °F to 86 °F/15 °C to 30 °C). Invert the tube back and forth 10 times every 10 minutes		
Cartridge Stability	Do not expose cartridges in the foil pouch to direct sunlight. Once warmed to room temperature, cartridge must be used within that day. Do not return warmed cartridges to the refrigerator. Use cartridges taken from the foil pouch within 10 minutes		
Storage	Refrigerate at 36 °F to 46 °F/2 °C to 8 °C		
Shelf Life	The expiration date is printed on the pouch label		
Time to results	Approximately 10 minutes		

7.3. Test Requirements

7.3.1. Materials and Equipment

The following materials and equipment are required in order to perform a Heska Element COAG™ PT/aPTT COAG Combo Test on the Heska Element COAG™ Analyzer:

- Heska Element COAG™ Analyzer
- PT/aPTT COAG Combo Test Cartridge
- Pipette (included in the sealed pouch with the test cartridge)
- Syringes with a 22-gauge needle or larger
- Sample tubes containing 3.2% sodium citrate as an anticoagulant
- Package insert for the PT/aPTT COAG Combo Test

7.3.2. Blood Sample Preparation

Use a syringe with a 22-gauge needle or larger when drawing the blood to avoid hemolysis. Collect the blood directly into the tube containing citrate as the anticoagulant. The result of a coagulation analysis is very much dependent on the quality of the blood sample and the correct concentration of anticoagulant in the sample. Follow standard blood-drawing procedures at all times and pay special attention to the following:

- Blood samples, if possible, should be collected about 5 minutes before testing to stabilize the mixture of the blood and the citrate.
- The sample collection tube must *not* be over- or under-filled. Even though the assay requires only 60 µL of whole blood, it is very important that the sample collection tube has been filled to the correct filling line.
- Slowly invert the tube containing the blood sample 10 times every 10 minutes as an alternative if a blood rocker is not available.
- The blood sample should be kept at room temperature, in case the testing is delayed. Blood may be tested up to two hours after it has been collected without affecting the test result.
- Contamination from thromboplastin, alcohol and intravenous solutions will interfere with the coagulation assay.
- Hemolysis and foaming of the blood sample are potential sources of inaccurate and imprecise test results.

7. PT/aPTT Combination Test

- When collecting the blood sample, it is important that exhilaration of the patient be minimized. Exhilaration or excitement increases the amount of blood cells in the blood. This can increase platelet count and/or aggregation, levels of Von Willebrand factors, fibrinogen and factors V and VIII, which have significant influence on the coagulation cascade.
- Sedatives and analgesics can also influence blood coagulation.



The accuracy of the PT/aPTT COAG Combo Test is mainly dependent on the quality of the blood sample. The way the blood is collected and has been handled can greatly affect the blood quality.

7.4. Limitations

The veterinarian is always the final arbiter of test result interpretation and impact on diagnosis. Therefore it is highly recommended that Heska Element COAG™ test results should be scrutinized in the light of a specific patient's condition and medical history, as well as current or potential therapy.

Any test result exhibiting inconsistency with a patient's status should be repeated and/or supplemented with additional diagnostic tests.

The accuracy of Heska Element COAG™ Analyzer test results is largely dependent on the quality of the blood specimen which in turn is dependent on:

- The blood sample collection
- The proper volume of blood/citrate
- The proper mixing of the citrated blood
- The proper introduction of the blood sample into the cartridge well.

Blood samples with a hematocrit of less than 15% or greater than 65% are not recommended for use with the Heska Element COAG™ Analyzer. Blood samples outside this range may result in an instrument error or inaccurate test result.



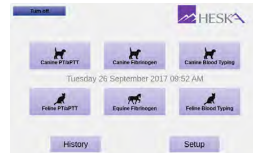
Please observe all precautions cited in this guide and use good blood sampling technique at all times.

7.5. Test Procedure

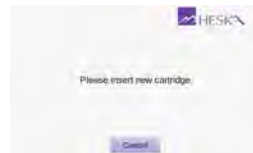
Verify that you have the necessary materials and equipment for performing a PT/aPTT COAG Combo test, see [Section 7.3](#).

Afterward, follow these simple test procedures:

- STEP 1: Remove a pouch with a test cartridge from the refrigerator and let the pouch and cartridge reach room temperature 59 °F to 86 °F/15 °C to 30 °C before starting the test.
- STEP 2: Draw blood from the patient into a sample tube containing 3.2% sodium citrate as an anticoagulant.
- STEP 3: From the Home Screen, touch either the **Canine PT/aPTT** or the **Feline PT/aPTT** button to start the test.



- STEP 4: When the message *Please insert new cartridge* is shown on the screen, insert the test cartridge completely into the cartridge slot on the front of the Analyzer.



The cartridge must have the label facing upward and the sample well sticking out of the Analyzer.

- STEP 5: On the on-screen keyboard, enter the cartridge code (printed on the cartridge pouch label) in the entry field and touch **Done**.



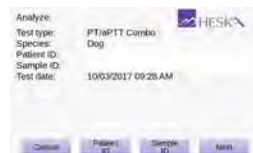
- STEP 6: Touch **Confirm** to acknowledge that the blood has been obtained in a citrate test tube and that the tube was appropriately filled.



- STEP 7: Touch **Patient ID** and enter the necessary information using the on-screen keyboard.

Touch **Done** to confirm.

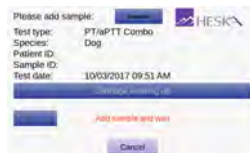
Entering Sample ID is optional but recommended to aid in finding the result in the Analyzer's database.



7. PT/aPTT Combination Test

- STEP 8: Touch **Next** to continue. The **Cartridge Warming Up** screen opens.

It takes approximately 90 seconds for the Analyzer to warm up the test cartridge to 99 °F or 37 °C depending on the environment's temperature. Lower and higher room temperatures may change the warm up time.



Do not add blood samples while the cartridge is warming up. Wait until a prompt appears on the screen instructing you to add the sample.

*By default, a message **Add blood and wait** flashes on the screen and a single beeping sound can be heard which signals that the blood sample can now be added to the cartridge.*

- STEP 9: Gently invert the test tube back and forth 10 times to obtain a uniform mixture of blood cells and plasma.

When the message **Add blood and wait** appears on the screen, use the disposable one-time-use pipette supplied with the cartridge to add a droplet of blood sample to the cartridge's sample well.



Be sure to fill the sample well with at least 60 µL blood.

The measurement starts automatically as soon as the sample is detected. The test progress is shown on the screen. Measurement takes approximately 10 minutes.

*If the Analyzer alerts you that an insufficient amount of sample was placed into the sample well, repeat the measurement with a new cartridge. Touch **Cancel** to terminate the ongoing test.*

- STEP 10: The test result is displayed on the screen when the test is finished.

If a printer is connected to the instrument, touch **Print** to print the test result.



Touch **Done** to return to the Home screen. Remove the used test cartridge and dispose of it properly.

8. Equine Fibrinogen Test

The Heska Element COAG™ Fibrinogen cartridge used with the Heska Element COAG™ Analyzer is designed to measure the concentration of clottable fibrinogen in an equine (horse) plasma sample using the Ellis–Stransky method.

Each Fibrinogen cartridge contains dual optical detection windows filled with micro-channels.

The Heska Element COAG™ test cartridge measures the fibrinogen concentration from 100 μ L diluted plasma with nominal test duration of approximately 10 minutes including warm-up time.



FIGURE 8.1: The Heska Element COAG™ Fibrinogen test kit.

8.1. Fibrinogen Testing

Fibrinogen is an acute phase protein (APP), used as a clinical indicator of acute or chronic systemic inflammation. APPs are quickly released into the bloodstream as a reaction to injury or infection. APPs are proteins in which plasma concentration either increase or decrease by at least 25 % after an inflammatory stimulus [5, 6].

Early detection of systemic inflammation is particularly significant in formulating and initiating an effective treatment plan [7]. Inflammation that is undiagnosed or unrecognized can impair growth and performance. Fibrinogen plasma concentration normally increases within 24 to 48 hours in response to inflammation. Elevated levels of fibrinogen indicate a degree of systemic inflammatory response. Increase in fibrinogen concentration is related to the magnitude of inflammation and often occurs before clinical evidence of disease [8–13]. Low levels of fibrinogen may indicate a potential bleeding and/or liver problem. Quick and accurate diagnosis is essential for successful outcome of treatment.

When measured in citrated plasma, a level above the normal range of 2.0 g/L to 4.0 g/L indicates a systemic inflammatory response. Age and breed have to be taken into

8. Equine Fibrinogen Test

consideration when evaluating the fibrinogen level [14]. Newborn foals normally have 40% less plasma fibrinogen reaching normal level 4 to 7 days after birth meaning that normal fibrinogen range in newborn foals is expected to be lower compared to older foals and adult horses [15–17].

Detection of low levels of fibrinogen can indicate a systemic activation of the clotting system, with consumption of clotting factors faster than synthesis. Excessive clotting factor consumption is known as Disseminated Intravascular Coagulation (DIC). In the context of acute critical illness such as sepsis or trauma, DIC can be difficult to diagnose, but a strong clue is detection of low fibrinogen and concomitant observation of prolonged clotting time (PT and aPTT). Liver problems can also result in decreased levels of fibrinogen.

8.2. Test Specifications

An overview of the Heska Element COAG™ Fibrinogen test specifications is given in Table 8.1. The test has been validated for use with diluted equine (horse) plasma extracted from citrate-stabilized whole blood. Under normal operating conditions, test results have a precision of 0.3 g/L or better.

A Fibrinogen test takes approximately 10 minutes to perform. The actual time depends on the blood sample and test environment. At room temperature, it takes about 5 minutes for the Analyzer to warm up the test cartridge to 99 °F(37 °C). Lower and higher ambient temperatures may change the warm up time. Once the procedure of the assay begins, the result is reported within approximately 10 minutes.

Each test cartridge is individually packed in a sealed pouch with a desiccant bag and a disposable pipette tip. The pouch should be kept at refrigerated temperatures (36 °F to 46 °F/2 °C to 8 °C). Remove the pouch from the refrigerator and allow the cartridge to reach room temperature prior to running the test. Once the pouch has been warmed to room temperature, the cartridge should be used within the same day. After opening the foil package, the cartridge must be used within 10 minutes. Do not return the cartridge to the refrigerator once warmed to room temperature. If stored in accordance with these guidelines, the test cartridges are stable until the expiration date printed on the pouch label. One pre-filled tube with diluent should be used with each test. Dispose of the diluent tube after running a test.

The test cartridge can be used only once and only in combination with the Heska Element COAG™ Analyzer. Once used, the cartridge, pipette tip, diluent tube, and sample collection tube should be considered as potentially infectious. Dispose of them properly in accordance with the policies and regulations at the place of operation.



Always strictly adhere to all biohazard safety guidelines pertaining to handling and disposing of animal blood samples.

TABLE 8.1: Specifications for the Heska Element COAG™ Fibrinogen Test.

Measurement Technology	Light absorbance, turbidity-based plasma assay		
Result Units	mg/dL, g/L or g/dL		
Reference Range	Species	mg/dL	g/L
	Horse (equine)	150 to 400	1.5 to 4.0
Dynamic Range		mg/dL	g/L
		0 to 2000	0.0 to 20.0
Sample Type	Platelet poor plasma		
Sample Volume	100 µL		
Sample Collection	3.2% or 3.8% concentration sodium citrate tube		
Sample Stability	12 hours at room temperature (59 °F to 86 °F or 15 °C to 30 °C) for whole blood sodium citrate samples.		
	3 hours at room temperature (59 °F to 86 °F or 15 °C to 30 °C) for plasma extracted.		
	30 days at freezing temperature (14 °F or -10 °C) for plasma samples extracted from a citrate tube and placed in a red-top tube.		
Cartridge Stability	Do not expose cartridges in the foil pouch to direct sunlight or leave at room temperature for more than one day. Use cartridges taken from the foil pouch within 10 minutes		
Storage	Refrigerate at 36 °F to 46 °F or 2 °C to 8 °C		
Shelf Life	The expiration date is printed on the pouch label.		
Time to results	Approximately 10 minutes		

8.3. Test Requirements

The Heska Element COAG™ Analyzer must be calibrated to run the Fibrinogen Test cartridge. The Analyzer will be pre-calibrated from the factory.

8.3.1. Materials and Equipment

The following materials and equipment are required in order to perform an Equine Fibrinogen Test on the Heska Element COAG™ Analyzer:

- Heska Element COAG™ Analyzer
- Fibrinogen Test Cartridge
- Pipette tip (included in the sealed pouch with the test cartridge)
- 100 µL fixed-volume pipette
- Pre-filled diluent tube (included in each box of cartridges)
- Syringes with a 22-gauge needle or larger
- Sample tubes containing 3.2% or 3.8% sodium citrate as an anticoagulant
- Package insert for Heska Element COAG™ Fibrinogen Test cartridge
- Centrifuge minimum 7000 g × minutes.

8.3.2. Centrifuge

Table 8.2 lists the required centrifugation time as a function of centrifuge radius and revolutions per minute to obtain platelet-poor plasma as needed by the Heska Element COAG™ Fibrinogen Test.

Some centrifuges do not display the g -loading of the sample, but instead show the revolutions per minute (RPM) of the centrifuge. In that case, use the table to find the required centrifugation time for a given RPM and centrifuge radius¹.

¹ The centrifuge radius is the distance between the axis of rotation and the center of the test-tube when placed in the centrifuge.

TABLE 8.2: Centrifugation time for various combinations of centrifugation speeds and centrifuge radius.

Radius [cm]	RPM [1/min]	Acc. [g]	Time [min]	Radius [cm]	RPM [1/min]	Acc. [g]	Time [min]
2.5	5000	698	11	7.5	7000	4104	2
2.5	6000	1005	7	7.5	8000	5360	2
2.5	7000	1368	6	7.5	9000	6784	2
2.5	8000	1787	4	7.5	10 000	8375	1
2.5	9000	2261	4	10.0	2000	447	16
2.5	10 000	2792	3	10.0	3000	1005	7
5.0	5000	1396	6	10.0	4000	1787	4
5.0	6000	2010	4	10.0	5000	2792	3
5.0	7000	2736	3	10.0	6000	4020	2
5.0	8000	3574	2	10.0	7000	5472	2
5.0	9000	4523	2	10.0	8000	7147	1
5.0	10 000	5584	2	10.0	9000	9045	1
7.5	5000	2094	4	10.0	10 000	11 167	1
7.5	6000	3015	3				

8.3.3. Sample Preparation

Use a syringe with a 22-gauge needle or larger when drawing the blood to avoid hemolysis. Collect the blood directly into the blue top tube containing citrate as the anticoagulant. The result of a Fibrinogen analysis is dependent on the quality of the blood sample and the extracted plasma.

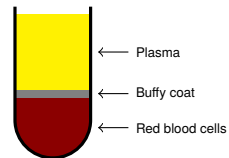


FIGURE 8.2: Whole blood sample after centrifugation.

To extract platelet-poor plasma from the whole blood sample, centrifuge the blood for a minimum $7000\text{g} \times \text{minutes}$. The rotation speed and necessary spin time is dependent on the centrifuge size. Please refer to [Table 8.2](#) for minimum centrifuge requirements.

Make sure to collect plasma for the Fibrinogen Test from the upper part of the plasma in the tube to avoid contaminating the plasma with RBCs.

As part of the test procedure, the extracted platelet-poor plasma must be diluted in accordance with the on-screen instruction on the Heska Element COAG™ Analyzer.

Follow standard blood-drawing procedures at all times and pay special attention to the following:

8. Equine Fibrinogen Test

- Contamination from thromboplastin, alcohol and intravenous solutions will interfere with the fibrinogen assay. Hemolysis and foaming of the blood sample are potential sources of erroneous test results.
- Do not use blood that has been stabilized in any other way than using 3.2% or 3.8% citrate collection tubes.
- Do not use blood from over-filled or under-filled citrate tubes.
- Do not use plasma from samples that have been centrifuged at less than 7000 g × minutes.
- Do not use blood samples with visible clotting or debris accumulation.
- Do not use plasma exhibiting signs of hemolysis, lipemia or other conditions that may affect turbidity. A general guideline is that the sample should be clear and more yellow than red in color.
- To avoid mechanical hemolysis, the needle used should have a 22-gauge or larger.
- The vein puncture site should be cleaned with alcohol and allowed to air-dry completely.
- When diluting the platelet poor plasma, ensure that no diluent is caught in the cap of the pre-filled micro tube by tapping the cap prior to opening the tube.
- Use only the supplied Heska Element COAG™ Fibrinogen pre-filled micro tube with diluent. The Fibrinogen test will not work correctly if other diluents are used.
- To avoid contaminating the plasma with red and white blood cells, please extract the required volume from the upper half of the plasma.
- Do not touch the part of the pipette tip that will come in contact with the plasma when removing the pipette tip from the pouch.
- Test results may be impaired if sample is older than 12 hours or the extracted plasma is older than 3 hours.



The accuracy of the Heska Element COAG™ Fibrinogen Test is mainly dependent on the quality of the blood sample and the extracted plasma. The way the blood is collected and has been handled can greatly affect the blood and plasma quality.

8.4. Limitations

The veterinarian is always the final arbiter of test result interpretation and impact on diagnosis. Therefore, it is highly recommended that Heska Element COAG™ test results should be scrutinized in the light of a specific patient's condition and medical history, as well as current or potential therapy.

Any test result exhibiting inconsistency with a patient's status should be repeated and/or supplemented with additional diagnostic tests.

The accuracy of Heska Element COAG™ Analyzer test results is largely dependent on the quality of the sample specimen which in turn is dependent on:

- The blood sample collection
- The proper volume of blood/citrate
- The proper mixing of the citrated blood
- The proper extraction of platelet-poor plasma
- The proper introduction of the sample into the cartridge well.



Please observe all precautions cited in this guide and use good blood sampling technique at all times.

8.5. Test Procedure

Verify that you have the necessary materials and equipment for performing a Fibrinogen test, see [Section 8.3](#).

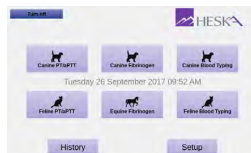
Afterward, follow these simple test procedures:

- STEP 1:** Remove a pouch with a test cartridge from the refrigerator and let the pouch and cartridge reach room temperature 59 °F to 86 °F or 15 °C to 30 °C before starting the test.
- STEP 2:** Draw blood from the patient into a sample tube containing 3.2% or 3.8% sodium citrate as an anticoagulant. The Fibrinogen assay requires only 100 µL platelet poor plasma but the tube should be full to ensure the correct concentration of sodium citrate.
- STEP 3:** Separate the whole blood by centrifuging the blood sample in the collection tube into platelet poor plasma. To achieve sufficiently platelet poor plasma, the blood sample must be centrifuged at minimum 7000 g × minutes, see the [Table 8.2](#) for a list of required centrifugation time.

The plasma should be extracted as soon as possible after collecting the blood sample. The whole blood sample can be kept for maximum 12 hours provided that the temperature does not exceed 86 °F/30 °C. It is recommended to store the sample at room temperature until testing. Do not expose to direct sunlight.

8. Equine Fibrinogen Test

STEP 4: From the Home Screen, touch the **Equine Fibrinogen** button to start the test.



STEP 5: When the message *Please insert new cartridge* flashes on the screen, insert the Heska Element COAG™ test cartridge completely into the cartridge slot on the front of the Analyzer.

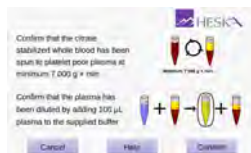


The cartridge must have the label facing upward and the sample well sticking out of the Analyzer.

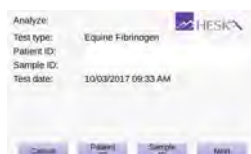
STEP 6: On the on-screen keyboard, enter the cartridge code (printed on the cartridge pouch label) in the entry field and touch **Done**.



STEP 7: Touch **Confirm** to acknowledge that the blood has been obtained in a citrate test tube, that the tube was appropriately filled, and that whole blood sample was spun to platelet poor plasma at minimum 7000 g × minutes.



STEP 8: Touch **Patient ID** and enter the necessary information using the on-screen keyboard. Touch **Done** to confirm.



Entering Sample ID is optional but recommended to aid in finding the result in the Analyzer's database.

STEP 9: Touch **Next** to continue. The **Cartridge Warming Up** screen opens.



It takes approximately 5 minutes for the Analyzer to warm up the test cartridge to 99 °F or 37 °C depending on the environment's temperature. Lower and higher room temperatures may change the warm up time.



*Do not add sample while the cartridge is warming up. Wait until a prompt appears on the screen instructing you to add the sample. By default, a message **Add sample and wait** flashes on the screen and a single beeping sound can be heard which signals that the diluted plasma sample can now be added to the cartridge.*

STEP 10: Ensure that no diluent is caught at the top of the diluent tube by tapping the tube on a hard surface. Using the supplied pipette tip, puncture the foil on the diluent tube. Extract 100 μL platelet poor plasma from the collection tube using the 100 μL fixed volume pipette and supplied pipette tip. Dilute the platelet poor plasma by aspirating into the supplied diluent tube and ensure proper mixing by aspirating a minimum of 5 times.



Make sure that no diluent is caught in the lid of the diluent tube.

STEP 11: When the message **Add 100 μL sample and wait** appears on the screen, use a 100 μL fixed-volume pipette and the supplied pipette tip to add 100 μL diluted plasma to the cartridge's sample well.

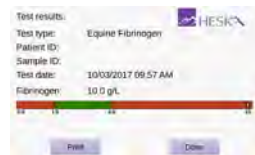


Be sure to fill the sample well with 100 μL diluted platelet poor plasma. The measurement starts automatically as soon as the sample is detected. The test progress is shown on the screen. Measurement takes approximately 10 minutes.

*If the Analyzer alerts you that an insufficient amount of sample was placed into the sample well, repeat the measurement with a new cartridge. Touch **Cancel** to terminate the ongoing test.*

STEP 12: The test result is displayed on the screen when the test is finished.

If a printer is connected to the instrument, touch **Print** to print the test result.



Touch **Done** to return to the Home screen.

STEP 13: Remove the used test cartridge and dispose of it properly.

9. Canine Fibrinogen Test

The Heska Element COAG™ Canine Fibrinogen cartridge used with the Heska Element COAG™ Analyzer is designed to measure the concentration of clottable fibrinogen in a canine (dog) plasma sample using the Ellis–Stransky method.

Each Canine Fibrinogen cartridge contains dual optical detection windows filled with micro-channels.

The Canine Fibrinogen test cartridge measures the fibrinogen concentration from 100 µL diluted plasma with nominal test duration of approximately 10 minutes including warm-up time.



FIGURE 9.1: Heska Element COAG™ Canine Fibrinogen Test kit.

9.1. Fibrinogen Testing

Fibrinogen (clotting factor I) is a coagulation protein produced by the liver and present in plasma of all vertebrates [18, 19]. It plays an important role in blood coagulation, cellular interactions, inflammation and wound healing. Fibrinogen is also known as an acute phase protein (APP) and has been widely used as a clinical indicator of acute or chronic inflammation or tissue damage in mammals [18, 20–22].

The canine normal range of plasma circulated fibrinogen is 1.2 g/L to 3.0 g/L. When evaluating canine fibrinogen level, age has to be taken into consideration: younger dogs show slight but statistically significant higher fibrinogen level [23].

In response to ongoing inflammation, fibrinogen plasma concentration changes within 24 to 48 hours [24]. The function and quantity of plasma fibrinogen can be altered by both inherited and acquired disorders [25]. Fibrinogen is an essential component of the hemostatic process and its level may be increased in response to inflammation, or reduced due to consumption [26]. Low plasma fibrinogen concentration can indicate a systemic activation of the clotting system, where consumption of clotting factors is faster than synthesis, with increased risk of bleeding as a consequence.

9. Canine Fibrinogen Test

In dogs, during active acute or chronic hepatitis, hyperfibrinolysis is observed frequently in association with liver cell necrosis or apoptosis [27–29]. Therefore, the main purpose of measuring fibrinogen level in canine medicine is to indicate blood coagulation disorders in which the concentration of fibrinogen falls [30]. Moreover, measurement of fibrinogen level, together with determination of other APPs, provides accurate information of the course of the disease and allows better monitoring of treatment.

9.2. Test Specifications

An overview of the Canine Fibrinogen test specifications are given in [Table 9.1](#). The test has been validated for use with diluted canine (dog) plasma extracted from citrate-stabilized whole blood. Under normal operating conditions, test results have a precision of 0.3 g/L or better.

A Fibrinogen test takes up to 10 minutes to perform. The actual time depends on the blood sample and test environment. At room temperature, it takes about 5 minutes for the Analyzer to warm up the test cartridge to 99 °F(37 °C). Lower and higher ambient temperatures may change the warm up time. Once the procedure of the assay begins, the result is reported within approximately 10 minutes.

Each test cartridge is individually packed in a sealed pouch with a desiccant bag and a disposable pipette tip. The pouch should be kept at refrigerated temperatures (36 °F to 46 °F/2 °C to 8 °C). Remove the pouch from the refrigerator and allow the cartridge to reach room temperature prior to running the test. The pouch should not be exposed to direct sunlight and should be used within the same day it is warmed to room temperature. Once the pouch has been opened, the cartridge should be used within the 10 minutes. If stored in accordance with these guidelines, the test cartridges are stable until the expiration date printed on the pouch label. One pre-filled tube with diluent should be used with each test. Dispose of the diluent tube after running a test.

The test cartridge can be used only once and only in combination with the Heska Element COAG™ Analyzer. Once used, the cartridge, pipette tip, diluent tube, and sample collection tube should be considered as potentially infectious. Dispose of them properly in accordance with the policies and regulations at the place of operation.



Always strictly adhere to all biohazard safety guidelines pertaining to handling and disposing of animal blood samples.

TABLE 9.1: Specifications for the Heska Element COAG™ Canine Fibrinogen Test.

Measurement Technology	Light absorbance, turbidity-based plasma assay		
Result Units	mg/dL, g/L or g/dL		
Reference Range	Species	mg/dL	g/L
	Dog (canine)	120 to 300	1.2 to 3.0
Dynamic Range		mg/dL	g/L
		0 to 2000	0.0 to 20.0
Sample Type	Platelet poor plasma		
Sample Volume	100 µL		
Sample Collection	3.2% or 3.8% concentration sodium citrate tube		
Sample Stability	12 hours at room temperature (59 °F to 86 °F or 15 °C to 30 °C) for whole blood sodium citrate samples.		
	3 hours at room temperature (59 °F to 86 °F or 15 °C to 30 °C) for plasma extracted.		
	30 days at freezing temperature (14 °F or -10 °C) for plasma samples extracted from a citrate tube and placed in a red-top tube.		
Cartridge Stability	Do not expose cartridges in the foil pouch to direct sunlight or leave at room temperature for more than one day. Use cartridges taken from the foil pouch within 10 minutes		
Storage	Refrigerate at 36 °F to 46 °F or 2 °C to 8 °C		
Shelf Life	The expiration date is printed on the pouch label.		
Time to results	Approximately 10 minutes		

9.3. Test Requirements

9.3.1. Materials and Equipment

The following materials and equipment are required in order to perform a Canine Fibrinogen Test on the Heska Element COAG™ Analyzer:

- Heska Element COAG™ Analyzer
- Canine Fibrinogen Test Cartridge
- Pipette tip (included in the sealed pouch with the test cartridge)
- 100 μ L fixed-volume pipette
- Pre-filled diluent tube (included in each box of cartridges)
- Syringes with a 22-gauge needle or larger
- Sample tubes containing 3.2% or 3.8% sodium citrate as an anticoagulant
- Package insert for Canine Fibrinogen Test cartridge
- Quick Guide for Canine Fibrinogen Test
- Centrifuge minimum 7000 g \times minutes.

9.3.2. Centrifuge

Table 9.2 lists the required centrifugation time as a function of centrifuge radius and revolutions per minute to obtain platelet-poor plasma as needed by the Canine Fibrinogen Test.

Some centrifuges do not display the g -loading of the sample, but instead show the revolutions per minute (RPM) of the centrifuge. In that case, use the table to find the required centrifugation time for a given RPM and centrifuge radius¹.

9.3.3. Sample Preparation

Use a syringe with a 22-gauge needle or larger when drawing the blood to avoid hemolysis. Collect the blood directly into the test tube containing citrate as the anticoagulant. The result of a Fibrinogen analysis is dependent on the quality of the blood sample and the extracted plasma.

¹ The centrifuge radius is the distance between the axis of rotation and the center of the test-tube when placed in the centrifuge.

TABLE 9.2: Centrifugation time for combinations of centrifugation speed and centrifuge radius.

Radius [cm]	RPM [1/min]	Acc. [g]	Time [min]	Radius [cm]	RPM [1/min]	Acc. [g]	Time [min]
2.5	5000	698	11	7.5	7000	4104	2
2.5	6000	1005	7	7.5	8000	5360	2
2.5	7000	1368	6	7.5	9000	6784	2
2.5	8000	1787	4	7.5	10 000	8375	1
2.5	9000	2261	4	10.0	2000	447	16
2.5	10 000	2792	3	10.0	3000	1005	7
5.0	5000	1396	6	10.0	4000	1787	4
5.0	6000	2010	4	10.0	5000	2792	3
5.0	7000	2736	3	10.0	6000	4020	2
5.0	8000	3574	2	10.0	7000	5472	2
5.0	9000	4523	2	10.0	8000	7147	1
5.0	10 000	5584	2	10.0	9000	9045	1
7.5	5000	2094	4	10.0	10 000	11 167	1
7.5	6000	3015	3				

To extract platelet-poor plasma from the whole blood sample, centrifuge the whole blood in a centrifuge for minimum 7000 g × minutes. The rotation speed and necessary spin time is dependent on the centrifuge size. Please refer to [Table 9.2](#) for minimum centrifuge requirements.

Centrifugation will separate the Red Blood Cells (RBC) from the plasma, see [Figure 9.2](#) for a schematic representation of a sample tube after centrifugation. Make sure to collect plasma for the Canine Fibrinogen Test from the upper part of the plasma in the tube to avoid contaminating the plasma with RBCs.

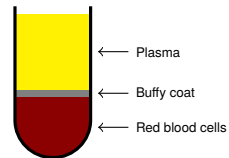


FIGURE 9.2: Whole blood sample after centrifugation.

Other than centrifugation, no special sample preparation is needed before initiating the Canine Fibrinogen Test. As part of the test procedure, the extracted platelet-poor plasma must be diluted in accordance with the on-screen instruction on the Heska Element COAG™ Analyzer.

Follow standard blood-drawing procedures at all times and pay special attention to the following:

- Contamination from thromboplastin, alcohol and intravenous solutions will interfere with the fibrinogen assay. Hemolysis and foaming of the blood sample are potential

9. Canine Fibrinogen Test

sources of erroneous test results.

- Do not use blood that has been stabilized in any other way than using 3.2% or 3.8% citrate collection tubes.
- Do not use blood from over-filled or under-filled citrate tubes.
- Do not use plasma from samples that have been centrifuged at less than 7000 g × minutes.
- Do not use blood samples with visible clotting or debris accumulation.
- Do not use plasma exhibiting signs of hemolysis, lipemia or other conditions that may affect turbidity. A general guideline is that the sample should be clear and more yellow than red in color.
- To avoid mechanical hemolysis, the needle used should have a 22-gauge or larger.
- The vein puncture site should be cleaned with alcohol and allowed to air-dry completely.
- When diluting the platelet poor plasma, ensure that no diluent is caught in the cap of the pre-filled micro tube by tapping the cap prior to opening the tube.
- Use only the supplied Heska Element COAG™ Fibrinogen pre-filled micro tube with diluent. The Fibrinogen test will not work correctly if other diluents are used.
- To avoid contaminating the plasma with red and white blood cells, please extract the required volume from the upper half of the plasma.
- Do not touch the part of the pipette tip that will come in contact with the plasma when removing the pipette tip from the pouch.
- Test results may be impaired if the sample is older than 12 hours or the extracted plasma is older than 3 hours.



The accuracy of the Canine Fibrinogen Test is mainly dependent on the quality of the blood sample and the extracted plasma. The way the blood is collected and has been handled can greatly affect the blood and plasma quality.

9.4. Limitations

The veterinarian is always the final arbiter of test result interpretation and impact on diagnosis. Therefore, it is highly recommended that Heska Element COAG™ test results should be scrutinized in the light of a specific patient's condition and medical history, as well as current or potential therapy.

Any test result exhibiting inconsistency with a patient's status should be repeated and/or supplemented with additional diagnostic tests.

The accuracy of Heska Element COAG™ Analyzer test results is largely dependent on the quality of the sample specimen which in turn is dependent on:

- The blood sample collection
- The proper volume of blood/citrate
- The proper mixing of the citrated blood
- The proper extraction of platelet-poor plasma
- The proper introduction of the sample into the cartridge well.



Please observe all precautions cited in this guide and use good blood sampling technique at all times.

9.5. Test Procedure

Before performing any tests, be sure that the Heska Element COAG™ Analyzer has been installed properly in accordance with the instructions in this guide. See [Chapter 3](#) for details regarding how to set the Analyzer up correctly.

Verify that you have the necessary materials and equipment for performing a Heska Element COAG™ Canine Fibrinogen test, see [Section 9.3](#).

Afterward, follow these simple test procedures:

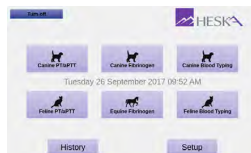
- STEP 1:** Remove a pouch with a test cartridge from the refrigerator and let the pouch and cartridge reach room temperature 59°F to 86°F or 15°C to 30°C before starting the test.
- STEP 2:** Draw blood from the patient into a sample tube containing 3.2% or 3.8% sodium citrate as an anticoagulant. The Fibrinogen assay requires only 100 µL platelet poor plasma but the tube should be full to ensure the correct concentration of sodium citrate.
- STEP 3:** Fractionate the whole blood by centrifuging the blood sample in the collection tube into platelet poor plasma. To achieve sufficiently platelet poor plasma, the blood sample must be centrifuged at minimum 7000 g × minutes, see the [Table 9.2](#) for a list of required centrifugation time.

The plasma should be extracted as soon as possible after collecting the blood sample. The whole blood sample can be kept for maximum 12 hours provided that the temperature does not exceed 86°F/30°C. It is recommended to store the sample at room temperature until testing. Do not expose to direct sunlight.

- STEP 4:** Remove the cartridge and pipette tip from the pouch and the pre-filled tube with diluent from the kit box.

9. Canine Fibrinogen Test

STEP 5: From the Home Screen, touch the **Canine Fibrinogen** button to start the test.



STEP 6: When the message *Please insert new cartridge* flashes on the screen, insert the Heska Element COAG™ test cartridge completely into the cartridge slot on the front of the Analyzer.

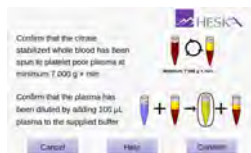


The cartridge must have the label facing upward and the sample well sticking out of the Analyzer.

STEP 7: On the on-screen keyboard, enter the cartridge code (printed on the cartridge pouch label) in the entry field and touch **done**.



STEP 8: Touch **Confirm** to acknowledge that the blood has been obtained in a citrate test tube, that the tube was appropriately filled, and that whole blood sample was spun to platelet poor plasma at minimum 7000 g × minutes.

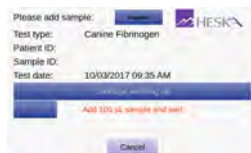


STEP 9: Touch **Patient ID/Sample ID** and enter the necessary information using the on-screen keyboard. Touch **Done** to confirm.



Entering Sample ID is optional but recommended to aid in finding the result in the Analyzer's database.

STEP 10: Touch **Next** to continue. The **Cartridge Warming Up** screen opens.



It takes approximately 5 minutes for the Analyzer to warm up the test cartridge to 99 °F or 37 °C depending on the environment's temperature. Lower and higher room temperatures may change the warm up time.



*Do not add sample while the cartridge is warming up. Wait until a prompt appears on the screen instructing you to add the sample. By default, a message **Add sample and wait** flashes on the screen and a single beeping sound can be heard which signals that the diluted plasma sample can now be added to the cartridge.*

STEP 11: Ensure that no diluent is caught at the top of the diluent tube by tapping the tube on a hard surface. Using the supplied pipette tip, puncture the foil on the diluent tube. Extract 100 μ L platelet poor plasma from the collection tube using the 100 μ L fixed volume pipette and supplied pipette tip. Dilute the platelet poor plasma by aspirating into the supplied diluent tube and ensure proper mixing by aspirating a minimum of 5 times.



Make sure that no diluent is caught in the lid of the diluent tube.

STEP 12: When the message **Add 100 μ L sample and wait** appears on the screen, use a 100 μ L fixed-volume pipette and the supplied pipette tip to add 100 μ L diluted plasma to the cartridge's sample well.



Be sure to fill the sample well with at least 100 μ L diluted platelet poor plasma.

The measurement starts automatically as soon as the sample is detected. The test progress is shown on the screen. Measurement takes approximately 10 minutes.

*If the Analyzer alerts you that an insufficient amount of sample was placed into the sample well, repeat the measurement with a new cartridge. Touch **Cancel** to terminate the ongoing test.*

STEP 13: The test result is displayed on the screen when the test is finished. If a printer is connected to the instrument, touch **Print** to print the test result.



Touch **Done** to return to the Home screen.

STEP 14: Remove the used test cartridge and dispose of it properly.

10. Canine DEA 1 Blood Typing

The Canine DEA 1 Test Cartridge is used in conjunction with the Heska Element COAG™ Analyzer for in vitro blood group determination testing. The Canine DEA 1 cartridge is intended for use in performing a rapid blood group determination for Canine DEA 1 from a drop of diluted EDTA-stabilized canine whole blood.

10.1. Canine Blood Typing

While it is broadly true that dogs do not possess alloantibodies to incompatible blood groups and, thus, will generally tolerate well an initial incompatible transfusion, sound practice of veterinary medicine dictates that such transfusions be avoided. The half life of the transfused incompatible cells will be quite short and, thus, the intended therapeutic result may not even be attained. Also, the potential future needs of the canine patient must be considered. Antibodies resulting from a transfusion of incompatible blood may form in only 5 to 7 days and will have long-term viability [31–35]. This eliminates the option of using incompatible blood in a future emergency situation.

In addition, antibodies developed in bitches by sensitization resulting from transfusion of incompatible blood groups must be of special concern to breeders. Since antibodies are present in the colostrum, bitches with alloantibodies to a given blood type should not be bred to a sire possessing that blood group if they are expected to nurse the resulting puppies [32]. The nursing puppies will develop isoerythrolysis and may be susceptible to disease or even die due to hemolytic anemia [32, 36–38].



FIGURE 10.1: The Canine DEA 1 test kit.

10.1.1. Blood Groups

Eight specific antigens have been identified on the surface of the canine erythrocytes [31, 39]. The internationally accepted canine blood group system, the Dog Erythrocyte Antigen (DEA), is based on these antigens. It currently characterizes eight common blood groups, the antigens DEA 1, 1.2, 3, 4, 5, 6, 7, and 8.

As occurred in human medicine, new antigens are now being discovered on the red cells of dogs. One, DAL, has been reported and is the subject of journal articles. These are often breed specific and, thus, can be considered rare.

The DEA 1 blood group is the most significant blood factor in the dog. The DEA 1 blood group is highly antigenic and is the primary lytic factor in canine transfusion medicine [32, 39–47]. Although all of the blood group antigens are capable of stimulating formation of alloantibodies, DEA 1 has the greatest stimulation potential. Thus, most reactions resulting from the transfusion of incompatible cells occur when DEA 1 positive blood is given to a DEA 1 negative recipient [32]. Clinically significant reactions to DEA 1.2 may occur but are less severe. DEA 7 may be a factor in transfusion reactions, but since it is a cold agglutinin and a naturally occurring isoantibody, it is considered to have very low clinical significance. The remaining antigens are considered to cause clinically insignificant transfusion problems [32].

10.1.2. Blood Transfusion

Ideally, all transfused blood would be DEA 1 negative. However, until the concept of using blood rapidly available from commercial sources is more widely accepted, transfusion from dogs that are present in the area at the time of need will remain the norm.

It is estimated that 40% of all dogs are DEA 1 positive [31]. Because a number of dogs auto-agglutinate and because a very anemic dog may give equivocal results, typing prior to an urgent need for the information is indicated. Identifying a particular dog as DEA 1 positive or negative at birth greatly simplifies future decision making. A DEA 1 positive dog can receive both DEA 1 positive and negative blood. A dog that is DEA 1 negative should not receive DEA 1 positive blood.

The Canine DEA 1 test cartridge used with the Heska Element COAG™ Analyzer is intended for use to classify dogs as DEA 1 positive, negative or inconclusive.

10.2. Test Specifications

Test results obtained under normal operating conditions have an accuracy of 95% or better. A small percentage of blood samples is not possible to type definitely using the Heska Element COAG™ Analyzer. The results for these samples will be reported as

Inconclusive. A minimum of 95% of correctly collected blood samples are typable using the Canine DEA 1 Blood Typing Test.

All components of the test kit are stable at refrigerated temperatures (36 degree F to 46 degree F or 2 °C to 8 °C) until the expiration date printed on the pouch label. Once warmed do not return cartridge to the refrigerator and use within the same day. After opening the pouch and cartridge must be used within 10 minutes. Kits and components should not be exposed to direct sunlight. Once warmed do not return cartridge to the refrigerator and use within the same day. After opening the pouch and cartridge must be used within 10 minutes. The time it takes to perform a blood type determination with the Heska Element COAG™ Analyzer depends on factors such as type of test and test environment. At room temperature, it takes about 90 seconds for the instrument to warm up the test cartridge to 99 °F or 37 °C. Lower and higher room temperatures may change the warm up time. Once the procedure of the assay begins, an answer should be available within 5 minutes.

TABLE 10.1: Specifications for the Canine DEA 1 Blood Typing Test.

Measurement Technology	Agglutination detection using light absorbance
Species	Canine (Dog)
Possible results	Positive, Negative and Inconclusive
Sample Type	Diluted whole blood
Sample Volume	100 µL of whole blood
Sample Collection	EDTA collection tube
Sample Stability	Use the blood within the day of collection. Do not dilute the sample until prompted to do so on-screen.
Cartridge Stability	Do not expose the cartridges in the foil pouch to direct sunlight or leave them at room temperature for more than one day. Use cartridges taken from the foil pouch within 10 minutes
Storage	Store at 36 °F to 77 °F/2 °C to 25 °C
Shelf Life	The expiration date is printed on the pouch label.
Warm-up time	Approximately 90 seconds. The actual time depends on the blood sample and test environment. Very low or high ambient temperatures may change the warm-up time.
Time to results	Approximately 5 minutes from adding the sample to the cartridge

10. Canine DEA 1 Blood Typing

Each Canine DEA 1 Blood Typing Test cartridge contains a monoclonal antibody specific to the DEA 1 antigen on a red blood cell. Each cartridge is individually packed with a disposable plastic pipette tip in a sealed pouch containing a desiccant bag to keep it moisture free. A torn or otherwise damaged pouch may allow moisture to reach the test cartridge and adversely affect performance. Do not use a test cartridge from a damaged pouch. Open the pouch just prior to use.

The test cartridge can be used only once and only in combination with the Heska Element COAG™ Analyzer. Once used, the cartridge, pipette tip, diluent tube, and sample collection tube should be considered as potentially infectious. Dispose of them properly in accordance with the policies and regulations at the place of operation.



Always strictly adhere to all biohazard safety guidelines pertaining to handling and disposing of animal blood samples.

10.3. Test Requirements

10.3.1. Materials and Equipment

In order to perform a Canine DEA 1 Blood Typing Test with the Heska Element COAG™ Analyzer, the following materials and equipment are required.

The following materials are required but not provided with the Canine DEA 1 Blood Typing Test:

- Heska Element COAG™ Analyzer
- Syringes with a 22-gauge needle or larger
- Sample collection tube with EDTA as the anticoagulant
- 100 µL fixed volume pipette

The following materials are required and supplied with the Canine DEA 1 Blood Typing Test:

- Canine DEA 1 Blood Typing cartridge
- Dropper bottle pre-filled with diluent. The plastic bottle contains phosphate buffered saline (PBS) at pH 7.4. The dropper tip dispenses approximately 40 µL of fluid. The bottle contains enough fluid to perform all the tests in the kit
- Tube for sample preparation (one for each cartridge)
- Plastic pipette tip (one for each cartridge)

The following materials are optional:

- Package insert for the Canine DEA 1 Blood Typing Test (shipped with each box of cartridges)
- Quick Guide for the Canine DEA 1 Blood Typing Test (shipped with the software update for the Canine DEA 1 Blood Typing Test)

10.3.2. Blood Sample Preparation

Use a syringe with a 22-gauge needle or larger to avoid hemolysis. Collect blood directly into the EDTA test tube. The result of any blood analysis is dependent on the quality of the blood sample. Follow standard blood-drawing procedures at all times and pay special attention to the following:

- Blood samples, if possible, should be collected within the day of testing. Ensure proper mixing of the anticoagulant into the blood sample.
- If a blood rocker is not available, slowly invert the tube containing the blood sample 10 times every 10 minutes.
- The blood sample should be kept at room temperature, in case the testing is delayed.
- Inspect the blood sample for hemolysis when measuring the hematocrit. As a general rule, the plasma must be clear and more yellow than red in order for the sample to be suitable for testing with the Canine DEA 1 Blood Typing Test.



The accuracy of the Canine DEA 1 Blood Typing Test is mainly dependent on the quality of the blood sample. The way the blood is collected and has been handled can greatly affect the blood quality.

10.4. Limitations

The veterinarian is always the final arbiter of test result interpretation and impact on diagnosis. Therefore it is highly recommended that Heska Element COAG™ test results should be scrutinized in the light of a specific patient's condition and medical history, as well as current or potential therapy.

Any test result exhibiting inconsistency with a patient's status should be repeated and/or supplemented with additional diagnostic tests.

The accuracy of Heska Element COAG™ Analyzer test results is largely dependent on the quality of the blood specimen.

10. Canine DEA 1 Blood Typing

- The accuracy of the test results is dependent on the quality of the blood sample. The quality of the blood sample is dependent upon the blood sample collection, the proper blood to EDTA ratio, and the proper introduction of the sample and diluent into the sample well. Please observe all precautions cited in this manual and use good blood sample collection techniques at all times.
- A very limited number of canine patients exhibit auto-agglutination of varying degrees due to serum factors that cause agglutination of the patient's own red cells. The Canine DEA 1 cartridge has two channels – a reference channel and a test channel. If auto-agglutination occurs in the reference channel, this will be indicated on the results screen. If auto-agglutination occurs the blood should not be used for transfusion and the dog should only be transfused with blood from a DEA 1 negative donor. This occurs in only a very small percentage of patients.
- Being an absorption assay, the test accuracy is dependent on proper dilution of the whole blood before adding the sample to the cartridge. Always measure the hematocrit of the sample prior to testing and follow the on-screen dilution procedure.
- Hemolyzed blood samples may cause false DEA 1 negative results because the Analyzer is unable to distinguish RBC agglutinates from the plasma containing hemoglobin. Always verify that the sample is not hemolyzed when measuring the hematocrit. As a general guideline, the plasma must be clear and more yellow than red. If the sample is severely hemolyzed, a new blood sample should be drawn.
- Blood samples with a hematocrit of less than 10% or greater than 70% are not recommended for use with the Heska Element COAG™ Analyzer. Blood samples outside this range may result in an instrument error or inaccurate test result.

10.5. Test Procedure

Verify that you have the necessary materials and equipment for performing a Canine DEA 1 Blood Typing test, see [Section 10.3](#).

- STEP 1: Remove a pouch with a test cartridge from the refrigerator and let the pouch and cartridge reach room temperature 59/degree F to 86/degree F/15 °C to 30 °C before starting the test.
- STEP 2: Draw blood from the patient into a tube coated with or containing EDTA as an anticoagulant. The assay requires only 100uL of whole blood but the syringe or tube should be full to ensure the correct concentration of EDTA. If the blood type is not to be determined immediately, nutrients such as CPDA should not be added.
- STEP 3: Determine the hematocrit of the sample.

- STEP 4: Remove the cartridge and pipette tip from the pouch and the pre-filled tube with diluent from the kit box.
- STEP 5: From the Home Screen, touch the **Canine Blood Typing** button to start the test.



- STEP 6: When the message *Please insert new cartridge* flashes on the screen, insert the test cartridge completely into the cartridge slot on the front of the Analyzer.



The cartridge must have the label facing upward and the sample well sticking out of the Analyzer.

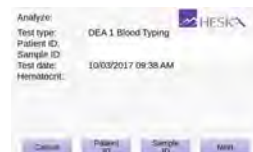
- STEP 7: On the on-screen keyboard, enter the cartridge code (printed on the cartridge pouch label) in the entry field and touch **Done**



- STEP 8: Touch **Confirm** to acknowledge that the blood has been obtained in a EDTA test tube and that the tube was appropriately filled.



- STEP 9: Touch **Patient ID** and enter the necessary information using the on-screen keyboard. Touch **Done** to confirm. Entering Sample ID is optional but recommended to aid in finding the result in the Analyzer's database.



- STEP 10: Enter the previously measured hematocrit value in percent using the on-screen keyboard. Based on the specified hematocrit the Heska Element COAG™ Analyzer will calculate the number of diluent drops needed for correct dilution of the sample.



Touch **Next** to continue.

10. Canine DEA 1 Blood Typing

STEP 11: Dilute the sample following the on-screen instructions. First, dispense the number of drops of diluent stated on the screen into one of the supplied sample tubes. Then mix 100 μ L of blood into the diluent using the fixed volume pipette and supplied pipette tip. Ensure proper mixing by aspirating a couple of times using the pipette.



STEP 12: Touch **Next** to continue. The **Cartridge Warming Up** screen opens.



It takes approximately 90 seconds for the Analyzer to warm up the test cartridge to 99 °F or 37 °C depending on the environment's temperature. Lower and higher temperatures may change the warm up time.

! Do not add the sample while the cartridge is warming up. Wait until a prompt appears on the screen instructing you to add the sample. By default, a message **Add 100 μ L sample and wait** flashes on the screen and a single beeping sound can be heard which signals that the blood sample can now be added to the cartridge.

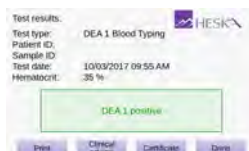
STEP 13: Gently invert the test tube back and forth 10 times to obtain a uniform mixture of blood cells and diluent.

When the message **Add 100 μ L sample and wait** appears on the screen, use the fixed volume pipette and the pipette tip supplied with the cartridge to add 100 μ L of diluted blood to the cartridge's sample well.

i Be sure to fill the sample well with at least 100 μ L blood. The measurement starts automatically as soon as the sample is detected. The test progress is shown on the screen. Measurement takes approximately 5 minutes. If the Analyzer alerts you that an insufficient amount of sample was placed into the sample well, repeat the measurement with a new cartridge. Touch **Cancel** to terminate the ongoing test.

STEP 14: The test result is displayed on the screen when the test is finished.

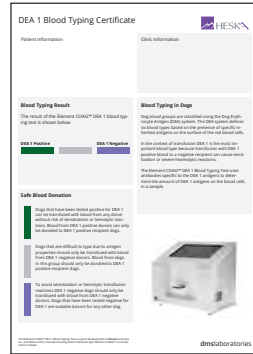
If a printer is connected to the instrument, touch **Print** to print the test result.



Touch **Done** to return to the Home screen.

If the printer supports printing on A4-paper, it is possible to print the result on a pre-formatted Heska Element COAG™ Blood Typing Certificate.

The user-supplied clinic information and Patient and Sample ID will appear on the printed certificate.



STEP 15: Remove the used test cartridge and dispose of it properly.

11. Feline A, B and AB Blood Typing

The Feline A & B Blood Typing Test Cartridge is used with the Heska Element COAG™ Analyzer for in vitro blood group determination. The Feline A & B Blood Typing cartridge is intended for use in performing a rapid blood group determination for cats from a drop of diluted EDTA-stabilized whole blood.

11.1. Feline Blood Typing

11.1.1. Feline Blood Groups

The AB system is the major blood group system in domestic cats. The common blood types are A and B. Cats with blood type A have naturally occurring anti-B antibodies at a low titer and cats with blood type B have naturally occurring anti-A antibodies at a high titer. A third rare type AB is also known. Cats with the rare AB type do not have anti-A or anti-B antibodies. There are however no null phenotype and as a consequence, there is no universal donor [48].

The A and B blood groups are genetically determined and blood type A is the most common among cats but the frequency varies significantly by breed and geographic location. Breeds that do not have the B type are Siamese, Burmese, American Shorthair, Oriental Shorthair and Tonkinese. Breeds with high incidence of the B blood type are Abyssinian, Japanese Bobtail, Birman, Persian, Scottish Fold, British Shorthair, Cornish Rex, Exotic Shorthair, Somali, Sphynx, Turkish Van, Turkish Angora and Devon Rex [49].

The inheritance of the rare AB group is not well understood and the incidence of the AB type is reported to be less than 1 %. Breeds that have the very rare type AB blood



FIGURE 11.1: The Feline A & B Blood Typing test kit.

11. Feline A, B and AB Blood Typing

include Birman, British Shorthair, Scottish Fold, Somali, and Sphynx. Somalis are more likely than average to have the rare type AB blood [49].

11.1.2. Blood Transfusion Risks

Cats that are transfused, even once, with an incompatible blood type, are at risk for a transfusion reaction. Cats with Type B blood exhibit an immediate and catastrophic systemic anaphylactic reaction and a Hemolytic Transfusion Reaction (HTR) when transfused with Type A blood, because of their natural high-titered anti-A antibody. As an outcome death of the patient is extremely likely.

Cats with type A blood exhibit a natural low-titered anti-B antibody response when transfused with type B blood. In this case, the reaction is mild but the transfused cells will have a shortened life span. The recipient will develop moderate titers of anti-B antibody that will result in a serious reaction if a subsequent incompatible transfusion is administered [48].

11.1.3. Mating risks

Serious problems can also result from accidental or mismatched mating. A mating of a type B queen with a type A tom will result in their type A kittens being at risk for neonatal isoerythrolysis (“NI”), commonly known as “fading kitten syndrome”. The maternal naturally occurring highly titered anti-A antibody occurs in the colostrum where from it can be absorbed by the newborn kittens. The absorbed antibody attacks the kittens’ type A erythrocytes. Although the kittens can seem normal at birth, they develop signs after nursing, fade and die within the first days of life. Determining the blood type of the queen and the tom prior to mating, coupled with appropriate genetic counseling, can minimize the risk of NI. Furthermore, immediate blood type determination of the newborn kittens will alert the client to remove the kittens and to begin surrogate nursing where necessary [48].

11.2. Test Specifications

The Feline Blood Typing test cartridge used with the Heska Element COAG™ Analyzer is intended for use to classify cats as A positive, B positive, or A and B positive. Test results obtained under normal operating conditions have an accuracy of 99.31 %.

All components of the test kit are stable at refrigerated temperatures (36 °F to 77 °F or 2 °C to 25 °C). Kits and components should not be exposed to direct sunlight. Once warmed to room temperature, the cartridge must be used within that day and should not be returned to the refrigerator.

The time it takes to perform a blood type determination with the Heska Element COAG™ Analyzer depends on factors such as type of test and test environment. At room temperature, it takes about 90 seconds for the instrument to warm up the test cartridge to 99 °F or 37 °C. Lower and higher room temperatures may change the warm up time. Once the procedure of the assay begins, an answer should be available within 5 minutes.

Each Heska Element COAG™/RapidVet® Test cartridge contains a monoclonal antibody or a lectin specific to the A antigen on a red blood cell or to the B antigen. Each cartridge is individually packed with a sealed pouch containing a desiccant bag to keep it moisture free. A torn or otherwise damaged pouch may allow moisture to reach the test cartridge and adversely affect performance. Do not use a test cartridge from a damaged pouch. Open the pouch just prior to use. Once the pouch has been opened, the test cartridge should be used within 10 minutes.

TABLE 11.1: Specifications for the Heska Element COAG™/RapidVet® Feline Blood Typing Test.

Measurement Technology	Agglutination detection using light absorbance
Species	Feline (Cat)
Possible results	A, B or AB
Sample Type	Diluted whole blood
Sample Volume	100 µL of whole blood (in cases with low hematocrit of the blood (below 29%), more volume will be needed.)
Sample Collection	EDTA collection tube
Sample Stability	Use the blood within the day of collection. Do not dilute the sample until prompted to do so on-screen.
Cartridge Stability	Do not expose the cartridges in the foil pouch to direct sunlight, or leave at room temperature for more than one day. Use cartridges taken from the foil pouch within 10 minutes
Storage	Store at 36 °F to 77 °F/2 °C to 25 °C
Shelf Life	The expiration date is printed on the pouch label.
Warm-up time	Approximately 90 seconds. The actual time depends on the blood sample and test environment. Very low or high ambient temperatures may change the warm-up time.
Time to results	Approximately 5 minutes from adding the sample to the cartridge

11. Feline A, B and AB Blood Typing

The expiration date of each cartridge is printed on the pouch label. Do not use the cartridge after the expiration date.

The test cartridge can be used only once and only in combination with the Heska Element COAG™ Analyzer. Once used, the cartridge, pipette tip and diluent tube should be considered as potentially infectious. Dispose of them properly in accordance with the policies and regulations at the place of operation.



Always strictly adhere to all bio-hazard safety guidelines pertaining to handling and disposing of animal blood samples.

11.3. Test Requirements

11.3.1. Materials and Equipment

In order to perform a Feline Blood Typing Test with the Heska Element COAG™ Analyzer, the following materials and equipment are required.

The following materials are required but not provided with the Feline Blood Typing Test:

- Heska Element COAG™ Analyzer
- Syringes with a 22 gauge or larger needle
- Sample collection tube with EDTA as the anticoagulant
- 100 µL fixed volume pipette.

The following materials are required and supplied with the Feline Blood Typing Test:

- Feline A & B Blood Typing cartridge
- Tube pre-filled with diluent (one for each cartridge). Each tube contains phosphate buffered saline (PBS) at pH 7.4 and contains enough fluid to perform one test on a cartridge.
- Pipette tips.
- Package insert for the Feline Blood Typing Test (shipped with each box of cartridges)

11.3.2. Blood Sample Preparation

Use a syringe with a 22 gauge or larger needle to avoid hemolysis. Collect blood directly into the EDTA test tube. The result of any blood analysis is dependent on the quality of the blood sample. Follow standard blood-drawing procedures at all times and pay special attention to the following:

- Blood samples, if possible, should be collected within the day of testing. Ensure proper mixing of the anticoagulant into the blood sample.
- If a blood rocker is not available, slowly invert the tube containing the blood sample 10 times every 10 minutes.
- The blood sample should be kept at room temperature, in case the testing is delayed.



The accuracy of the Feline A & B Blood Typing Test is mainly dependent on the quality of the blood sample. The way the blood is collected and has been handled can greatly affect the blood quality.

11.4. Limitations

The veterinarian is always the final arbiter of test result interpretation and impact on diagnosis. Therefore it is highly recommended that Heska Element COAG™ test results should be scrutinized in the light of a specific patient's condition and medical history, as well as current or potential therapy.

Any test result exhibiting inconsistency with a patient's status should be repeated and/or supplemented with additional diagnostic tests.

The accuracy of Heska Element COAG™ Analyzer test results is largely dependent on the quality of the blood specimen.

- The quality of the blood sample is dependent upon the blood sample collection, the proper blood to EDTA ratio, and the proper introduction of the sample and diluent into the sample well. Please observe all precautions cited in this manual and use good blood sample collection techniques at all times.
- Being an absorption assay, the test accuracy is dependent on proper dilution of the whole blood before adding the sample to the cartridge. Always measure the hematocrit of the sample prior to testing and follow the on-screen dilution procedure.
- Auto-agglutinated or hemolyzed blood samples may cause false results. The Analyzer is unable to distinguish RBC agglutinates from plasma containing hemoglobin. Always verify that the sample is not hemolyzed when measuring the hematocrit. As a general guideline, the plasma must be clear and more yellow than red. If the sample is severely hemolyzed a new blood sample should be drawn.

11. Feline A, B and AB Blood Typing

- Blood samples with a hematocrit of less than 4% or greater than 60% are not recommended for use with the Heska Element COAG™ Analyzer. Blood samples outside this range may result in an instrument error or inaccurate test result.

11.5. Test Procedure

Before performing any tests, be sure that the Heska Element COAG™ Analyzer has been installed properly in accordance with the instructions in this guide. See [Chapter 3](#) for details regarding how to set the Analyzer up correctly.

Verify that you have the necessary materials and equipment for performing a Feline A & B Blood Typing test, see [Section 11.3](#).

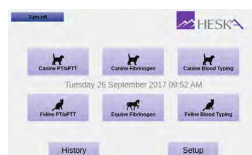
STEP 1: Remove a pouch with a test cartridge from the refrigerator and let the pouch and cartridge reach room temperature 59 °F to 86 °F/15 °C to 30 °C before starting the test.

STEP 2: Draw blood from the patient into a tube coated with or containing EDTA as an anticoagulant. The assay requires only 100uL of whole blood but the syringe or tube should be full to ensure the correct concentration of EDTA. If the blood type is not to be determined immediately, nutrients such as CPDA should not be added.

STEP 3: Determine the hematocrit of the sample.

STEP 4: Remove the cartridge and pipette tip from the pouch and the pre-filled tube with diluent from the kit box.

STEP 5: From the Home Screen, touch the **Feline Blood Typing** button to start the test.



STEP 6: When the message *Please insert new cartridge* flashes on the screen, insert the Feline A & B Blood Typing test cartridge completely into the cartridge slot on the front of the Analyzer. The cartridge must have the label facing upward and the sample well sticking out of the Analyzer.



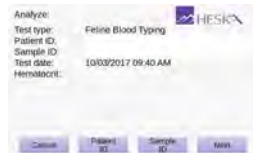
STEP 7: On the on-screen keyboard, enter the cartridge code (printed on the cartridge pouch label) in the entry field and touch **Done**



STEP 8: Touch **Confirm** to acknowledge that the blood has been obtained in a EDTA test tube and that the tube was appropriately filled.



STEP 9: Touch **Patient ID** and enter the necessary information using the on-screen keyboard. Touch **Done** to confirm. Entering Sample ID is optional but recommended to aid in finding the result in the Analyzer's database.

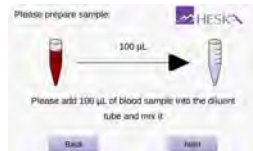


STEP 10: Enter the hematocrit value in percent using the on-screen keyboard and touch **Next**. Based on the specified hematocrit the Analyzer will calculate the amount of blood needed to be added to the diluent tube in order to obtain the correct dilution of the sample for the test.

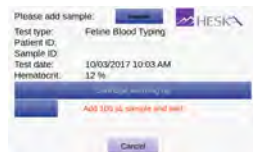


STEP 11: Ensure that no diluent is caught at the top of the pre-filled diluent tube by tapping the tube on a hard surface prior to piercing the lid. Using the supplied pipette tip, puncture the foil on the diluent tube.

STEP 12: Dilute the sample following the on-screen instructions. Add the amount of blood stated on the screen into one of the supplied tubes and mix it with the diluent using the 100 μ L fixed volume pipette. Ensure proper mixing by aspirating a couple of times using the pipette.



STEP 13: Touch **Next** to continue. The **Cartridge Warming Up** screen opens.



It takes approximately 90 seconds for the Analyzer to warm up the test cartridge to 99 °F or 37 °C depending on the environment's temperature. Lower and higher temperatures may change the warm up time.

11. Feline A, B and AB Blood Typing



*Do not add the sample while the cartridge is warming up. Wait until a prompt appears on the screen instructing you to add the sample. By default, a message **Add 100 µL sample and wait** flashes on the screen and a single beeping sound can be heard which signals that the blood sample can now be added to the cartridge.*

STEP 14: When the message **Add 100 µL sample and wait** appears on the screen, use the fixed volume pipette and the pipette tip supplied with the cartridge to add 100 µL of diluted blood to the cartridge's sample well.



*Be sure to fill the sample well with at least 100 µL diluted blood. The measurement starts automatically as soon as the sample is detected. The test progress is shown on the screen. Measurement takes approximately 5 minutes. If the Analyzer alerts you that an insufficient amount of sample was placed into the sample well, repeat the measurement with a new cartridge. Touch **Cancel** to terminate the ongoing test.*

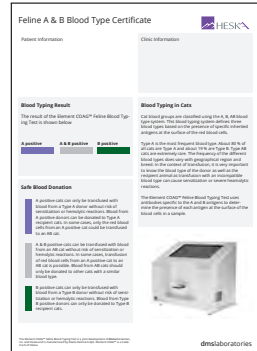
STEP 15: The test result is displayed on the screen when the test is finished.

If a printer is connected to the instrument, touch **Print** to print the test result.

Touch **Done** to return to the Home screen.

If the printer supports printing on A4-paper, it is possible to print the result on a pre-formatted Heska Element COAG™ Blood Typing Certificate.

The user-supplied clinic information and Patient and Sample ID will appear on the printed certificate.



STEP 16: Remove the used test cartridge and dispose of it properly.

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