

IDEXX **Coag Dx*** Analyzer



Operator's Guide

Proprietary Rights Notice

Information in this document is subject to change without notice. Companies, names and data used in examples are fictitious unless otherwise noted. No part of this document may be reproduced or transmitted in any form or by any means, electronic, mechanical or otherwise, for any purpose, without the express written permission of IDEXX Laboratories. IDEXX may have patents or pending patent applications, trademarks, copyrights or other intellectual or industrial property rights covering this document or subject matter in this document. The furnishing of this document does not give a license to these property rights except as expressly provided in any written license agreement from IDEXX Laboratories.

© 2013 IDEXX Laboratories, Inc. All rights reserved. • 06-14005-01

*IDEXX VetLab and Coag Dx are trademarks or registered trademarks of IDEXX Laboratories, Inc. in the United States and/or other countries. All other product and company names and logos are trademarks of their respective holders.



One IDEXX Drive
Westbrook, Maine 04092 USA
idexx.com

Contents

Preface	vii
About this Guide.....	vii
Safety Precautions.....	viii
International Symbol Descriptions.....	ix
Chapter 1: Getting Started	1
1.1 Introduction.....	1
1.2 Summary and Explanation.....	1
1.3 Principles of Operation.....	2
1.4 Definitions and Terms.....	3
1.5 Analyzer Components.....	3
1.5.1 Keys.....	4
1.5.2 Display Panel.....	5
1.6 Analyzer Menus.....	5
1.7 IDEXX Coag Dx Cartridges.....	6
Chapter 2: Installing the Analyzer	7
2.1 Analyzer Materials.....	7
2.2 Preparing and Using the Battery.....	7
2.2.1 Charging the Battery.....	7
2.2.2 Battery Charge Indicators.....	8
2.2.3 Battery Warnings.....	8
2.3 Connecting to the IDEXX VetLab Station [†]	9
Chapter 3: Setting Up the Analyzer	10
3.1 Starting the IDEXX Coag Dx Analyzer.....	10
3.2 Shutting Down the Analyzer.....	12
3.3 Setting the System Time and Date.....	12
3.4 Viewing System Information.....	14
3.5 Configuring Display Contrast, Brightness and Illumination.....	14
3.6 Setting the Language.....	15
3.7 Using the Supervisor Functions.....	16
3.7.1 Using the Supervisor Print Options.....	16
3.7.2 Setting Up the Communications and Network Ports.....	16
3.7.3 Setting the Electronic Quality Control Options.....	17
3.7.4 Setting the Supervisor PIN.....	17
Chapter 4: Testing Patient Samples	18
4.1 Identifying the Patient.....	18
4.1.1 Receiving an IDEXX VetLab Station [†] Request (Connected Coag Dx Analyzer).....	18
4.1.2 Entering Client and Patient IDs and Species (Stand-alone Coag Dx Analyzer).....	19
4.2 Collecting and Running Blood Samples.....	20
4.2.1 Fresh Whole Blood Samples.....	20
4.2.2 Citrated Blood Samples.....	22
4.2.3 Limitations.....	24

Chapter 5: Quality Control	25
5.1 Self-Check	25
5.2 Verifying the Analyzer's Temperature.....	25
5.3 Running Electronic Quality Control.....	25
Chapter 6: Database Management	27
6.1 Viewing Total Test Counts and Remaining Test Counts.....	27
6.2 Reviewing Patient and EQC Test Results	28
6.3 Deleting Patient and EQC Test Results	29
Chapter 7: Troubleshooting	30
7.1 IDEXX Technical Support Contact Information.....	30
7.2 Acronyms for Error Messages.....	30
7.3 Analyzer Error Messages.....	31
Appendixes	34
Appendix A: IDEXX Coag Dx Analyzer Specifications	34
Appendix B: Service and Maintenance	35
B.1 Routine Maintenance	35
B.2 Service	35
B.3 Battery Care.....	35
B.4 Analyzer Disposal	35
Appendix C: Printing (Stand-alone Coag Dx Analyzer).....	36
C.1 Connecting a Printer.....	36
C.2 Defining the Printed Report Header	36
C.3 Printing System Information	37
C.4 Using the Supervisor Print Options	37
C.5 Printing Patient Results.....	38
C.6 Printing Electronic Quality Control Results.....	39
Appendix D: Safety Standards	41
D.1 Standard Safety Requirements and Directives	41

Preface

About this Guide

Use This Chapter...	To Learn About...
1 Getting Started	<ul style="list-style-type: none">• How the analyzer works• Analyzer components and menus• Coag Dx* Cartridges
2 Installing the Analyzer	<ul style="list-style-type: none">• Analyzer materials (required and suggested)• Preparing and using the battery• Connecting to a printer• Connecting to the IDEXX VetLab* Station†
3 Setting Up the Analyzer	<ul style="list-style-type: none">• How to turn the analyzer on and off• Setting the time and date• Displaying system information• Configuring the analyzer to meet your needs• Using the Supervisor functions
4 Testing Patient Samples	<ul style="list-style-type: none">• Identifying a patient• Collecting and running blood samples• Printing patient results (from the IDEXX VetLab* Station†)
5 Quality Control	<ul style="list-style-type: none">• Running quality control• Printing quality control results
6 Database Management	<ul style="list-style-type: none">• Viewing total and remaining test counts• Reviewing patient and QC results• Deleting patient and QC results
7 Troubleshooting	<ul style="list-style-type: none">• IDEXX Technical Support contact information• Acronyms for error messages• Error messages
Appendixes	<ul style="list-style-type: none">• Analyzer specifications• Service and maintenance information• Printing (Stand-alone Coag Dx* Analyzer)• Safety standards

†IDEXX VetLab* Station, software version 2.30 or later

Safety Precautions

Before operating the IDEXX Coag Dx Analyzer, we recommend that you review these safety precautions:

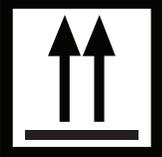
- **Do not** remove the AC/DC Power Module from the analyzer by pulling on the cord.
- **Do not** open the analyzer. There are no user-serviceable parts. Opening the analyzer violates the warranty and/or maintenance agreement.
- **Do not** use non-IDEXX cartridges.
- **Do not** use cartridges that are past their marked expiration date or have been improperly stored.
- **Do not** force a cartridge into the analyzer. If you encounter resistance when inserting a cartridge, gently remove the cartridge and examine the test chamber. Remove any obstruction before attempting further use of the analyzer. (See *Appendix B: Service and Maintenance* for more information.)
- **Do not** use excessive force when pressing the analyzer's keys.
- **Do not** drop the analyzer. **Do not** use the results if the analyzer is dropped during a test.
- If the equipment is used in a manner other than specified, the protection provided by the instrument may be impaired.
- All biohazard safety guidelines pertaining to the handling and disposal of animal blood should be strictly adhered to when collecting and handling blood specimens and when operating the IDEXX Coag Dx Analyzer.
- Used IDEXX Coag Dx Cartridges should be considered potentially infectious. They should be handled according to individual institutional policies concerning the disposal of potentially infectious materials.
- **Do not** replace the Lithium Ion (Li-Ion) battery in the analyzer. Only authorized IDEXX service centers are approved to replace the battery.
- The IDEXX Coag Dx analyzer is designed to safely function with only the provided Li-Ion battery.
- The battery should only be charged with the power supply provided for use with the IDEXX Coag Dx analyzer (for more information, see section 2.2.1 *Charging the Battery*).
- The battery may become warm during charging—this is normal.
- In the event of a battery leak, do not allow the liquid to come in contact with the skin or eyes. If contact has been made, wash the affected area with water and seek medical advice.
- In the event that the battery leaks or is not functioning appropriately, please contact IDEXX to arrange for service of the instrument.
- **Do not** use this instrument in close proximity to sources of strong electromagnetic radiation (e.g., unshielded intentional RF sources), as these may interfere with proper operation.

International Symbol Descriptions

International symbols are often used on packaging to provide a pictorial representation of particular information related to the product (such as expiration date, temperature limitations, batch code, etc.). IDEXX Laboratories has adopted the use of international symbols on our analyzers, product boxes, labels, inserts and guides in an effort to provide our users with easy-to-read information.

If you are unsure of the meaning for a particular symbol, see the table below for a description of each symbol that can be found on IDEXX Laboratories packaging.

Symbol	Description	Symbol	Description
	Use by date À utiliser avant la date Verwendbar bis Usare entro Usar antes de 使用期限		Temperature limitation Limite de température Zulässiger Temperaturbereich Limite di temperatura Límite de temperatura 保存温度(下限)
	Batch Code (Lot) Numéro de lot Chargenbezeichnung (Ch.-B.) Codice del lotto (partita) Código de lote (Lote) ロット番号		Upper limit of temperature Limite supérieure de température Temperaturobergrenze Limite superiore di temperatura Límite superior de temperatura 保存温度(上限)
	Serial Number Numéro de série Seriennummer Numero di serie Número de serie シリアル番号		Consult instructions for use Consulter la notice d'utilisation Gebrauchsanweisung beachten Consultare le istruzioni per l'uso Consultar las instrucciones de uso 取扱説明書をご参照ください。
	Catalog Number Numéro de catalogue Katalognummer Numero di catalogo Número de catálogo 製品番号		Authorized Representative in the European Community Représentant agréé pour la Communauté européenne Autorisierte EG-Vertretung Rappresentante autorizzato nella Comunità Europea Representante autorizado en la Comunidad e Europea EC内の正規販売代理店
	Control positive Contrôle positif Positive Kontrolle Controllo Positivo Control Positivo 陽性コントロール		Control negative Contrôle négatif Negative Kontrolle Controllo Negativo Control Negativo 陰性コントロール
	Manufacturer Fabricant Hersteller Ditta produttrice Fabricante 製造元		Date of manufacture Date de fabrication Herstellungsdatum Data di produzione Fecha de fabricación 製造年月日:

Symbol	Description	Symbol	Description
	<p>Keep away from sunlight Conserver à l'abri de la lumière du soleil Vor direkter Sonneneinstrahlung schützen Tenere lontano dalla luce diretta del solar Mantener alejado de la luz solar 遮光してください。</p>		<p>WEEE Directive 2002/96/EC Directive 2002/96/CE (DEEE) WEEE-Richtlinie 2002/96/EG Direttiva RAEE 2002/96/CE Directiva 2002/96/CE RAEE 廃電気電子機器指令 (WEEE Directive 2002/96/EC)</p>
	<p>Caution, consult accompanying documents Attention, consulter les documents joints Achtung, Begleitdokumente beachten Attenzione, consultare la documentazione allegata Precaución, consultar la documentación adjunta 注意、添付文書をご参照ください。</p>		<p>Do Not Reuse Ne pas réutiliser Nicht wiederverwenden Non riutilizzare No reutilizar 再利用しないでください。</p>
	<p>Caution, hot surface Attention, surface très chaude Vorsicht, heiße Oberfläche Attenzione, superficie rovente Precaución, superficie caliente 高温注意</p>		<p>Electrostatic-sensitive device Appareil sensible aux charges électrostatiques Gerät ist sensibel auf elektrostatische Ladung Dispositivo sensibile alle scariche elettrostatiche Dispositivo sensible a descargas electrostáticas 静電気の影響を受ける装置</p>
	<p>Keep dry Conserver dans un endroit sec Vor Nässe schützen Tenere al riparo dall'umidità Mantener seco 濡らさないこと。</p>		<p>Fragile Fragile Zerbrechlich Fragile Frágil 取扱注意</p>
	<p>This side up Haut Diese Seite nach oben Alto Este lado hacia arriba この面を上にする。</p>		<p>Biological Risks Risques biologiques Biogefährlich Rischi biologici Riesgos biológicos 生物学的リスク</p>

Symbol	Description
GHS P 304	<p>IF INHALED: EN CAS D'INHALATION: BEI EINATMEN: IN CASO DI INALAZIONE: EN CASO DE INHALACIÓN: 吸引した場合</p>
GHS H 303/313/333	<p>May be harmful if swallowed, on contact with skin, and if inhaled Peut être nocif par ingestion, inhalation, par contact avec la peau et par inhalation Kontakt mit der Haut, einatmen oder verschlucken kann Gesundheitschäden verursachen Può essere nocivo in caso di ingestione, inalazione, e contatto con la pelle Puede ser nocivo en caso de ingestión, en contacto con la piel o en caso de inhalación 吸入、接触または飲み込むと有害 のおそれ。</p>

Symbol	Description
GHS P 312	<p>Call a POISON CENTER or doctor/physician if you feel unwell Appeler un CENTRE ANTIPOISON ou un médecin en cas de malaise. Bei Unwohlsein GIFTINFORMATIONSZENTRUM oder Arzt anrufen In caso di malessere, contattare un CENTRO ANTIVELENI o un medico Llamar a un CENTRO DE INFORMACIÓN TOXICÓLOGICA o a un médico en caso de malestar 気分が悪くなった時は医師に連絡 すること</p>

Chapter 1: Getting Started

1.1 Introduction

The IDEXX Coag Dx* Analyzer helps you detect a patient's clotting ability and provides you with vital information for patients that require critical care and/or emergency and surgical procedures. The IDEXX Coag Dx* Analyzer is an AC- or battery-operated, hand-held analyzer that performs individual point-of-care coagulation tests on fresh whole blood or citrated whole blood. These tests include Activated Partial Thromboplastin Time (aPTT and Citrate aPTT) and Prothrombin Time (PT and Citrate PT). The Coag Dx Analyzer is validated for use with canine and feline samples for all four test types and is validated for use with equine samples for Prothrombin Time (PT and Citrate PT) tests only. The Coag Dx Analyzer is for use only with IDEXX Coag Dx* Cartridges.

The IDEXX Coag Dx Analyzer:

- Provides accurate, patient-side coagulation testing
- Uses veterinary-specific parameters to help detect clotting disorders in dogs, cats and horses
- Measures coagulation time (the time to clotting and fibrin formation)
- Stores up to 600 patient results and 600 quality control results
- Tags test results with the test run's date and time
- Allows for the entry of Patient ID, Client ID and species
- Prints results (when connected to IDEXX VetLab* Station[†] or a compatible printer)

The IDEXX Coag Dx Analyzer is a part of the IDEXX VetLab* Suite. Patient results collected and stored on the analyzer can be uploaded to the IDEXX VetLab Station[†] where they are incorporated into one comprehensive patient report.

The IDEXX Coag Dx Analyzer is for veterinary use only and is not for human diagnostic use.

1.2 Summary and Explanation

Events that lead to the formation of a blood clot are simplified in coagulation theory into two interactive coagulation cascades that are referred to as the **intrinsic** and the **extrinsic** pathways, both leading to the **common** pathway and the formation of a stable fibrin clot.

The clotting factors involved in these pathways are numbered I through V and VII through XIII. The intrinsic pathway begins with the contact activation of factor XII and, through the interaction of several coagulation factors, results in the conversion of soluble fibrinogen to insoluble fibrin strands and the formation of a stable fibrin clot. The extrinsic pathway is initiated through the interaction of tissue factor with factor VII. Platelets, essential cofactors in this reaction, provide the platelet phospholipid surface on which coagulation reactions occur.

Activated Partial Thromboplastin Time (aPTT and Citrate aPTT) and Prothrombin Time (PT and Citrate PT) tests are general coagulation screening tests that are used to measure the functionality of the blood coagulation cascade.

[†]IDEXX VetLab* Station, software version 2.30 or later

IDEXX Coag Dx* aPTT Tests (validated for veterinary use with canine and feline samples)

The **IDEXX Coag Dx* aPTT Test** is a unitized test system that measures the intrinsic and common coagulation pathways. The intrinsic pathway involves all coagulation factors except factors VII and III (tissue factor). The aPTT test improves the PTT test through use of a contact activating substance, which standardizes activation of factor XII to provide a more precise and sensitive assay for low level heparin monitoring.

The **IDEXX Coag Dx* Citrate aPTT Test** performs the same measurement as the aPTT test, using a citrated whole blood sample.

IDEXX Coag Dx* PT Tests (validated for veterinary use with canine, feline and equine samples)

The **IDEXX Coag Dx* PT Test** measures the extrinsic and common coagulation pathways assessing coagulation factors VII, X, V, II and fibrinogen. PT results may be abnormal in patients with liver disease or Vitamin K deficiency. The PT test is a unitized test system that uses a highly sensitive thromboplastin for improved specificity and sensitivity.

The **IDEXX Coag Dx* Citrate PT Test** performs the same measurement as the PT test, using a citrated whole blood sample.

1.3 Principles of Operation

The IDEXX Coag Dx Analyzer provides many features for ease of use and reliability, including a patented clot detection system, a data storage module, interfaces for the IDEXX VetLab Station[†] and a streamlined user-interface panel.

The Coag Dx Analyzer measures whole blood clotting times using disposable single-use IDEXX Coag Dx Cartridges. Each cartridge contains all of the reagents necessary for a specified test.

After a cartridge is inserted into the Coag Dx Analyzer and warmed to 37°C ± 1.0°C (98.6°F ± 2.0°F), the analyzer beeps, indicating that a blood sample can be added to the cartridge and the test started. Once a blood sample is placed in the cartridge's sample well and the Start key is pressed, the analyzer measures the required volume of blood and automatically moves it into the cartridge test channel, where the blood is mixed with reagents. The remaining sample not needed for testing is automatically drawn out of the sample well and into an enclosed waste channel on the cartridge.

After mixing with the reagent, the sample is moved back and forth at a predetermined rate within the test channel and monitored for clot formation. The test channel is maintained at 37°C ± 1.0°C (98.6°F ± 2.0°F) during the test.

The rate of movement of the sample is monitored by a series of LED optical detectors that are aligned with the test channel. When the blood clots, the flow of the blood sample within the test channel is impeded, reducing its rate of flow between the optical detectors. This reduction in flow below a predetermined value signals to the analyzer that a clot has formed. The analyzer also emits an audible beep when clot formation occurs, indicating the end of the test. An internal timer measures the elapsed time between the start of the test and the clot formation. When the test is complete, the whole blood clotting time (in seconds) is displayed.

The test results remain on the display as long as the cartridge remains in the analyzer. When connected to IDEXX VetLab Station[†] or an external printer, results can be automatically printed along with the time and date the test was run, the Patient ID, Client ID, species and other information, if entered. Results are also saved in an internal database. Up to 600 patient test results and 600 quality control test results can be stored in the analyzer for later printing or downloading.

[†]IDEXX VetLab* Station, software version 2.30 or later

1.4 Definitions and Terms

The following acronyms and abbreviations are used in this guide, on the analyzer's screens and on printouts:

aPTT	Activated Partial Thromboplastin Time
DB	Data Base
EQC	Electronic Quality Control (System Verification)
CID	Client Identification Number
PAT	Patient
PID	Patient Identification Number
PT	Prothrombin Time
QC	Quality Control
TQC	Temperature Quality Control

1.5 Analyzer Components

The Coag Dx Analyzer is a hand-held device (Figures 1-1 and 1-2). It contains a **test chamber** that warms a test cartridge to the required temperature, and it performs all operations to measure the clotting time of a whole blood sample after it is placed in the test chamber and the test is started by the operator.

Operator instructions are shown on the **display panel**, and the operator enters commands and information using the **keypad**. When the test is completed, the results are shown on the display panel and stored in system memory for printing or downloading.

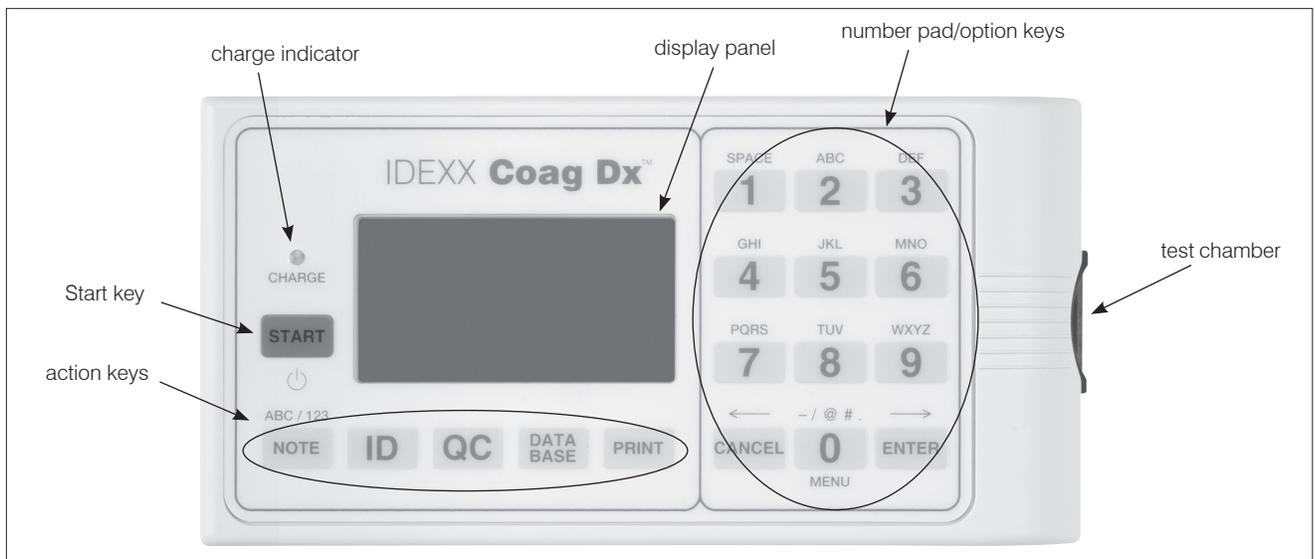


Figure 1-1: Top view of the IDEXX Coag Dx Analyzer

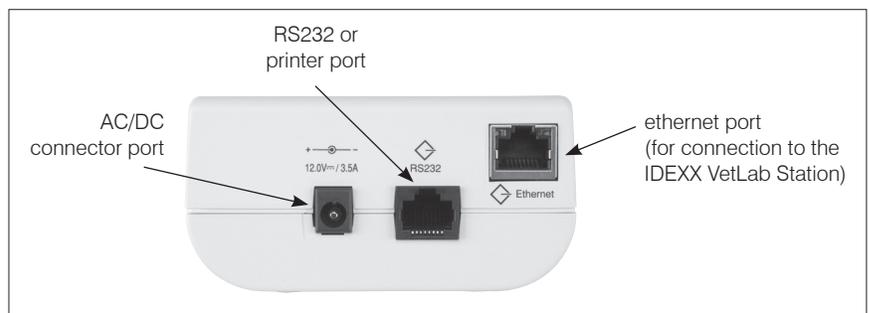


Figure 1-2: Side view of the IDEXX Coag Dx Analyzer

1.5.1 Keys

Use the **number pad/option keys** to select a specific command or to enter characters for patient information.

The **action keys** display a menu of commands according to the label on the key. For example, the **Print** key displays printing commands.

Note: The 0 (zero) key is used as both a numeral key and an action key.

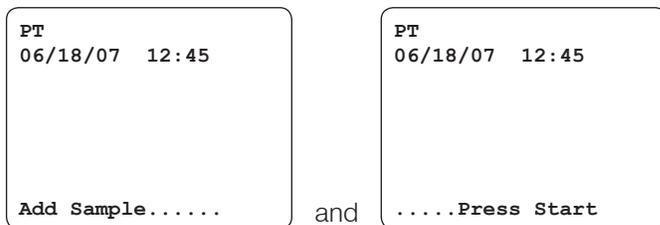
The keys display and activate various commands for operating and configuring the analyzer. A description of each key on the front panel of the Coag Dx Analyzer follows:

Key	Description
Start	<ul style="list-style-type: none"> • Turns the analyzer on or off. • Initiates a test after a test cartridge has reached 37°C ± 1.0°C and the sample is added.
Note	<ul style="list-style-type: none"> • Toggles between alphabetic (ABC) and numeric (123) characters when in data entry mode. • Displays the Notes screen where you can enter a note to add to the patient record. Note: This feature is currently not available.
ID	Displays the Identify Patient menu where you can: <ul style="list-style-type: none"> • Enter a Client ID (CID). • Enter a Patient ID (PID). • Select a species. • Recall the last client/patient for which a test was run.
QC	<ul style="list-style-type: none"> • Displays the QC Status menu where you can initiate an EQC (Electronic Quality Control) test. The test chamber must be empty for an EQC test to be run. • Displays the Quality Control menu, where you can run liquid quality controls. Note: This menu is currently not available.
Database	Displays the Data Base menu where you can: <ul style="list-style-type: none"> • Display the number of patient or QC test results that are currently stored in the analyzer and the number of additional test results that can be stored. • Display results of the stored patient or EQC tests. • Delete patient or EQC records.
Print	Displays the Print menu where you can: <ul style="list-style-type: none"> • Print results on an external printer. You can print the last test result, the patient database or quality control database, or you can print all test results for a specified patient. • Test the printer. • Enter a customized header for the printed report. • Print system information for the analyzer.
0 through 9	<ul style="list-style-type: none"> • Selects a menu option. • Enters alphabetic and numeric characters when in data entry mode (e.g., a Client ID, a Patient ID, a time or a date). • Displays the main menu (press 0 when no tests are running and no menu is active). • Displays previous (7) or next (9) results when viewing patient or quality control results.

Key	Description
Cancel	<ul style="list-style-type: none"> • Cancels an operation and returns the analyzer to its previous state. • Returns the analyzer to the Home screen (“Insert...Cartridge” screen). • Moves the cursor to the left when in data entry mode.
Enter	<ul style="list-style-type: none"> • Accepts and stores an entry (e.g., a Client ID, a Patient ID, a time or a date). • Moves the cursor to the right when in data entry mode.

1.5.2 Display Panel

Use the display panel to communicate with the IDEXX Coag Dx Analyzer. For example, the messages “Add Sample” and “Press Start” are alternately displayed after a test cartridge reaches the correct operating temperature:

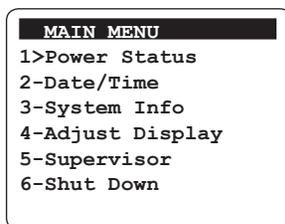


The display is illuminated to enhance visibility in low light conditions. To conserve power during battery operation, the display is not illuminated when the test chamber is empty or when a test is running. The display is momentarily illuminated after a key is pressed or when results of a completed test are displayed. While a test is running, the display can be momentarily illuminated by pressing the **Cancel** key, the **Enter** key or any numeric key.

Note: For information on how to set the illumination time, see section 3.5 *Configuring Display Contrast, Brightness and Illumination*.

1.6 Analyzer Menus

The Main menu on the IDEXX Coag Dx Analyzer is shown below. To access the Main menu, press **0** (zero).



To execute a command on any menu, press the applicable number key for that command. For example, on the Main menu, press **6** to shut down the system or press **3** to display system information.

Note: You cannot access the Main menu if a cartridge is in the test chamber. You must first remove the cartridge before you can access the Main menu.

1.7 IDEXX Coag Dx Cartridges

Tests are performed with single-use disposable IDEXX Coag Dx* Cartridges (Figure 1-3). Each cartridge contains a **label**, a **sample well** with an **overflow area**, a **test channel** containing reagents, an enclosed **waste reservoir**, and one or more **optical detection windows**.

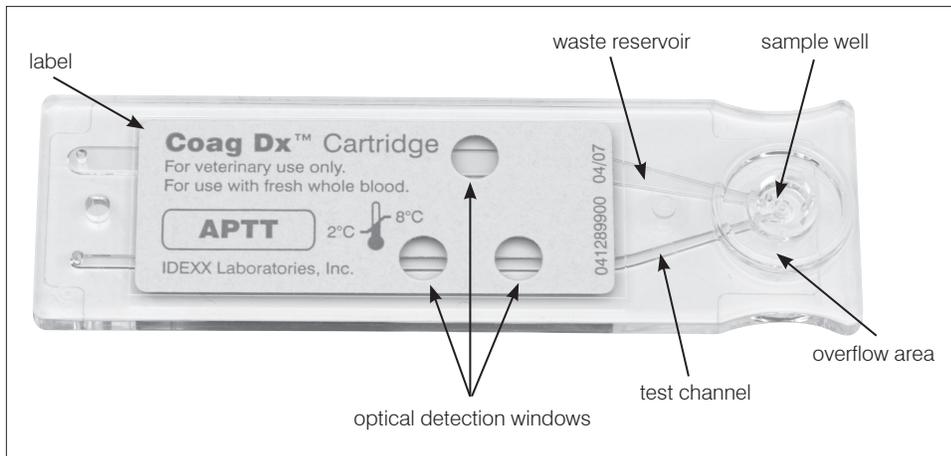


Figure 1-3: IDEXX Coag Dx* Cartridge

The cartridge label is human- and analyzer-readable. The current test is automatically read by the analyzer and displayed for confirmation when you insert the cartridge into the test chamber. After the cartridge has warmed (from 30–90 seconds), the messages “Add Sample” and “Press Start” are displayed. These messages indicate that you can place the sample in the sample well and begin the test by pressing the **Start** key.

Note: Refer to the cartridge's package insert for storage and handling instructions.

Four IDEXX Coag Dx Cartridges are available for use on the IDEXX Coag Dx Analyzer:

- IDEXX Coag Dx Activated Partial Thromboplastin Time (aPTT)
- IDEXX Coag Dx Citrate Activated Partial Thromboplastin Time (Citrate aPTT)
- IDEXX Coag Dx Prothrombin Time (PT)
- IDEXX Coag Dx Citrate Prothrombin Time (Citrate PT)

Chapter 2: Installing the Analyzer

2.1 Analyzer Materials

Important: Inspect each analyzer component for damage when unpacking. If you see damage, contact your distributor or an IDEXX Technical Support representative immediately.

1. Remove any protective packaging that may be present around the analyzer.
2. Examine the packaging material to be sure that the power supply, connecting cables or other components have been removed. The materials that are provided are listed below.

Note: Do not discard the packaging material.

Materials Provided

- IDEXX Coag Dx Analyzer
- Ethernet Cable
- AC/DC Power Module (including a power cord and AC adapter)
- IDEXX Coag Dx Analyzer Operator's Guide
- Quick Reference Guide
- Sample Testing Quick Guide

Materials Required (Not Provided)

IDEXX Coag Dx Cartridges

Optional Materials

- IDEXX VetLab Station[†]
- Router
- Seiko Thermal Printer (model DPU-414-30 B)
Note: This printer is not available from IDEXX Laboratories, Inc.

2.2 Preparing and Using the Battery

2.2.1 Charging the Battery

You must charge the battery before using the IDEXX Coag Dx Analyzer.

To charge the battery:

1. Connect the power cord and the AC adapter.
2. Connect the AC adapter to the AC/DC connector port on the side of the Coag Dx Analyzer and plug the power cord into an AC outlet. The charge indicator on the analyzer's keypad will illuminate.
3. Allow the battery to charge for at least **8 hours**.

Notes:

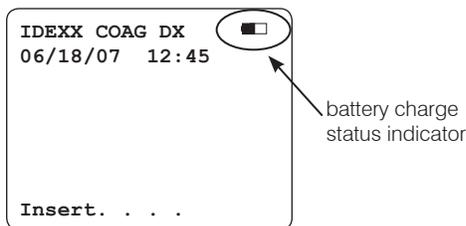
- The AC/DC Power Module can remain connected all the time.
- To ensure an adequate charge, leave the analyzer connected to the charger for a minimum of 8 hours. This eliminates the risk of the analyzer powering down during a test.

[†]IDEXX VetLab* Station, software version 2.30 or later

2.2.2 Battery Charge Indicators

A battery charge LED on the front panel illuminates whenever the battery is being charged. The LED flashes when the remaining battery power is low.

A battery charge status indicator is also displayed in the upper right corner of the screen when the analyzer is disconnected from the AC/DC Power Module and is ready to run a test.



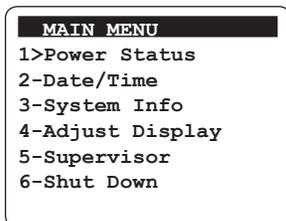
2.2.3 Battery Warnings

The message "Charge Battery" displays intermittently when the remaining battery power is insufficient to ensure test completion. The message "Battery Fault" displays when the battery is completely discharged and cannot be used to run additional tests. The AC/DC Power Module must be used for additional tests until the battery is recharged.

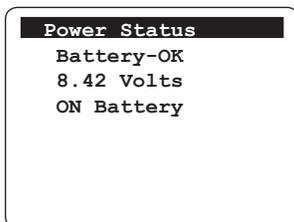
If either the battery voltage or the AC/DC Power Module voltage is too high, the analyzer beeps continuously and displays the message "Disconnect AC Adapter Immediately." The AC/DC Power Module must be disconnected to shut down the analyzer in this condition.

To check the battery:

1. Press and hold **Start** to turn on the analyzer.
2. Press **0** (zero) to display the Main menu:



3. Press **1**. The battery power status is displayed:



Note: The battery status is displayed as OK or LOW.

4. Press the **Cancel** key twice to return to the "Insert....Cartridge" screen.

2.3 Connecting to the IDEXX VetLab Station†

Connecting your IDEXX Coag Dx Analyzer to the IDEXX VetLab Station† lets you identify your client and patient, and automatically transfer your coagulation results to the patient's record.

Important: When the Coag Dx Analyzer is connected to the IDEXX VetLab Station†, you cannot initiate a test run from the Coag Dx Analyzer. All test runs must be initiated from the IDEXX VetLab Station†.

To connect the Coag Dx Analyzer to the IDEXX VetLab Station† (Figure 2-1):

1. Be sure the Coag Dx Analyzer and the IDEXX VetLab Station† are turned on.
2. Plug one end of the ethernet cable into the ethernet port on the side of the Coag Dx Analyzer.
3. Plug the other end of the ethernet cable into the router that is connected to the IDEXX VetLab Station†. Use the first available LAN port (labeled 1, 2, 3, etc.).

Important: Do not use the WAN port, which connects to the Internet.

4. When the Coag Dx icon appears on the Home screen on the IDEXX VetLab Station†, your connections are complete.

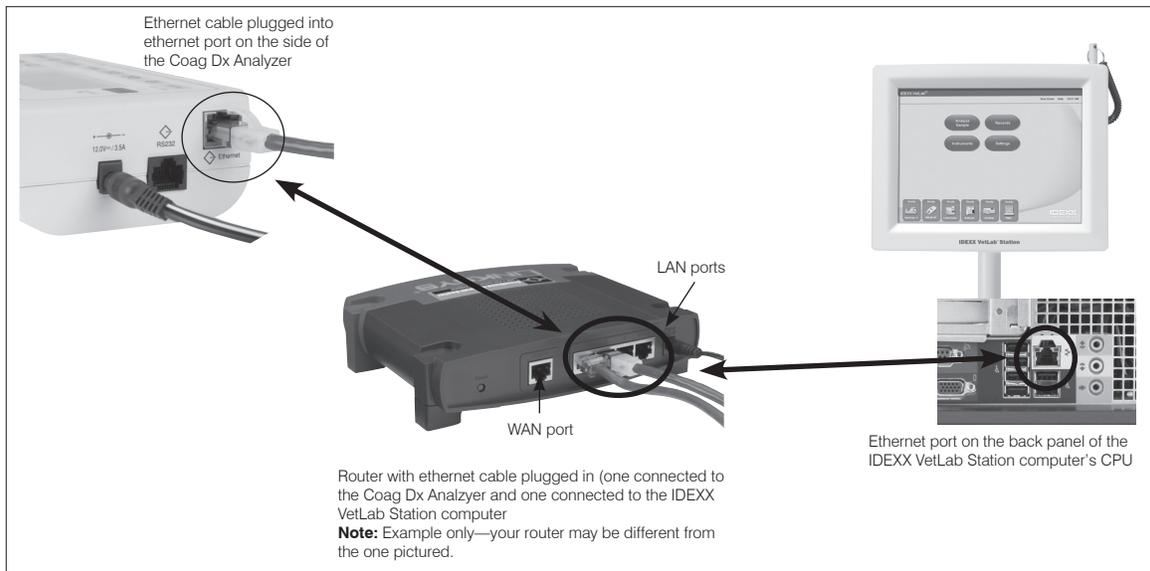


Figure 2-1: Coag Dx Analyzer to IDEXX VetLab Station connection

†IDEXX VetLab* Station, software version 2.30 or later

Chapter 3: Setting Up the Analyzer

3.1 Starting the IDEXX Coag Dx Analyzer

You can start the IDEXX Coag Dx Analyzer by pressing and holding the Start key or by inserting a Coag Dx Cartridge.

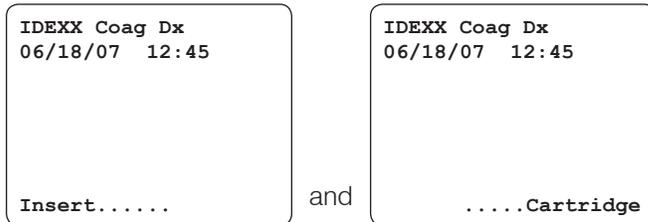
To turn on the analyzer using the Start key:

- Press and hold the **Start** key. The following screens display briefly:



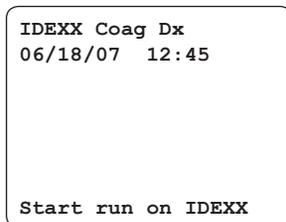
Stand-alone Coag Dx Analyzer:

When the message “Insert....Cartridge” displays, the analyzer is ready to accept a cartridge for testing.



Coag Dx Analyzer connected to the IDEXX VetLab Station[†]:

When the message “Start run on IDEXX VetLab Station” displays across the bottom of the screen, the analyzer is ready to accept a request for a test run from the IDEXX VetLab Station[†].



[†]IDEXX VetLab* Station, software version 2.30 or later

To start the analyzer by inserting a cartridge:

Note: If the Coag Dx Analyzer is connected to the IDEXX VetLab Station[†], you must start the analyzer using the Start key. See the previous set of instructions.

1. Let an IDEXX Coag Dx Cartridge (e.g., PT) reach room temperature (15°–30°C/ 59°–86°F) before opening the pouch. This will take 30–60 minutes.

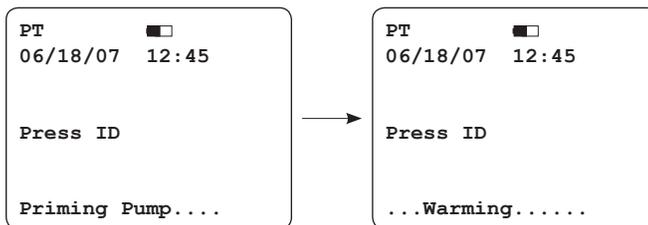
Note: Refer to the cartridge's package insert for additional information regarding cartridge storage and handling.

2. Insert the Coag Dx Cartridge (e.g., PT) with the label facing up into the analyzer's test chamber (Figure 3-1). Push the cartridge all the way in until it stops.



Figure 3-1: Insert cartridge, label facing up

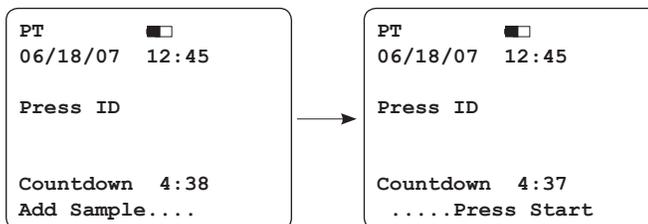
The following screens display:

**Notes:**

- The test name for the inserted cartridge displays in the upper left corner of the screen.
 - Inserting a cartridge initiates the warming/self-check mode.
3. Check the display for fault messages while the analyzer warms the cartridge to 37°C ±1°C (98.6°F ±2°F). This warming cycle takes 30–90 seconds.

Note: If a fault message displays, see *Chapter 7: Troubleshooting* for the procedure to resolve the fault message.

When the cartridge reaches the correct temperature, the analyzer beeps and alternately displays the following screens.



4. You are now ready to add a sample to the cartridge and run a test. See *Chapter 4: Testing Patient Samples* for more information on running a sample test.

Important: You must add the sample to the cartridge and press Start within five minutes of the cartridge reaching the correct temperature.

[†]IDEXX VetLab* Station, software version 2.30 or later

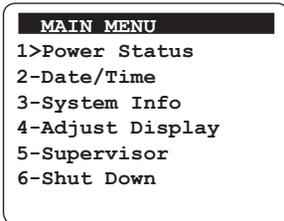
3.2 Shutting Down the Analyzer

Note: IDEXX recommends that you leave the Coag Dx Analyzer turned on so that the automatic Electronic Quality Control (EQC) process runs. For more information on the EQC process, see *Chapter 5: Quality Control*.

You can shut down the analyzer in one of the following ways.

From the Main menu:

1. Press **0** (zero) to display the Main menu.



2. Press **6**. The analyzer shuts down.

Using the Start key:

Press and hold the **Start** key for four seconds. The analyzer shuts down.

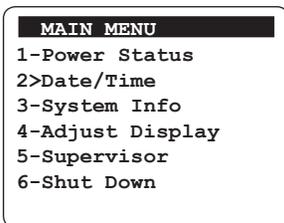
3.3 Setting the System Time and Date

The time and date a test is run is saved with the test results. The default settings for the time and date are 12-hour and MM/DD/YY, respectively. You can change the default system time and date.

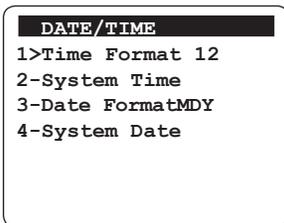
Note: If the analyzer has been off for an extended period of time (or if the battery is very weak), you will be prompted to enter or verify that the time and date are correct.

To set the time:

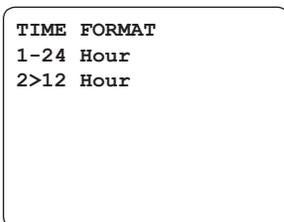
1. Press **0** (zero) to display the Main menu.



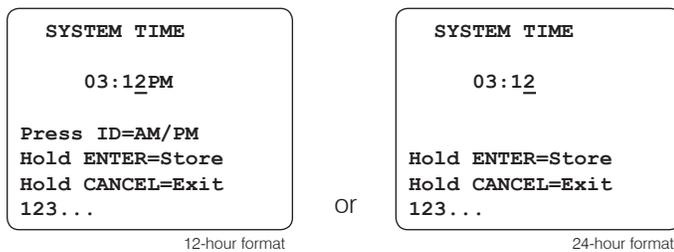
2. Press **2** to display the Date/Time menu.



3. Press **1** to display the Time Format screen. The default system time is 12-hour.



4. Press **1** to display the time in a 24-hour format or **2** for the 12-hour format. After you make your selection, press **Cancel** to return to the Date/Time menu.
5. Press **2** on the Date/Time menu to display the System Time screen.



6. Do one of the following:
 - **24-hour format:** Enter the new time using the numeric keys. For example, enter 15:30 for 3:30 p.m. or 06:30 for 6:30 a.m.
 - **12-hour format:** Enter the time using the numeric keys. Then press the **ID** key to specify a.m. or p.m.

Tip: When entering the time:

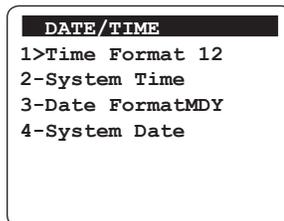
- Press **Cancel** to move the cursor to the left.
- Press **Enter** to move the cursor to the right.

Note: The leading zero is required for single digit times.

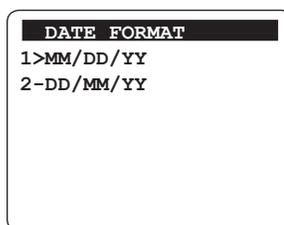
7. Press and hold **Enter**. The message “Stored” displays and the entry is saved.
8. Press **Cancel** to return to the Main menu.

To set the date:

1. Press **0** (zero) to display the Main menu.
2. Press **2** to display the Date/Time menu.

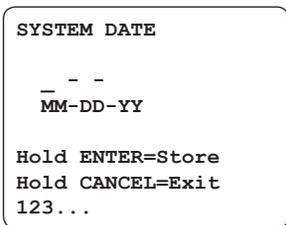


3. Press **3** to display the Date Format screen. The default system date format is MM/DD/YY.



4. Press **1** to use the month-day-year date format or **2** to use day-month-year format.
5. Press **Cancel** to return to the Date/Time menu.

- Press **4** on the Date/Time menu to display the System Date screen.



- Enter the date using the numeric keys. For example, if you selected MM/DD/YY, then enter 06-18-07 for June 18, 2007.

Note: The leading zero is required for single digit dates.

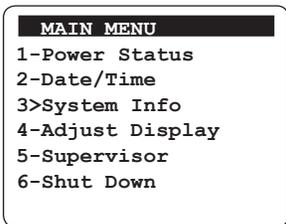
- Press and hold **Enter**. The message “Stored” displays and the entry is saved.
- Press **Cancel** twice to return to the “Insert...Cartridge” screen.

3.4 Viewing System Information

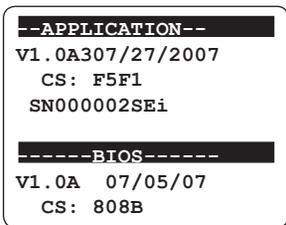
You can view the analyzer’s software version, serial number and other system software information.

To view system information:

- Press **0** (zero) to display the Main menu.



- Press **3** to display the system information.



(example only)

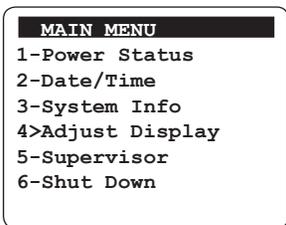
Note: The Main menu displays again after several seconds, or you can press **Cancel** to return to the “Insert...Cartridge” screen.

3.5 Configuring Display Contrast, Brightness and Illumination

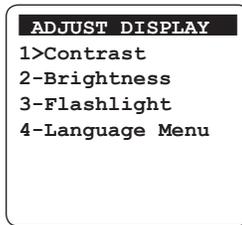
You can adjust the brightness and contrast of the display as well as the length of time that the display remains illuminated after a test is completed or a key is pressed.

To adjust the display:

- Press **0** (zero) to display the Main menu.



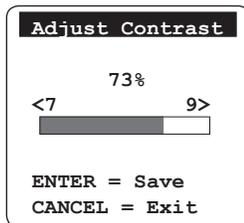
- Press **4** to display the Adjust Display menu.



- Do one of the following:

Adjust the contrast:

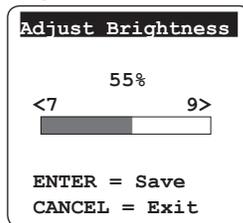
- Press **1** to display the Contrast menu.



- Press **7** to decrease the contrast, or press **9** to increase the contrast.

Adjust the brightness:

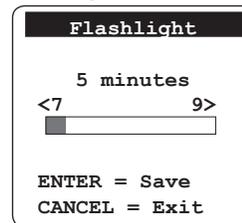
- Press **2** to display the Brightness menu.



- Press **7** to decrease the brightness, or press **9** to increase the brightness.

Adjust the illumination:

- Press **3** to display the Flashlight menu.



- Press **7** to decrease the length of time the display remains illuminated, or press **9** to increase the time.

Tip: Pressing and holding a key for more than one second causes it to auto-repeat.

Note: You can opt to have the display always illuminated. On the Flashlight menu, press **7** until the message “Always On” appears.

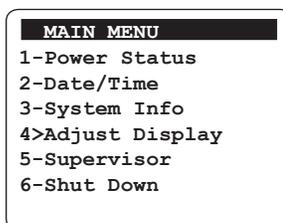
- Press **Enter** to store the new setting and to return to the Main menu.

3.6 Setting the Language

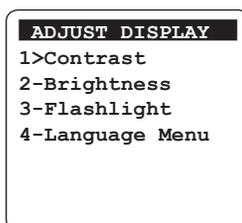
The display language for the IDEXX Coag Dx Analyzer is English only. Future upgrades of the Coag Dx software will provide additional languages from which you can choose.

To set the language:

- Press **0** (zero) to display the Main menu.



- Press **4** to display the Adjust Display menu.



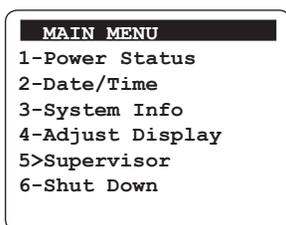
3. Press **4** to display the Language menu.
4. Press the number of the language you want to display for the analyzer. The message "[Language] Selected" appears briefly and then the Adjust Display menu appears.

3.7 Using the Supervisor Functions

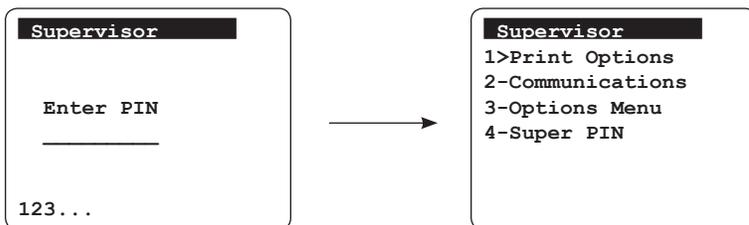
The Supervisor functions let you print analyzer information, set the baud rate for an external printer (the rate at which data is transmitted), set up communication and network ports, set up the electronic quality control feature, and set a password to limit access to these functions.

To access the Supervisor menu:

1. Press **0** (zero) to display the Main menu.



2. Press **5** to display the Supervisor menu and enter the personal identification number (PIN) to access this menu. If a PIN has not yet been assigned, **press and hold the Enter** key to access the menu.



3.7.1 Using the Supervisor Print Options

The ability to store and print IDEXX Coag Dx Cartridge Lot information (Option 1) and Quality Control Lot information (Option 2) will be available in a future software release.

3.7.2 Setting Up the Communications and Network Ports

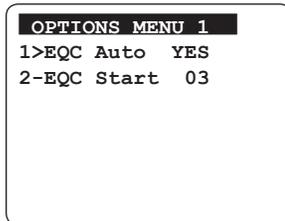
Communication and network port parameters may need to be entered for the IDEXX Coag Dx Analyzer to communicate over a network. Contact IDEXX Technical Support for assistance with these functions. See *Chapter 7: Troubleshooting* for technical support information.

3.7.3 Setting the Electronic Quality Control Options

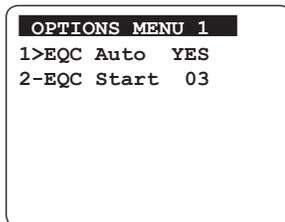
The Supervisor Options Menu lets you automate the electronic quality control (EQC) process. The factory default to automatically run EQC on the IDEXX Coag Dx Analyzer is set for 3:00 a.m. You can set EQC to run every day at a certain time. Or, you can turn off this option and manually run EQC whenever needed.

To automate the EQC process:

1. From the Supervisor menu, press **3** to display the Options menu.



2. Press **1** to turn on or off automated EQC. YES or NO appears to the right of option 1 on the Options menu. If you want to automate the EQC, be sure **YES** is displayed.



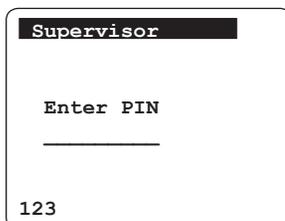
3. Press **2** on the Options menu to display the EQC Start screen.
4. Enter the number of hours after midnight that you want the EQC to begin. For example, to start the EQC at 2:00 a.m., enter **02**.
5. **Press and hold Enter** to save the specified number of hours. The message "Stored" displays briefly and then the Options menu displays.
6. Press **Cancel** to return to the Supervisor menu.

3.7.4 Setting the Supervisor PIN

The Supervisor PIN option lets you set up a personal identification number that restricts access to this menu. When you first use the Coag Dx Analyzer, no PIN is defined. You can simply bypass the Supervisor screen by pressing and holding the Enter key. Once a PIN has been defined, it must be entered before the Supervisor menu will display.

To set the Supervisor PIN:

1. From the Supervisor menu, press **4** to display the Supervisor screen.



2. Enter the PIN, up to 9 numbers, and then **press and hold Enter**. The message "Stored" displays briefly and the Supervisor menu appears.
3. Press **Cancel** twice to return to the "Insert. . . Cartridge" screen.

Chapter 4: Testing Patient Samples

Testing patient samples on the IDEXX Coag Dx Analyzer consists of the following steps:

1. Identifying the patient.
2. Collecting and running a blood sample for a patient.

Important: Review this section **before** testing a patient sample. The timing of a blood draw is critical to receiving accurate results.

3. Printing the patient's test results from the IDEXX VetLab Station†.

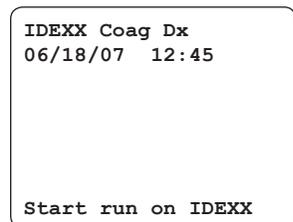
4.1 Identifying the Patient

4.1.1 Receiving an IDEXX VetLab Station† Request (Connected Coag Dx Analyzer)

When the IDEXX Coag Dx Analyzer is connected to the IDEXX VetLab Station†, test requests and results are shared between the two systems. The IDEXX VetLab Station† sends a request to the Coag Dx Analyzer. This request, which includes the Client ID, Patient ID and patient species, appears on the Coag Dx Analyzer's display panel. Once the test has been completed, the patient's results are automatically sent to the IDEXX VetLab Station† where they are stored in the patient's record. These results can now be viewed on and printed from the IDEXX VetLab Station†.

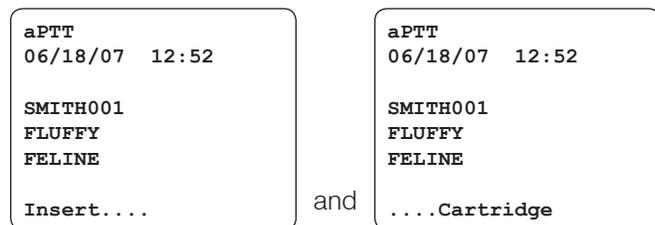
Important: When the Coag Dx Analyzer is connected to the IDEXX VetLab Station†, you can only run tests that are initiated from the IDEXX VetLab Station†. You cannot start a test run from the Coag Dx Analyzer.

When there is no test run pending from the IDEXX VetLab Station†, the Coag Dx Analyzer displays the message "Start run on IDEXX VetLab Station."



Note: For information on how to specify a patient on the IDEXX VetLab Station† touch screen and initiate a Coag Dx Analyzer test run, refer to the IDEXX VetLab Station Operator's Guide.

When the Coag Dx Analyzer receives a request from the IDEXX VetLab Station†, the Coag Dx Analyzer displays the Client ID, Patient ID, species and the message "Insert...Cartridge."



†IDEXX VetLab* Station, software version 2.30 or later

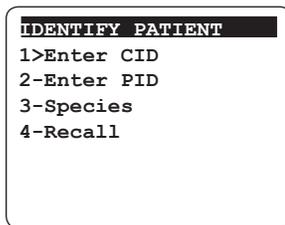
4.1.2 Entering Client and Patient IDs and Species (Stand-alone Coag Dx Analyzer)

A Client ID (CID) and/or a Patient ID (PID) can be entered for each test. You can also specify the patient's species. The IDs and species are stored with the test results. Client and Patient IDs and species are optional; you do not have to enter this information to run a patient sample.

To enter a Client ID, Patient ID or species:

1. Insert a cartridge into the test chamber and then press the **ID** key to display the Identify Patient menu.

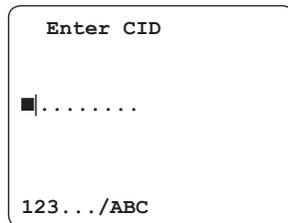
Note: The Identify Patient menu is only accessible if a cartridge is in the test chamber.



2. Do the following:

Enter Client ID:

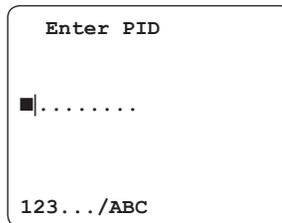
- a. Press **1** to display the Enter CID screen.



- b. Enter the CID using the keypad and then **press and hold the Enter key**. The CID is saved and the message "**Stored**" displays briefly.

Enter Patient ID:

- a. Press **2** to display the Enter PID screen.



- b. Enter the PID using the keypad and then **press and hold the Enter key**. The PID is saved and the message "**Stored**" displays briefly.

Enter species:

- a. Press **3** to display the Species List screen.



- b. Enter the applicable number for the species you are testing. The species is saved and the message "**[Species] Selected**" displays briefly.

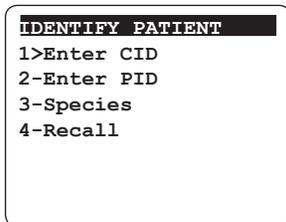
Notes:

- You can enter numeric and/or alphabetic characters for a Client or Patient ID. Press the **Note** key to switch between numeric and alphabetic characters.
 - When entering a Client or Patient ID, press **Cancel** to move the cursor to the left or press **Enter** to move the cursor to the right.
 - An acceptable CID/PID is any combination of 1 to 20 alphanumeric characters. A Client ID or Patient ID longer than 16 characters will wrap to the next line.
3. When you are finished entering the Client ID, Patient ID or species, press **Cancel** to return to normal operation. The Client ID, Patient ID and species you just entered displays on the screen.

To recall the most recently entered Client/Patient ID:

1. Press the **ID** key to display the Identify Patient menu.

Note: The Identify Patient menu is only accessible if a cartridge is in the test chamber.



2. Press **4**. The message "Stored" appears briefly and the analyzer returns to the "Warming..." screen. The most recently entered Client ID, Patient ID and species are displayed and you are ready to run a sample.

4.2 Collecting and Running Blood Samples

Accurate coagulation testing requires that blood samples be prepared and collected as follows:

- Minimize patient excitement. A clean stick is critical for accurate coagulation testing.
- Use nonheparinized 18- to 23-gauge needles to collect blood.
- Avoid prolonged venous stasis and excessive probing for vessel.
- Ensure that samples are free of hemolysis, air bubbles and clots.
- Ensure that all IDEXX Coag Dx Cartridges are warmed to room temperature (15°–30°C/59°–86°F) before opening the pouch. This will take 30–60 minutes.
- Open the cartridge pouch immediately before use.

After the analyzer is started, a cartridge has been inserted and the warming cycle has completed (30–90 seconds), the analyzer beeps once to signal that it is ready for the sample. The messages "Add Sample" and "Press Start" are displayed along with a timer that counts down. You have five minutes to add the sample to the cartridge and start the test.

Note: The message "Start...TIMED OUT" displays on the screen if the test is not started within five minutes. If this occurs, you must repeat the test using a new cartridge.

4.2.1 Fresh Whole Blood Samples

IMPORTANT: Fresh whole blood samples for use with the IDEXX Coag Dx PT and aPTT cartridges must NOT be collected until the analyzer indicates "Add Sample...Press Start."

To collect and run non-anticoagulated whole blood samples:

1. Remove IDEXX Coag Dx PT and/or aPTT cartridges from refrigerated storage and allow them to come to room temperature (15°–30°C/59°–86°F). This takes 30–60 minutes. **Do not** open the pouch prior to use.
2. Prepare the venipuncture site by shaving fur (if necessary) and cleansing with alcohol. Allow the site to air dry completely, as alcohol interferes with the coagulation assay.

- With the label facing up, insert the appropriate PT or aPTT cartridge into the IDEXX Coag Dx Analyzer to warm (30–90 seconds) (Figure 4-1). Push the cartridge all the way in until it stops.

The analyzer displays the messages “Priming Pump...” and “Warming....”.

Note: If your Coag Dx Analyzer is not connected to the IDEXX VetLab Station[†], press the **ID** key and enter the Client ID, Patient ID and species. (See section 4.1.2 *Entering Client and Patient IDs and Species* for more information.)

Important: Wait until the analyzer displays the message “Add Sample...Press Start” before continuing with the next step.

- Obtain a minimum of 0.2 mL (0,2 cc) blood with a needle and plastic syringe.

Important: You have five minutes to add the sample to the cartridge and start the test. If the message “Start...TIMED OUT” appears, you must use a new cartridge for this test.

- Immediately** dispense one drop of blood into the sample well of the cartridge, filling from the bottom of the well up. This can be done with or without the needle (Figure 4-2).

Note: A sufficient quantity of blood must be added to the center of the sample well to fill it slightly over the top (Figure 4-3, sufficient vs. Figure 4-4, insufficient). The sample meniscus will protrude slightly above the sample well. Should a large drop of blood extend above the center sample well (Figure 4-5), use the needle to push the extra blood into the outer sample well (Figure 4-6).



Figure 4-1: Insert Coag Dx PT or aPTT cartridge



Figure 4-2: Add sample to center of well

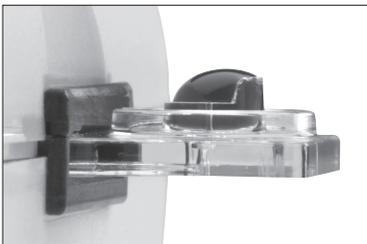


Figure 4-3: Sample is sufficient; meniscus protrudes slightly above sample well

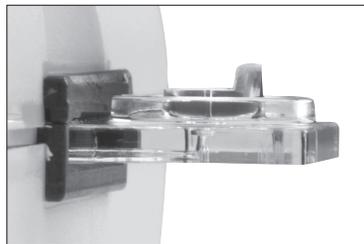


Figure 4-4: Insufficient sample

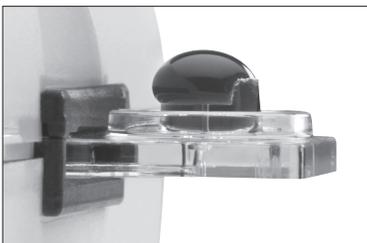


Figure 4-5: Sample too large

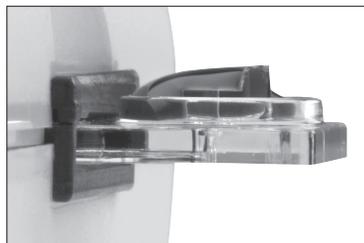


Figure 4-6: Sample pushed into outer well

6. Press the **Start** key (Figure 4-7). The elapsed time (in whole blood seconds) is displayed until the sample clots. When a clot is detected, the analyzer beeps once. Final results of the test are calculated and displayed on the screen.

Note: The error messages “Sample too small,” “Sample too large” or “Sample not seen” are displayed if an incorrect amount of sample was added. Repeat the test; you must draw a new sample and use a new cartridge.

7. Remove the cartridge. Results are saved and the client/patient information is cleared so that another patient sample can be tested. Discard used needles, syringes and cartridges in the appropriate waste containers.



Figure 4-7: Press Start key

Notes:

- Each Coag Dx* Cartridge insert provides feline and canine reference intervals. Equine reference intervals are provided only for PT and citrated PT tests.
- **Stand-alone Coag Dx:** When the cartridge is removed, results are saved in the database and printed if a printer is connected. The date and time of the test, Client ID, Patient ID, species and fault message (if an error is detected for the test or sample) are printed with the test result.
- **Connected to the IDEXX VetLab Station†:** When the cartridge is removed from the test chamber on the Coag Dx Analyzer, results are sent to the IDEXX VetLab Station† where they are stored with the patient's record. You can print these results from the IDEXX VetLab Station†.

Refer to the IDEXX VetLab Station Operator's Guide for instructions on how to print patient results.

4.2.2 Citrated Blood Samples

All citrated samples should be run **within 2 hours of collection**. Be sure to keep the sample at room temperature.

Note: Blood samples for testing should be collected **at least 5 minutes prior to** testing to allow for adequate equilibration of the sodium citrate with the sample.

To collect and run citrated whole blood samples:

1. Remove IDEXX Coag Dx Citrate PT and/or Citrate aPTT cartridges from refrigerated storage and allow them to come to room temperature (15°–30°C/ 59°–86°F). This takes 30–60 minutes. **Do not** open the pouch prior to use.
2. Prepare the venipuncture site by shaving fur (if necessary) and cleansing with alcohol. Allow the site to air dry completely, as alcohol interferes with the coagulation assay.
3. Use **one** of the following methods to collect the blood sample:
 - Collect the sample directly into a 3.2% sodium citrate evacuated tube and allow the blood to be drawn into the tube until it reaches the tube's stated draw volume.
 - Collect the sample in a plastic (not glass) syringe and then use the syringe needle to puncture the stopper of an evacuated tube containing 3.2% sodium citrate. Allow the blood to be drawn into the tube until it reaches the tube's stated draw volume.

Note: You must fill the citrate tube to its stated draw volume.

†IDEXX VetLab* Station, software version 2.30 or later

- Mix gently by inverting the tube at least 4 times. Allow the sample to equilibrate with the citrate for at least 5 minutes before testing.
- With the label facing up, insert the appropriate Citrate PT or Citrate aPTT cartridge into the IDEXX Coag Dx Analyzer to warm (30–90 seconds) (Figure 4-8). Push the cartridge all the way in until it stops.

Note: If your Coag Dx Analyzer is not connected to the IDEXX VetLab Station[†], press the **ID** key and enter the Client ID, Patient ID and species. (See section 4.1.2 *Entering Client and Patient IDs and Species* for more information.)

Important: Wait until the analyzer displays the message “Add Sample...Press Start” before continuing with the next step.

- Again, gently mix the sample by inverting the tube at least four times.
- Using the disposable plastic pipette provided with the Coag Dx Cartridge, collect the sample from the evacuated tube (Figure 4-9) and then dispense one drop of blood into the sample well of the cartridge, filling from the bottom of the well up (Figure 4-10).



Figure 4-8: Insert Coag Dx Citrate PT or Citrate aPTT cartridge



Figure 4-9: Collect sample from 3.2% sodium citrate evacuated tube



Figure 4-10: Add sample to center of well

Note: A sufficient quantity of blood must be added to the center of the sample well to fill it slightly over the top (Figure 4-11, sufficient vs. Figure 4-12, insufficient). The sample meniscus will protrude slightly above the sample well. Should a large drop of blood extend above the center sample well (Figure 4-13), use the plastic pipette to push the extra blood into the outer sample well (Figure 4-14).

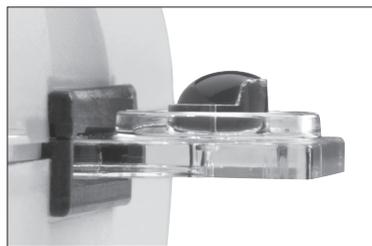


Figure 4-11: Sample is sufficient; meniscus protrudes slightly above sample well

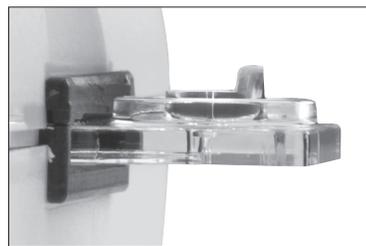


Figure 4-12: Insufficient sample



Figure 4-13: Sample too large

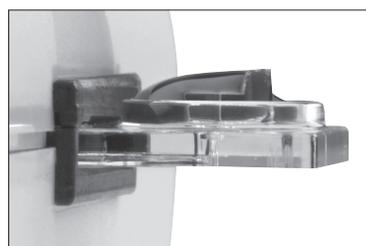


Figure 4-14: Sample pushed into outer well

[†]IDEXX VetLab[®] Station, software version 2.30 or later

8. Press the **Start** key (Figure 4-15). The elapsed time (in whole blood seconds) is displayed until the sample clots. When a clot is detected, the analyzer beeps once. Final results of the test are displayed on the screen.

Note: The error messages “Sample too small,” “Sample too large” or “Sample not seen” are displayed if an incorrect amount of sample was added. Repeat the test; you must use a new cartridge.

9. Remove the cartridge. Results are saved and the client/patient information is cleared so that another patient sample can be tested. Discard used needles, syringes, pipettes and cartridges in the appropriate waste containers.



Figure 4-15: Press Start key

Notes:

- Each Coag Dx* Cartridge insert provides feline and canine reference intervals. Equine reference intervals are provided only for PT and citrated PT tests.
- **Stand-alone Coag Dx:** When the cartridge is removed, results are saved in the database and printed if a printer is connected. The date and time of the test, Client ID, Patient ID, species and fault message (if an error is detected for the test or sample) are printed with the test result.
- **Connected to the IDEXX VetLab Station†:** When the cartridge is removed from the test chamber on the Coag Dx Analyzer, results are sent to the IDEXX VetLab Station† where they are stored with the patient's record. You can print these results from the IDEXX VetLab Station†.

Refer to the IDEXX VetLab Station Operator's Guide for instructions on how to print patient results.

4.2.3 Limitations

Important: IDEXX Coag Dx Analyzer test results are affected by improper technique during blood collection and delivery to the sample well. The accuracy of the test is largely dependent upon the quality of the blood specimen, which is dependent upon the blood sample collection and the transfer of blood to the test cartridge. Refer to the individual cartridge's package insert for specific limitations.

IDEXX Coag Dx Analyzer test results should always be scrutinized in light of a specific patient's condition or anticoagulant therapy. Any test results exhibiting inconsistency with the patient's clinical status should be repeated or supplemented with additional diagnostic tests.

Samples with a hematocrit less than 20% or greater than 55% are not recommended, due to an optical density outside the detection level of the IDEXX Coag Dx Analyzer.

†IDEXX VetLab* Station, software version 2.30 or later

Chapter 5: Quality Control

Routine quality control testing should be part of a comprehensive quality control program. Quality control testing of the IDEXX Coag Dx Analyzer consists of testing system performance and verifying system temperature using the internal Electronic Quality Control (EQC) system. The factory default to automatically run EQC on the IDEXX Coag Dx Analyzer is set for 3:00 a.m.

5.1 Self-Check

The IDEXX Coag Dx Analyzer performs a “self-check” every time it is activated and a test is performed. When a test is initiated by inserting a cartridge, system checks are automatically performed and include:

- Verification of adequate battery power to complete a full test.
- Verification of the test type on the screen display to ensure that the LEDs used for identifying the test are functioning properly.
- Verification that the cartridge temperature is warmed to $37^{\circ}\text{C} \pm 1.0^{\circ}\text{C}$ ($98.6^{\circ}\text{F} \pm 2.0^{\circ}\text{F}$). If this temperature is not achieved or is exceeded, an appropriate error message displays and testing is prohibited.
- Verification that the sample is present and is of sufficient size to run the test. This ensures that the pumps and sample-sensing LEDs are functioning properly and that the cartridge is adequately sealed. If these analyzer and sample parameters are not appropriate, the test is terminated and an error message displays.
- Verification that the internal timers function correctly for each test. If the system timer and assay timer disagree, a “real-time clock error” message displays and the test result is not reported.

5.2 Verifying the Analyzer’s Temperature

The IDEXX Coag Dx Analyzer’s temperature is automatically checked whenever an EQC is performed. The analyzer temperature check verifies that a temperature of $37^{\circ}\text{C} \pm 1.0^{\circ}\text{C}$ ($98.6^{\circ}\text{F} \pm 2.0^{\circ}\text{F}$) is maintained during the test.

Note: If the temperature reading is out of range, contact IDEXX Technical Support.

5.3 Running Electronic Quality Control

The automatic internal Electronic Quality Control (EQC) provides a two-level electronic verification of the analyzer’s performance. EQC is performed automatically (daily) if the IDEXX Coag Dx Analyzer is plugged into the AC/DC Power Module and is turned on. EQC results are stored in the database and are displayed for five minutes (or until you press **Cancel**).

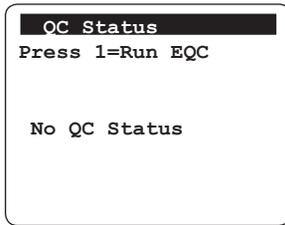
Notes:

- The factory default to automatically run EQC on the IDEXX Coag Dx Analyzer is set for 3:00 a.m. You can reset this time or turn off the automatic EQC option. See section 3.8.4 *Setting the Electronic Quality Control Options* for instructions.
- You can cancel an EQC process, if necessary. Simply press **Cancel** and then press **1**.

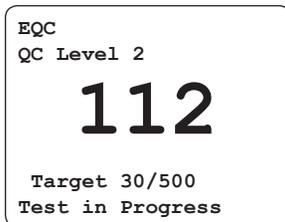
Important: Be sure to remove cartridges from the analyzer after completing a sample test. If the EQC runs while a cartridge is inserted, the message “Detector Blocked” displays and the EQC test fails.

To run the electronic quality control:

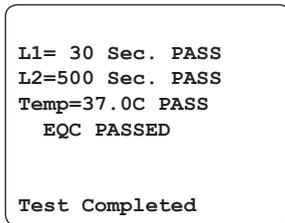
1. Ensure that the test chamber is empty.
2. Press **QC** to display the QC Status menu.



3. Press **1** to initiate the EQC process. The test chamber warms to 37°C ±1.0°C (98°F ±1.0°F) and the EQC test begins. The results are displayed while the test is progressing.



When the test is completed, the results are displayed on the screen and written to the QC database.



Note: The internal EQC checks two levels of quality control and the temperature, and it stores each result. If one result fails, the test stops and records all results as failed. If you abort the internal EQC test, the test is not saved to the database or printed.

4. Press **Cancel** to exit the screen.

Chapter 6: Database Management

The IDEXX Coag Dx Analyzer can store up to 600 patient test results and 600 quality control (QC) test results along with the date and time of each test. If a Client ID and/or Patient ID are entered for a patient test, this information is also stored.

Note: If an error occurs with the test or the sample, the applicable error message is stored with the result and is included on the printout. See *Chapter 7: Troubleshooting* for error messages, their cause and their resolution.

The database management feature of the IDEXX Coag Dx Analyzer lets you:

- View the total number of patient and QC test results currently stored
- View the total number of additional patient and QC test results that can be stored
- Review the stored patient and QC test results
- Erase patient and QC test results to make room for additional tests

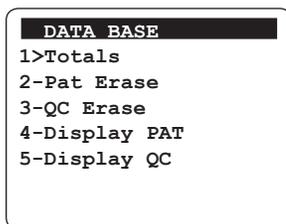
Caution: Results from the oldest test are overwritten if a test is run when the database is full.

6.1 Viewing Total Test Counts and Remaining Test Counts

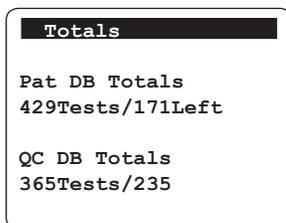
You can view the total number of patient and QC test results that are currently stored on the IDEXX Coag Dx Analyzer as well as the remaining number of additional patient and QC test results that can be stored.

To view the totals for tests:

1. Press **Data Base** to view the Data Base menu.



2. Press **1** to view the Totals screen.

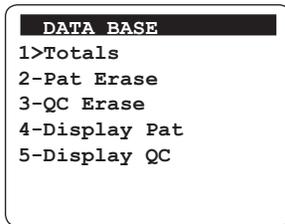


3. Review the information. The screen automatically returns to the Data Base screen after approximately five seconds.

6.2 Reviewing Patient and EQC Test Results

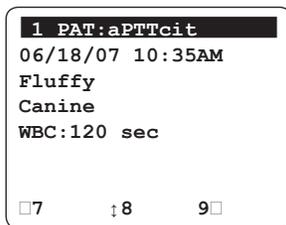
To review patient and EQC test results:

1. Press **Data Base** to view the Data Base menu.

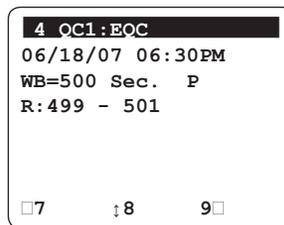


2. Do one of the following:

- Press **4** to view the first line of results for the most current patient test record.
- Press **5** to view the first line of results for the most current EQC test record.



Press **8** to display additional pages for this test result.



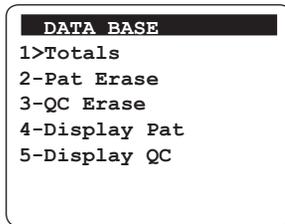
Press **8** to display additional pages for this test result.

3. To scroll through additional test records on either screen:
 - Press **9** to display the next test result
 - Press **7** to display the previous test result
4. Press **Cancel** twice to return to the "Insert...Cartridge" screen.

6.3 Deleting Patient and EQC Test Results

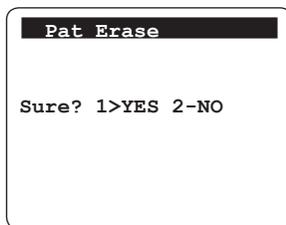
To delete patient and EQC test results:

1. Press **Data Base** to view the Data Base menu.

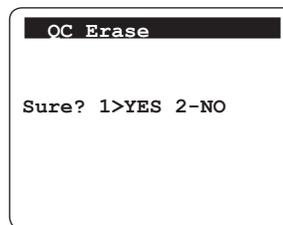


2. Do one of the following:

- Press **2** to view the Pat Erase screen.



- Press **3** to view the QC Erase screen.



3. On either screen, press **1** to erase all patient or QC test results. The analyzer displays the message "Completed" and returns to the Data Base screen.

Note: Press **2** or press **Cancel** to return to the Data Base screen without erasing any results.

Chapter 7: Troubleshooting

7.1 IDEXX Technical Support Contact Information

United States/Canada/Latin America

Toll-free Technical Support 1-800-248-2483

Toll-free Fax..... 1-800-248-3010

www.idexx.com

Europe

Toll-free Technical Support00800 1234 3399

Toll-free Fax.....00800 1234 3333

www.idexx.nl

Australia

Toll-free Technical Support 1800 655 978

Toll-free Fax..... 1800 634 409

www.idexx.com.au

Japan

Toll-free Technical Support 0120-71-4921

Toll-free Fax..... 0422-71-4922

www.idexx.co.jp

New Zealand

Toll-free Technical Support 0800-102-084

Asia

Toll-free Technical Support 0800-291-018

7.2 Acronyms for Error Messages

The following table lists the acronyms for Error Messages when viewing stored Patient or EQC records:

Display Message	Description	Acronym
Out of Range-Hi	Out of Range High	ORH
Out of Range-Lo	Out of Range Low	ORL
Sample Not Seen	Sample Not Seen	SNS
Sample Too Small	Sample Too Small	STS

Display Message	Description	Acronym
Sample Too Large	Sample Too Large	STL
Heater Too Cool	Temp Timeout	TTO
Heater Too Hot	Temp Too High	TTH
Sample Pos Fault	Sample Position Fault	SPF
User Abort	User Aborted Test	UAT
Battery Fault	Battery Fault	BAT
Premature Sample	Premature Sample	PMS
Detector Fault	Detector Fault	DEF
Battery Too High	Battery Too High	BTH
External Too High	External Power Too High	XTH
RTC Fault	Real Time Clock Fault	RTC

7.3 Analyzer Error Messages

The error messages that can be displayed while operating the IDEXX Coag Dx Analyzer are listed below. The probable cause and corrective action are shown for each message.

Some messages designate a test or sample fault. This message is included in the printed results for the affected sample. A list of the acronyms used in these messages can be found in section 7.2 *Acronyms for Error Messages*.

Error Message	Cause	Corrective Action
RTC....FAULT	Cannot communicate with external Real Time Clock.	Contact IDEXX Technical Support.
CHARGE BATTERY	Battery power depleted below predetermined level.	Connect to AC/DC Power Module and charge battery for 8 hours.
BATTERY FAULT	Battery is discharged.	Charge battery for 8 hours. If message persists, contact IDEXX Technical Support.
EXTERNAL TOO HIGH	AC/DC Power Module voltage exceeds 12.7 volts.	Disconnect the AC/DC Power Module. Contact IDEXX Technical Support.
BATTERY TOO HIGH	Battery voltage exceeds 8.8 volts.	Disconnect the AC/DC Power Module. Contact IDEXX Technical Support.

Error Message	Cause	Corrective Action
Heater Too Cool	Incubator remained below 36°C after 90 seconds of warming on external power or for up to 150 seconds on battery.	Repeat test, then charge battery. If message persists, contact IDEXX Technical Support.
Heater Too Hot	Incubator exceeded 38°C for 2.5 seconds.	Repeat test with new cartridge. If message persists, contact IDEXX Technical Support.
Detector Fault	Light path between LED and detectors is blocked.	Repeat test with new cartridge. If message persists, contact IDEXX Technical Support.
EQC Failed	EQC is being run while a cartridge is inserted.	Remove the cartridge and repeat the EQC.
Sample Pos Fault	Sample has moved outside of testing area in cartridge.	Contact IDEXX Technical Support.
Sample Not Seen	Sample has not reached front detector in specified time period.	Repeat test with new cartridge. If message persists, contact IDEXX Technical Support.
Cartridge Removed	Cartridge was prematurely removed from analyzer while testing in progress.	Repeat test with new cartridge.
Sample Too Small/ Too Large	Excess or insufficient sample.	Repeat test with new cartridge.
Premature Sample	Sample was detected at front detector before specified time period. May occur if sample is added before pump-priming sequence is complete.	Repeat test with new cartridge. If message persists, contact IDEXX Technical Support.
Start . . . TIMED OUT	The Start key was not pressed within 5 minutes after entering ready mode.	Remove cartridge and repeat test with new cartridge.
Unsupported Assay	Cartridge cannot be identified by analyzer.	Remove cartridge and repeat test with new cartridge. Use IDEXX cartridges only.
Nothing Stored	Operator attempted to print data when none is stored in database.	N/A
User Abort	The test was aborted by the user.	Repeat test.
Invalid Lot #	The incorrect format was entered for the lot number.	Repeat the entry using the correct format.
Lot Expired	The cartridge and/or QC material that is being used has reached its expiration date.	Remove the cartridge and repeat the test using supplies that are within their expiration date.

Error Message	Cause	Corrective Action
Out of Range-Lo	<ul style="list-style-type: none"> • Test result is outside clinical range. <ul style="list-style-type: none"> – PT and citrate PT WB <7 sec – aPTT and citrate aPTT WB <12 sec • Sample has clotted prematurely, or did not mix correctly in cartridge. • Bubbles may be present. 	Repeat test with new cartridge.
Out of Range-Hi	Test result is outside clinical range. <ul style="list-style-type: none"> – PT and citrate PT WB >100 sec – aPTT WB >350 sec – Citrate aPTT WB >300 sec 	Repeat test with new cartridge.
Check Time/Date	Low Battery or RTC has lost its Time/Date Tracking.	Enter or verify the time and date. Charge the battery.
Dark Photo Fault	Hardware malfunction.	Contact IDEXX Technical Support.

Appendixes

Appendix A: IDEXX Coag Dx Analyzer Specifications

Specifications for the IDEXX Coag Dx Analyzer are listed below.

Dimensions and Weight

Depth	9.4 cm (3.7 in)
Width	19 cm (7.5 in)
Height	5 cm (2.0 in)
Weight	0.53 kg (1.2 lb)

Operation

Test Chamber	1
Timing Range	0 second to 500 seconds
Incubation Temperature	37°C ±1.0°C (98.6°F ±2.0°F)
Incubation Warm-Up Time	30 seconds to 90 seconds
Full-Charge Operating Time	>2 hours
Battery Life	500 recharges
Battery Type	Lithium Ion
Throughput (Full Charge)	49 test cycles (at 150 sec per test) 17 test cycles (>500 sec per test)
Operating Environment	15°C to 30°C (59°F to 86°F)
Transport/Storage	-20°C to 70°C (-4°F to 158°F)

AC/DC Power Module

Input Power	100 to 240 VAC, 50 to 60 Hz
Output Power	12.0 VDC, 3.4 Amps (40 Watts) minimum

Calibration

The IDEXX Coag Dx Analyzer is calibrated at the manufacturing facility to test and verify all functions. The analyzer is also self-calibrating, as all analyzer functions are continuously monitored and verified by the analyzer software when a test is performed. The analyzer does not require additional calibration by the user.

Appendix B: Service and Maintenance

B.1 Routine Maintenance

Inspect and clean the cartridge opening as necessary. Remove residual dried blood or other foreign matter using water-moistened cotton swabs.

Remove any residual water with dry cotton swabs. If a disinfectant is needed, use a 0.5% solution of sodium hypochlorite or a 10% dilution of household bleach in water. Wipe analyzer with a water-dampened cloth to remove residual bleach from the plastic surfaces.

Apply solution to clean and disinfect areas contaminated with blood. **Do not** use solvents or strong cleaning solutions as they may damage the analyzer's plastic components. Routine maintenance other than cleaning normally is not required.

B.2 Service

The IDEXX Coag Dx Analyzer self-monitors its internal circuitry and reports problems to the display screen automatically. Malfunctions are indicated by error messages; see *Chapter 7: Troubleshooting*. The analyzer has no user-serviceable parts.

B.3 Battery Care

To optimize battery life, it is recommended that the IDEXX Coag Dx Analyzer be run on its battery during the day. It can be plugged into an AC outlet overnight to allow the batteries to recharge. The life of the lithium battery is optimized when the battery is exercised in this manner.

When the batteries are drained to the point that valid testing cannot be performed, the analyzer will display "CHARGE BATTERY" (see *Chapter 7: Troubleshooting*). At this point, the analyzer must be plugged in for operation and recharging. Once plugged into an AC outlet, the analyzer can be used immediately.

B.4 Analyzer Disposal

If disposal is necessary, follow local regulations for disposal of Lithium Ion batteries and electronic devices. For more information, visit http://www.idexx.co.uk/html/en_gb/corporate/weee-home-uk.html.

Appendix C: Printing (Stand-alone Coag Dx Analyzer)

The IDEXX Coag Dx Analyzer can be connected to a Seiko Thermal Printer (model DPU-414-30 B). However, IDEXX does not provide or support external printers for the Coag Dx Analyzer. Coag Dx Analyzer results can be printed by connecting to an IDEXX VetLab Station[†] (see section 2.4 Connecting to the IDEXX VetLab Station.)

C.1 Connecting a Printer

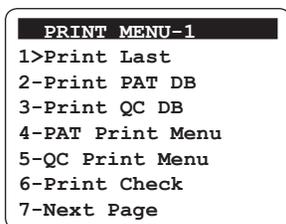
To connect the IDEXX Coag Dx Analyzer to a Seiko Thermal Printer:

1. Obtain a printer interface cable.
2. Connect one end of the cable to the RS232 port on the side of the Coag Dx Analyzer.
3. Connect the other end of the printer cable to the printer.
4. Follow the printer manufacturer's directions to install or connect the printer.

Note: For additional assistance in connecting an external printer, contact IDEXX Technical Support.

To print a test page on the printer:

1. Press and hold **Start** to turn on the analyzer.
2. Press **Print** to display the Print Menu-1 screen.



3. Press **6** to print an ASCII character set to the attached printer to verify that the printer port functions properly.
4. Press **Cancel** to return to the "Insert....Cartridge" screen.

C.2 Defining the Printed Report Header

The default header that appears at the top of each printout is:

- - - - IDEXX - - - -

You can customize this header as needed.

To customize the report header:

1. Press **Print** to display the Print Menu-1 screen.
2. Press **7** to display the next page, the Print Menu-2 screen.
3. Press **1** to display the Enter Header screen.
4. Use the numeric keypad to enter the header you want to appear on IDEXX Coag Dx Analyzer printouts.
5. When you are finished entering the report header, press and hold the **Enter** key to save the header.

Note: Press and hold the **Cancel** key to return to the Print Menu-2 screen without saving the new header.

Tips:

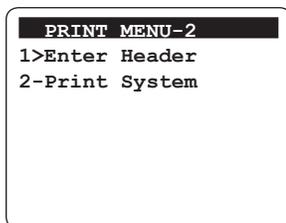
- Press the **Note** key to change the keypad data entry mode from numeric to alphabetical.
- When entering alphabetic characters, advance from the displayed letter to the next letter on that key by pressing the key again before the cursor advances. Release the key (for at least one second) when the selected character is displayed. The character is saved and the cursor advances to the right.
- Use the **Cancel** key as a left-arrow key and the **Enter** key as a right-arrow key.

[†]IDEXX VetLab* Station, software version 2.30 or later

C.3 Printing System Information

To print system information (to an external printer only):

1. Press **Print** to display the Print Menu-1 screen and then press **7** to display the Print Menu-2 screen.



2. Press **2** to print the system software version, system serial number and program parameters. Press **Cancel** twice to return to the "Insert....Cartridge" screen.

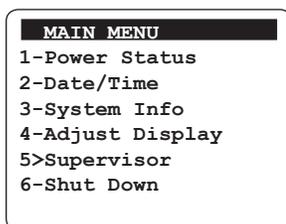
C.4 Using the Supervisor Print Options

To print Coag Dx Cartridge lot information and QC lot information:

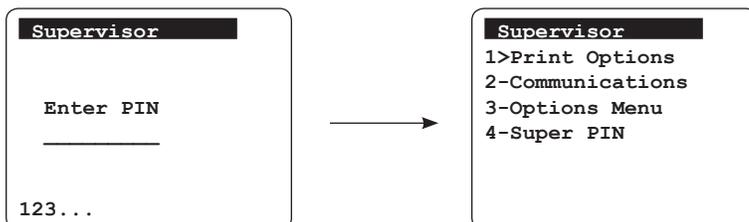
The ability to store and print IDEXX Coag Dx Cartridge Lot information (Option 1) and Quality Control Lot information (Option 2) will be available in a future software release.

To set the baud rate for the printer:

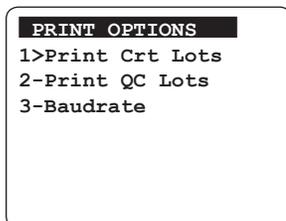
1. Press **0** (zero) to display the Main menu.



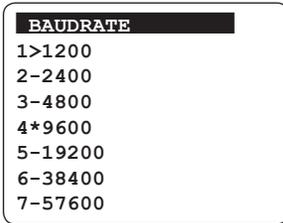
2. Press **5** to display the Supervisor menu and enter the personal identification number (PIN) to access this menu. If a PIN has not yet been assigned, **press and hold the Enter** key to access the menu.



3. From the Supervisor menu, press **1** to display the Print Options menu.



- Press **3** to display the Baud Rate menu.



Note: The asterisk (*) indicates the current selection for the baud rate.

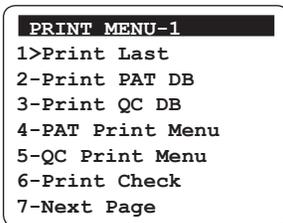
- Enter the number of the baud rate you want to set for your printer. The message “[Baud Rate] Data Stored” displays briefly.
- Press **Cancel** to return to the Print Options menu.
- Press **Cancel** again to return to the Supervisor menu.

C.5 Printing Patient Results

You can print the test results for the last test run, for all results in the database or for a specific patient.

To print results for the last test run:

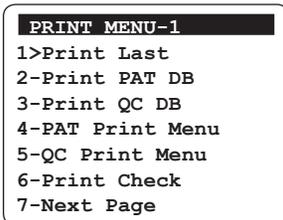
- Press **Print** to display the Print menu.



- Press **1** to print the results for the last test run on the analyzer.
- Press **Cancel** to return to the “Insert...Cartridge” screen.

To print all results in the patient database:

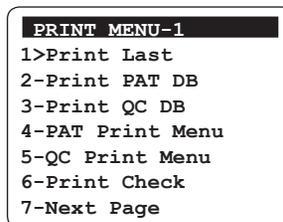
- Press **Print** to display the Print menu.



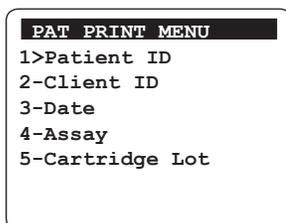
- Press **2** to print all the results stored in the patient database.
- Press **Cancel** to return to the “Insert...Cartridge” screen.

To print patient-specific results:

- Press **Print** to display the Print menu.



- Press **4** to display the menu for printing patient results.



- Print the results for the desired tests:

- **Patient ID**—Press **1** to display the Patient ID screen. Enter the Patient ID and then **press and hold Enter**. All test results for the specified patient are printed.
- **Client ID**—Press **2** to display the Client ID screen. Type the Client ID and then **press and hold Enter**. All patient results assigned to this client are printed.
- **Date**—Press **3** to display the Date screen. Enter the date using the keypad and then **press and hold Enter**. All patient test results obtained on the specified date are printed.
- **Assay**—Press **4** to display the Assay screen. Enter the number of the assay or quality control for which you want to print results and then **press and hold Enter**. All test results for the specified assay or quality control are printed.
- **Cartridge Lot**—The ability to print IDEXX Coag Dx Cartridge Lot information will be available in a future software release.

- Press **Cancel** to return to the Print menu. Press **Cancel** again to return to the “Insert...Cartridge” screen.

Tips:

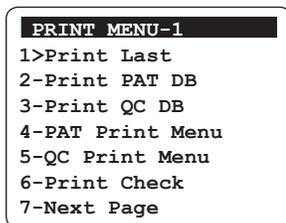
- Press the **Note** key to change the keypad data entry mode from numeric to alphabetical.
- When entering alphabetic characters, advance from the displayed letter to the next letter on that key by pressing the key again before the cursor advances. Release the key (for at least one second) when the selected character is displayed. The character is saved and the cursor advances to the right.
- Use the **Cancel** key as a left-arrow key and the **Enter** key as a right-arrow key.

C.6 Printing Electronic Quality Control Results

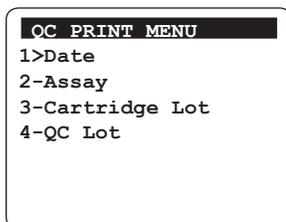
You can print all of the electronic quality control results stored in the analyzer, or you can print date-specific EQC results.

To print EQC results:

- Press **Print** to display the Print Menu-1 screen.



- Press **5** to display the QC Print Menu screen.



3. Print the desired QC results:
 - **Date**—Press **1** to display the Date screen. Enter the date and then **press and hold Enter**. All EQC results obtained on the specified date are printed.
 - **Assay**—Press **2** to display the Assay screen and then press **1** to print the EQC results. All EQC test results for the specified assay are printed.

Note: The ability to print IDEXX Coag Dx Cartridge Lot information (Option 3) and Quality Control Lot information (Option 4) will be available in a future software release.
4. Press **Cancel** twice to return to the “Insert...Cartridge” screen.

Appendix D: Safety Standards

D.1 Standard Safety Requirements and Directives

The IDEXX Coag Dx Analyzer complies with the following safety standard requirements and directives:

Safety

CAN/CSA C22.2 No. 61010-1:2012

CAN/CSA C22.2 No. 61010-2-010:2009

UL 61010-1:2012

EN 61010-1:2010

EN 61010-2-010:2003

Emissions

EN 55011:2009 A1:2010 Group 1 Class A

EN 61326-1:2006 Class A limit.

This instrument has been designed and tested to CISPR 11 Class A. In a domestic environment it may cause radio interference, in which case, you may need to take measures to mitigate the interference.

Immunity

EN 61326-1:2006 Table 2 limits.

Protection Against Ingress of Liquids: Ordinary (no protection as defined by IEC 60529)

Product Cleaning and Disinfection: Only according to recommendations of the manufacturer's accompanying documentation

Mode of Operation Of Equipment: Continuous

Degree of Safety of Application in the Presence of Flammable Anesthetic Mixture With Air, Oxygen or Nitrous Oxide: Not Suitable

Note: As defined in the above standards, the classification of Not Suitable is not intended to indicate that the analyzer is not suitable for use in an Operating Room (OR) environment. Rather, it is intended to indicate that the analyzer is not suitable for use in the direct presence of a flammable anesthetic mixture with air, oxygen or nitrous oxide.

It is IDEXX's responsibility to provide electromagnetic compatibility information to the customer or users. It is the user's responsibility to ensure that a compatible electromagnetic environment for the instrument can be maintained so that the device will perform as intended.

All relevant documentation is kept on file at IDEXX Laboratories, Inc. in Westbrook, Maine USA.



One IDEXX Drive
Westbrook, Maine 04092 USA
idexx.com