

HUMAN HEALTH

ENVIRONMENTAL HEALTH

TOTAL PROCESS MANAGEMENT FOR YOUR NEWBORN SCREENING LABORATORY



Specimen Gate® software


PerkinElmer
For the Better



**GIVE LIFE A
SAFE START
WITH SPECIMEN GATE®**

MANAGE YOUR ENTIRE SCREENING PROCESS

Newborn screening generates vast amounts of data that require continuous tracking. With effective information management, you can increase process throughput and reduce costs. Our dedicated informatics solutions for newborn screening laboratories keep vital information flowing from sample punching to patient results and beyond.

As the global leader in newborn screening, PerkinElmer was well-positioned to develop the world's first laboratory information management system specifically intended for newborn screening. Specimen Gate® software is the result of years of continuous development, and the product is widely used in all parts of the world.

Specimen Gate® software is designed to simplify the data collection and workflow processes involved with receiving specimens, screening for abnormalities, managing patient information, generating specimen reports, and following up abnormal and unsatisfactory specimens.

In continuous development since 1994, PerkinElmer's Specimen Gate® software is a suite of configurable applications designed specifically to provide a Total Process Management Solution for your newborn screening laboratory. Specimen Gate® includes four modules providing control and monitoring tools for the entire screening process:

LABORATORY™

**SCREENING
CENTER™**

PATIENTCARE™

eREPORTS™

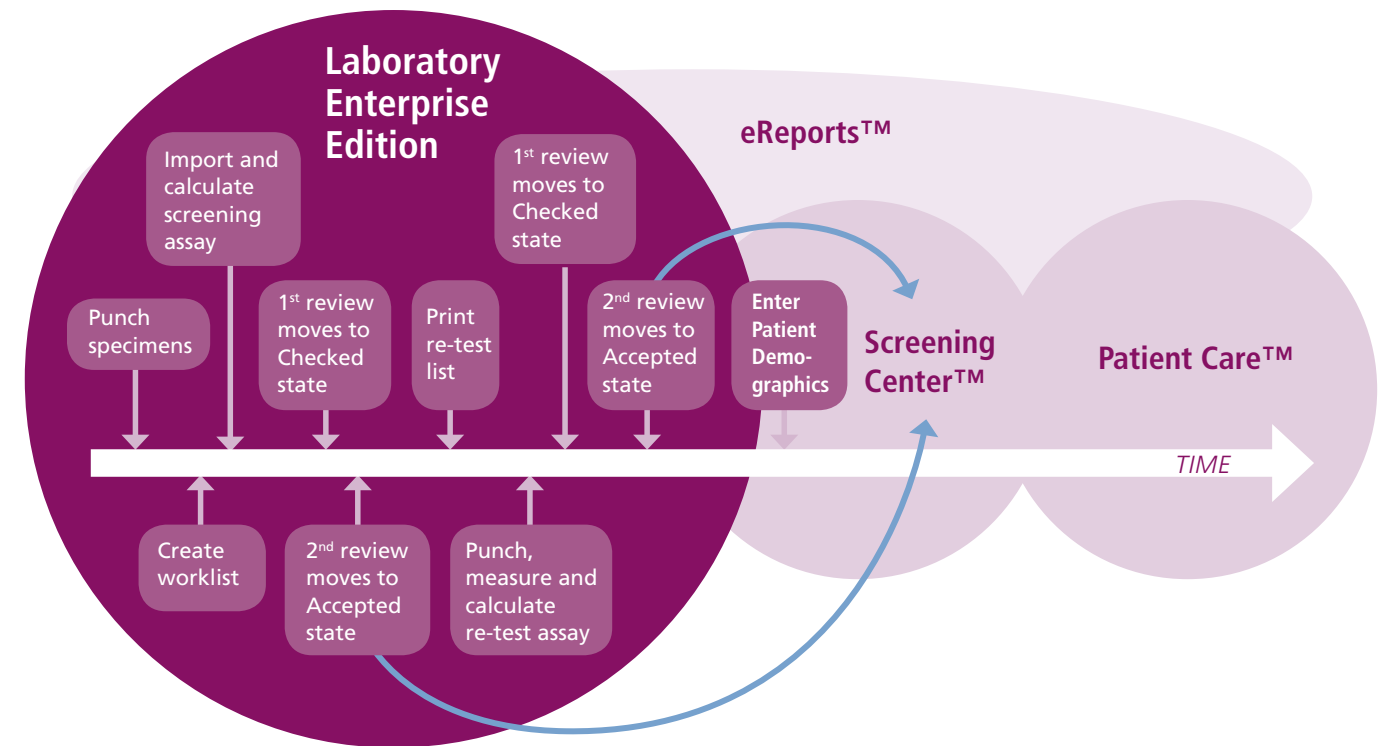
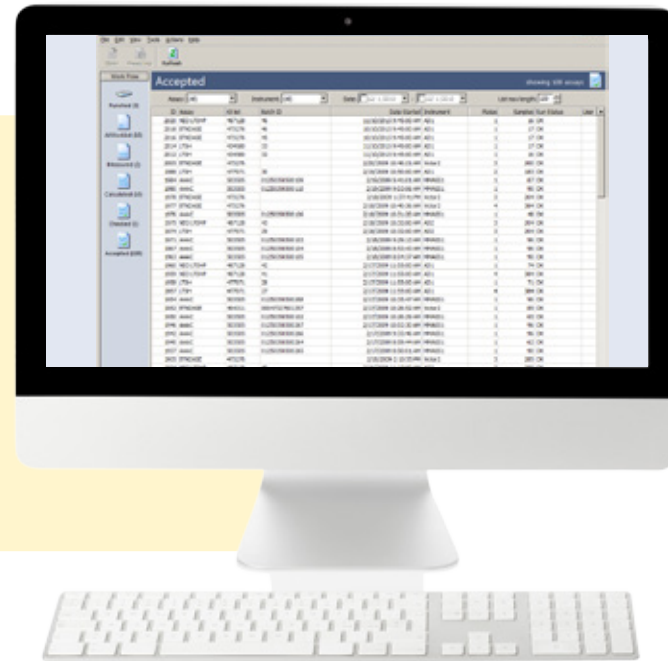
SPECIMEN GATE DATABASE

Application-specific configuration information and all data collected by Specimen Gate® (e.g. specimen information, test results, and patient information) are stored in a series of databases collectively known as the Specimen Gate Database. All of the Specimen Gate software applications require the Specimen Gate database for proper operation. The Specimen Gate Database is a Microsoft® SQL Server database.

COLLECT AND MANAGE DATA WITH SPECIMEN GATE® LABORATORY™ SOFTWARE

Specimen Gate Laboratory software models the processes involved in punching blood spot samples, calibrators and controls in screening and diagnostic laboratories. It also provides a means of electronically gathering test results and storing data in a central location, thus allowing users and other Specimen Gate modules to access this data and generate reports.

Specimen Gate Laboratory software provides the ability to collect and manage data obtained during sample processing and testing.



Sample identification

A Kit Number, in conjunction with an Accession Number, is used to associate a given blood sample to a particular patient.

Sample roles and plate maps

Specimen Gate Laboratory allows users to specify the purpose of each well on a 96-well microtiter plate. The collection of individual wells and their roles is referred to as a plate map.

Barcoding

To promote positive identification and reduce errors, PerkinElmer requires placing barcodes upon the blood cards, microtiter plates, and control material to be integrated in Specimen Gate. This approach enables Specimen Gate Laboratory software to ensure that users load plates according to the defined plate maps.

Punching

Specimen Gate Laboratory electronically tracks punching operations, regardless of the type of sample being processed (blood spot samples, calibrators, or controls). The punching devices supported by the Specimen Gate Laboratory include the Wallac DBS Puncher and Panthera-Puncher™ 9.

Specimen Gate software requires users to identify each specimen to the puncher. This allows Specimen Gate software to track worklists electronically, enabling positive sample identification throughout the screening and diagnostic processes.

Instrument interface

A worklist combines the location of each well and its designated role into an electronic representation of the plate. This electronic plate map allows an instrument to properly correlate test results to each sample on a given plate.

Result Import

Specimen Gate supports the import of quantitative test results from a variety of PerkinElmer newborn screening instruments.

Specimen Gate also supports manual results entry for tests using qualitative analysis. Regardless of the method of import, Specimen Gate tracks each individual sample's results based upon the worklist, plate map, and barcode information.

Analyte flagging

Results are flagged as normal, borderline (i.e. moderate), elevated, or decreased on a per analyte basis, as defined by laboratory. Each disorder is associated with a fixed (static) group of analytes.

Quality control

The Quality Control module provides an interface for users to develop and maintain quality control information. Specimen Gate uses several key concepts to maintain integrity in testing. In addition, the target and standard deviation can be based on the actual mean of a particular series of data points or a value defined by the user.

Kit lot editor

Specimen Gate Laboratory provides an interface to create and maintain information about each kit lot used for each assay.

Viewing results

Specimen Gate Laboratory also provides the Result Viewer module to view test

results. The Result Viewer user interface models typical laboratory processes and allows users to view assays at various stages throughout the testing process.

Specimen history

Specimen History provides a detailed listing of all specimens received such as patient, specimen, test and answer information.

Cutoff analyzer

The Cutoff Analyzer application provides tools for filtering test results to help further evaluate and refine cutoff values. Statistical information is provided for the returned data set and is available for display in several different formats.

Additional features

Specimen Gate Laboratory also provides additional functions, such as Pending List, Request List, Specimen Search and Create Worklist.

MONITOR YOUR PERFORMANCE WITH SPECIMEN GATE® SCREENING CENTER™ SOFTWARE

Screening Center™ software focuses on the activities associated with patient demographics, patient reports, and the overall management of newborn screening programs. Thus, Screening Center offers the ability to enter and track patient and contact information, create and maintain business rules governing the content of patient reports as well as how and when the patient reports are to be created, and statistical information to monitor the performance of the program.

Because the Specimen Gate® database is shared across applications (see Specimen Gate Database on page 3 for more information), Screening Center may be used to monitor overall program performance including data collected from Laboratory, PatientCare™, and eReports™.



Business rules and workflow

Screening Center software includes basic business rules and workflow practices based on input from a wide variety of newborn screening programs around the world.

Screening Center software:

- generates patient reports,
- stores electronic images (PDF) of each patient report created
- delivers patient reports via fax, eReports or HL7 and prints them for mail delivery
- automatically creates cases to track Positive (Elevated or Decreased) and Unsatisfactory specimens, thus allowing users to document follow up activities.

It also provides a number of default validation rules for use in Data Entry.

Searches, reports and statistics

Screening Center's search capabilities are designed to simplify searching, viewing, and working with data. Search results may

also be combined with a report template for viewing within Screening Center or exporting to hardcopy/paper reports, .pdf files, and Microsoft® Excel® files.

Screening Center software provides three standard Statistical Reports:

- Dashboard, which shows a breakdown of the different stages in the screening process and the number of specimens in each stage
- Laboratory Throughput, which is a histogram displaying the specimens currently being processed based upon the number of hours that the specimen has been in the laboratory
- Clerk Performance, which shows details regarding the number of specimens entered by each person in Data Entry

Additional statistical reports may also be created.

Data entry

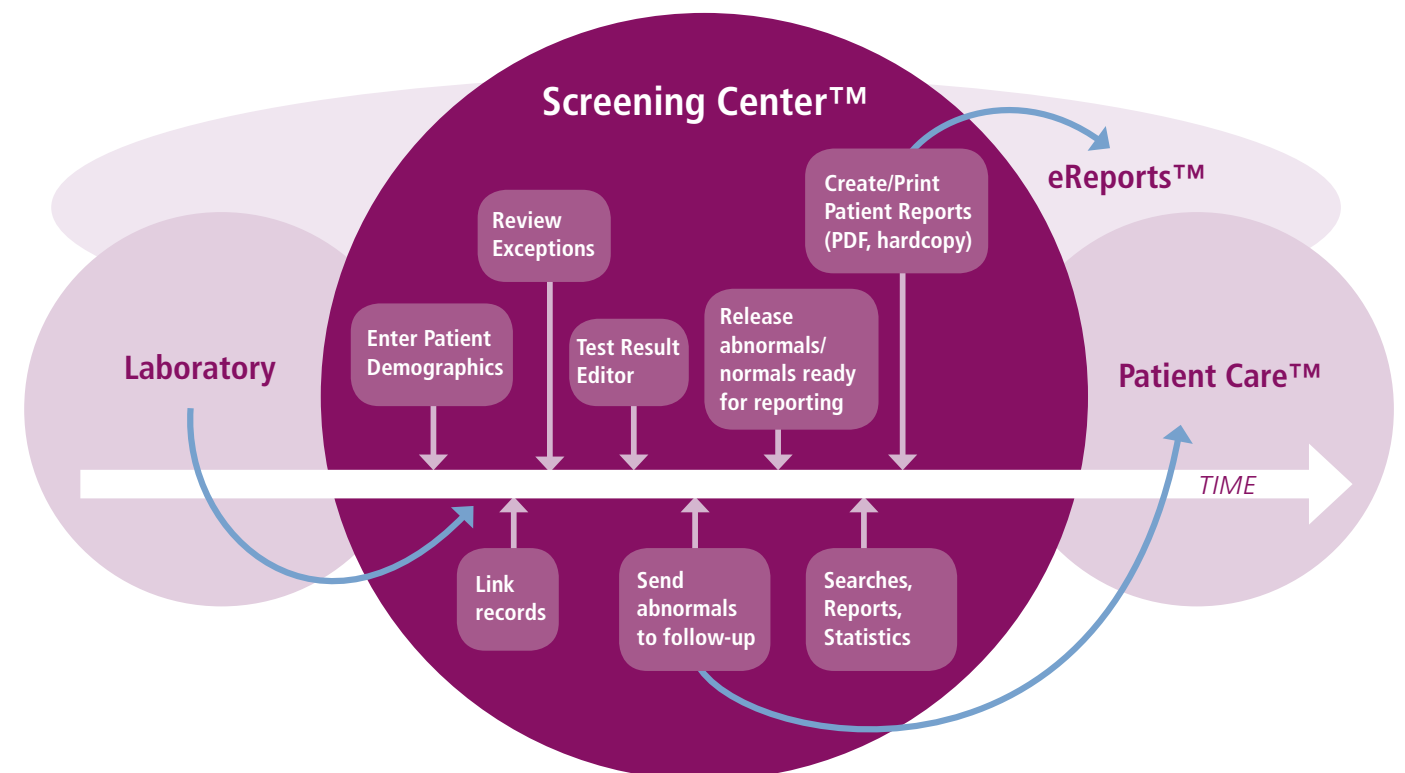
Users can enter patient, hospital, doctor and specimen information through the Data Entry module. By default, Screening Center offers a standard set of data entry fields commonly found on bloodcards used throughout the world. In addition, the Data Entry screen may be configured to reflect the layout of a specific blood collection card.

Validation rules may be configured to enforce certain policies.

Screening Center's Data Entry module also offers a number of features designed to simplify the processes involved in data entry.

Multi-language capabilities

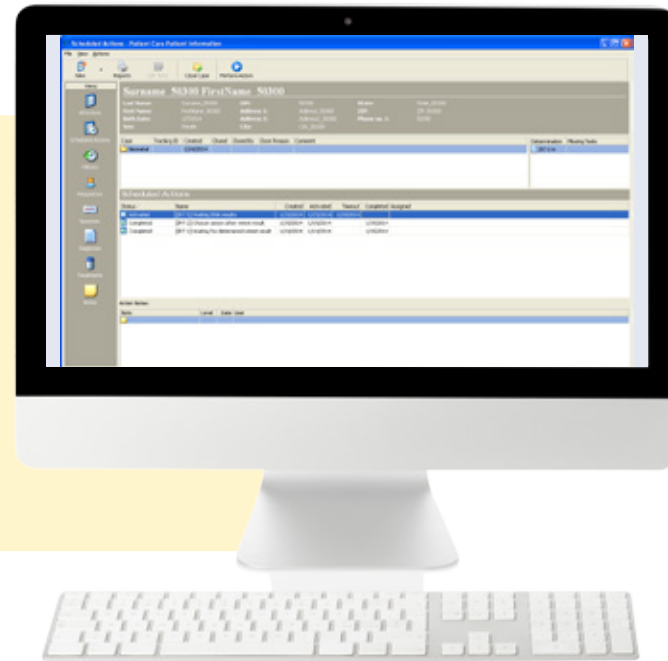
Screening Center is available in English, Spanish, Brazilian Portuguese, French and Italian languages.



ORGANIZE YOUR WORKFLOWS WITH SPECIMEN GATE® PATIENTCARE™ SOFTWARE

General workflow

PatientCare software allows users to define follow up procedure templates for each disorder in the test panel. Each template is made up of individual tasks which, when executed properly, will lead to a diagnosis or case resolution. Examples of individual tasks include requests for repeat specimens, requests for whole blood tests, the process of printing and sending a letter to a physician, and the process of calling a physician and recording notes from the conversation. Workflows follow a linear path.



Worksheet

The PatientCare Worksheet is an interface that allows users to view, sort, and search for cases. Cases can be grouped by a variety of criteria including:

- Type of disorder
- Status
- Summary information
- Cases with pending actions
- Cases awaiting repeat specimens
- Cases awaiting a response from an external healthcare professional or facility

Action status

The status of each action can be viewed and modified in the PatientCare Patient Information view. The status types are:

- Activated
- Waiting
- Completed
- Completed Unsuccessfully

Scheduled actions

A PatientCare template defines the steps required to properly follow up a particular type of case. When a case is created, PatientCare uses the tasks defined in the template to generate the case's task list. Users then execute the tasks listed in the case.

The Patient Information view can display all actions that have been scheduled for a specific determination.

Follow up letters

PatientCare allows users to create letters to be used for activities such as requesting duplicate samples or informing parents and physicians of the test results.

Specimen history

Specimen History provides a detailed

listing of all specimens received for a given patient, including patient information, specimen information and test and answer information.

Requestors

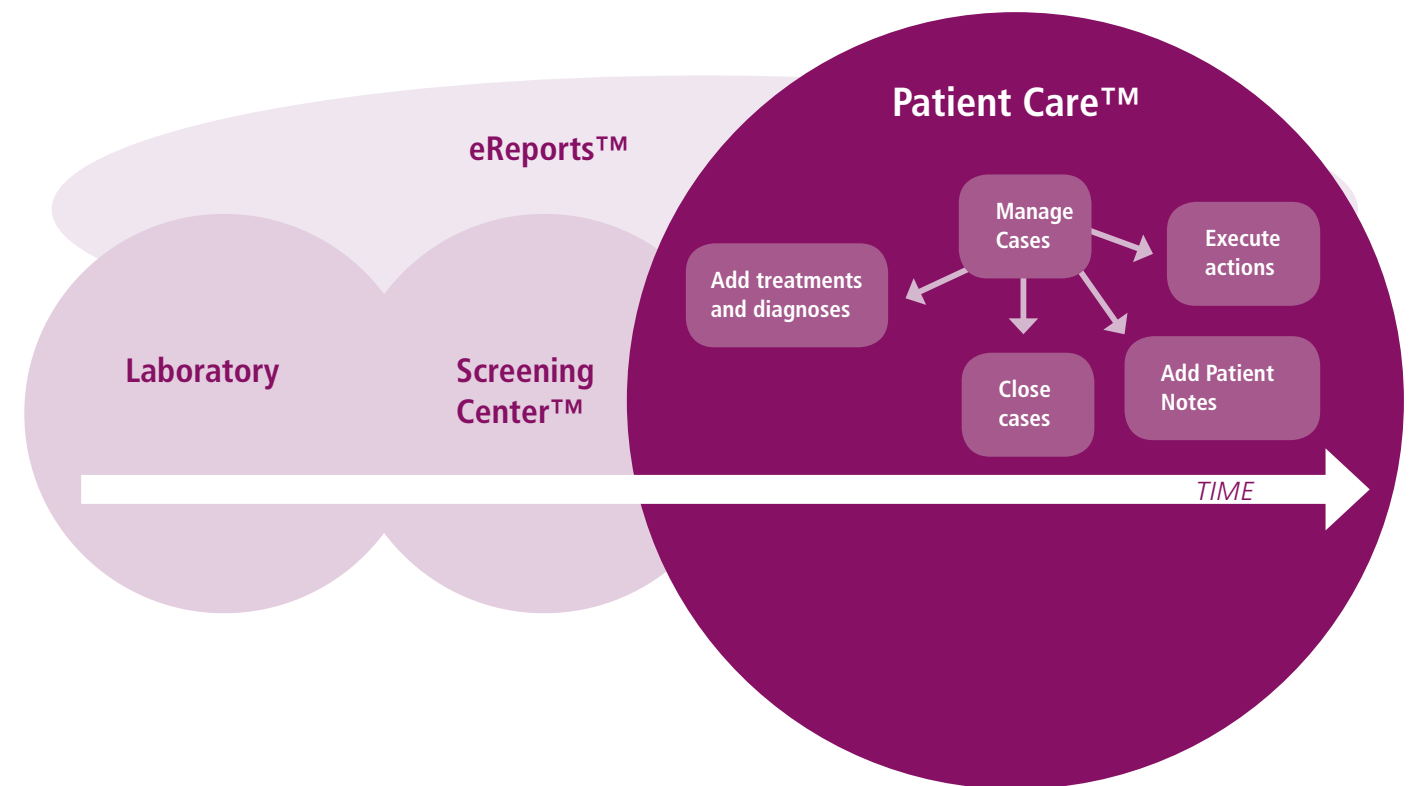
A Requestor is a healthcare professional, facility, or authority requiring information on a case.

History

PatientCare History provides a summary of all information within the Specimen Gate software pertaining to a given case.

Notes

Patient Care allows users to enter additional information about a patient, specimen, determination, or a case. This information can be viewed, entered, and modified in various places throughout the application.



VIEW PATIENT REPORTS ONLINE WITH SPECIMEN GATE® eREPORTS™ SOFTWARE

Specimen Gate® eReports™ software allows end users such as hospitals, clinics, doctors, and midwives the ability to view electronic patient reports via the internet. Currently, all such reports are provided in .pdf format, though eReports supports additional file types such as .jpg and .bmp images, and documents in .xls, .txt, and .doc formats.

The application acts as an intermediary between end-users and the Specimen Gate production server, displaying information to users with appropriate access rights. The eReports application is designed to be hosted on a web server provided and maintained by the customer to ensure that customers retain direct control over the information to which end users have access.



Searching for a specimen

eReports users may search for patient reports and other specimen information using up to six different data fields as well as partial names. eReports will display the search results in a list containing relevant patient data as well as report status, demographics window, results window

Viewing and downloading reports

eReports end users with appropriate permissions may view and download electronic patient reports in a PDF format. These PDF reports are electronic images of the laboratory reports that are typically sent to end users via regular post or courier. eReports end users will be able to view the PDF report as soon as it is created by the Specimen Gate software in real time.

Data entry

eReports provides the ability for users to send data from their web browser directly to the laboratory. All information entered

via eReports is stored separately from the Specimen Gate database to allow the laboratory to validate information submitted via eReports.

Forms

eReports allows users to upload and download forms, which makes it easy for the laboratory to post files for its users to download.

Multi-language capabilities

eReports is currently available in the following languages: English, German, Brazilian Portuguese, French, Spanish and Italian.

Infrastructure

The infrastructure is comprised of the following:

- Laboratory production server, which stores all patient information and electronic specimen reports
- Web server, which hosts the eReports application and is provided and

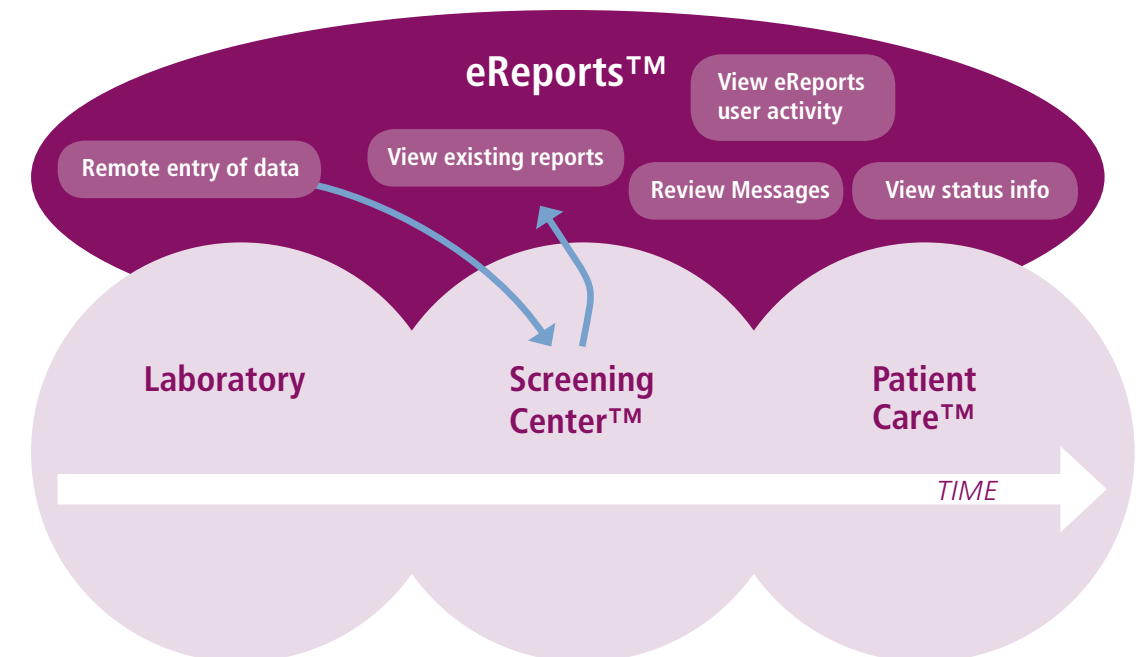
maintained by the customer

- Network infrastructure, which, along with security, is typically provided and maintained by the customer

Please contact your local support representative for more information about web server requirements.

Audit

eReports monitors and records the actions of all user accounts from the time users log in until the time users log out. In addition, information from different Specimen Gate applications (such as eReports and Screening Center) may be assembled into one or more queries.



Security

Specimen Gate Laboratory, Screening Center and Patient Care software require users to be able to authenticate to the Specimen Gate Database server using domain authentication (mixed mode). Specimen Gate software utilizes integrated security for user authentication by validating that the Windows® user name is setup as a Specimen Gate user. Specimen Gate software can restrict access to applications and components based on the Windows® user name.

Specimen Gate eReports software provides a user-friendly interface to allow the laboratory's Information Technology (IT) staff to create and edit user accounts. In addition, eReports allows the laboratory's IT staff to specify how users may access the application.

Credentials

Specimen Gate® software is developed using Agile (Scrum) development techniques according to the FDA's Good Manufacturing Practices (GMP) guidelines in an ISO certified and FDA inspected facility. Our credentials for development and manufacturing site Quality System compliance are:

- ISO 9001 since 1992
- ISO 13485 since 2003/CMDCAS since 2003
- OHSAS 18001 since 2008.

Installed in more than 90 laboratories in over 20 countries worldwide, Specimen Gate® software is used to screen more than 7 million specimens each year.

ORDER INFORMATION

Please contact your local PerkinElmer representative.

Products in this brochure may not be available in all countries. Confirm availability with your local PerkinElmer representative.

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