ACUSERA 24•7

ONLINE QC SOFTWARE WITH REAL-TIME PEER GROUP STATISTICS
BENEFITS

Our vast array of features have been designed to speed up data review and troubleshooting procedures for smarter QC data management.

Unique dashboard interface
- Instantly flags any rule violations from the last 7 days, reducing time spent analysing QC data.
- Warns you when QC lots are approaching expiry, avoiding the use of expired QC material.

True real-time peer group statistics *
- Peer data is uniquely updated live in real-time ultimately reducing time and money spent troubleshooting, re-running samples and performing instrument maintenance.
- Instantly discover how you compare to other laboratories using the same lot of QC material and identify if issues are unique to your laboratory or a widespread issue.
- No submission deadlines for QC data.  

* T&Cs apply

Advanced statistical analysis
- Sigma scores, Bias%, Total Error and other performance indicators are automatically calculated, enabling enhanced performance assessment and improved QC strategy design.
- Reject or alert data based on QC multi-rules or user-defined performance limits including RilIBAK, CLIA and Biological Variation.
- Uncertainty of Measurement (UM) is automatically calculated for each assay and QC lot helping to meet ISO 15189:2012 requirements.

Fully interactive charts
- Levey-Jennings, Histogram and Performance Summary Charts can be generated on-demand for quick and easy performance monitoring.
- The ability to add events and multiple data sets to a single chart ultimately allows for better identification of trends across multiple instruments.

Comprehensive reports
- Specifically designed to speed up the review process, our comprehensive range of easy-to-read reports includes: Data Review, Exception Report, Statistical Analysis Report and Statistical Metrics Report.
- Reports can be customised to show data for a specific date range and can be filtered to display data for a particular test or instrument.

Automated data import via Acusera 24•7 Connect
- An optional software solution that allows easy and automated upload of QC data direct to Acusera 24•7 via LIMS or Middleware.
- Eliminates problems associated with manual data entry and increases laboratory efficiency.
- Capable of bi-directional communication with LIMS and Middleware.

Highly flexible to meet individual laboratory needs
- Custom configuration of performance limits, multi-rules, consensus groups and target values for each instrument or QC lot.
- Although intended for use with the Acusera control range, the software’s internal functions may be used with any manufacturer’s QC material.
Simple and intuitive interface
• The software is fast, powerful and easy to use, therefore delivering an enhanced user experience.
• Colour coded throughout, providing an instant visual indication of poor performance.
• Simple assay configuration with ability to share a configuration across multiple instruments or affiliated labs.

Online access anytime, anywhere
• Cloud based software, eliminating the need for local installation and frequent back ups.

Multiple lab management
• Compare performance to a global peer group or other laboratories in your affiliate network in real-time.
• Stay on top of individual laboratory performance and activity from a central ‘co-ordinator’ account – accessible anywhere, anytime by users with ‘co-ordinator’ level access.
• Easily compare performance of individual laboratories within the affiliate group via multi Levey-Jennings, Histogram, Performance Summary Charts and Statistics.

Technical support
• Expert technical support is available from our team of highly trained specialists.
• Remote access enables immediate troubleshooting without the need for on-site assistance.

World class controls
• World leading controls offering unrivalled commutability, consolidation, stability and consistency.

Compatible for use with the Acusera range of third party controls, the Acusera 24+7 software provides a tool to track QC results and manage daily QC activities from all laboratory analysers on one centralised platform. With access to an impressive range of features, including interactive charts and real-time peer group data generated from our extensive database of laboratory participants, Acusera 24+7 is the most comprehensive package available on the market.
STRESS FREE QC ANALYSIS

Designed to assist in the management of daily QC activities, Acusera 24•7 will help to improve analytical performance, meet regulatory requirements and ensure accurate patient results by helping you to:

1. Monitor and interpret IQC data
2. Compare results to live peer group statistics for rapid and effective troubleshooting

Identify trends, system errors and reagent issues
- Access to interactive charts & comprehensive reports allows immediate detection of QC failures.
- Assess whether performance issues are unique to your laboratory with real-time peer group statistics.

Minimise false rejections
- Apply user-defined QC multi-rules to help reduce false rejections, maintain high error detection and make important decisions on whether to accept/reject results.

Facilitate regulatory requirements

Bridge the gap between IQC and EQA
- Daily monitoring of IQC provides added confidence in test system performance between EQA challenges.

Confidence in assigned target values
- Access to peer group data provides immediate confidence in assigned target values.

Get an independent perspective
- Together with Randox true third party controls, Acusera 24•7 reduces the potential for bias and delivers a true assessment of analytical performance.

‘The laboratory shall have a procedure to prevent the release of patient results in the event of quality control failure. When the quality control rules are violated and indicate that examination results are likely to contain significant errors the results shall be rejected… Quality Control data shall be reviewed at regular intervals to detect trends in examination performance’.

ISO 15189:2012
SOFTWARE OVERVIEW

Manage multiple sites, instruments, tests and QC levels on one centralised platform for greater confidence in analytical testing.

Peer Data Comparison
- Performance Summary Charts
- Statistical Analysis Report
- Statistical Metrics Report
- Peer Group Statistics

Configuration
- Multi-lingual
- Compatible with other manufacturers’ QC
- Support for multiple devices
- Multiple configurable/customisable levels of user access

Data Entry
- Manual
- Semi-automated upload via EDI
- Automated upload of QC data (via Acusera 24•7 Connect)

Utilities
- Audit trail
- Acusera Advisor
- Bi-directional activity

Internal Performance Review
- Levey-Jennings Chart
- Histogram
- Result History
- Dashboard
- Data Review
- QC Multi-Rules
- Exception Report
- Performance Limits (RIQAS, RiviBAK, CLIA, Biological Variation, User-defined)

Performance Indicators
- Bias%
- CVI
- SDI
- Sigma Score
- Uncertainty of Measurement
- Total Error

With access to peer group data, automatic calculation of QC statistics and easy identification of performance via interactive charts and reports, Acusera 24•7 is an essential QC tool for laboratories of all sizes.
Available to you at no additional cost, the unique Dashboard ensures instant identification of any QC failures and alerted results over the last seven days. Designed to significantly reduce the time spent analysing data, this highly convenient and user-friendly function means corrective actions can be taken immediately, with minimum disruption to the laboratory’s output.

Alerts are also provided when a control lot is reaching expiry, reducing the risk of using expired material. If using EDI or Connect to upload QC results, a message will be displayed advising the number of results that have been inserted successfully.
The result history view displays all QC results entered for a particular test. Results are conveniently colour coded red for reject and orange for alert, ensuring quick and easy performance assessment. Monthly and Cumulative statistics including the Mean, SD, %CV, Bias%, Total Error, Sigma score, UM and Expanded UM are automatically calculated and displayed for each lot of control. Results may be filtered to display rule violations or rejected>alerted results for a particular instrument or lot of control.

The ability to add comments and manually accept/reject results directly from the result history view speeds up the review process. Group co-ordinators can visualise results from each individual lab within their affiliated group, allowing for in-depth performance analysis from a remote location.
Levey-Jennings charts are easily generated, providing an instant, visual indication of test system performance over time. The ability to conveniently combine multiple instruments, analytes, QC lots and labs on a single chart allows for comparative performance assessment and immediate visualisation of any ongoing or emerging trends. Customisation in this way will improve troubleshooting capabilities, enabling you to quickly identify whether an issue is unique to a particular test or instrument. The user-friendly interface and interactive nature of the chart allows you to view data for a specific date range, zoom in on a specific data point and record events including instrument service or maintenance for enhanced review of trends. Group co-ordinators can also easily compare performance between laboratories within their affiliated group for quick identification of performance issues. Using the legend, data can be added or removed for side by side comparison.
Generated at the touch of a button, the Histogram allows rapid identification of any test system bias for a given time period. Designed to be completely interactive, multiple instruments, analytes, QC lots and labs can be added to a single chart, delivering comparative performance assessment, easy identification of trends and faster troubleshooting capabilities. Using the legend, data can be added or removed from the chart as required. There is also an option to print charts directly from the software.

Using the Histogram, Group Co-ordinators will be able to quickly identify any labs experiencing performance issues within their affiliated group.
The Performance Summary Chart provides a graphical representation of individual laboratory performance, compared to your chosen peer group. Data is displayed in a colour coded, easy to interpret chart allowing for fast and efficient performance assessment.

Performance Summary Charts can be customised to conveniently display data for multiple analytes and labs within an affiliated group, allowing visual identification of trends. Several flexible review options are available; depending on individual preferences, data can be based on monthly/ cumulative statistics or world/affiliate group statistics.
The Statistical Analysis Report provides a complete overview of laboratory performance for a specified date range. Encompassing many vital performance indicators including the Mean, SD, CV, SDI and CVI, it can be used to compare both monthly and cumulative data for each individual test to your chosen peer group.

Reports are instantly generated for a user defined date range and may be exported as an excel file or PDF. Group Coordinators can also review statistical data for each lab within the affiliated group, allowing for simple data analysis from a central hub.

### Statistical Analysis Report

#### Participant and World

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Displays statistical metrics including Bias%, Sigma and Total Error (TE) for each test alongside those for your chosen peer group. The Bias% provides an indication of your laboratory’s performance compared to the Peer Group Mean, while TE gives an indication of the overall error within a test system, taking into account both imprecision and inaccuracy.

The availability of a Sigma Score provides a measure of how much your data varies from the TEa% and may be used to design an appropriate QC strategy. Group Co-ordinators can also review statistical data for each lab within the affiliated group, allowing for simple data analysis from a central hub.
The unique Uncertainty of Measurement report displays the UM of all QC tests currently in use, helping you to meet ISO 15189:2012 requirements. To calculate UM, simply enter the SD or Standard Error of the Mean (SEM) of the intra assay precision for each test and level of control. Based on performance history, the software will then automatically calculate the SD of the inter assay precision.

Reports are instantly generated for a user-defined date range and may be exported in Excel or PDF format.
EXCEPTION REPORT

View assays which show a higher error rate.

Designed to quickly and easily identify assays with a high percentage of errors, the new exception report provides an on-screen summary of the number of QC results for each individual assay and control lot that fall within the following categories: <2SD, 2-3SD and >3SD.

Reports are instantly generated for a user-defined date range and may be exported in Excel or PDF format.
Access true real-time peer group statistics

The Peer Group Statistics report provides access to peer data for all lots of Quality Control. Data is instantly updated in real-time*, delivering unique access to the most up-to-date information available. Analysis of peer data in this way will help you to determine if an out of control result is an instrument problem or a widespread issue. You may even be able to identify issues before they arise in your lab. Data may be filtered by lot number, date range, analyte, method, instrument and reagent supplier. Data may be based on the global peer group, or to other laboratories in your affiliate group. The final report can be exported to excel or PDF displaying the Mean, SD, CV and number of participants.

* T&Cs apply
Acusera Advisor is an optional tool designed to help you select the optimum QC strategy for each individual test in use. Not only will the Advisor tool recommend a set of QC multi-rules, it will also suggest a minimum QC frequency based upon the performance of the method in question. The use of QC multi-rules will reduce false rejections, unnecessary troubleshooting and the need for costly repeat tests, without affecting error detection.

Recommendations can be made once you have entered a minimum of 20 results for at least 2 levels of control and set performance limits.

Recommendations are based upon normalised OPSpec charts. Once performance limits have been defined, the software will determine the CV% and Bias%. These are then used to calculate the normalised operating point. A normalised OPSpec chart is then used to select the appropriate QC strategy.

A report can be easily generated displaying a list of all assays along with the Analytical Quality Assurance (AQA) achieved with the currently used multi-rules and a suggested minimum QC frequency.
The Audit Trail Report is a secure, computer generated, electronic report displaying all events leading to the creation, modification and deletion of an electronic record. Regulatory bodies frequently require laboratories to document the review of their QC data. Actions, comments and audit trails, when used in combination, provide an effective way of documenting the review process whilst providing a secure method of storing data.

The report can be filtered by any of the following criteria; date, instrument ID, lot number, test or action. The report can be easily converted to PDF and printed for reference.
DATA ENTRY OPTIONS

There are three options for QC data entry with Acusera 24•7

Manual result entry
Easily create custom panels for faster result entry of multiple tests at once, with the option to enter single or summarised data for each test or panel.

1. Analyser generates QC result.
2. QC result is manually entered by the user into the Acusera 24•7 software.

Semi-automated result entry via EDI
EDI is the ideal solution for laboratories that don’t want the hassle of manual data input but still want to benefit from a reduction in time and elimination of transcription errors.

1. An export file containing the QC result and associated information is generated by the analyser, LIMS or Middleware.
2. The user imports the EDI file into the Acusera 24•7 software at their desired frequency.

Note: First time users must create a new configuration for the EDI file and carry out EDI mapping.

Fully automated import of QC data direct from your LIMS/Middleware
Automatically capture data directly from your LIMS/Middleware with Acusera 24•7 Connect and import into Acusera 24•7 without the need to import files or manually input data.

• Reduce workload by eliminating manual data entry or file import
• Eliminate transcription errors
• Secure real-time connection without disruption to the laboratory workflow

Several options are available for automated data entry, our Acusera 24•7 Connect team will work directly with you and your IT team to implement the best solution for your lab’s requirements.

1. An export file containing the QC result and associated information is generated by the LIMS/Middleware. The Acusera 24•7 Connect software will then securely collect and process QC data directly from the LIMS/Middleware and import to Acusera 24•7.

Note: First time users must create a new configuration for the EDI file and carry out EDI mapping.
Randox offers several options for participation in the Acusera 24•7 program ranging from basic to advanced user options. The table below is designed to help determine the best solution for your laboratory.

## OPTIONS FOR PARTICIPATION

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<tr>
<td>Automatic calculation of %Bias and Total Error</td>
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<td>Automatic calculation of Inter-Precision, Sigma Scores, Uncertainty of Measurement and Expanded Uncertainty</td>
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<td><strong>Reports</strong></td>
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<td>Peer Group Statistics Report</td>
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<td>Exception Report</td>
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<td>Statistical Metrics Report</td>
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<td>Data Review</td>
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## ORDERING DETAILS

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<thead>
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<th>Description</th>
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<tr>
<td>Acusera 24•7 Platinum (1 - year licence)</td>
<td>QC4218</td>
<td>Acusera 24•7 Connect Box</td>
<td>QC4227</td>
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<tr>
<td>Acusera 24•7 Gold (1 - year licence)</td>
<td>QC10232</td>
<td>Acusera 24•7 Cloud Connect</td>
<td>QC4228</td>
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<tr>
<td>Acusera 24•7 Silver (1 - year licence)</td>
<td>QC10233</td>
<td>Installation of Randox Connect Box (Onsite)</td>
<td>QC4229</td>
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<td>Acusera 24•7 Configuration/Mapping</td>
<td>QC4224</td>
<td>Installation of Customer Connect Box (Onsite)</td>
<td>QC4230</td>
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<td>Acusera 24•7 Training (on-site)</td>
<td>QC4225</td>
<td>Installation of Customer Connect Box (Remote)</td>
<td>QC4231</td>
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<td>Acusera 24•7 Training (remote)</td>
<td>QC4226</td>
<td>Acusera 24•7 End User Cloud Connect *</td>
<td>QC4232</td>
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</table>

* 1 connection
FAQs

How secure is Acusera 24•7?
To authenticate users, a number of security measures are used, including: participant number, username and a password combination (for individual role-based accounts). Password complexity standards are enforced on user account setup. CAPTCHA is enforced after several failed login attempts to prevent or guard against automated attacks. HTTPS and X509 certificate authentication are in place, meeting industry security standards.

Are there any additional software requirements?
You must have the most up to date version of the preferred browser, i.e. Google Chrome or Mozilla Firefox.

Is Acusera 24•7 Connect required to import QC data?
Acusera 24•7 Connect is only required if you wish to import QC data automatically. Data can also be entered manually using the data entry screen or in a semi-automated manner using the EDI function.

What if I forget my username or password?
If an individual with user level or manager level access forgets their username and password, they should contact the laboratory administrator. If an administrator or group co-ordinator forgets their username or password, there is a reset password link available for you to reset your details.

How many user levels are available?
There are five user levels available: administrator, manager, user, group co-ordinator & technical support. Co-ordinators will have access to all group data but will not be able to edit, delete or add any data. User access may be customised per user to ensure access to only the required functionality.

How is Acusera 24•7 upgraded?
Any new Acusera 24•7 releases will be available online automatically. Additional installation of software is not required.

How do I register for Acusera 24•7?
New Acusera 24•7 participants can register their details on the Randox QC Platform, after which login information will be sent to the laboratory administrator. The laboratory administrator will then set up all other users with their access level, username and password.
**Bias%**

In Acusera 24•7, Bias is the difference between the Peer Group Mean and the observed value.

\[
\text{Bias\%} = \frac{\text{Laboratory Mean - Peer Group Mean}}{\text{Peer Group Mean}} \times 100
\]

**Coefficient of Variation Index (CVI)**

The CVI compares the precision from your laboratory to the precision of other laboratories in your chosen peer group.

\[
\text{CVI} = \frac{\text{Laboratory CV}}{\text{Peer Group CV}}
\]

**Standard Deviation Index (SDI)**

SDI provides an indication of how well your Mean compares to the Peer Group Mean for a given assay and control lot.

\[
\text{SDI} = \frac{\text{Laboratory Mean - Peer Group Mean}}{\text{Peer Group Standard Deviation}}
\]

**Total Error (TE)**

Total Error represents the overall error in a test result that is attributed to imprecision (%CV) and inaccuracy (Bias%).

\[
\text{TE} = \text{Bias\%} + (1.96 \times \%CV)
\]

**Sigma**

Sigma looks at the number of standard deviations (SD) or ‘sigmas’ that fit within the quality specifications of the process. In the laboratory, the quality specifications relate to the Total Allowable Error (TEa). The higher the number of standard deviations that fit between these limits, the higher the sigma score and the more robust the process or method is.

\[
\text{Sigma} = \frac{\text{TEa\%} - \text{Bias\%}}{\%CV}
\]

**Uncertainty of Measurement (UM)**

With every result generated in the laboratory, there will always be a degree of error. Uncertainty of Measurement (UM) looks at the doubt that exists for the result of any measurement.

\[
u = \sqrt{A^2 + B^2}
\]

\[
U = 2 \times u
\]

\[
U = 2 \times u
\]

“The laboratory shall determine measurement uncertainty for each measurement procedure in the examination phases used to report measured quantity values on patients’ samples. The laboratory shall define the performance requirements for the measurement uncertainty of each measurement procedure and regularly review estimates of measurement uncertainty.”

ISO 15189:2012
RELATED PRODUCTS

ACUSERA True Third Party Quality Controls

As a world leading manufacturer of multi-analyte true third party controls, thousands of laboratories rely on Randox to accurately assess test system performance and ultimately empower them with the confidence required to release patient test results. With more than 390 analytes available, the number of individual controls required to cover your test menu is significantly reduced while simultaneously reducing costs, time and storage space. A choice of formats is available, including liquid or lyophilised, which ensures flexibility and suitability for laboratories of all sizes and budgets. Helping you to meet ISO 15189:2012 requirements:

• Designed to react to the test system in the same manner as a patient sample, helping to reduce inconvenient shifts in QC results when reagent batch is changed and ultimately providing a true indication of laboratory performance.

• The presence of analytes at key decision levels ensures accurate instrument performance and eliminates the need for additional low/high controls at extra expense.

• Manufactured independently from any instrument, the Acusera range delivers unbiased performance assessment with any instrument or method, while eliminating the need for multiple instrument specific controls.

Product Portfolio

Antioxidants | Blood Gas | Cardiac Markers | Routine Chemistry | Coagulation | Haematology | Diabetes | Immunoassay Immunology | Infectious Diseases (Serology) | Lipids | POCT | Therapeutic Drugs | Toxicology | Urine Chemistry

Uniquely combining more than 100 analytes conveniently in a single control, laboratories can significantly reduce costs and consolidate without compromising on quality. As true third party controls, unbiased performance assessment with any instrument or method is guaranteed.
RIQAS  Randox International Quality Assessment Scheme

Boasting over 45,000 participants and more than 360 parameters across 33 comprehensive & flexible EQA programmes, RIQAS is the largest international EQA scheme. Designed to cover all areas of clinical testing, each of our multi-analyte programmes is designed to reduce the number of individual programmes required saving precious laboratory time and money. In addition each programme benefits from a wide range of concentrations, frequent reporting, rapid feedback and informative yet user-friendly reports.

- Programmes accredited to ISO/IEC 17043 helping laboratories to meet ISO 15189:2012 requirements.
- Simple one page per parameter report format enables at-a-glance performance assessment saving time spent analysing results.
- Rapid report turnaround within 72 hours from the submission deadline ensures any corrective actions can be taken quickly, minimising the number of sample repeats required.
- Laboratories can register up to 5 instruments per programme at no extra cost and receive a complimentary multi-instrument report for comparative performance assessment.

Programme Offering

Ammonia/Ethanol | Anti-TSH Receptor | Blood Gas | BNP | Cardiac | Cerebrospinal Fluid (CSF) | Clinical Chemistry
Coagulation | CO-Oximetry | CYFRA 21-1 | ESR | Glycated Haemoglobin (HbA1c) | Haematology | Human Urine
Immuonoassay | Immunoassay Speciality 1 | Immunoassay Speciality 2 | Immunosuppressant | Lipid | Liquid Cardiac
Maternal Screening | Serology (EBV) | Serology (HIV/Hepatitis) | Serology (Syphilis) | Serology (ToRCH)
Specific Proteins | Sweat Testing | TDMs | Trace Elements in Blood | Trace Elements in Serum
Trace Elements in Urine | Urinalysis | Urine Toxicology

With over 45,000 lab participants, peer group numbers are maximised ensuring availability of data for a wide range of instruments and methods.
MOLECULAR INFECTIONOUS DISEASES

Our complete quality control solutions for molecular infectious disease testing comprise hundreds of characterised viral, bacterial and fungal targets. Covering a wide range of transplant associated diseases, respiratory infections, blood borne viruses, sexually transmitted infections and more, our Molecular IQC and EQA range covers the full laboratory portfolio. Both our product offering are manufactured using only the highest quality material and the availability of whole pathogen samples ensures the performance of the patient sample is mimicked throughout.

RX SERIES

Renowned for quality and reliability, the RX series combines robust hardware and intuitive software with the world leading RX series test menu comprising an extensive range of high quality reagents including routine chemistries, specific proteins, lipids, therapeutic drugs, drugs of abuse, antioxidants and diabetes testing. The RX series offers excellence in patient care delivering unrivalled precision and accuracy for results you can trust, guaranteeing real cost savings through consolidation of routine and specialised tests onto one single platform.

REAGENTS

Randox offers an extensive range of third-party diagnostic reagents which are internationally recognised as being of the highest quality; producing accurate and precise results. At Randox, we re-invest significantly in R&D to ensure we meet the ever-changing needs of the laboratory. Consequently, Randox offer a range of novel and superior performance assays, including: sdLDL-C, Lipoprotein (a), H-FABP, Adiponectin, Copper and Zinc. Applications are available detailing instrument-specific settings for the convenient use of Randox Reagents on numerous clinical chemistry analysers.

EVIDENCE SERIES

In 2002, Randox invented the world’s first, Biochip Array Technology, offering highly specific tests, coupled to the highly sensitive chemiluminescent detection, providing quantitative results instantly changing the landscape of diagnostic testing forever. The Randox Evidence Series of multi-analyte immunoanalysers provide an unrivalled increase in patient information per sample offering diagnostic, prognostic and predictive solutions across a variety of disease areas with a highly advanced clinical and toxicology immunoassay test menu including cardiac, diabetes, drugs of abuse, metabolic and renal markers.
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