

OMNI-Lab NBS

A complete single database Laboratory Information Management System that meets all the requirements of the Newborn Screening Laboratory. **OMNI-Lab NBS** includes all functionality for management of Patients, Tests and Results, Reporting and Patient Follow-up Outcomes. All features are fully integrated into **OMNI-Lab NBS** by design and are not add-on modules.

OMNI-Lab NBS is Patient/Baby-centric and not Card/Sample-centric. From Patient and Card Registration through Results Entry and Authorization to Report Delivery, **OMNI-Lab NBS** provides all the features necessary to successfully manage the Newborn Screening Laboratory.

OMNI-LAB NBS FEATURES

- Single high performance and scalable database
- Roles based on security access
- Test, Test Panel and Test Battery Management
 - Controlled by client
 - Meets current and future screening assay requirements
- Analyzer and Puncher interfaces
 - Bi-directional if supported by Analyzer
 - Host Query if supported by Analyzer
 - ASTM, HL7, proprietary messaging or file transfer
 - Analyzer/Puncher Vendor Independent
- 2-Stage Report Release
 - Result Validation
 - Result Authorization
- Workflow Automation and Business Rules
 - User configured with Rules Wizard

- Worksheet module
- QC and QA Management
- Inbound interfaces for baby demographics
- Outbound interfaces for report delivery
- Automatic notification for follow- up
 - Missing data
 - Repeat card
 - Others as defined by users
- Result Inquiry by secure browser for external organizations
- Q-Writer Adoc Reporting tool for user-defined reports
 - ODBC connection for external PC tools

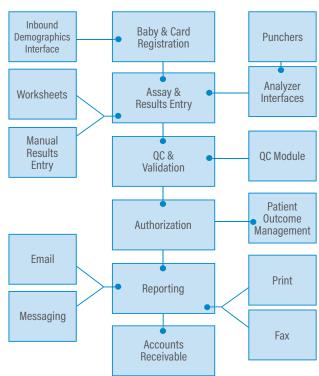


Workflow Automation Using Business Rules ___

USING THE RULES WIZARD, USERS CAN AUTOMATE THEIR LABORATORY WORKFLOW.

Examples include:

- Automatic Notification of Unsuitable Bloodspot
- Automatic Result Calculation
- Automatic Report Comments
- Add 'In-Lab' repeat assays on the same sample
- Repeat Card requests
 - By print, fax or email delivery
- Request for Missing Bloodspot Card data
- Positive Results Notifications and Alerts
 - By print, fax or email or SMS



SCALABLE AND FLEXIBLE

OMNI-Lab NBS can be adapted by individual laboratories to suit a wide variety of workflows. Test assays, panels and batteries are user-defined allowing authorized laboratory staff to create assays suitable to their laboratory. Test management includes the ability to define units, reference ranges and report template layouts. Tests are version-controlled and time-stamped to allow changes in methodologies, units and reference ranges to occur over time without impacting historic result data. Laboratories can add new Test Assays to **OMNI-Lab NBS** at any time without the need for programming or other services. Test analyses can be defined as reportable or non-reportable assays. This feature records all analytical results, but only reports interpretative results such as "Not Suspected", "Suspected", "Repeat Required" or other appropriate result. The availability of raw results allows the laboratory to perform retrospective analysis of counts and results for determining more accurate cut-off points.

RESULT ENTRY

The following methods can be used to enter screening test results into OMNI-Lab NBS:

- Analyzer Interfaces
 (bi-directional and/or host query if analyzer supported)
- Worksheet Entry
- On-screen Manual Entry
- File Import

Automatically user-defined calculated results and comments based on specific analyte values, QC and Delta Checks provide increased productivity, accuracy and consistency. Workflow Rules allow automatic requesting of 'In-Lab' repeats or additional test assays such as DNA or confirmatory tests.

REPORT RELEASE

OMNI-Lab NBS provides 2-stage release of results for final reporting. **Validation** provides a scientific release based on QC and Delta checks. **Authorization** is the final review and release with the opportunity to add clinical comments to the report.

Result Reporting

OMNI-LAB NBS REPORT PORTAL

Access to reports is available at any time using secure web connection to the **Omni-Lab NBS** report portal. This provides secure access to all current and historic reports for a referring organization. Where electronic links from hospitals or birth registries are enabled this can provide fail-safe check reporting.

Reports can be scheduled to run at defined times or run manually at any time. Report formats are user-defined and available in PDF as:

- List of results per referring organization
- Single Report per baby
- Online Report browser

Report delivery mechanisms can be specific to the referring organization and include:

- Print, fax. and email
- Electronic message (HL7 and others)



Ad-Hoc Management and Statistical Reporting

OMNI-LAB NBS DATABASE

OMNI-Lab NBS is a fully ODBC compliant database which exposes all data elements to the user for searching, filtering, sorting and reporting. This includes user-defined test assays, result fields and codes.

Q-WRITER

Q-Writer, as part of **OMNI-Lab NBS**, allows the creation and storage of report definitions. It uses standard SQL to identify data elements for the report and a WYSIWYG graphical report layout form to display the data elements selected.

Q-REPORTER AND Q-QUERY

All Q-Writer reports are available with Q-Reporter, under security, for users to run at any time or schedule as required. Q-Reporter allows output as PDF, Text, CSV, XLS, RTF or HTML and delivered by print, email or fax.

Q-Query provides the ability to define query lists for on-screen display. Q-Query lists can be added to the laboratory management process, and are also available directly from the Favorites menu.

Being ODBC compliant, **OMNI-Lab NBS** can be accessed by a variety of third party tools. This includes MS Excel, MS Access, MS SQL Server, Business Objects, Crystal Reports, Cognos and many other statistical and reporting tools.

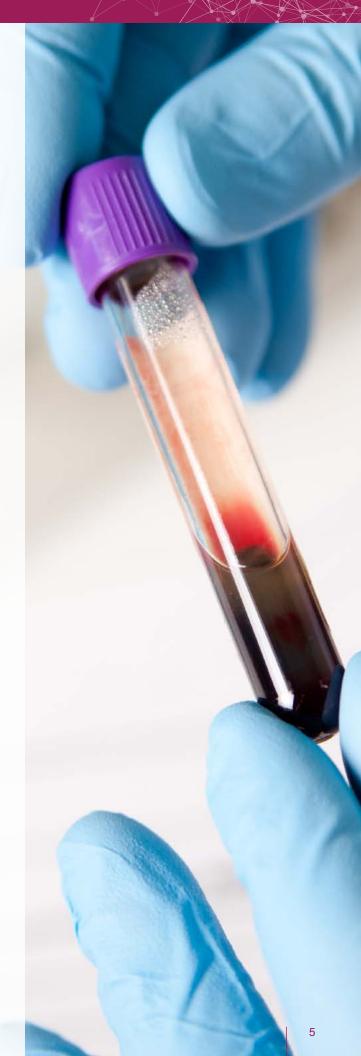
INTEGRATED SOFTWARE SOLUTIONS (ISS)*

Integrated Software Solutions is a global software company dedicated to Diagnostic Laboratory Information Systems. With sites in Australia, United States, Canada, United Kingdom and Middle East, ISS offers 24x7x365 day support from their offices in Sydney, Australia and Winchester, UK and Salt Lake City, USA.

* ISS is a wholly owned subsidiary of Waters Corporation.

OMNI-LAB

OMNI-Lab has been continually developed and supported since its inception in 1982. It is designed by lab people for lab people and requires minimal IT involvement. It is configurable by appropriate lab staff to meet the changing laboratory regulatory and clinical environment.



Testimonials

"Even though we had anticipated the changes being brought about by the National Programme for IT and the individual choices being made by Primary Care Trusts in the region, we wanted a company on board that would be able to work with us and be flexible enough to achieve our goals. With ISS I believe we've chosen the right company, because we can discuss things with them and can get changes made and upgrades incorporated at a reasonable cost." He adds: "I've found ISS's response to be very good. They're always willing to try things for us and were particularly helpful when we needed to convert 25 years of historic data and bring it into a new national system of coding for reporting results, a massive undertaking they achieved for us with complete success."

- Paul Griffiths, Director of Newborn Screening, Birmingham Children's Hospital, UK

"The new ISS software has greatly reduced the number of manual checks required and has streamlined the repeat requesting processes. Overall it has made a huge difference to the efficiency and monitoring of the newborn screening programme."

- Jacqui Calvin, Director of Newborn Screening, Addenbrooke's Hospital, UK

"The OMNI-Lab interface to our various analyzers has vastly improved the way we manage the newborn screening process. OMNI-Lab also automatically manages requests for repeat samples...I can't imagine life without it!"

- Jackie Udall, Chief Biochemical Scientist, Biochemical Genetics Unit, Addenbrooke's Hospital, UK

"We've got a system now that's bespoke for us, but which is fully supported by ISS. We've built up the capability in house such that we've got experts on site and don't have to wait for ISS to come up with the solutions to problems for us - we can start working on them ourselves, which is a massive bonus. Having said that, we've had a lot of support from the ISS guys both in Winchester, here in the UK and in Australia and that's ongoing. Although the implementation hasn't been without teething problems, we're getting there and we feel an awful lot safer than we did previously. We've also got interfaces to all our analyzers, something we didn't have before. In phase two of the project we're looking to introduce messaging with child health and maternity units through an N3 secure data connection, allowing us to download patient details and populate our database automatically."

- Analie Booth, Service Delivery Manager, GSTS Laboratories, London, UK

OTHER OMNI-LAB NBS USERS

Newborn Screening Lab, Great Ormond Street Children's Hospital, London, UK
Newborn Screening Lab, Oxford University Hospitals, Oxford, UK
Newborn Screening Ontario, Children's Hospital of Eastern Ontario, Ontario, Canada

OMNI-Lab NBS is currently being used to manage the laboratory screening of bloodspots, taken by heel-prick, from over 1 Million bloodspot cards collected each year.

Services

ISS SERVICES

ISS provides complete installation, project management, configuration and on-site core user training to ensure the successful implementation of **OMNI-Lab NBS**.

HELP DESK

OMNI-Lab NBS is provided with 24x7x365 support services. This includes a help desk contact and provides fixes to any issues at no additional cost. The Support Level Agreement also includes updates and new versions of software, as and when released, at no additional licensing cost.

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