LifeCycle™ manages the entire maternal health program

LifeCycle™ with Elipse risk calculation engine is a comprehensive informatics package for maternal health monitoring and risk assessment. An accessible patient data management system is coupled with a flexible risk calculation engine, which can be configured to meet local variations. Because the system has been fully validated and all calculation methods, algorithms and values are supported by current published literature, LifeCycle will give you full confidence in your maternal risk assessment program.

This Features Guide may NOT be distributed in the USA.
Providing one source for support
Maternal health screening programs involve more than just analyzing samples, reporting results, and ensuring quality of data. A much wider range of functions must be considered when initiating a program either at a regional or national level. The program will have to be specific to the relevant policies, standards and population parameters, and tools need to exist to allow for its validation. The ability to collect outcome information and perform an annual audit facilitates this process.

With regular performance monitoring, the ability to react quickly to any changes revealed, is vital for the success of the program. Educating people working on the program is also important, as is the ability to provide current and easy to understand counseling for screened individuals.

PerkinElmer Life and Analytical Sciences aims to work closely with maternal health programs providing a total solution meeting all of the various needs. This allows one source for our customers to get support for their program.

Informatics facilitates managing of an effective and high-quality risk assessment program
Informatics plays a role at every step of the maternal health risk assessment process. There are two main requirements for the software. It must be able to perform complex calculations with flexible parameter options and it must be able to monitor quality for the entire program.

PerkinElmer’s LifeCycle with Elipse technology is an advanced screening information management system, which facilitates managing an effective and high-quality screening program. Flexible and dynamic database design is coupled with an extensive query facility to provide accessible demographic information and full patient history records.
LifeCycle with Elipse allows management of the complete maternal health monitoring program

Informatics
Instruments
Reagents
Independent QC material
Median service
Training materials

- Policies standards
- Population parameters
- Annual audit
- Outcome data
- Patient counseling
- Median check
- Performance monitoring
- Lab QC
- Accredited ultrasound
- External QA
- Education Training
- Quality of patient data
The Elipse risk calculation engine can be configured for local variations

Traditional prenatal testing software packages have been monolithic, combining functionality for patient demographics, risk calculation, reporting and laboratory management. Calculations have been hard-coded and embedded into software. This has made systems difficult to modify for different populations or with new calculation methods.

To address these issues, PerkinElmer has separated risk calculation from patient data management. LifeCycle data management software links to Elipse, an advanced risk calculation engine developed at the University of Leeds and the Leeds Teaching Hospitals NHS Trust, the leading team in decision support software.

Elipse is fully configurable; there are no hardwired calculations. This gives each screening program the ability to configure the system to local requirements and allows improvements such as inclusion of new biochemical and clinical markers to be implemented without the need for software upgrades. All calculation methods, algorithms and values used by Elipse are supported by current published literature.

LifeCycle™ facilitates an empirical validation of the risk assessment program

LifeCycle includes outcome storage to record details of the presence or absence of birth defects. Using LifeCycle’s reporting and statistics package, audit reports, can be easily produced for multiple interest groups.

LifeCycle can also produce multiple monitoring reports that indicate changes in the marker performance. This facilitates quick reaction time to all affecting factors.

LifeCycle’s query facility also supports exporting data sets for more advanced statistical analysis and research.

LifeCycle™ can link multiple sites to share information at a regional or national level

The design of LifeCycle reflects the need to link testing sites to enable the use of sub-population medians. As illustrated in the examples on the next page, multiple screening center databases can be linked for the purposes of sharing information, identifying variations in screening performance and to produce audit reports to meet local and national needs. Combining of screening centers can be achieved in many different ways, either physically or virtually.

LifeCycle™ and Elipse bring confidence to the risk results

Confidence in the reported results is essential for maternal health screening programs. To ensure the quality of software, LifeCycle and Elipse have been subjected to extensive, multi-level, testing procedures, starting with functional testing to check that each menu item and command button in the software produces a correct result and ending up with 3rd party assurance that the entire system is accurate and correct. As a result of these thorough tests, LifeCycle with Elipse is a CE marked product, designated as such by a notified body.
Demographic data entered and biochemical markers measured on week 9

**Firewall**

Application server farm running LifeCycle

Data entry over secure network connection

Ultrasound markers measured and combined risk is produced on week 12

National level:
- Performance monitoring
- Optimization of medians
- Parameter analysis also for sub-populations
- Annual audit

**Installation example 2.**

Hub database:
- Centralized quality assurance
- Parameter analysis
- Identify variance in laboratories
- Audit

Database replication or on-line connection

Clinic 1

Clinic 2

Clinic 3

www.perkinelmer.com
Main features of LifeCycle™

**Risk assessment**
- Ellipse risk calculation engine developed by the leading team in prenatal decision support software provides estimates for Down's syndrome (T21), Edwards' syndrome (T18) and open neural tube defects
- Empirically validated screening engine based on latest published data
- Suitable for 1\* and 2\* trimester testing using biochemical and clinical markers
- Ability to add new clinically validated markers, for example, Inhibin-A
- Option for nasal bone marker
- Full flexibility in the choice of biochemical and clinical markers even on each patient individually, for example, 1\* trimester test with nuchal translucency and biochemical markers in combination or alone.
- User definable screening policies: high-risk cut-offs, timing of risk calculation, rounding methods and marker sets
- Ability to configure parameters for sub-populations
- Gestational age calculation from BPD or CRL measurements or LMP date
- Risk estimation is based on age specific background risk modified according to the results of the marker levels using a multivariate Gaussian population model. Population model is configurable with default values derived from current published literature.
- Marker levels using gestational age specific multiples of the normal medians (MoM values) adjusted with user definable correction factors for multiple conditions: maternal weight, ethnicity, smoking, insulin dependent diabetes and previous affected pregnancies
- Using MoM values makes Ellipse independent of the reagent or instrument used and allows local adjustments. Ellipse is supplied with ready to use DELFIA medians for serum markers (AFP, hCG, free ßhCG, uE3 and PAPP-A) and for clinical markers (nuchal translucency)

**Data management**
- Long-term storage of patient information with unlimited capacity with accessible query and data mining tools
- Responsive and open database design by the leading team in screening informatics
- Customizable data entry form with data validation rules, user-definable coded comments and free-text comments
- User-definable patient matching to create patient history files
- Configurable look-ups for patients, specimens and requestors
- Automatic selection of a test panel based on selected demographic information
- Automatic instrument interfaces or manual results entry
- Sample tracking
- Unlimited number of result fields. Also ability to add additional measurements, for example, folate testing

**Workflow management**
- Sample tracking with positive patient identification in every step
- Pictorial step-by-step presentation of the workflow with ability to configure the optimal way of working
- Patient or batch oriented model for accomplishing the daily workload
- Ready made printouts for work lists, result lists, patient/ requester reports etc.
Reporting and performance monitoring
• Monitor screening performance with ready-made set of reports, for example MoM trends or median performance
• Identify and react quickly to any drift in the normal median values
• Estimate expected screening performance values
• Easy-to-use query and data mining tool to retrieve any information stored in the database and print or export it
• Design custom report layouts using ready-made templates and Microsoft Access
• Customer report layouts available from PerkinElmer on request
• Export query results in text file, Microsoft Excel, or XML format for further statistical analysis or for hospital information system

Flexible and modular design
• Risk calculation separated into an independent module, Ellipse, to form full flexibility on screening options
• Scaleable from a single computer to a multi-user, client-server system
• Option for multi-site architecture for centralized quality assurance, sharing of information, calculation of medians and other parameters from combined data, audit and performance monitoring and statistics
• Add-on PerkinElmer Specimen Gate® LIMS modules
• Customizable and upgradeable solutions which can be expanded to meet growing needs
• Easy way to adopt future technologies
• Security system limits access to modules or functions

Outcome follow-up and audit
• Record details of the presence or absence of birth defect for monitoring performance
• Store outcome of the invasive testing procedures or the pregnancy (any complications, date of birth etc.)
• Print observed screening performance, detection rate and false positive rate and total number of Down's syndrome and other affected pregnancies identified
• Facilitates empirical validation of the screening program
All PerkinElmer Life and Analytical products may not be available in all countries. For information and availability please contact your local representative. The example results and reports in this document are for illustration purposes only and have no clinical validity. PerkinElmer does not bear responsibility for the NT results used in calculations. The company strongly recommends that only NT values from certified clinicians, e.g. certified by FMF, are utilized to provide a 1st trimester risk.

For more information about PerkinElmer products, please visit our website:

www.perkinelmer.com/gds

Specific information on Elipse is also available at:

www.elipse.org.uk