

DELFIA® Xpress features guide



AFP (6001-0010)
Free hCG β (6002-0010)
PAPP-A (6003-0020)
uE3 (6005-0010)

General Description

DELFIA® Xpress is a complete solution for prenatal screening. It is a continuous loading system, which will support kits for both 1st and 2nd trimester screening. It is a single cup based fully automated random access DELFIA analyser platform. The instrument supports decreased technical skills from operators and flexible working practices.

The DELFIA Xpress clinical random access system is able to perform sampling from carousel, processing and measurement of the defined DELFIA time-resolved fluorescence technology analytes. Sampling is done from a rack based sample carousel of serum and plasma tubes. The reaction takes place in coated dry cups specific for each analyte where the required reagents are pipetted during the process. At the end of the analyte specific process the reaction cup is washed, enhancement solution is added and the cup is measured using time resolved fluorescence technology. The system reports quantitative results for the markers.

It is a small bench top unit, which can be easily placed according to customer's wishes. DELFIA Xpress platform supports effective prenatal screening by clinics and laboratories.

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System components (6000-0010)

- Analyzer
- PC (Windows based Workstation)
- Hand held barcode reader for kitlot data barcode reading
- Printer for result printing
- Sample Racks and Calibrator Racks

Instrument specifications

- Throughput: 40 results/hour
- Process time: 30 min. /cup
- Incubation time: 20 min. /cup
- On-board pen capacity: positions for 30 pens
- On-board cup capacity: 360 cups
- Kit capacity: 96 tests
- Buffer vial rack capacity: 6 buffer positions
- Reagent vial rack capacity: 12 reagent positions
- Wash solution capacity: 2 L
- Distilled water capacity: 2 L
- Liquid waste capacity: 2 L
- DELFIA Inducer capacity: 50mL
- Solid waste capacity: 200 cups
- Sample volume: 10 μ L or 15 μ L
- Reaction volume: 40 μ L or 60 μ L
- Sample identification: barcode reader or keyboard input
- Incubation temperature: 35 \pm 2°C
- Continuous loading possibility: addition of samples, reagents, buffers and pens is possible during the process (indicated by the traffic lights)
- Operating conditions: 15-30° C, 10-80% relative humidity (<30% humidity inside the penholder)
- Sample tube size: inner diameter 8-16mm, height 45-100 mm
- Start up time: 5 min
- Warm up time: 30 min

Reagent capacity with one loading is enough for continuous loading of 60 samples on 3 analytes.



Pen pack



Buffer rack



Assay cup



Bulk reagents compartment

Analyte kit components

DELFIA Xpress platform is intended for the quantitative determination of biochemical markers in maternal serum. The kit content of Free hCG β , PAPP-A, AFP and uE3 is sufficient for 96 assays and includes:

- Pens each with 12 cups; cups have an analyte specific capture antibody coating
- Vials of Eu³⁺-label reagent
- Vials of buffer
- Calibrators (max six levels)
- Kit insert including kit lot data sheet

Pens and cups

The cup volume is 330 μ l. The cups are packed in pens containing 12 cups.

The pens are packed individually in plastic bags, which protect them from humidity. Stability of the sealed packs is guaranteed for 9 months. Storage should be at +2 - +8°C until the expiry date stated on the label.

After the plastic bags are opened, the cups are exposed to moisture and have reduced stability. Thus the pens should be placed immediately in the penholder of the analyzer, where they are stored at 30 % relative humidity. Stability in the instrument is 12 days.

Reagents

Reagents (Eu³⁺-label) are supplied in ready-to-use liquid form, and delivered in 3 ml vials or 500 ml V-insert vials inside standard size 3 ml vials. Storage should be at +2 - +8°C until the expiry date stated on the label. Stability in the instrument is 2 - 5 days.

Buffers

Buffers are delivered in 3 ml vials. Storage should be at +2 - +8°C until the expiry date stated on the label. Stability in the instrument is 2 - 5 days.

Calibrators

A set of six 3 ml vial calibrators is included in the kit. Free hCG β , PAPP-A and uE3 calibrators are lyophilized,

and must be reconstituted before use. AFP calibrators are in liquid form. The whole set is run when the kit lot changes and the derived calibration curve is stored. Calibrators C and E may be run periodically or when controls are out of their specified limits in order to adjust the calibration curve. Storage is at +2 - +8°C until the expiry date stated on the label. Store reconstituted calibrators at -20°C.

All the kit components are uniquely barcoded to enable automatic inventory checking and positive identification.

Bulk reagents (Ordered separately)

DELFIA Inducer (3013-0010)

The enhancement solution, DELFIA Inducer is a ready-for-use solution delivered in 50 ml bottles. Protect the product from light. The stability of the solution is 5 days in the instrument. Storage is at +2 - +8°C until the expiry date stated on the bottle label. Delivery is in a set of 8 bottles/kit.

DELFIA Wash Concentrate (3014-0010)

Wash solution is a 1:25 dilution of DELFIA Wash Concentrate. It is used for washing the cups and the sample pipettor probe. The reconstituted wash solution remains stable for 10-14 days in a container. 40 ml concentrate is delivered in 50 ml bottles. Delivery is in a set of 8 bottles/kit.

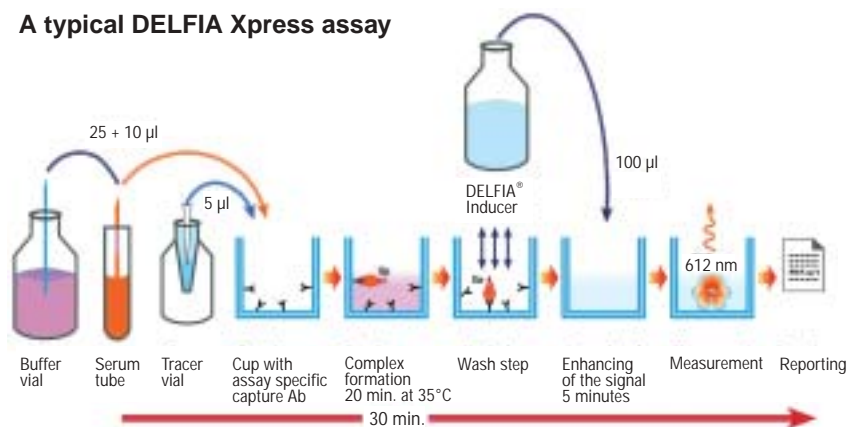
Water

Rinse water (Type 1 water) is used to rinse the tubings.

Disposable Reagent pipette tips (6000-4010)

Disposable tips of type Finntip 10 are used for reagent pipetting. They are delivered in boxes of 96 tips.

A typical DELFIA Xpress assay



Hand held barcode reader

Assay chemistry

The chemistry is based on time-resolved fluorescence. Analyte specific capture antibody is coated to the bottom of a cup. Analyte specific buffer and tracer are also required. Addition of sample, assay specific buffer and assay specific reagent starts the immuno-reaction. Incubation is at 35° C with continuous shaking for 20 minutes. After incubation the cup is washed and 100 µL of DELFIA Inducer is added. Finally the fluorescence of the Eu³⁺-tracer is measured. A quantitative result is reported. The whole process takes approximately 30 minutes from sampling to result.

Suitable sample types:

- Serum
- EDTA plasma (not for PAPP-A)
- Heparin plasma (not for PAPP-A)

Analyte calibration

Each new kit lot has to be calibrated prior to use. This is done with the set of six calibrators included in the kit box. The kit lot data barcode on the front of the kit insert includes the concentrations of the calibrators. In the analyte calibration process the calibrators are measured and the calibration curve is calculated using the known concentrations.

Waste

- The liquid waste bottle has a liquid sensor.
- The cups are dropped directly into a waste box, which has a capacity of 200 cups. This waste is dry and easy to handle.

Electronic control

An unattended electronic control procedure can be selected. The procedure takes about five minutes and after the procedure an Electronic Control Report, listing the functions tested with Passed or Failed status for each function, is shown in the display and may be printed.

Assay quality control

Assay quality control is based on measuring controls. The use of control sera is advised to assure the day-to-

day validity of results. (See Options on next page) The laboratory determines the use of controls. The user may use two level calibration as a quality control or curve adjustment tool. Results for controls are stored in the Quality Control module.

Checks and alarms

The user is notified of possible problems in the process by blinking traffic light(s) and a message on the display.

Physical dimensions

Height: 66 cm
Depth: 56 cm
Width: 85 cm
Weight: 65 kg

User interface

The user interface operates under the Windows XP environment. The Workstation software has four main sections: Routine use, Maintenance, Inventory and Settings. The Windows Workstation Software of DELFIA Xpress is easy to use and learn. The analyser has an Arcnet connection to the controlling PC workstation.



Workstation software, Inventory – Pens display

Hand held barcode reader

The hand held barcode reader is used for kit lot data barcode reading from the kit insert. It can also be used for manual feeding of the specimen barcode. The hand held barcode reader model is WelchAllyn IT 3220.

Connections

The DELFIA Xpress system can be connected to LIS and other systems for e.g. to provide test requests, to do risk calculation and to export results. Methods can vary from simple file export to realtime bi-directional communication between DELFIA Xpress and LIS. DELFIA Xpress system can also be linked to the Wallac Life Cycle risk calculation software which provides the test requests, stores the results and calculates the risk. It is also possible to use any software development tool supporting COM to develop applications that meet the customer specific needs. (See Options)

Power requirements

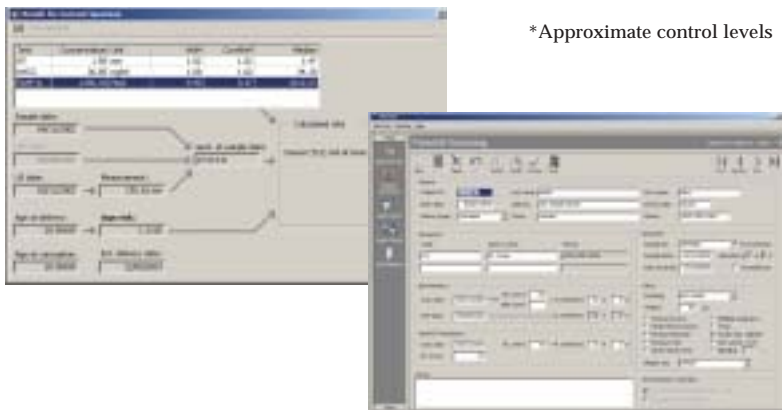
Power frequency: 50/60Hz
Input voltage: 110-230V +/-10%

PC Configurations

Minimum requirements for the PC is a Windows XP compatible Pentium computer, minimum 256 MB memory, equipped with CD-ROM, Super VGA display with minimum resolution 1024 x 780 pixels and true colours. It is equipped with Ethernet connection using RJ45 connector. Model supplied with the system is Dell Optilex GX260, 15" LCD.

Printer

An external printer is used for the result, etc. concentration of samples printing.
Model supplied with the system is Lexmark E320 2011-0030. Connections to the PC via parallel port.



Options

LifeCycle for Prenatal Screening with Elipse Screening Engine (product number 5002-8020 incl. PC).

DELFLIA Xpress system is supported by LifeCycle; a complete data management software package for prenatal screening. LifeCycle is an advanced prenatal screening system, which facilitates the management of an effective and high quality screening program. Flexible and open database design is coupled with an extensive query facility for reports to provide accessible demographic information and full patient history records. LifeCycle is backed by the Elipse, validated prenatal screening engine developed at the University of Leeds and the Leeds Teaching Hospitals NHS Trust.

LifeCycle Main Features:

- Complete Data Management and Reporting
- Confident Risk Calculation
- Coherent Program Integration
- Performance Auditing

Maternal Health Control – Early (3015-0010)

Prenatal QC material is available for 1st trimester screening. The control contains PAPP-A and free hCGβ.

1st trimester control*

Analyte	Level 1	Level 2	Level 3
PAPP-A (mU/L)	4700	2300	530
Free hCGβ (ng/mL)	30	45	95

*Approximate control levels

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