

HUMAN HEALTH

ENVIRONMENTAL HEALTH

CONFIDENCE
IN YOUR
RESULTS



DELFA® XPRESS

random access platform for prenatal screening





FOR THE CLINIC OR
FOR THE LABORATORY



Dedicated random access prenatal screening platform from the leader in the field

DELFLIA® Xpress has been developed to streamline workflows in laboratories and clinics providing prenatal screening services. Already in use in more than 50 countries, DELFLIA Xpress offers a range of benefits critical for operational efficiency.

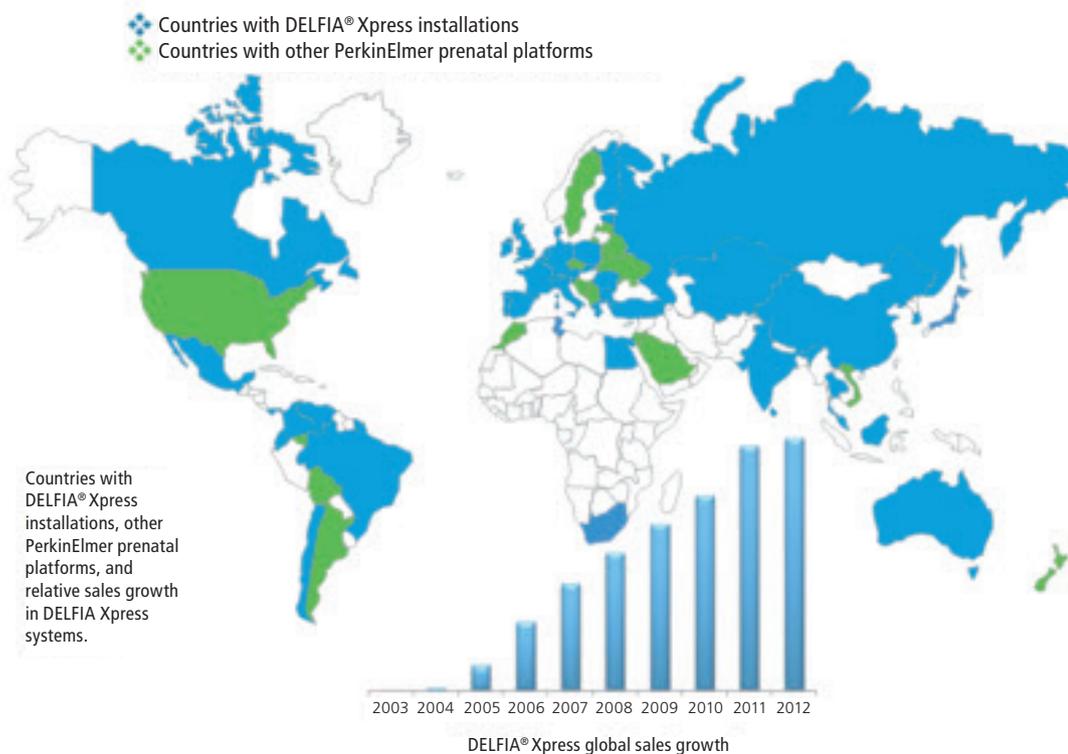
- The speed and flexibility of random access
- The simplicity and ease of use of a new generation instrument with up-to-date software design
- The security associated with barcoded reagents and samples to ensure positive identification
- The reassurance from using reliable, proven DELFLIA chemistry
- The flexibility to support connections to 3rd party software such as Viewpoint and Astraia, as well as PerkinElmer’s clinically validated LifeCycle™ screening management software with new MFH risk calculation engine with statistical analysis tool.

Leaders in prenatal screening for over 20 years

PerkinElmer provides state-of-the-art solutions to benefit maternal and fetal health. Our solutions comprise instruments, reagents and screening management software, all based on our broad-ranging expertise and understanding of today’s needs.

7.9 million screens per year

We are the global leader in products for detecting fetal anomalies during pregnancy, and our platforms are used in more than 50 countries to perform some 7.9 million prenatal risk assessments per year. The newest of PerkinElmer’s prenatal platforms, DELFLIA Xpress has become the platform of choice in many parts of the world.



DELFIA® XPRESS



The DELFIA Xpress instrument and first trimester assays for Free hCG β and PAPP-A are approved by the Fetal Medicine Foundation (FMF).

SUPPORTING TODAY'S AND FUTURE NEEDS

A full range of 1st and 2nd trimester kits are available for DELFIA Xpress and hence it supports the strategies being implemented by today's screening programs. The instrument is equally at home in clinics and in laboratories.

Our research investment in maternal health has led to the development of several new or soon-to-be-available products to allow a wider choice of strategies in aneuploidy screening, and to help programs that are considering pre-eclampsia screening.

Total flexibility to handle the workload

DELFIA Xpress provides all the benefits of a random access system. You can load multiple samples in one go or you can load individual samples as soon as they arrive for testing. The instrument takes 30 minutes to process a patient sample, and generates results at a rate of 40 per hour. The STAT capability provides total flexibility in the handling of patient samples, with the ability to introduce samples as priority if desired. From an operator point of view, all that is required to interrupt a run is to press the start/pause button, and the instrument's "traffic lights" indicate when the STAT sample can be loaded.

Positive identification of all components

All kit contents are bar-coded. When a reagent item is loaded into the DELFIA Xpress instrument, the bar code is automatically read. Specimen tubes, if they are bar-coded, are also read within the instrument. A hand-held bar code reader is used to input all kit lot information, and can also be used for manual feeding of specimen barcodes.

Saves space in the laboratory or clinic

Many instruments compete for space in today's modern laboratories. DELFIA Xpress is a new generation bench-top instrument that maximizes performance from a footprint of only 85 x 56 cm. Operation of the instrument is handled through the PC based workstation software, designed to facilitate easy navigation.

The reliability of DELFIA® chemistry

The reliable clinical performance of DELFIA Xpress assays owes much to the well-established, superior DELFIA chemistry employed by the system. DELFIA reagents are widely used in research, drug discovery, neonatal and prenatal screening, and diagnostics.

Optimized controls available

Ideal for use with DELFIA Xpress, Maternal Health Control – Early is a set of controls with PAPP-A and free hCG β targeted at clinically important levels for 1st trimester screening. Available exclusively through PerkinElmer, the controls are produced by Sero AS, a specialist in quality control material.

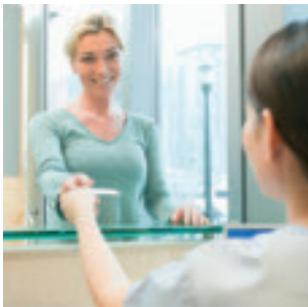
Ideal for OSCAR

An ideal solution for delivering OSCAR (one stop clinic for assessment of risk) services, DELFIA Xpress has been chosen by several pioneering programs. Among these are the Early Prenatal Risk Assessment Program of Calgary, Ontario, Canada, and the program of the Harris Birthright Research Centre for Fetal Medicine based at King's College, London, UK.

New assays for early pre-eclampsia screening

Pre-eclampsia is the most common of the serious complications of pregnancy, and early identification of high risk pregnancies is an important step towards improved management of such cases. However, screening on the basis of maternal history alone provides inadequate sensitivity and specificity. A more effective method of screening for pre-eclampsia is provided by combining maternal history with other markers. One of today's preferred serum markers is placental growth factor (PIGF).

PIGF also has value in improving the performance of Down syndrome screening. Optimized for first trimester measurement, the DELFIA Xpress PIGF assay provides a result that is valid in both pre-eclampsia and Down syndrome risk calculations.



EASY TO USE SYSTEM FROM SAMPLE TO RESULTS

DELFIA® Xpress is logical and straightforward

in its operation. Simply load samples, scan and press the start/pause button. Patient results are ready in 30 minutes. Daily maintenance is equally straightforward. Routine activities include emptying waste, refilling bulk reagents bottles and loading replacement kit components. When taking a new kit lot into use, all kit lot information is rapidly

input using the system's bar code reader.

Assay-specific kits

Each DELFIA Xpress kit contains all of the assay-specific reagents needed including pens, buffer, reagent and calibrators. Each pen contains 12 cups in which the immunoassay is carried out. All the kit components are bar-coded and can be loaded directly into the instrument.



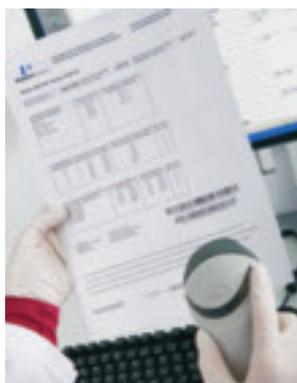
The assay-specific reagents come in easy-to-store packs with sufficient contents for 96 tests. To support lower throughput needs, smaller 72-test packs are also available.

Bulk reagents for convenient work processes

For general convenience, reagents required for all assays are supplied in bulk. The status of reagents and samples loaded in the instrument, can be checked real-time through the inventory module of the DELFIA Xpress workstation software.

Flexibility in sample handling

Five sample racks, holding 6 samples each, form a sample carousel. These can hold a variety of tube types with inner diameter 8-16 mm and height 45-100 mm.



Easy to perform calibrations

Calibration is just as automatic as the processing of samples. A six-point calibration is performed every time a new kit lot is taken into use. Subsequent calibrations may then be run periodically using just two calibrators. Bar-coded calibrators are supplied with every kit.

Intuitive DELFIA® Xpress Workstation software

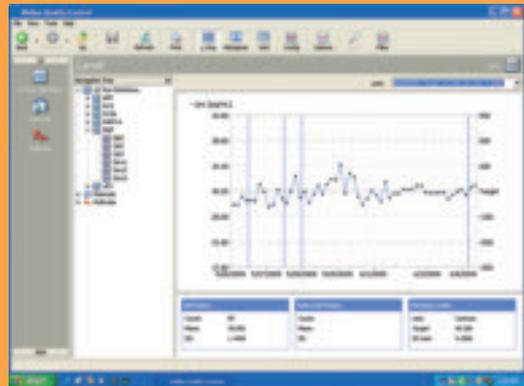
DELFIA Xpress Workstation software is used for all operations, including calibration, running assays, QC functions, inventory and maintenance. DELFIA Xpress Workstation is easy and intuitive, with the overall look and feel of a Microsoft Windows-based program.

QUALITY – AN IMPORTANT PART OF ANY SCREENING PROGRAM

A valuable feature of DELFIA Xpress workstation software is its dedicated quality control module, which provides considerable flexibility in monitoring assay performance. You can create the control materials and select the analytes to be measured with them. Multirule, target value and expected standard deviation can be set separately for each control level. Westgard rules are provided as standard, however, customised rules may be used as well, or instead of the default. The target values and expected standard deviations can be based on the actual measurements or set by the user.

The QC program has a similar visual structure to that of the DELFIA Xpress Workstation software. It supports various plot options to allow easy monitoring of the controls.

Once measured, the control results will be sent automatically to the QC Program, where they can be viewed as a Levey-Jennings plot, in Histogram view or in numerical Grid view. The results can easily be printed or saved as a pdf-file.



Excellent agreement between DELFIA® Xpress units, and with AutoDELFIA®

In a study reported from the Netherlands* samples with free hCG β and PAPP-A were analyzed by six DELFIA Xpress systems and one PerkinElmer AutoDELFIA system over a period of 2 years. For both analytes, excellent agreement was demonstrated between results for the various DELFIA Xpress units, and also between results for DELFIA Xpress and AutoDELFIA.

* Linskens IH et al. (2009) Performance of free β -human chorionic gonadotrophin (free β -hCG) and pregnancy associated plasma protein-A (PAPP-A) analysis between Delfia Xpress and AutoDelfia systems in The Netherlands. Clin Chem Lab Med 47(2): 222–226.

DELFLIA® Xpress reagents for maternal health screening

Aneuploidy risk assessment

- PAPP-A
- Free hCG β
- hAFP
- uE3
- hCG
- PIGF

Early pre-eclampsia risk assessment

- PIGF

Specifications

- Throughput 40 tests per hour
- Process time 30 minutes per test
- Sample volume 10 or 15 μ L per test (or 40 μ L per test for PIGF)
- Sample dilution As pre-assay stage, automatically within instrument
- Kit capacity 96 tests or 72 tests
- Bulk reagents capacity 180 - 250 tests
- Dimensions (instrument)
height 66 cm x depth 56 cm x width 85 cm
- Weight (instrument) 65 kg
- Power requirement 100/240 +/- 10% V, 50/60 Hz
- Workstation environment Windows XP

All DELFLIA® Xpress products are not available in USA, Canada, China and Japan. Products may also be unavailable in Latin-American and some Asian countries prior to registration notifications.

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