Dear customers,

the first week in October was interesting for most people mainly due to the outdoor temperature being at record levels; however, for PLIVA-Lachema Diagnostika it was significant due to another matter – on 7 October it became a part of ERBA Diagnostics Mannheim, a multinational group of companies. As regards our company, it represents not only a major step into the future but also, and mainly, the possibility to offer you – in the near future – more top--quality products.

In addition to information related to the aforementioned merger, we would like to present some new products designed for biochemical and microbiological laboratories. We believe that these novelties will find a place in your laboratory and that they will start to simplify your work soon.

Your PLIVA-Lachema Diagnostika

ERBA, Germany acquires Lachema Diagnostika

PRESS RELEASE
Brno, 7. října 2009

Following successful negotiations, the prosperous and healthy part of PLIVA Lachema - PLIVA-Lachema Diagnostika, a company located at Brno in Czech Republic and operating in the area of In Vitro Diagnostic products, was acquired by ERBA Diagnostics Mannheim GmbH. The acquisition process was officially concluded yesterday. ERBA Diagnostics Mannheim GmbH also operates in the field of In Vitro Diagnostics using distribution network of its Group, in over 60 countries in the world. For about 125 employees of PLIVA-Lachema Diagnostika and its Russian subsidiary, it provides them security and an exciting opportunity for their career growth along with successful development of the company.

ERBA Diagnostics Mannheim GmbH, a German company based in Mannheim, Germany forms part of the Transasia Bio-Medicals Group, the largest Indian In Vitro Diagnostics Group which has served the Indian and global market for more than 30 years. Transasia Bio-Medicals Limited and ERBA Diagnostics Mannheim GmbH supply diagnostic products to more than 60 countries worldwide; the turnover of the Group exceeds CZK 1.3 billion and it employs more than 850 people. Transasia Bio--Medicals Group is led by its Chairman and Managing Director, Mr. Suresh Vazirani, who is one of the pioneers of diagnostic industry in India.

PLIVA-Lachema Diagnostika was established in 2005 after the diagnostic business was spun off by PLIVA-Lachema a.s., a pharmaceutical company. It operates in the branch of development, production and marketing of products for In Vitro Diagnostics consisting of products for urine analysis, biochemistry and microbiology. Its tradition reaches back to 1960s and it is a successor of the diagnostic production portfolio of the former Lachema, a stateowned enterprise. Lachema Diagnostika is currently a major player in the markets of Central and Eastern Europe. Together with its subsidiary Zao Lachema International based at Moscow, Russia, it employs 125 people. Barr-PLIVA Group, an integral part of ownership of the TEVA Pharmaceuticals, an Israeli group of companies that focuses on generic pharmaceuticals. Due to its different overall product portfolio, TEVA decided to find a new owner for this prosperous and healthy part of PLIVA Lachema.

PLIVA-Lachema Diagnostika with its extensive marketing and distribution network in the countries of Central and Eastern Europe and its product line, adequately complement the current market potential and product line of the new owner. In addition to the possibilities of creating synergy, ERBA Diagnostics Mannheim GmbH appreciates the product know-how of Lachema as well as the potential of its certified manufacturing procedures and top-quality development background that serves as an important basis for further development and growth of Lachema.

„We regard the acquisition as a great opportunity for our products to enter both the markets in Western Europe and dynamically developing markets in Asia and South America through the strong distribution network of ERBA Group. Furthermore, our current customers in Central and Eastern Europe will have access to ERBA Group's extensive product range in Clinical Chemistry, Immunoturbidimetry and Immunology products. This basket of products of Lachema and ERBA will be definitely appreciated by our business partners and customers alike," claims Jaroslav Řehůřek, Managing Director of the company.

In addition to development in the area of manufacturing of the current products, ERBA Diagnostics Mannheim GmbH plans to increase the development capacities of Lachema in the coming months to increase the current manufacturing capabilities and add new products in the medium-term time horizon.

„In spite of the global financial crisis, ERBA Diagnostics Mannheim plans to invest more than CZK 20 million in our company as early as in the first year," adds Řehůřek.

HbA1C

Make correct and efficient measurements of HbA1C!

Diabetes mellitus is a typical civilization disease, in case of which the frequency of occurrence has increased rapidly. In the past 20 years the level of occurrence in the Czech Republic has almost doubled and at present it equals 7.5% - with a forecast of up to 10%.

Timely and high-quality diagnostics as well as a suitably selected and continuously maintained treatment and its monitoring prove to be essential in order to decrease the risk of diabetes-related complications such as diabetic neuropathy and retinopathy. Hba1C measurements contribute to **monitoring of the retrospective glucose level in blood,** thus representing a significant **tool for forecasting of development of diabetes-related complications.**

ILT HbA1C Direct kit is designed for direct measurement of HbA1C and it is based on the principle of latex immunoturbidimetry. The method uses the interaction of an antigen and an antibody for the purpose of direct measurement of the percentage of HbA1c in haemolysates of whole blood. The total amount of haemoglobin and HbA1C shows an identical non-specific absorption rate of latex particles, which occurs following mixing of R1 agent with the respective sample. A latex - HbA1c – mouse monoclonal antibody complex is created following addition of the mouse monoclonal antibody against human HbA1c (an integral part of R2). An interaction of goat monoclonal antibody against mouse IgG present in R2 with the monoclonal antibody results in agglutination of a proportional amount of HbA1c absorbed to the surface of latex particles. The quantitative rate of agglutination is measured using the turbidimetric method – on the basis of deduction of one value of turbidance of the sample.
The product range obviously comprises also a calibration device and control materials used for measurement of HbA1C. ILT HbA1C Calibrator kit contains 4 different calibrator levels (0.5 ml increments) and ILT HbA1C Control kit contains 2x2 different levels of control materials (0.5 ml increments). Customers may also order a haemolysing agent (ILT HbA1C Haemolysing Agent kit contains 5x100 ml).

A comparison of ILT HbA1C Direct kit with HPLC method proved an excellent level of correlation (r=989, y=1,032x-0,40). Furthermore, results of the external quality assessment procedure proved suitability of the kit for its routine use in laboratories.
The principal benefit of the immunoturbidimetric measurement pertains to its **simple application** to the existing analytical systems, **without the need for investment into single-purpose instrumentation.** Thanks to the aforementioned fact this method represents also a highly effective and economical solution.
Another benefit of ILT HbA1C Direct kit pertains to direct **measurement of the percentage of HbA1C without the need for measurement of haemoglobin,** and therefore solely 1 channel on the analyzer proves to be sufficient for the measurement.
In spite of the fact that it uses a different type of material (sample) than most other measurements used in clinical biochemistry (whole blood or haemolysate), the immunoturbidimetric measurement of HbA1C represents a **major contribution to consolidation of a laboratory.**

Benefits of the kit:

- simple application
- efficiency thanks to use of the existing analytical systems in the laboratory
- direct measurement of the percentage of HbA1C

Creatinine Enzymatically

BLT Creatinine Enzymatically Liquid 204 kit – the right solution for creatinine determination

The enzymatic manner of determination of creatinine **solves the principal problem of the traditional Jaffe Method,** i.e. non-specificity of determination. The serum matrix naturally contains analytes which falsely increase (proteins, glucose, ketone bodies, ascorbic acid, etc.) or decrease (bilirubin) the level of creatinine determined using the Jaffe Method. The aforementioned effects are the most significant in the area of reference values.

BLT Creatinine Enzymatically Liquid 204 kit offers a **two-reagent liquid** *ready-to-use* method. In the course of the first reaction creatinase and sarcosine oxidase hydrolyze endogenous creatine while creating hydrogen peroxide which is eliminated by catalase. Following adition of creatininase and 4-aminoantipyrine, solely creatine created from creatinine on the basis of effects of creatininase is subsequently hydrolyzed by creatinase and sarcosine oxidase while creating hydrogen peroxide. The newly created hydrogen peroxide reacts with N-ethyl-N-sulfopropyl-m-toluidine (ESPMT) in the course of a catalysis using peroxidase. Absorbance of the created complex at 546 nm is directly proportional to the concentration of creatinine in the sample.
The value used for calibration of the enzymatic method is specified in the certificate accompanying BLT Lyonorm Calibrator as well as in the control materials for BLT Lyonorm HUM N and P.

Benefits of the kit:

- specific method
- stable, ready-to-use agents
- validation for common types of analyzers

Innovated LAURA® urine reader

In the second quarter of 2009 PLIVA-Lachema Diagnostika presented the innovated LAURA® urine reader, which represents a follow-up of several years of successes of its predecessor. Innovation of LAURA® urine reader is fully in line with the current trends and requirements in the area of urine analysis performed in clinical biochemistry laboratories.

Like the preceding model, the innovated LAURA® reader proves to be based on the principle of reflection photometry and it allows for use of seven and ten-parameter diagnostic strips (HeptaPHAN® LAURA and DekaPHAN® LAURA) which are **completely automatically recognized** by the reader. In comparison with the original model, the colour touch screen, which **increases the level of users' comfort, represents a major new feature.** Furthermore, the touch screen features bigger dimensions, which allow for use of bigger characters, thus ensuring a **higher level of legibility for operators.** The **possibility to describe** the analyzed urine sample using a definition of the respective **nebula and colour,** i.e. factors that might negatively affect results of analyses, represents another major feature. Furthermore, the innovation of LAURA® urine reader offers also the **possibility of recording notes prior to as well as following completion of a measurement.** Thanks to the increased capacity of its memory, **as many as last 1000 results are available.** The device may be interconnected with the laboratory information system.

The innovated LAURA® urine reader offers an objective and efficient solution to the matter of urine analysis in your laboratory.

Benefits:

- touch screen
- specification of analyzed sample – possibility of recording nebula and colour
- increased capacity of memory (up to last 1000 results are available)
- possibility of recording notes prior to and following completion of measurements
- innovated SW
- automatic identification of used diagnostic strips.

URINORM control urines

Urine analysis under control

URINORM control urines represent a new product in the product portfolio of PLIVA-Lachema Diagnostika. It is a liquid synthetic material containing concentrations of individual **analytes in the normal** (URINORM N) **and pathological** (URINORM P) ranges. The product is designed for **verification of accuracy and correctness of urine analysis** in case of use of PHAN® diagnostic strips as well as LAURA® and LAURA® Smart readers (for visual and objective evaluation).

URINORM control urines contain analytes designed for determination of specific gravity, leucocytes, nitrites, proteins, pH, glucose, ketones, bilirubin, urobilinogen and blood. They do not contain human urine, **and therefore they are not classified as a potentially contagious material.** Each package contains 3 vials of URINORM N and 3 vials of URINORM P, i.e. **up to 30 tests** in the normal and pathological ranges may be performed using one package. The product is to be stored at (+2 to +8)°C. Once opened, URINORM control urines remain stable for 30 days and/or 10 measurements (whichever factor occurs first).

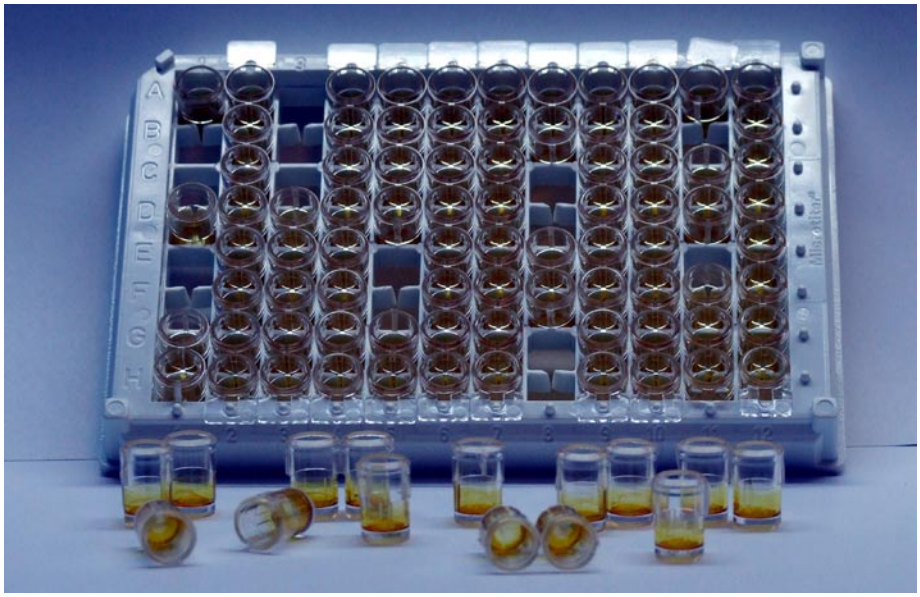
URINORM control urines complete the range of urine analysis (diagnostic strips – urine analyzers – control material) and they offer the possibility of performance of systematic checks of diagnostic strips and urine readers **at an affordable price.** URINORM control urines may become an **essential means of assistance in relation to preparation of your laboratory for accreditation or certification.**

On the basis of use of URINORM control urines **users may become reassured** that the system comprising diagnostic strips & a urine reader works accurately and correctly.

Benefits:

- simplicity of completion – ready-to-use solutions
- guarantee of correct results of urine analysis thanks to a simple check
- results within 1 minute
- assistance with preparation of your laboratory for accreditation/certification

Novelties in the MIKRO-LA-TEST® range



OFtest allowing for a correct and fast decision

We designed a **simple version of OF-test which is based** – like the standard test-tube test – **on the Hugh-Leifson medium.** A bacterial suspension is applied to a hole in the micro-titration plate, which contains glucose, and covered by a layer of liquid paraffin. **The most significant benefit of the new OFtest** definitely **pertains to its speed.** The result may be generally viewed as early as **after the elapse of 2 hours,** however no later than after 4 hours of incubation, thus allowing for selection of the right identification kit (ENTEROtest or NEFERMtest) on the very same day. Even though the standard test-tube OFtest may be used, in addition to differentiation of the fermentative and oxidative metabolism of glucose, for determination of other features pertaining to the monitored bacteria (gas production and mobility), the result is known as late as after the elapse of 24 hours in that case. Furthermore, you will definitely appreciate the fact that OFtest is supplied **on cut-off micro-titration plates,** thus allowing for use of the required number of holes only.

The most significant benefit of the new OFtest definitely pertains to its speed.

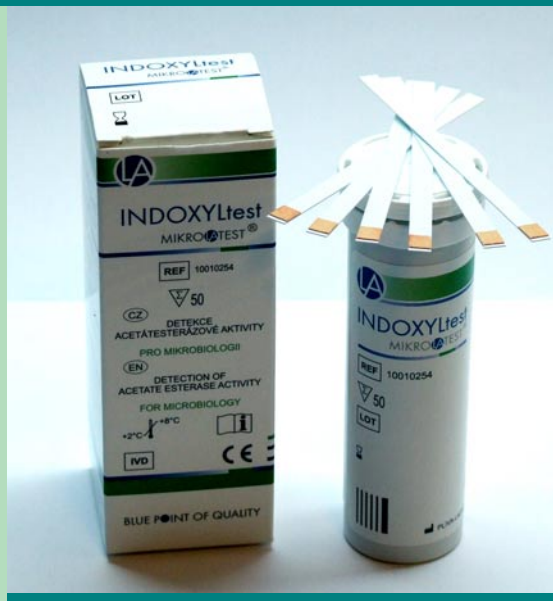
Benefits of OFtest:

- possibility of separation of the required number of tests
- use without the need for any additional reagents
- simple handling
- speed of completion
- economic efficiency

New strip tests: INDOLtest and INDOXYLtest

The indol production test represents one of the most commonly used biochemical tests in microbiological laboratories. That is the reason why we selected a **simple strip configuration** for our new test and we based in on the principle of a reaction that is one of the most sensitive amongst the routine methods. INDOLtest **detects the activity of bacterial tryptophanases.** A tryptophanase represents a complex of enzymes catalyzing splitting of tryptophane to indol. The test is based on the principle of reaction of created indol with the substrate forming a part of the diagnostic zone of the strip while producing a blue-green compound. The reaction does not require addition of any agents. **The respective result is available within 1 - 5 minutes** from the time of application of bacteria to the diagnostic zone. INDOLtest may be used as an individual biochemical test or as an auxiliary test essential for the developed ENTEROtest 24 and NEFERMtest 24 agent-free kits, which are to be launched early next year.

INDOXYLtest was developed for the purpose of accelerated **differentiation of *Moraxella catarrhalis.*** A positive reaction to the aforementioned species is shown by a blue colour visible **within 2 - 5 minutes** from the time of application of the genus to the diagnostic zone. The test may **also** be used for the purpose of **differentiation of species within the scope of *Campylobacter.*** As regards identification of campylobacter, the result is to be read after the elapse of 30 minutes. INDOXYLtest detects acetate-esterase activity of bacteria; the test is based on the principle of hydrolysis of a substrate to the leuco form of indigo, which is transformed to a chromogenic form of indigo at the presence of oxygen.

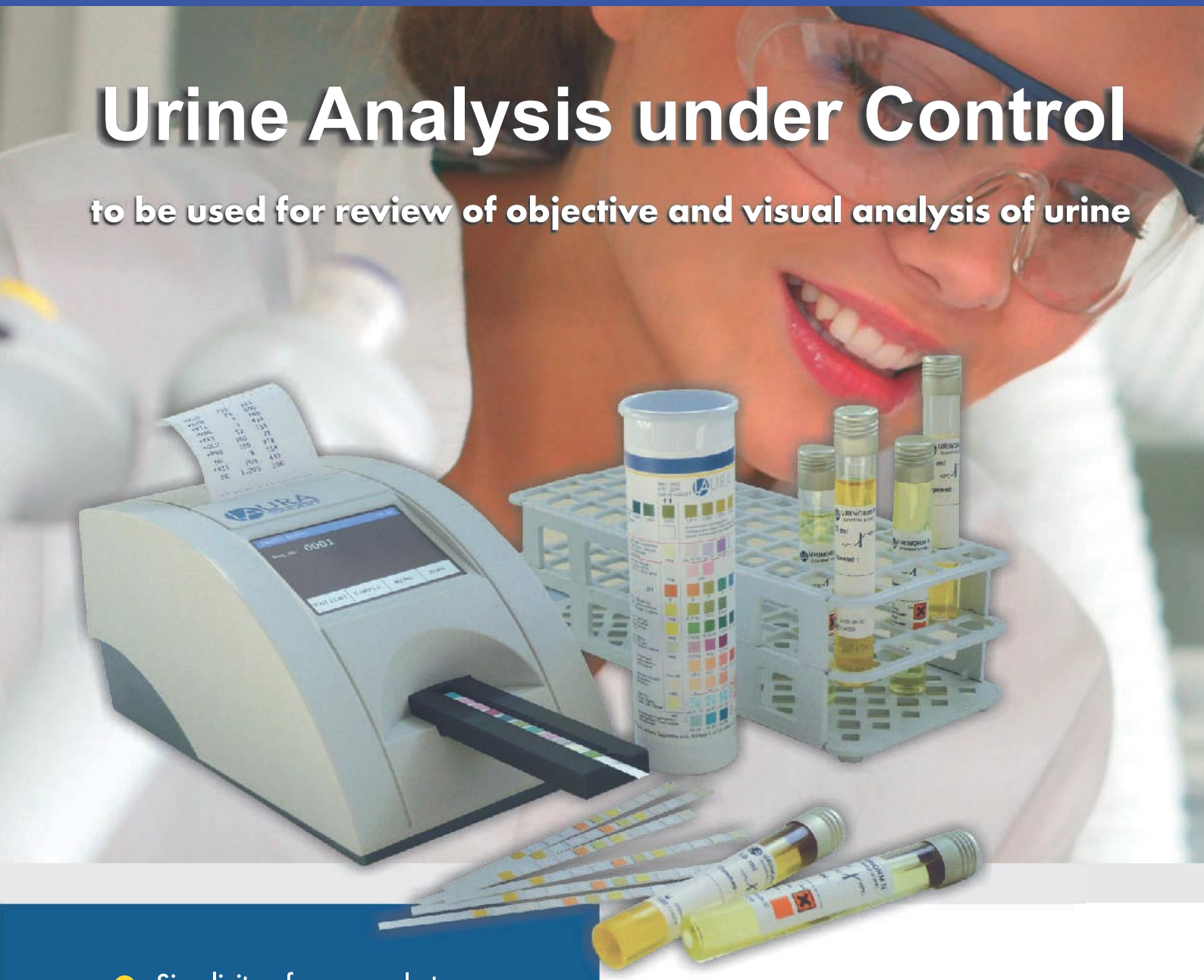


Benefits of the new strip tests:

- use without the need for any other reagents
- simple handling
- speed of completion
- practical size of the package

Urine Analysis under Control

to be used for review of objective and visual analysis of urine



- Simplicity of use - ready to use solutions
- Security of correctness of results of urine analysis thanks to simple reading
- Results within 1 minute
- Assistance with preparation of your laboratory for accreditation/certification at an affordable price

www.lachema.com

Control Urines

URINORM

PLIVA-Lachema Diagnostika s.r.o