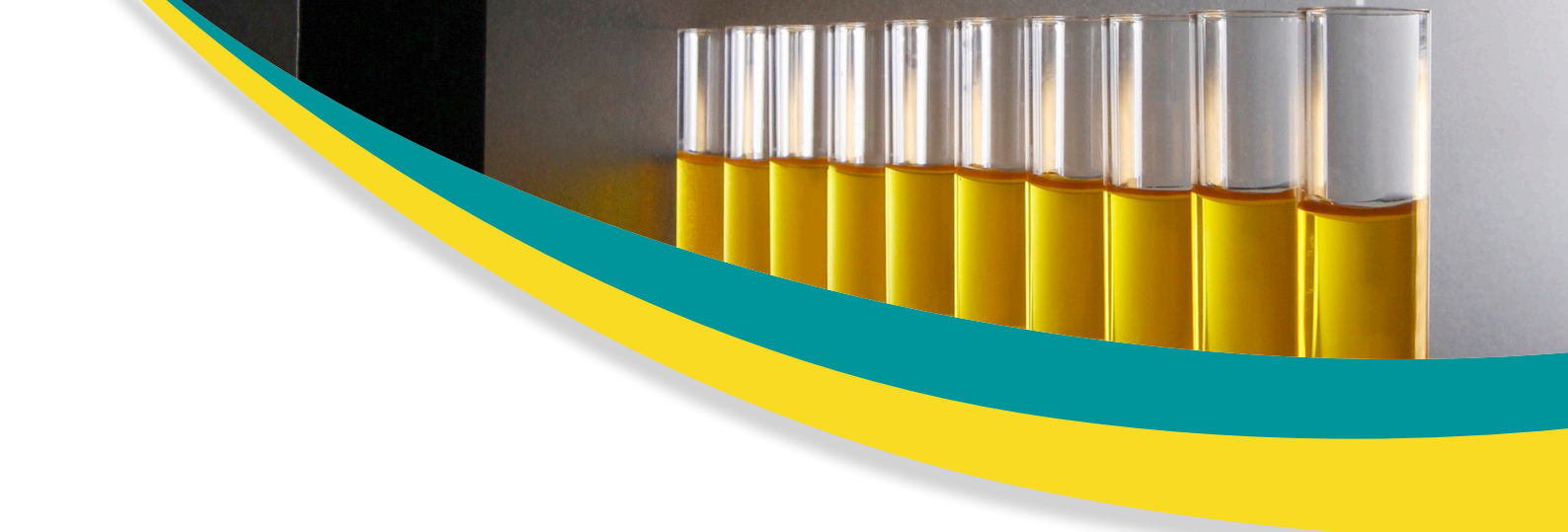




Clinical Utility

Urinalysis is carried out in both inpatient and outpatient settings, due to its high information content and accessibility. Its importance in diagnosis has been understood throughout history. In fact, Sumerian and Babylonian physicians dating back to 4,000 BC recorded their assessment of urine on clay tablets⁵.

Today, urinalysis is used to screen for, diagnose and monitor numerous renal, urological and metabolic disorders including:



Chronic Kidney Disease (CKD)



Cardiovascular Disease (CVD)



Glycosuria



Bladder Cancer



Urinary tract infections (UTIs)



Haematuria



Bilirubin



Microscopic examination of urine

5. Armstrong JA. Urinalysis in Western culture: A brief history. *Kidney International*. 2007; 71 (5):384-387.

Bringing urinalysis solutions to growing labs everywhere

Erba Mannheim is a fully integrated global in vitro diagnostics company, offering a comprehensive suite of clinical testing products to the growing number of smaller hospitals, reference labs, and physician clinics in the developed and emerging markets with reliable, affordable and innovative health care products.

In 2017, Calbiotech Inc. joined the Erba Mannheim group, bringing over 20 years of expertise in developing immunoassay kits that have been manufactured and distributed to over 80 countries across the globe.

List of abbreviations

BACC	Cocci-like Bacteria
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BACR	Rod-like Bacteria
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CaOX	Calcium Oxalate
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CAST	Casts
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CKD	Chronic Kidney Disease
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CVD	Cardiovascular Disease
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HYA	Hyaline Cast
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MUC	Mucus
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NSE	Non-Squamous Epithelial Cells
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RBC	Red Blood Cell
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SPRM	Sperm
-------------	-------

SQEP	Squamous Epithelial Cells
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TRIP	Triple Phosphate
-------------	------------------

UA	Uric Acid
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UUN	Urinary Nitrogen Concentration
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UTI	Urinary Tract Infection
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WBC	White Blood Cell
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WBCC	White Blood Cell Count
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YST	Yeast
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For more details, please contact your local Erba Mannheim associate.

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Introduction to Urinalysis

Urinalysis is one of the most frequently performed clinical investigations. It's used to screen for, diagnose, and monitor a wide variety of renal, urological and metabolic conditions.

Manual urinalysis involves visual examination, dipstick test, and microscopy of the urinary sediment. Manual urinalysis is time and labour-intensive, requires specific expertise and is prone to analytical errors. Automatic urine analysers are now commonplace in larger laboratories.

The Laura XL (Erba Mannheim) is a fully automated urine analyser, combining urine strip reading with digital microscopy, aimed at mid-sized laboratories. It uses the gravity sedimentation technique for automatic microscopy, producing clear, high-resolution digital images reducing the need for additional manual microscopy. 125-160 tests per hour can be performed, and just 0.9 mL of urine is needed for full analysis.

The Laura XL features active humidity protection and automatic programmed maintenance. There are 3 operating modes (chemistry only, sediment only, and hybrid), 10 chemistry parameters, 16 automated sediment categories, another 16 manual sediment categories, and 4 customised sediment categories. The Laura XL is compact, powerful, fast and economical.

The Laura XL analyser is being used in the large CITILAB laboratory in Moscow. Staff felt that it increased their productivity and so conducted a comparison with another fully automated urine analyser, which uses flow cytometry for sediment examination.

The number of urine samples which required additional manual microscopic examination was evaluated for each analyser. For the flow cytometry analyser, 18.6% of samples required additional microscopic examination compared to 1.7% for the Laura XL. This amounted to 577 ± 11.2 samples per work shift for the flow cytometry analyser, compared to just 5.1 ± 2.0 samples for the Laura XL ($p < 0.0001$).

The difference can be explained by one of the key features of the Laura XL. When pathological or atypical elements appear on the Laura XL screen, the operator can check the accuracy of the automatic identification and, if necessary, make changes.

Modern fully automated urine analysers, such as the Laura XL, make it possible to avoid many of the errors characteristic of visual and semi-automated examinations, since sampling, chemical and microscopic analysis, as well as the issuance of results occur automatically in compliance with specified criteria.

Manual Urinalysis

The urinalysis strategy recommended by the European Urinalysis Guidelines¹ is a two-step process:

Step 1: Visual examination and dipstick test

Step 2: If there is erythrocyturia, leukocyturia, bacteriuria or proteinuria, urine samples are subjected to further analysis by microscopy

As the dipstick test has poor sensitivity and negative predictive value, screening by this method alone carries the risk of missing infections and other diseases.²

Until recently, the most widely accepted urinalysis methodology was microscopic urine sediment analysis. There are different manual methods for urine sediment examination. Counting can be done in a standardised or a non-standardised way; counting can be done from a sample under a coverslip or in a chamber, and from centrifuged or uncentrifuged samples. Other potential variables in manual urine microscopy include the speed of centrifugation, the time of centrifugation, the amount of urine remaining in the tube for resuspension, and whether the urine is stained.³

Manual urine microscopy is both time- and labour-intensive, and requires specific expertise which may not be available at all times of day. Both manual dipstick testing and manual microscopy are also associated with extensive analytical errors.⁴

Over the past 25 years, technological advancement has led to the development of automatic urine sediment analysers for high-volume laboratories. The demand for automation was fuelled by concerns over standardisation, inaccuracy, and the time and labour needed for manual microscopy. Progress in computer technology and informatics now allows automated microscopy based on pattern recognition.

Main errors associated with manual and semi-automated urine dipstick testing

- At the moment the strip is being immersed into the urine reservoir, all reaction sections of the strip are simultaneously wetted. This often leads to cross-carry and distortion of results.
- Analysis on test strips determines the parameters of urine sediment (leukocytes, red blood cells, bacteria) indirectly, that is, not the cells themselves are determined, but biochemical parameters.
- Limitations specific to strip technologies.

Main errors associated with manual microscopy of urine sediment

- Lack of standardisation for all stages of analysis
- Lack of quality control methods
- Lack of reference ranges
- Lack of a reference method for urine microscopy to provide correct identification of particles and accurate quantification⁶
- Several steps in manual microscopy, such as centrifugation, decantation, and resuspension can lead to cellular lysis and loss⁷

1. European Urinalysis Guidelines Scand. J Clin. Lab. Investig. 2000;60(Suppl 231):S1–S86.

2. Laine P, Toivonen E, Eklund K, Hohenthal U, Siren S, Maki T. Rapid dipstick urinalysis in the internal medicine clinic: what is missed? J. Intern Med. 1997;242:271–273.

3. Demet Ince F et al. The comparison of automated urine analyzers with manual microscopic examination for urinalysis automated urine analyzers and manual urinalysis. Pract Lab Med. 2016; 5: 14–20.

4. Oyaert M & Delanghe J. Progress in Automated Urinalysis. Ann Lab Med. 2019; 39(1): 15–22.

Harness the power of fully automatic urinalysis

The Laura XL is a fully automated urine analyser, combining urine strip reading with digital microscopy. Launched in 2019, it forms part of Erba Mannheim's Vertex range of diagnostics, aimed at mid-sized to large laboratories.



EFFICIENT

125 – 160 tests/h



POWERFUL

Fully Automatic chemistry and sediment analysis



EASY TO USE

Simple user interface

Making Automation Affordable
for Labs Everywhere