İdrar analizlerinde kalite gereksinimleri ve değerlendirilmesi

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Yanıt bekleyen sorular

1. İdrar materyali diğer biyolojik sıvılardan **farklı mıdır**?
2. İdrar testlerinin **yeterlilik değerlendirmeleri hangi kriterlere** göre yapılacaktır?
    1. İdrar kimyasal ve mikroskobi analizleri
    2. Kromatografik idrar testleri
        1. İlaç analizleri
        2. Toksikoloji testleri
        3. Metabolik testleri
3. Kalite kontrol **uygulamaları, kuralları, sıklıkları** ve değerlendirme prosedürleri nasıl uygulanacaktır?
4. **Nasıl bir ürün istiyorsunuz, nasıl değerlendireceksiniz ve uygunsuz ürün ile karşılaştırıldığında neler yapacaksınız?**

Tıbbi Laboratuvarlarda KALİTE-
Total Kalite Yönetimi

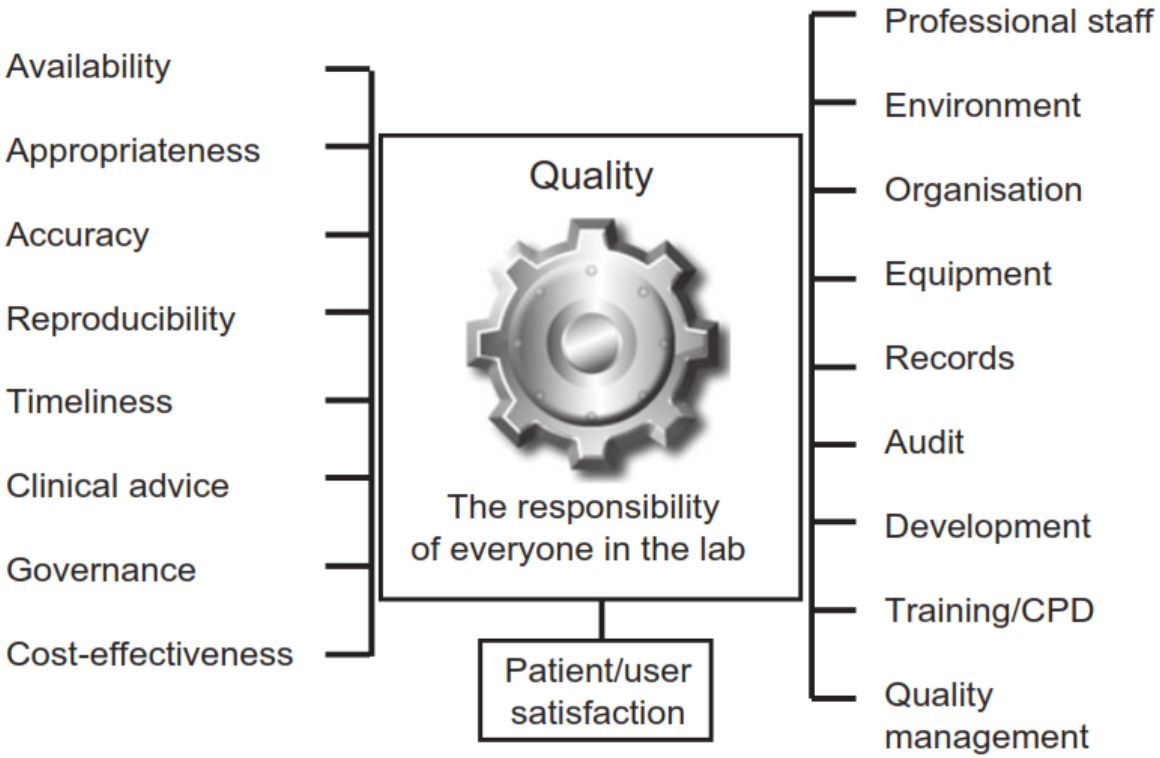
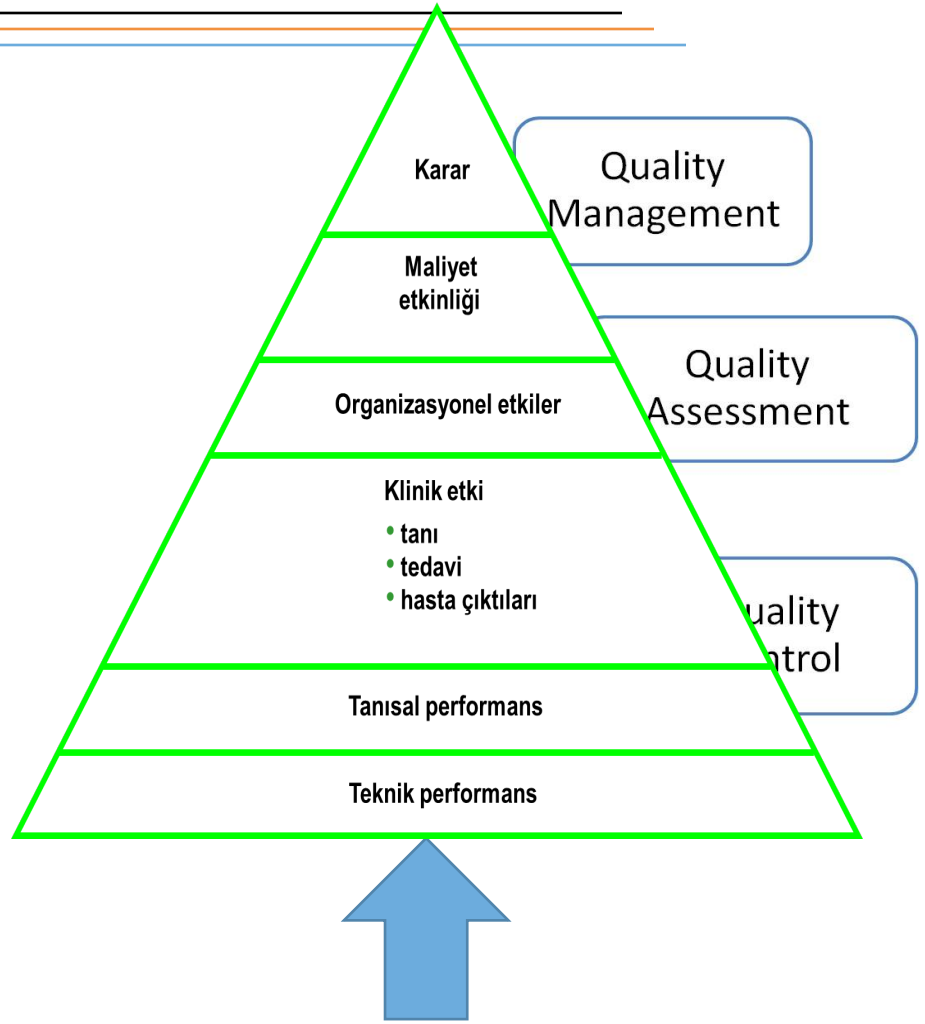


Figure 1 Assuring quality in laboratory medicine.



Clin Chem Lab Med 2013; 51(1): 221–227

ISO EN45001
ISO/IEC Guide 25, ISO 17025,
ISO EN 15189

İhtiyaç nedir?
Kalite gereksinimlerim nelerdir?

Rehberler

Evidence review

Automated urine screening systems

CEP10030

March 2010

CLINICAL AND LABORATORY STANDARDS INSTITUTE®

GP16-A3

Urinalysis; Approved Guideline—Thir

Susan King Strasinger

Marjorie Schaub Di Lorenzo

Urinalysis and Body Fluids

FIFTH EDITION

Diagnosis of UTI

Quick Reference Guide for Primary Care

Health Protection Agency

ARY SYMPTOMS IN ADULT WOMEN <65 DO NOT CULTURE ROUTINELY[1-5]

active young men and women with urinary symptoms consider *Chlamydia trachomatis*[C]

mptoms of UTI[4B+]
- Urgency
- Polyuria
- Haematuria

AND

NO vaginal discharge or irritation[2,5C]

90% culture positive

Give empirical antibiotic treatment

toms of UTI
ve)

Obtain urine specimen

Urine NOT cloudy 97% NPV[7-9B-]

Consider other diagnosis

Scand J Clin Lab Invest 2000; 60: 1–96

European Urinalysis Guidelines

SUMMARY

These **European Urinalysis Guidelines** are given under the auspices of the European Confederation of Laboratory Medicine (ECLM).

Medical needs for urinalysis

Classification of examiniations

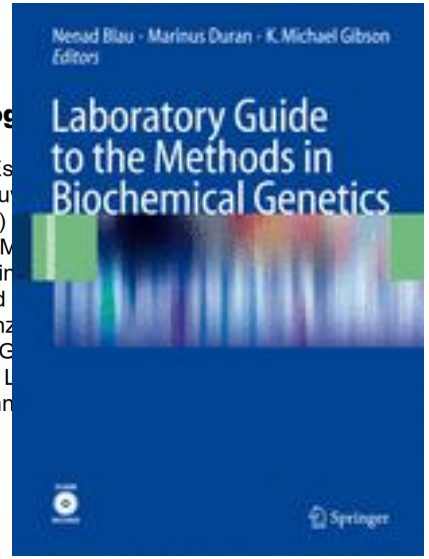
Examinations have been re-classified into four hierarchical levels based on accuracy of measurements (chemistry on Page 12, particle analysis on Page 23, microbiology on Page

uality Control

Guideline for quality control in forensic-toxicolog

Authors: L.D. Paul, Munich; F. Musshoff, Bonn; Subgroup "Es
the Scientific Committee Quality Control (B. Aebi, Bern; V. Au
Kraemer, Homburg; F.T. Peters, Jena; G. Skopp, Heidelberg)
M. Herbold, Heidelberg; G. Schmitt, Heidelberg; D. Thieme, M
Authors of the Guidelines that were replaced (see chapter Fir
Members of the Scientific Committee Quality Control chaired
Andresen, Hamburg; V. Auwaerter, Freiburg; J. Becker, Mainz
Briellmann, Basel; H.H. Bussemas, Dortmund; F. Erdmann, G
S. Kreutzberg, Berlin; G. Krueger, Berlin; F. Musshoff, Bonn; L
Jena; G. Schmitt, Heidelberg; G. Skopp, Heidelberg; S. Toenn
retired: L. Von Meyer, Munich).

Revision date: none – first version
Date: 1st of June 2009



Süreç tanımlanması, kayıt altına alınması

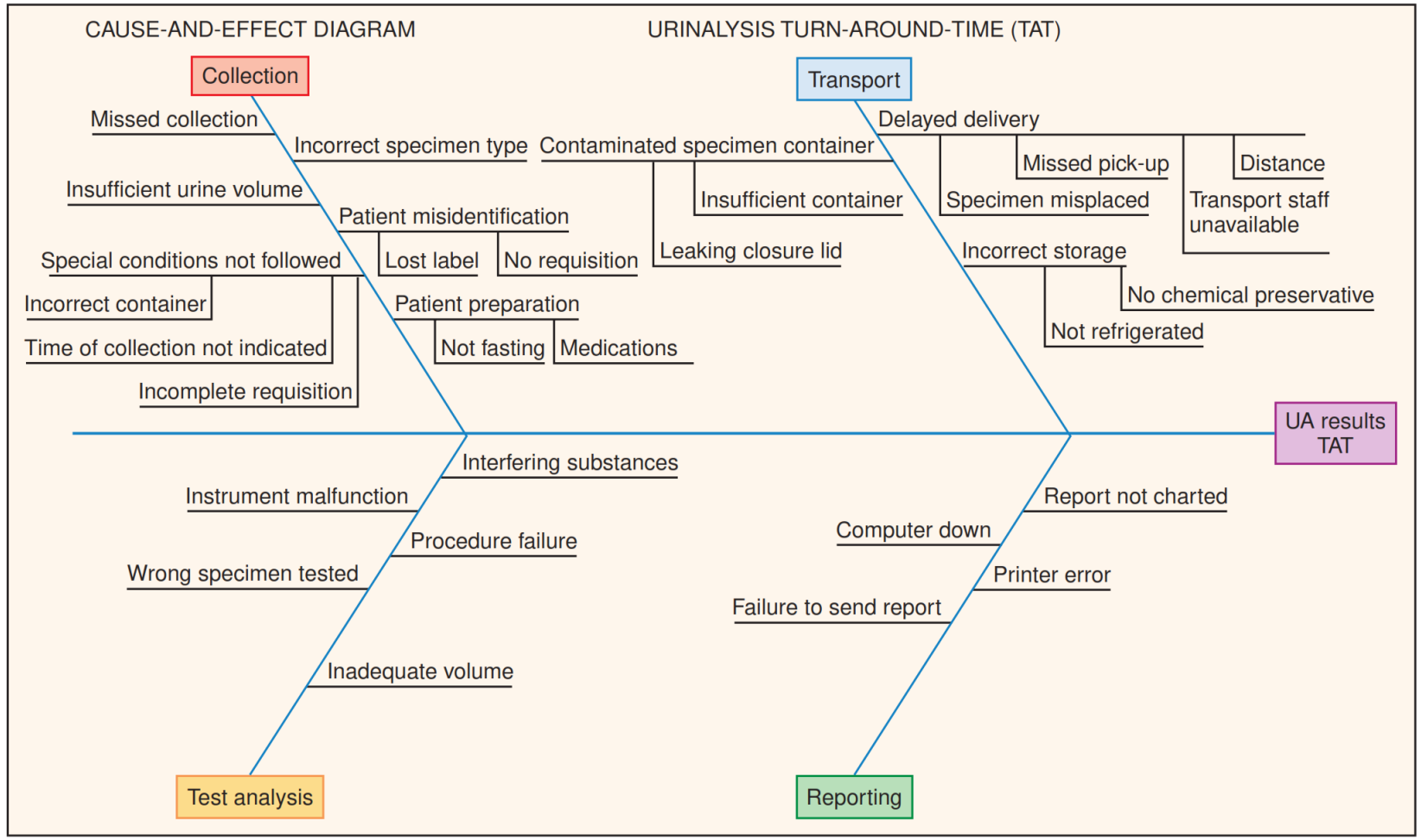


Figure 7–9 Cause-and-effect diagram for analyzing urinalysis TAT.

SUMMARY 1-1 Quality Assessment Errors

Preexamination

Patient misidentification
Wrong test ordered
Incorrect urine specimen type collected
Insufficient urine volume
Delayed transport of urine to the laboratory
Incorrect storage or preservation of urine

Examination

Sample misidentification
Erroneous instrument calibration
Reagent deterioration
Poor testing technique
Instrument malfunction
Interfering substances present
Misinterpretation of quality control data

Postexamination

Patient misidentification
Poor handwriting
Transcription error
Poor quality of instrument printer
Failure to send report
Failure to call critical values
Inability to identify interfering substances

2. MEDICAL NEEDS FOR URINALYSIS

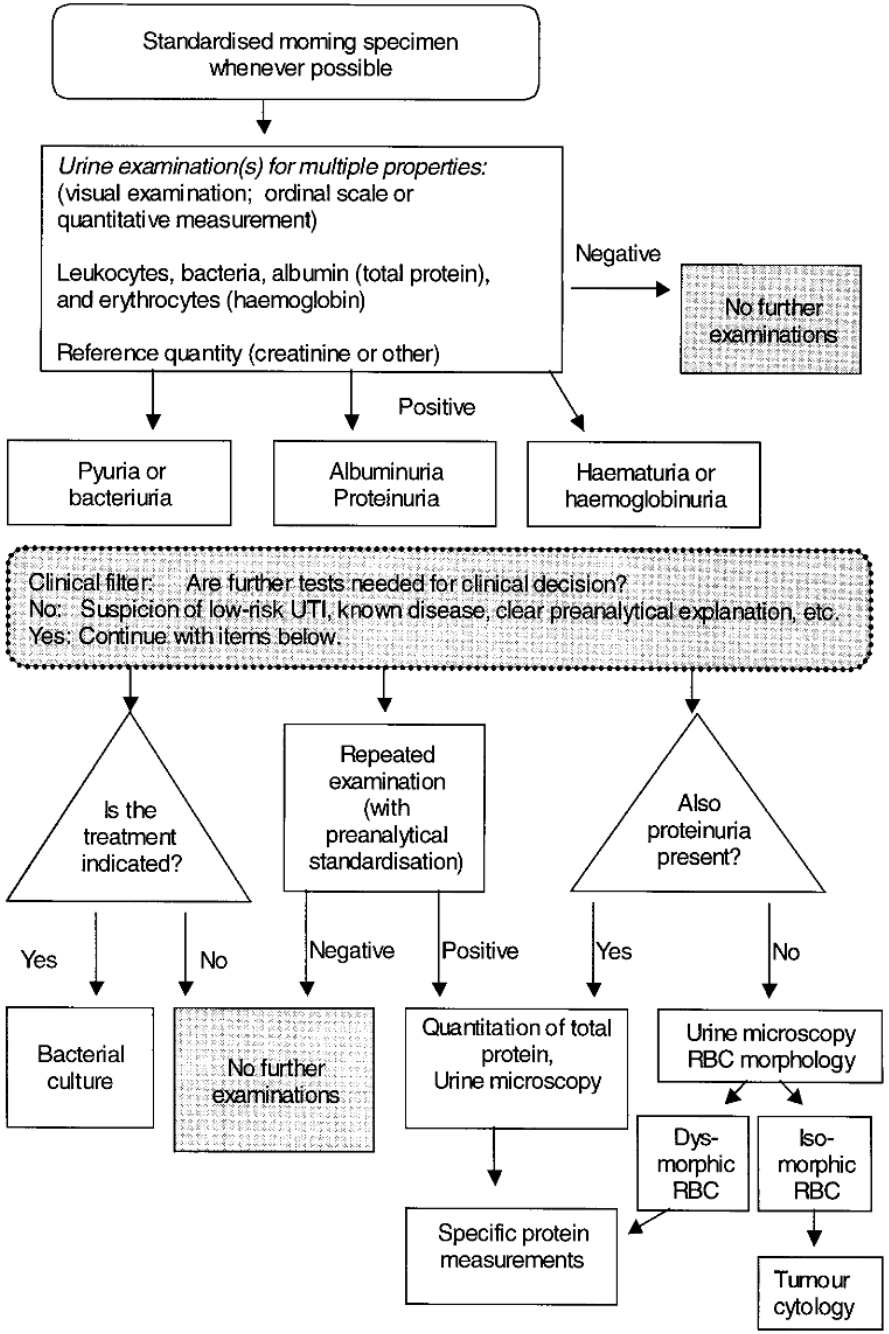
After a long history of clinical urinalysis there is a need to update the medical relevance of different investigations of urine. Cost/benefit analyses should guide the implementation of examinations for various populations. The always needs a paper or computerized request. The request reaching the laboratory may initiate a stepwise procedure agreed locally for a particular patient group. Such pre-determined strategies maximize diagnostic yield while maintaining cost-efficiency.

The importance of adequate clinical and specimen-related information for correct selec-

TABLE I. Medical indications for urinalysis.[a]

(1)	Suspicion or follow-up of symptoms or situations suggesting the possibility of urinary tract infection
(2)	Suspicion or follow-up of non-infectious renal disease, either primary or secondary to systemic diseases, such as rheumatic diseases, hypertension, toxaemia of pregnancy, or to the adverse effects of drugs
(3)	Suspicion or follow-up of non-infectious post-renal disease
(4)	Detection of glycosuria from specified patient groups, e.g., individuals admitted to hospital for various medical emergencies, or from pregnant women
(5)	Follow-up of only selected diabetes mellitus patients, e.g., children at home, to detect morning glycosuria and ketonuria in addition to blood glucose measurements
(6)	Detection or follow-up of selected metabolic states, e.g., vomiting and diarrhoea, acidosis/alkalosis, ketosis, or recurrent urinary stone formation

[a] If understood widely, urine quantities are measured in diagnostics of several endocrine, metabolic and inherited diseases, pregnancy, drugs of abuse, etc., most of which were not discussed in these guidelines which focus mainly on diseases of kidneys and urinary tract.



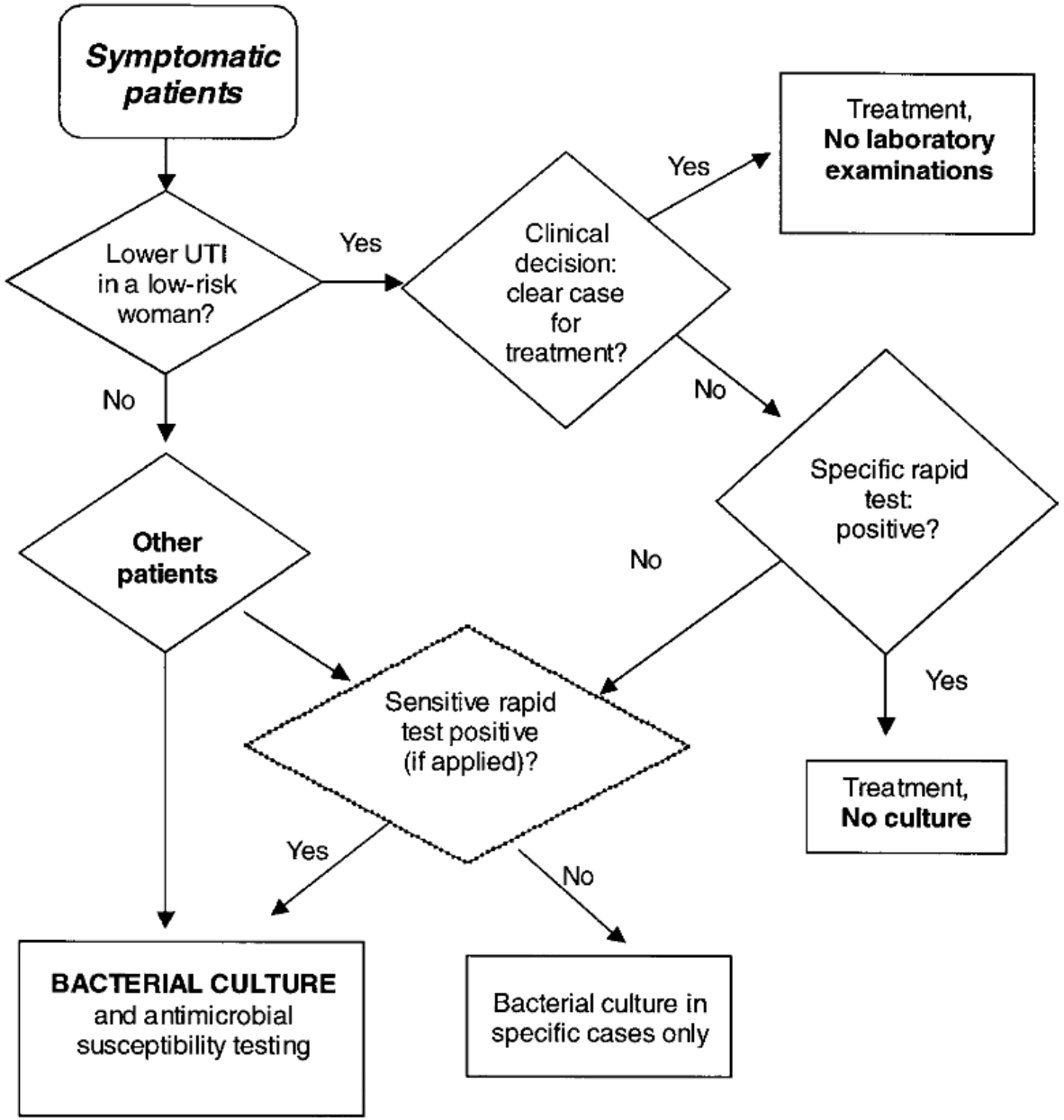


FIG. 3. A sieving strategy to reduce requests for bacterial cultures.

Standardizayon ve kalite

TABLE XXX. Summary of standardized urinary sediment examination.

Item	Standard	Method of checking
Delay	Investigate within 4 h from micturition (if stored at +4°C), or within 30 min at +20°C to allow evaluation of all cells; otherwise use preservatives after evaluation	Documented times of collection
Original volume of urine	5–12 mL	Line marked on the tube
Centrifugation	400 × *g* for 5 min, preferably at +4°C if delays occur	Check with the Supplier of the centrifuge
Removal of supernatant	Suction to a defined final concentration factor	Calibrate the final volume by weighing pooled urine (buffer solutions have a different surface tension)
Method of staining and microscopy	Phase-contrast microscopy, or staining + bright-field microscopy; polarized optics when needed; low and high-power magnification (×400)	Consult local supplier
Volume investigated under microscopic field	Define and calculate	Microscopic slide with a metric scale
List of reported components	Define the report format	These guidelines
Units of reporting	Particles/L (particles/400 × magnified high-power field)	Calculate the equivalence
Reproducible process	Written operating procedures	Training of personnel, blind peer reviews
Internal quality control	Training courses organized locally Double-check specimens weekly	Two independent investigations for the same specimen
External quality assessment	Participation in an EQA programme	Documents of results available
Calibration	Traceability of measured quantities	Evaluation against uncentrifuged specimens

Eur. J. Clin. Chem. Clin. Biochem.
Vol. 29, 1991, pp. 813–818

Personel: Bireyler arasında fark var mıdır?

The Reproducibility of Urinalysis Using Multiple Reagent Test Strips

All selected urine samples were examined twice by 3 "observers":

- an experienced laboratory technician (visual observation)
- a non-experienced laboratory-school student (visual observation)
- a spectrophotometric analyser, Urotron RL9 (Boehringer Mannheim, Almere, the Netherlands).

Tab. 1. Inter-observer agreement for the several pairs of observers, expressed as *Cohen*'s kappa for leukocyte esterase activity, nitrite, acidity (pH), protein, glucose, ketone bodies and blood.

Testpad	Observers		
	1 versus 2	1 versus 3	2 versus 3
Leukocyte esterase activity	0.74	0.57	0.70
Nitrite	0.91	0.98	0.95
pH	0.86	0.52	0.54
Protein	0.82	0.53	0.54
Glucose	0.62	0.46	0.34
Ketone bodies	0.92	0.37	0.36
Blood	0.83	0.72	0.58
Mean	0.81	0.59	0.59

1. Tecrübeli
2. Öğrenci
3. Fotometre

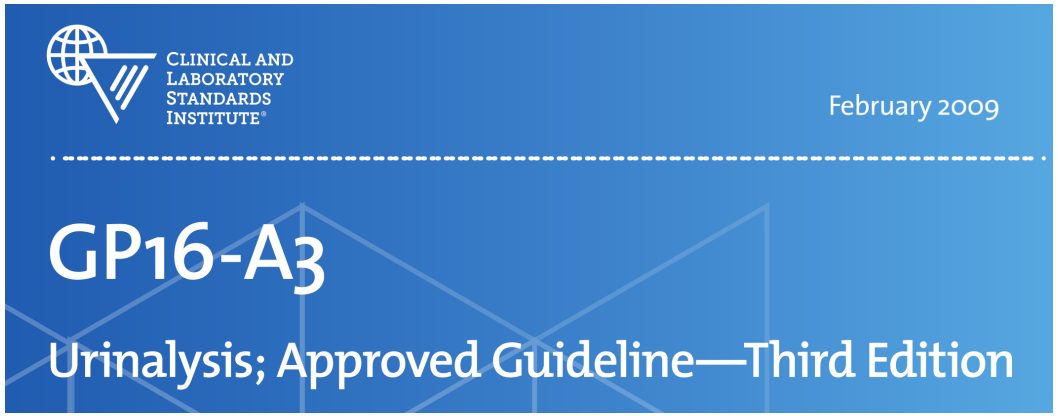
Short Report *Ann Clin Biochem* 2000; **37**: 220–221

Urine dipstick testing: comparison of results obtained by visual reading and with the Bayer CLINITEK 50

TABLE 1. *Number of differences for individual analytes when visual results are compared with CLINITEK 50 results (n = 208)*

	Protein	Blood	Glucose	Ketones
Number of differences	40 (19·2%)	25 (12·0%)	29 (13·9%)	46 (22·1%)
Direction of differences*	↑20:20↓	↑21:4↓	↑14:15↑	↑1:45↓

↓ = lower, ↑ = higher than machine reading.



11.5 Staff Competency

Morphologist qualification includes individual sediment microscopic identification against expected classification as a measure of trueness. A set of at least 50 photomicrographs is used to assess the ability of prospective examiners to correctly identify microscopic items found in the urine sediment. These photomicrographs can be obtained from in-house teaching collections, commercially available sets, or cases used in proficiency testing programs. To ensure objectivity of classification, cases should be chosen that have previously demonstrated high levels of consensus from large numbers of morphologists, rather than identification based on one person; such cases can be obtained from proficiency testing surveys, or archival material from proficiency-testing providers. Both normal and pathologic forms should be included, and a criterion established for competency (usually 80% to 90% correct identification).

Testin karakteri temel bilgidir

TABLE XXII. Detection principles and their limitations for multiple strips (modified from references 14 and 15).

Measurand	Measurement principle	False-negative results	False-positive results
Leukocytes (WBC)	Indoxyl esterase activity (granulocytes and macrophages; not present in lymphocytes)	Vitamin C (intake grams/day), protein > 5 g/L, glucose > 20 g/L, mucous specimen, cephalosporins, nitrofurantoin; mercuric salts, trypsin inhibitor, oxalate, 1% boric acid	Oxidizing detergents, formaldehyde (0.4 g/L), sodium azide, coloured urine (beet ingestion, bilirubinuria)
Bacteria (nitrate reductase positive)*	Nitrite detected with Griess's test (azo dye)	No vegetables in diet, short bladder incubation time, vitamin C, Gram-positive bacteria	Coloured urine, *in vitro* growth
Erythrocytes (RBC)	Pseudoperoxidase activity by the haem moiety of haemoglobin	High nitrite concentration, delayed examination, high density of urine, formaldehyde (0.5 g/L)	Microbial peroxidases, oxidizing detergents, hydrochloric acid
Albumin (protein)	Non-specific binding to indicator dye	Globulins, immunoglobulin light chains hardly detected; coloured urine	Alkaline urine (pH 9), quaternary ammonium detergents chlorhexidine, polyvinylpyrrolidone (blood substitute)
Glucose	Glucose oxidase and peroxidase	Vitamin C, urinary tract infection	Oxidizing detergents, hydrochloric acid
Ketone bodies (acetoacetate; acetone)	Nitroprusside reaction (Legal's test)	Improper storage, beta-hydroxybutyrate not detected	Free sulphhydryl groups (e.g. captopril) coloured urines, L-dopa
pH	Two indicator dyes giving a pH range between 5 and 9	Formaldehyde lowers pH	
Relative volumic mass (relative density; specific gravity)	Ionic solutes of urine react with poly-electrolytes on the strip	Falsely low: glucose, urea, alkaline urine	Falsely high: protein > 1 g/L, ketoacids
Creatinine	Oxidative reaction with copper complex	EDTA	Haemoglobin or myoglobin above 50 mg/L
Urobilinogen	Azo reaction with a diazonium salt; Ehrlich's aldehyde reaction	Formaldehyde (2 g/L), exposure to light	Sulphonamide and other drugs, coloured urine; porphobilinogen (Ehrlich)
Bilirubin	Azo reaction with a diazonium salt	Vitamin C, high nitrite concentration, exposure to light	Coloured urine, chlorpromazine metabolites
Ascorbic acid	Reduction reaction with an indole dye	Not known	Similar reducing agents

*Bacteria are detected on the basis of nitrate reductase present in most Gram-negative uropathogenic rods such as *E. coli* (Griess's test). Nitrate reductase is lacking from some common uropathogens, i.e. Gram-positive bacteria, such as *Staphylococcus saprophyticus* and *Enterococcus* spp.

Scand J Clin Lab Invest 2000; 60: 1–96

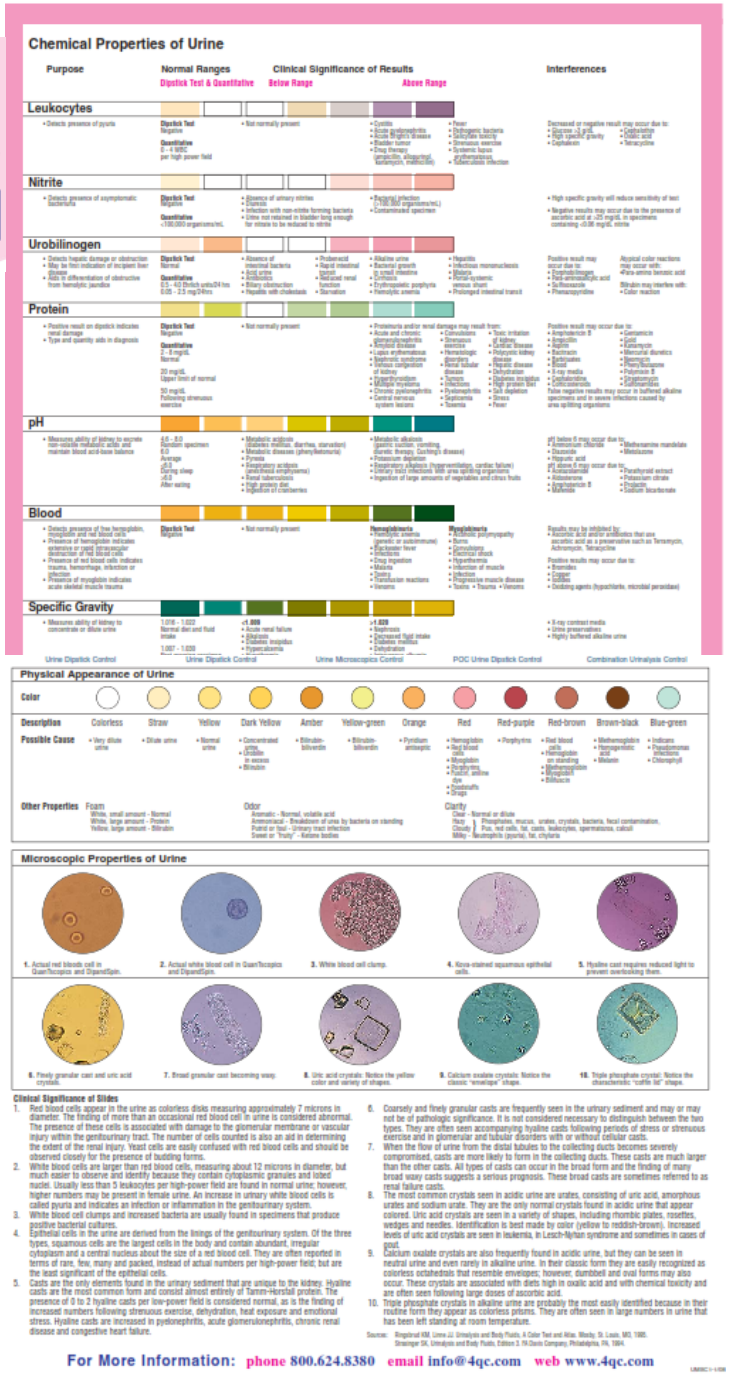
European Urinalysis Guidelines

Testin karakteri temel bilgidir

Örnek strip ile analiz

Chemical Properties of Urine

Purpose	Normal Ranges (Dipstick Test & Quantitative)	Clinical Significance of Results: Below Range	Clinical Significance of Results: Above Range	Interferences
Leukocytes • Detects presence of pyuria	**Dipstick Test** Negative **Quantitative** 0 - 4 WBC per high power field	• Not normally present	• Cystitis • Acute pyelonephritis • Acute Bright's disease • Bladder tumor • Drug therapy (ampicillin, allopurinol, kanamycin, methicillin) • Fever • Pathogenic bacteria • Salicylate toxicity • Strenuous exercise • Systemic lupus erythematosus • Tuberculosis infection	Decreased or negative result may occur due to: • Glucose >3 g/dL • High specific gravity • Cephalexin • Cephalothin • Oxalic acid • Tetracycline
Nitrite • Detects presence of asymptomatic bacteriuria	**Dipstick Test** Negative **Quantitative** <100,000 organisms/mL	• Absence of urinary nitrites • Diuresis • Infection with non-nitrite forming bacteria • Urine not retained in bladder long enough for nitrate to be reduced to nitrite	• Bacterial infection (>100,000 organisms/mL) • Contaminated specimen	• High specific gravity will reduce sensitivity of test • Negative results may occur due to the presence of ascorbic acid at >25 mg/dL in specimens containing <0.06 mg/dL nitrite
Urobilinogen • Detects hepatic damage or obstruction • May be first indication of incipient liver disease • Aids in differentiation of obstructive from hemolytic jaundice	**Dipstick Test** Normal **Quantitative** 0.5 - 4.0 Ehrlich units/24 hrs 0.05 - 2.5 mg/24hrs	• Absence of intestinal bacteria • Acid urine • Antibiotics • Biliary obstruction • Hepatitis with cholestasis • Probenecid • Rapid intestinal transit • Reduced renal function • Starvation	• Alkaline urine • Bacterial growth in small intestine • Cirrhosis • Erythropoietic porphyria • Hemolytic anemia • Hepatitis • Infectious mononucleosis • Malaria • Portal-systemic venous shunt • Prolonged intestinal transit	Positive result may occur due to: • Porphobilinogen • Para-aminosalicylic acid • Sulfisoxazole • Phenazopyridine Atypical color reactions may occur with: •Para-amino benzoic acid Bilirubin may interfere with: • Color reaction
Protein • Positive result on dipstick indicates renal damage • Type and quantity aids in diagnosis	**Dipstick Test** Negative **Quantitative** 2 - 8 mg/dL Normal 20 mg/dL Upper limit of normal 50 mg/dL Following strenuous exercise	• Not normally present	• Proteinuria and/or renal damage may result from: • Acute and chronic glomerulonephritis • Amyloid disease • Lupus erythematosus • Nephrotic syndrome • Venous congestion of kidney • Hyperthyroidism • Multiple myeloma • Chronic pyelonephritis • Central nervous system lesions • Convulsions • Strenuous exercise • Hematologic disorders • Renal tubular disease • Tumors • Infections • Pyelonephritis • Septicemia • Toxemia • Toxic irritation of kidney • Cardiac disease • Polycystic kidney disease • Hepatic disease • Dehydration • Diabetes insipidus • High protein diet • Salt depletion • Stress • Fever	Positive result may occur due to: • Amphotericin B • Ampicillin • Aspirin • Bacitracin • Barbituates • Blood • X-ray media • Cephaloridine • Corticosteroids • Gentamicin • Gold • Kanamycin • Mercurial diuretics • Neomycin • Phenylbutazone • Polymixin B • Streptomycin • Sulfonamides False negative results may occur in buffered alkaline specimens and in severe infections caused by urea splitting organisms



Çoklu test striplerinin saptama sınırları

TABLE XXV. Suggested detection and confirmation limits for multiple test strips.

Property	Comparison method	Detection limit (L_D)	Confirmation limit (L_C)
Leukocytes ($\times 10^6$/L)	Chamber counting[a]	20	100
Erythrocytes ($\times 10^6$/L)	Chamber counting[a]	10	50
Albumin (protein) (g/L)	Immunochemical (or dye binding for total protein)	0.1 (alb), 0.2 (prot)	0.5 (alb), 1 (prot)
Nitrite (mg/L)	Weighing out dry sodium nitrite; applicable comparison method	0.5	2.5
Glucose (mmol/L)	Quantitative method (glucose dehydrogenase or hexokinase method)	3	15
Ketones (acetoacetate; mmol/L)	Weighing out Li acetoacetate	1	5
pH	pH meter (potentiometry)	±1 unit[b]	N/A[b]
Relative volumic mass	Refractometry	±0.005[b]	N/A[b]
Creatinine (mmol/L)	Enzymatic; (kinetic Jaffé no more recommended)	±4[d]	N/A[b]
Urobilinogen (µmol/L)	Not commonly available	20[c]	100[c]
Bilirubin (µmol/L)	Bilirubin solution	10	50

[a] Microscopic chamber counting of fresh (less than 2 h) uncentrifuged specimens.
[b] N/A = detection and confirmation limits not applicable; an arbitrary class width is given.
[c] Commonly available comparison methods are lacking. Manufacturers should document their evaluation.
[d] Manufacturer reports an arbitrary scale of 0.9, 4.4, 8.8, 17.7 and 26.5 mmol/L.

TABLE XXVI. Analytical quality specifications suggested for sensitive albumin (rapid) examinations.

Property	Comparison method	Detection limit (L_D)	Confirmation limit (L_C)
Albumin (sensitive; mg/L)	Immunochemical	10	50
Albumin (sensitive): Creatinine ratio (g/mol)	Immunochemical, ratio to quantitative creatinine method	3	15

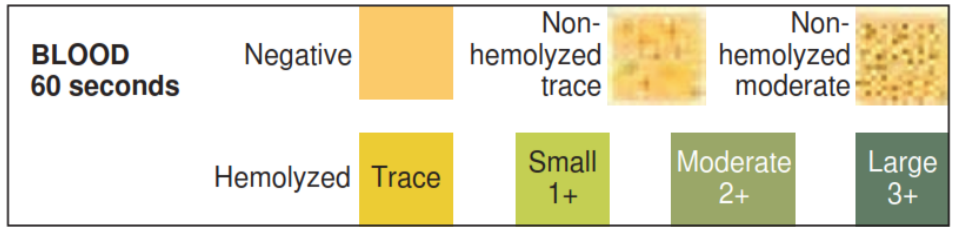
Scand J Clin Lab Invest 2000; 60: 1–96

European Urinalysis Guidelines

Stripler birbirinden farklı olabilir

Hemoglobin reaction:

$$H_2O_2 + \text{chromogen} \xrightarrow[\text{peroxide}]{\text{hemoglobin}} \text{oxidized chromogen} + H_2O_2$$



100 testi 6-18 $ (20-65 TL birim test 0.2-0.65 TL) (okuyucu hariç)

İdrar analizleri otomatize sistemlerde yaklaşık 3 TL
İdrar analiz ihalesinin %10-30 u strip den kaynaklanır

SUT

Strip ile	**1.20 TL**
Strip ve Mikroskopisi	**5 TL**

Table 4-5 Hemoglobin Chromogens and Sensitivities by Reagent Strip

BRAND AND SENSITIVITY	OXIDANT; CHROMOGEN
AimStick[9] (5 RBCs; 0.3 mg/dL Hb)	Diisoproplbenzene Dihydroperoxide; tetramethylbenzidine
Chemistrip[5] (5 RBCs; Hb ~ 10 RBCs)	2,5-Dimethylhexane-2,5-dihydroperoxide; tetramethylbenzidine
Combi-Screen PLUS[10] (5 Ery/*u*L)	Tetramethylbenzidine-dihydrochloride Isopropylbenzol-hydroperoxide
DiaScreen[11] (5 RBCs; 0.02 mg/dL Hb)	2,5-Dimethylhexane-2,5-dihydroperoxide; tetramethylbenzidine
Dirui H-Series[12] (5–15 Ery/*u*L)	Diisoproplbenzene Dihydroperoxide; tetramethylbenzidine
Mission[13] (0.018–0.060 mg/dL)	Diisoproplbenzene Dihydroperoxide; tetramethylbenzidine
Multistix[2] (5 RBCs; 0.015 mg/dL Hb)	Diisoproplbenzene Dihydroperoxide; tetramethylbenzidine
Self-Stik[14] (5–10 RBCs/mL urine)	Cumene hydroperoxide *O*-Tolidine
URiSCAN[15] (5 RBC/*u*L or 3–5 RBC/HPF; 0.015 mg/dL hemoglobin)	Cumene hydroperoxide Tetramethylbenzidine
Uritest 13G[16] (0.3–0.6 mg/L hemoglobin)	Cumene hydroperoxide 3,3′,5,5′-Tetramethylbenzidine
Uro-dip 10C[17] (0.05 mg/dL hemoglobin)	Cumene hydroperoxide Tetramethylbenzidine
URS[18] (0.015 mg/dL Hb or 5–10 intact RBCs/*u*L)	Cumene hydroperoxide Tetramethylbenzidine

Table 6. Calculated costs per test

	Manual microscopy	Automated microscopy (range)
MLA minutes / test	0	0.2 – 0.4
BMS minutes / test [2]	2.7 [11]	0.05
Purchase cost	£ 4,300 (est.)	£ 31,000 – 58,000
Annual service charge	£ 650 (est.)	£ 4,500 – 7,000
Consumables / test	£ 0.14[3]	£ 0.30 – 0.31
Resultant total cost / test (using above equation) N = 100 samples /day	£ 1.37	£ 0.60 – 0.80
Cost / test, N = 200	£ 1.37	£ 0.48 – 0.60
Cost / test, N = 400	£ 1.37	£ 0.42 – 0.50
Cost / test, N = 600	£ 1.37	£ 0.40 – 0.47

[2] Automated figure is estimated average, based on 15% expert review rate, 20 seconds per review
[3] Private communication, Royal Gwent Hospital

Genel standartlar- IKK- Sıklık

Item	Standard	Method of checking
Identification of specimen	Label the specimen	Compare label with the working list if analysing several specimens at once
Homogeneous specimen	Mix immediately before dipping	Even colour
Temperature of the specimen	+20°C	Allow to stand for 15–30 min before analysis
Quality of strips	Date still acceptable	Expiration date
Environment	Sufficient light	Artificial light is an adequate substitute for daylight to allow easy reading
	Calm space for working	Allow no other activity during the procedure
Dipping	Follow manufacturer's guidance	Observation by trainer
Timing	Use a timer showing seconds	Not possible afterwards
Reading	Compare with the colours on the packing vial	Train before actual patient analysis
Internal quality control	Control solutions measured daily if analysis is done daily	Follow-up charts maintained
External quality control	Participation expected, organized with local supporting laboratory	Reports available
Storage of strips	No physical problems associated with storage	Outlook of the strips (bent, wet, etc.), closed vials
Reporting	Use the predefined units. Fill in the patient record or working list immediately	Train before actual patient analysis

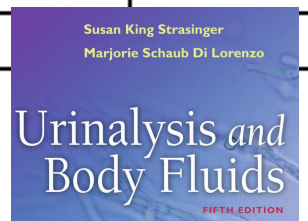
Scand J Clin Lab Invest 2000; 60: 1–96

European Urinalysis Guidelines

Quality Control

1. Test open bottles of reagent strips with known positive and negative controls every 24 hr.
2. Resolve control results that are out of range by further testing.
3. Test reagents used in backup tests with positive and negative controls.
4. Perform positive and negative controls on new reagents and newly opened bottles of reagent strips.
5. Record all control results and reagent lot numbers.

TEST	POSITIVE CONTROL	NEGAVTIVE CONTROL
Gluc	100mg/dL-250mg/dL	Negative
Ket	≥ Trace	Negative
Blo	Moderate-Large	Negative
pH	≥ 8.0	6.0-7.0
Prot	Trace-100mg/dL	Negative
Nit	Positive	Negative
Leu	Trace-Moderate	Negative



Summary of Reagent Strip Testing

Care of Reagent Strips

1. Store with desiccant in an opaque, tightly closed container.
2. Store below 30°C; do not freeze.
3. Do not expose to volatile fumes.
4. Do not use past the expiration date.
5. Do not use if chemical pads become discolored.
6. Remove strips immediately prior to use.

Technique

1. Mix specimen well.
2. Let refrigerated specimens warm to room temperature before testing.
3. Dip the strip completely, but briefly, into specimen.
4. Remove excess urine by withdrawing the strip against the rim of the container and by blotting the edge of the strip.
5. Compare reaction colors with the manufacturer's chart under a good light source at the specified time.
6. Perform backup tests when indicated.
7. Be alert for the presence of interfering substances.
8. Understand the principles and significance of the test, read package inserts.
9. Relate chemical findings to each other and to the physical and microscopic urinalysis results.

Quality Control

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5. Record all control results and reagent lot numbers.

Specific Gravity: This test is based on the apparent pKa change of certain pretreated polyelectrolytes in relation to the ionic concentration. In the presence of an indicator, the colors range from dark blue or blue-green in urine of low ionic concentration to green and yellow-green in urine of higher ionic concentration.

Blood: This test is based on the pseudoperoxidase action of hemoglobin and erythrocytes which catalyzes the reaction of 3,3', 5, 5'-tetramethyl-benzidine and buffered organic peroxide. The resulting colors range from orange to yellow-green and dark green. Very high blood concentration may cause the color development to continue to dark blue.

pH: This test is based on the well known double pH indicator method, where bromothymol blue and methyl red give distinguishable colors over the pH range of 5-9. The colors range from red-orange to yellow and yellow-green to blue-green.

Protein: This test is based on the protein error-of-indicator principle. At a constant pH, the development of any green color is due to the presence of protein. Colors range from yellow for a "Negative" reaction to yellow-green and green to blue-green for a "Positive" reaction.

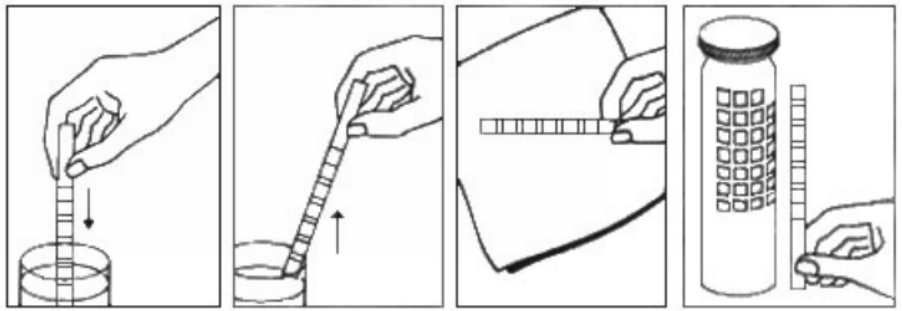
Urobilinogen: This test is based on a modified Ehrlich reaction in which *p*-diethylaminobenzaldehyde reacts with urobilinogen in a strongly acid medium. Colors range from light pink to bright magenta.

Nitrite: This test depends on the conversion of nitrate to nitrite by the action of Gram-negative bacteria in the urine. The nitrite reacts with *p*-arsanilic acid to from a diazonium compound in an acid medium. The diazonium compound in turn couples with 1,2,3,4-tetrahydrobenzo(h) quinolin to produce a pink color.

Leukocytes: This test is based on the action of esterase present in leukocytes, which catalyzes the hydrolysis of an indoxyl ester derivative. The indoxyl ester liberated reacts with a diazonium salt to produce a beige-pink to purple color.

TEST PROCEDURE

1. Remove from the bottle only enough strips for immediate use and replace cap tightly.
2. Completely immerse reagent areas of the strip in fresh, well-mixed urine. Remove the strip immediately to avoid dissolving out the reagent areas.
3. While removing, touch the side of the strip against the rim of the urine container to remove excess urine. Blot the lengthwise edge of the strip on an absorbent paper towel to further remove excess urine and avoid running over (contamination from adjacent reagent pads.)
4. Compare each reagent area to its corresponding color blocks on the color chart and read at the times specified. Proper read time is critical for optimal results.
5. Obtain results by direct color chart comparison.



Note: All reagent areas except Leukocytes may be read between 1-2 minutes for screening positive urine from negative urine. Changes in color after 2 minutes are of no diagnostic value.

QUALITY CONTROL

For best results, performance of reagent strips should be confirmed by testing known negative and positive specimens or controls whenever a new bottle is first opened. Each laboratory should establish its own goals for adequate standards of performance, and should question handling and testing procedures if these standards are not met.

Chemistry QC Statistics Report

2016-11-20 12:16 - 2016-11-30 11:16

GAZI UNIVERSITESI HASTANESI
IDRAR LABORATUARI

Control Identifier: CA
Report Time Stamp: 2016-12-01 11:23:04
Lot ID: CA
Expiration: 2017-02-28

CA Chemistry QC Results Table

Index	Date/Time	Operator	Dipstick ID	Status	BLD	BIL	URO	KET	GLU	PRO	NIT	LEU	PH	SG
1	2016-11-22 12:56:54	idrar	Iris	Pass	Eser	Negatif	Normal	Negatif	++++	+	Negatif	Negatif	9.0	1007

++++

Control Identifier: CB
Report Time Stamp: 2016-12-01 11:22:55
Lot ID: CB
Expiration: 2017-02-28

CB Chemistry QC Results Table

Index	Date/Time	Operator	Dipstick ID	Status	BLD	BIL	URO	KET	GLU	PRO	NIT	LEU	PH	SG	ASA
1	2016-11-22 12:57:08	idrar	Iris	Pass	Eser	Negatif	+	++	Normal	Negatif	Pozitif	+++	5.0	1012	Negatif

+++

Control Identifier: CC
Report Time Stamp: 2016-12-01 11:22:44
Lot ID: CC
Expiration: 2017-02-28

CC Chemistry QC Results Table

Index	Date/Time	Operator	Dipstick ID	Status	ASA
1	2016-11-22 12:57:23	idrar	Iris	Pass	++

Kalite kontrol sürecinin kayıt altına alınması

QUALITY CONTROL Month:_____20_____

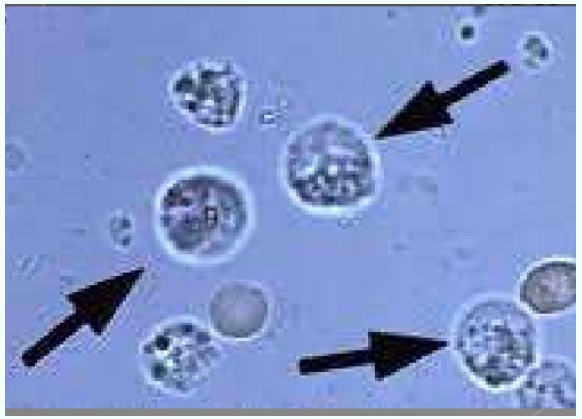
			Positive control									Negative control								
			GLU	BIL	KET	SP GR	BLD	PH	PROT	NIT	LEU EST	GLU	BIL	KET	SP GR	BLD	PH	PROT	NIT	LEU EST
			mg/dl		mg/dl	1.0			mg/dl			mg/dl		mg/dl	1.0			mg/dl		
Control values																				
Reagent	TECH	DATE																		
Lot #																				
EXP																				

Microscopy QC Statistics Report

2016-11-20 12:16 - 2016-11-30 11:16

GAZI UNIVERSITESI HASTANESI
IDRAR LABORATUARI

Mean Value:	1.25
Standard Deviation:	0.71
Coefficient of Variation:	56.57%
Minimum:	0
Maximum:	2
Target Value:	0

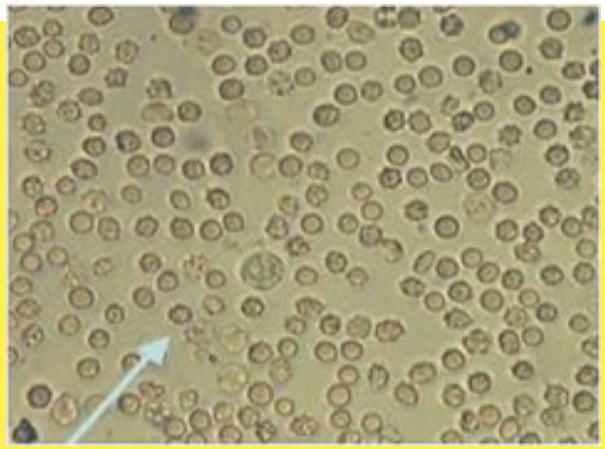


QC Results Table

Index	Date/Time	Operator	Count Result	Status	REF
8	2016-11-30 08:07:41	idrar	1	Pass	1.941
7	2016-11-29 07:30:10	idrar	2	Pass	1.941
6	2016-11-28 07:39:46	idrar	1	Pass	1.941
5	2016-11-25 07:26:32	idrar	0	Pass	1.941
4	2016-11-24 07:43:55	idrar	1	Pass	1.941

Microscopy QC Statistics Report

Mean Value:	1154.00
Standard Deviation:	36.65
Coefficient of Variation:	3.18%
Minimum:	1090
Maximum:	1210
Target Value:	1028
Upper Limit:	1234
Lower Limit:	822



Index	Date/Time	Operator	Count Result	Status	REF
8	2016-11-30 08:07:04	idrar	1152	Pass	1.941
7	2016-11-29 07:29:33	idrar	1210	Pass	1.941
6	2016-11-28 07:39:10	idrar	1193	Pass	1.941
5	2016-11-25 07:25:56	idrar	1160	Pass	1.941
4	2016-11-24 07:43:20	idrar	1153	Pass	1.941

Kalite kontrol materyalleri

Product Data Sheet

UA-Cellular™ for IQ
Cellular Urine Control for Iris iQ®

UA-Cellular™ for IQ is Streck's microscopy urinalysis control designed specifically for the Iris Diagnostics iQ® automated urine analysers.

Instrumentation controls should represent the same proceedural processes and reflect similar values to those expected by patient samples. UA-Cellular for IQ is a unique product that contains components at two clinically significant levels. The product evaluates the iQ instrument's ability to identify and quantify white blood cells, red blood cells, non-squamous epithelial cells and crystals.

The product is contained in convenient 120ml squeeze bottles with a flip top cap dispenser that accurately allots the exact amount of control needed into sample tubes without waste.

Stability for UA-Cellular for IQ
Store 2 - 10 C
Closed-vial stability - 105 days
Open-vial stability - 30 days

UA-Cellular for IQ is a true cellular control for the Iris iQ urine analysers, ensuring that enumeration of WBC, RBC and epithelial cells are accurate for patient samples.

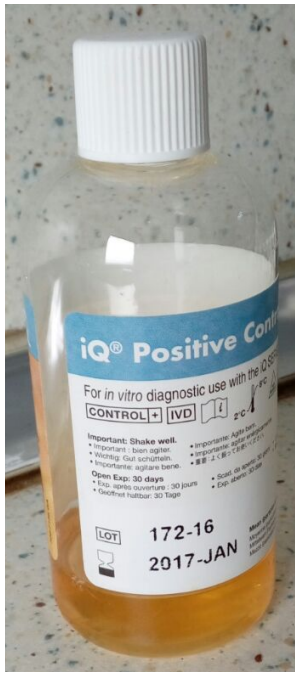
Typical RBC, WBC and non-squamous epithelial (NSE) levels for UA-Cellular for IQ

	WBC	RBC	NSE
Level 1	30-60 cells/µl	30-60 cells/µl	10-30 cells/µl
Level 2	180-240 cells/µl	180-240 cells/µl	60-120 cells/µl

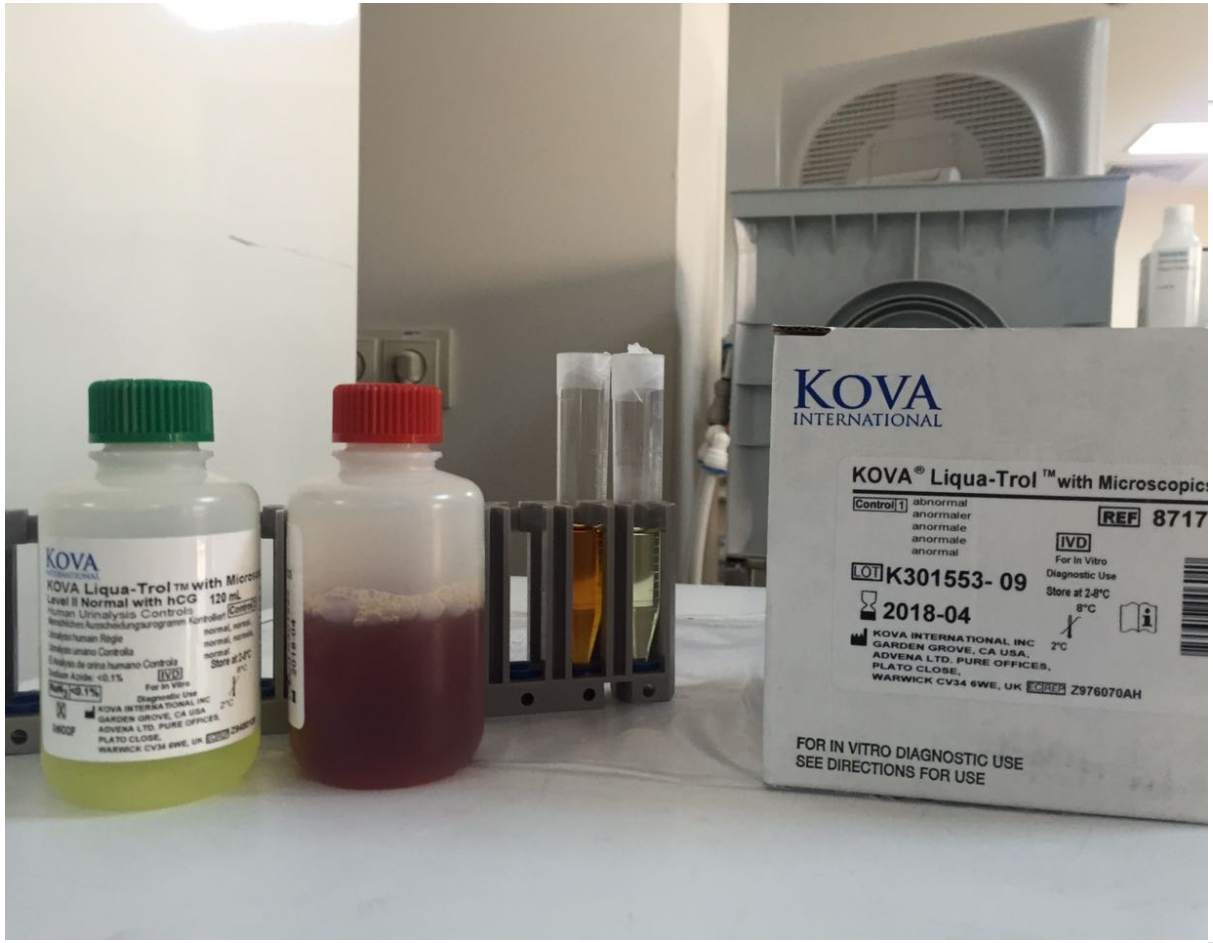
*Level 2 contains crystals

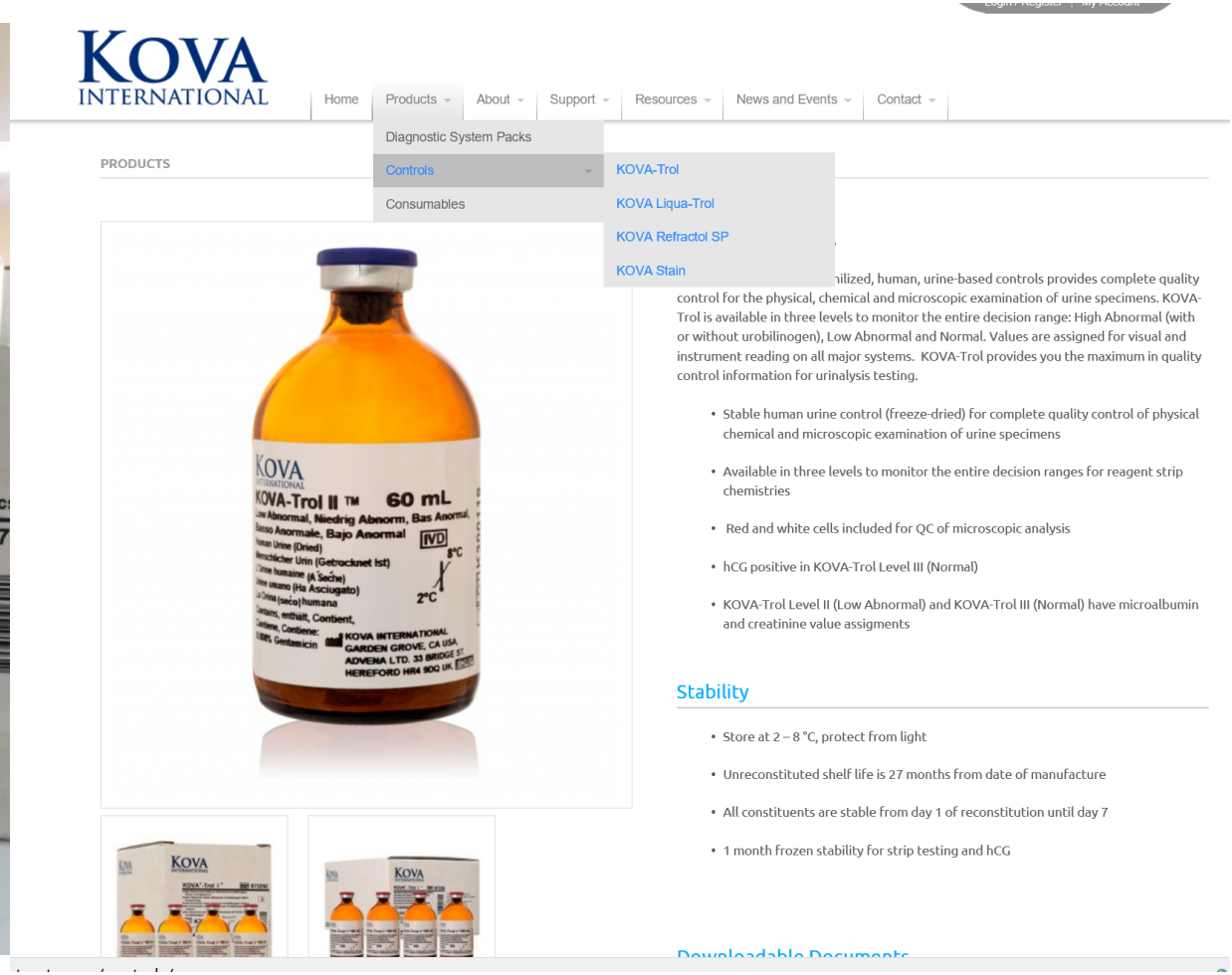
Cat. No.	Description	Size
213396	Levels 1 & 2	2 x 120ml

alphalaboratories www.alphalabs.co.uk Streck



Kalite kontrol materyali

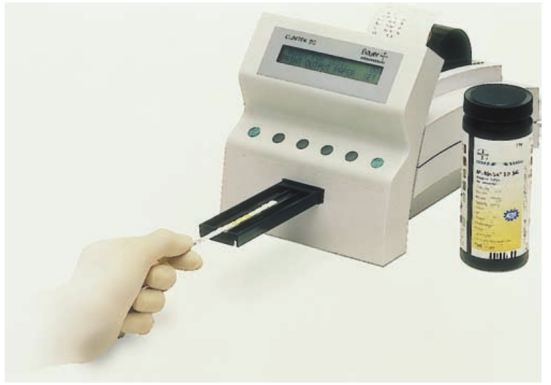




Otomatize idrar analizi

Table A–1 Urinalysis Automation

Equipment	Manufacturer
Waived Urine Chemistry Instruments	
Clinitek 50	Siemens Medical Solutions Diagnostics
Clinitek Status	Siemens Medical Solutions Diagnostics
Chemstrip 101	Roche Diagnostics
Ursys 1100 system	Roche Diagnostics
Semiautomated Chemistry Instruments	
Clinitek 200/200+	Siemens Medical Solutions Diagnostics
Clinitek 500	Siemens Medical Solutions Diagnostics
Chemstrip Criterion II	Roche Diagnostics
Chemstrip Urine Analyzer	Roche Diagnostics
Urisys 1800 system	Roche Diagnostics
Miditron Junior II	Roche Diagnostics
Fully Automated Chemistry Instruments	
Clinitek Atlas	Siemens Medical Solutions Diagnostics
Chemstrip Super Automated Urine Analyzer	Roche Diagnostics
Urisys 2400 system	Roche Diagnostics
Automated Microscopy	
UF-100 Urine Cell Analyzer	Sysmex
iQ200 Automated Urine Microscopy	Iris Diagnostics Division
Urine Analyzer (iQ200 Sprint)	
Automated Urinalysis Systems	
ADVIA Urinalysis WorkCell	Siemens Medical Solutions Diagnostics
iQ200 Automated Urinalysis System	Iris Diagnostics Division



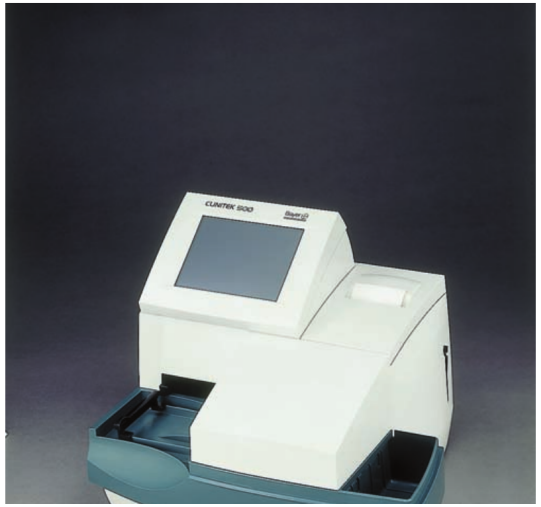


Figure A–3
Analyzer. (C
Tarrytown, I

–4 UF-100 Automated Urine Cell Analyzer. (Cour-
Sysmex, Mundelein, Ill.)

Example: 10 mL of urine is concentrated into 0.5 mL = 20-fold concentration; 0.05 mL stain is added. Then 13 µL is applied under a 18 × 18 mm coverslip. Thus the fluid layer = 13/(18 × 18) = 0.040 mm thick. If it is investigated under 10 × 40 magnification with ocular viewfield number 22 (diameter of the viewfield = 22 mm/40 = 0.55 mm), the volume of a high-power field (HPF) is then:

$$0.040 \times \pi \times (0.55/2)^2 = 0.00950 \text{ mm}^3 \text{ or } \mu\text{L}$$

Because of the 20-fold concentration and 10% dilution because of the dye, one HPF corresponds to 0.173 µL of original urine volume.

In this case, n RBC/HPF correspond to n RBC/0.173 µL = 5.8 × n RBC × 10^6/L.

E.g. 4 RBC/HPF equals to 23 RBC × 10^6/L.

For example, using 15 mL of urine:

- Diameter of the high-power field = 0.35 mm.
- Area of the high-power field = 0.096 mm^2.
- Area under the cover slip = 484 mm^2.
- $\frac{484}{0.096} = 5040 \frac{High\text{-}Power\ Fields}{Under\ Cover\ Slip}$
- Measure 0.020 mL of sediment onto the slide ≈ 1.2 mL urine.
- 5040 high-power fields ≈ 1.2 mL urine ≈ 4000 high-power fields/mL.

Therefore:

(Count/High-Power Field) • 4000 = *Count/mL.*

Reference / device	WBC	RBC	Bacteria	Cut off value
Kaneko [21] UF-100		0.61		Not stated
Dimech [31] UF-100	0.886	0.71		20 wbc, rbc / µl
Roggeman [35] UF-100	0.82	0.58		20 wbc, rbc / µl
Okada 2000 [37] UF-50			0.831	>5 wbc / ml and scatter >12 units
Hannemann-Pohl [38] UF-100	0.905	0.637		> 20 wbc, rbc /µl
Kouri [13] UF-100	0.94	0.82	0.55	>20 wbc, >10 rbc,>600 bact /µl

Sample volume	2 ml	4 ml (1 ml in manual mode)	0.2 ml

Automated urinalysis in the clinical lab

	Minimum Sample Volume (mL)	Analytical Volume (mcL)	Approximate Cost	Throughput (samples / hour)	Percent Flagged for Manual Review	Particles Quantified (flagged)
Sysmex UF-100[6]	4 1 by manual mode	800	Discontinued	86	31-33	—
Sysmex UF-1000i[18]	4 1 by manual mode	800	$125,000[a]	100	49	RBC, WBC, EC, casts[b], bacteria (pathological casts, crystals, small round cells, sperm, yeast, mucus)
Iris iQ200[6]	3	2	Contact company	Options available: up to 101 samples per hour	<4[c]	RBC, WBC, WBC clumps, casts[b], bacteria, yeast, crystals, mucus, sperm, EC[d]
SediMAX[8,12,17]	2	200	No response to request	80	22-25[e] 47[f]	RBC, WBC, bacteria, yeast, crystals[g], EC, casts[h], small round cells, mucus, sperm
Manual Microscopy	12	One drop	$5,000 / scope	~10 / FTE	—	RBC, WBC, EC[d], crystals[g], casts[h], bacteria, yeast, parasites, contaminants

Table 3. Technical specifications reported for automated urine sediment analyzers

[a] CLINITEK Atlas® Automated Urine Chemistry Analyzer and the Sysmex UF-1000i™ Urine Cell Analyzer from Siemens, 2012 list price
[b] hyaline and unclassified
[c] flagged by instrument, review and revision required an average of one minute, 50% required revision
[d] squamous and nonsquamous
[e] flagged due to discordant results with chemical strip test
[f] samples reclassified when WBC is negative and bacteria flags positive, but only small debris is present upon manual review of whole-field images
[g] calcium oxalate monohydrate, calcium oxalate dihydrate, uric acid, tri-phosphate
[h] hyaline and pathologic

	Cell	n	Concentration Range (cells/mcL)	Mean Concentration (cells/mcL)	Intra-assay %CV	Inter-assay %CV	References
Sysmex UF-100	RBC	10	4-15	—	37.3	39.6	6
		10	50-99	—	—	20.5	6
		10	310-430	—	10.6	—	6
		10	791-921	—	5.0	—	6
	WBC	10	7-39	—	23.1	21.6	6
		10	72-150	—	14.3	19.4	6
Sysmex UF-1000i		10	550-701	—	6.7	—	6
	RBC	10	<30	25.2	5.3	—	16
		10	<80	72.9	4.3	—	16
		10	<300	206.8	3.5	—	16
	WBC	10	<30	20.9	8.9	—	16
		10	<80	78.4	2.9	—	16
		10	<300	272.1	3.4	—	16
		10	<500	488.3	1.7	—	16
Iris iQ200	RBC	20	—	1.6	19.1	23.5	17
		10	0-9	—	45.5	46.8	6
		20	—	1.6	19.1	23.5	17
		10	50-99	—	—	21.2	6
		10	310-430	—	12.5	—	6
		10	791-921	—	4.8	—	6
	WBC	20	—	1.2	35.4	33.3	17
		10	7-39	—	34.1	24.7	6
		20	—	38.6	16.3	16.9	17
		10	72-150	—	13.0	17.6	6
		10	550-701	—	6.8	—	6
SediMAX	RBC	20	—	1.4	28.7	33.3	17
		20	—	7	17.8	—	8
		24	—	30	—	14.7	8
		20	—	45.7	7.1	10.1	17
		24	—	283	—	7.2	8
		20	—	447	6.7	—	8
	WBC	20	—	1.2	30.2	30.8	17
		20	—	4	16.6	—	8
		24	—	25	—	5.4	8
		20	—	37.8	13.1	15.2	17
		24	—	166	—	3.0	8
		20	—	258	4.4	—	8
Manual Microscopy	RBC	20	—	1.6	42.4	53.3	17
		10	1-17	—	62.3	—	6
		20	—	41.4	17.4	18.9	17
		10	190-360	—	22.0	—	6
		10	575-1150	—	21.4	6	6
	WBC	20	—	1.5	44.4	50.0	17
		10	4-24	—	57.7	—	6
		20	—	35.3	19.2	20.9	17
		10	55-150	—	25.4	—	6
		10	450-850	—	17.8	—	6

Table 2. Analytical specifications reported for automated urine sediment analyzers

Ve Tekrarlanabilirlik, doğruluk

% 5-50 % 20-50

TABLE 7. Within-Run (A) and Between-Run (B) Precision Studies

	UF-100		iQ200		Microscopy examination	
	Rank (/μL)	CV (%)	Rank (/μL)	CV (%)	Rank (/μL)	CV (%)
(A)						
RBC	4–15	37.3	0–9	45.5	1–17	62.3
	310–430	10.6	170–251	12.5	190–360	22.0
	791–921	5.0	680–791	4.8	575–1,150	21.4
WBC	7–20	23.1	6–18	34.1	4–24	57.7
	99–150	14.3	75–120	13.0	55–150	25.4
	550–701	6.7	495–601	6.8	450–850	17.8
(B)						
RBC	3–15	39.6	1–8	46.8		
	50–99	20.5	31–74	21.2		
WBC	20–39	21.6	23–48	24.7		
	72–140	19.4	99–181	17.6		

RBC: erythrocytes; WBC: leukocytes; CV: coefficient of variation.

TABLE 3. iQ200 vs. UF-100 Comparison

	Agreement		
Parameter	*n*	%	Spearman's ρ
Erythrocytes	477	75	0.506
Leukocytes	491	77	0.751
Epithelial cells	337	52	0.472
Bacteria	607	94	0.791
Crystals	608	95	0.170

r= 0.2-0.75

TABLE 4. Analyzers vs. Manual Examination of Sediment Comparison

	Erythrocytes			Leucocytes			Bacteria/Nitrites		
Analyzer	*n*	%	ρ	*n*	%	ρ	*n*	%	ρ
iQ200	523	81	0.473	475	73	0.695	564	87	0.538
UF-100	473	74	0.439	498	78	0.761	584	91	0.647
ATLAS	568	88	0.525	447	69	0.684	577	89	0.532
URISYS	556	86	0.539	461	71	0.620	581	90	0.561

%80 %70 %90

Journal of Clinical Laboratory Analysis 22:262–270 (2008)

Analitik uyum ne olacak?

TABLE XV. Analytical quality specifications expressed as Kappa coefficients.

	Optimum	Minimum
κ coefficient (simple) (2 – 3 classes)	> 0.8	> 0.6
κ coefficient (weighted) (4 – 5 classes)	> 0.9	> 0.7

Scand J Clin Lab Invest 2000; 60: 1 – 96

European Urinalysis Guidelines

Doğruluk ve tekrarlanabilirlikleri

TABLE XVII. Analytical specifications for trueness (expressed as relative deviation) and reproducibility (expressed as imprecision) in quantitative *urine* chemistry, with special reference to proteinuria.

Property	Performance level	
	Optimum	Minimum
Trueness, maximum deviation from the target value	10%	25%
Reproducibility, maximum imprecision $CV_{day\text{-}to\text{-}day}$	20%	50%

9.3.1. Calibration of the measurements. Calibration of urinary total protein is preferably performed using the CRM 470 (albumin) standard (see Appendix, Annex 11.2.3). Glucose measurements can be calibrated with the SRM909 material obtained from the National Institute of Standards and Technology [255]. There is also a reference method for urine glucose measurements approved by CDC/FDA/AACC/NRSCL [256].

Scand J Clin Lab Invest 2000; 60: 1–96

European Urinalysis Guidelines

Belirsizlik oranı

9.4.1 Statistical uncertainty. Counting at low particle concentrations needs special attention because of statistical uncertainty. Particle counting follows the Poisson distribution [261]:

$$s = \sqrt{m};\ \text{and}$$
$$CV_m(\%) = 100\%/\sqrt{m} = 100\%/\sqrt{T/n}$$
$$= CV_T(\%) \times \sqrt{n},\ \text{and}$$
$$CV_T = 100\%/\sqrt{T} = CV_m/\sqrt{n}$$

where T = total amount of counted cells and n = number of counted unit volumes (traditionally squares in a chamber or high-power fields under a coverslip); m = mean count = T/n, s = standard deviation, CV_m = coefficient of variation of the mean count, CV_T = coefficient of variation of the total count.

At low particle concentrations, imprecision of the total count becomes critical: If only 1 µL is counted at a concentration of 3×10^6 particles/L, the result has a theoretical $CV_T = 60\%$ with ideal procedures. Five microlitres of the same suspension gives $CV_T = 26\%$ and counting only 10 µL gives $CV_T = 18\%$, permitting the calculation of an estimate for the mean value.

T= Total sayılan hücre sayısı

n= hpf sayısı

m= ortalama sayım

s= Standart sapma

CVm= ortalama sayımdaki CV

CVt= total sayımdaki CV

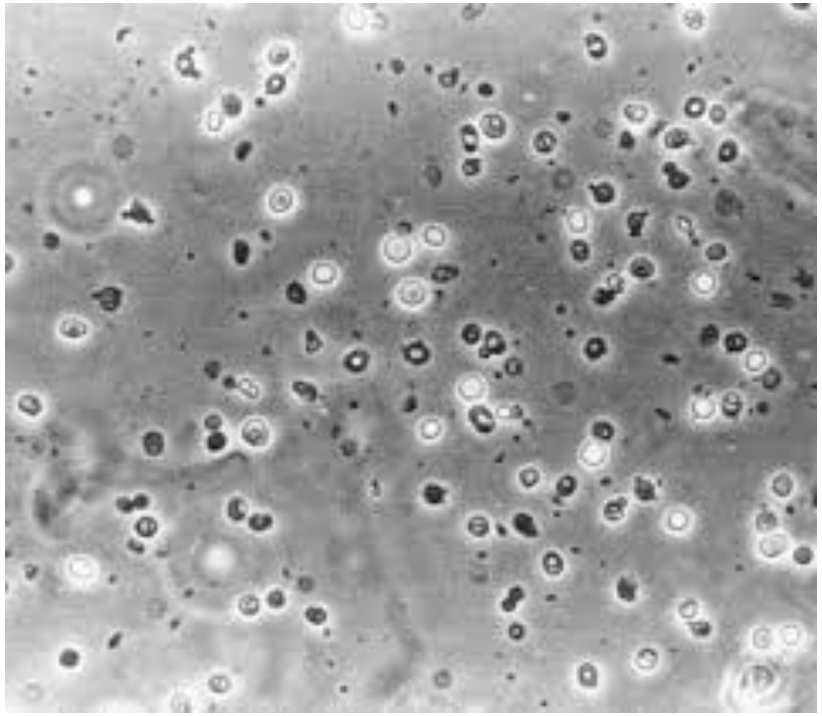
Scand J Clin Lab Invest 2000; 60: 1–96

European Urinalysis Guidelines

Yanlış Negatif oranları

TABLE XVIII. Maximum allowable false-negative rates in urine microscopy.

Particle type	Particle concentration ($\times 10^6$/L)	Maximum allowable false-negative rates (%)
RBC	10	20
	100	5
WBC	20	10
	200	5
Bacteria	10	20
	100	5
Casts	10	10
	50	5



Scand J Clin Lab Invest 2000; 60: 1–96

European Urinalysis Guidelines

Strip uygunluk kriterleri

detail). Optimal trueness of measurements is suggested to be a **FP rate <10% at L_D and a FN <5% at L_C** (compared with the most accurate, closely related method) (Tables XXIII & XXIV). In many situations, or with a less optimal comparison method, a minimum performance is acceptable (see Appendix, Annex 11.1.1 for principles of measurements). With

TABLE XXIII. Example data for estimation of trueness of test strip examinations.

Comparison method (WBC × 10^6/L)	Negative < 20	Grey zone 20–99	Positive ≥ 100	Total
Test strip result				
Negative	200 (a)	25 (c)	5 (e)	230
Positive (1+ or more)	80 (b)	100 (d)	40 (f)	220
TOTAL	280	125	45	450
Limits:		L_D	L_C	

TABLE XXIV. Analytical quality specifications for trueness of test strip examinations.

Performance	$FP_D = b/(a+b)$	$FN_G = c/(c+d)$	$FN_C = e/(e+f)$
Optimum	<10%	<30%	<5%
Minimum	<20%	<50%	<10%

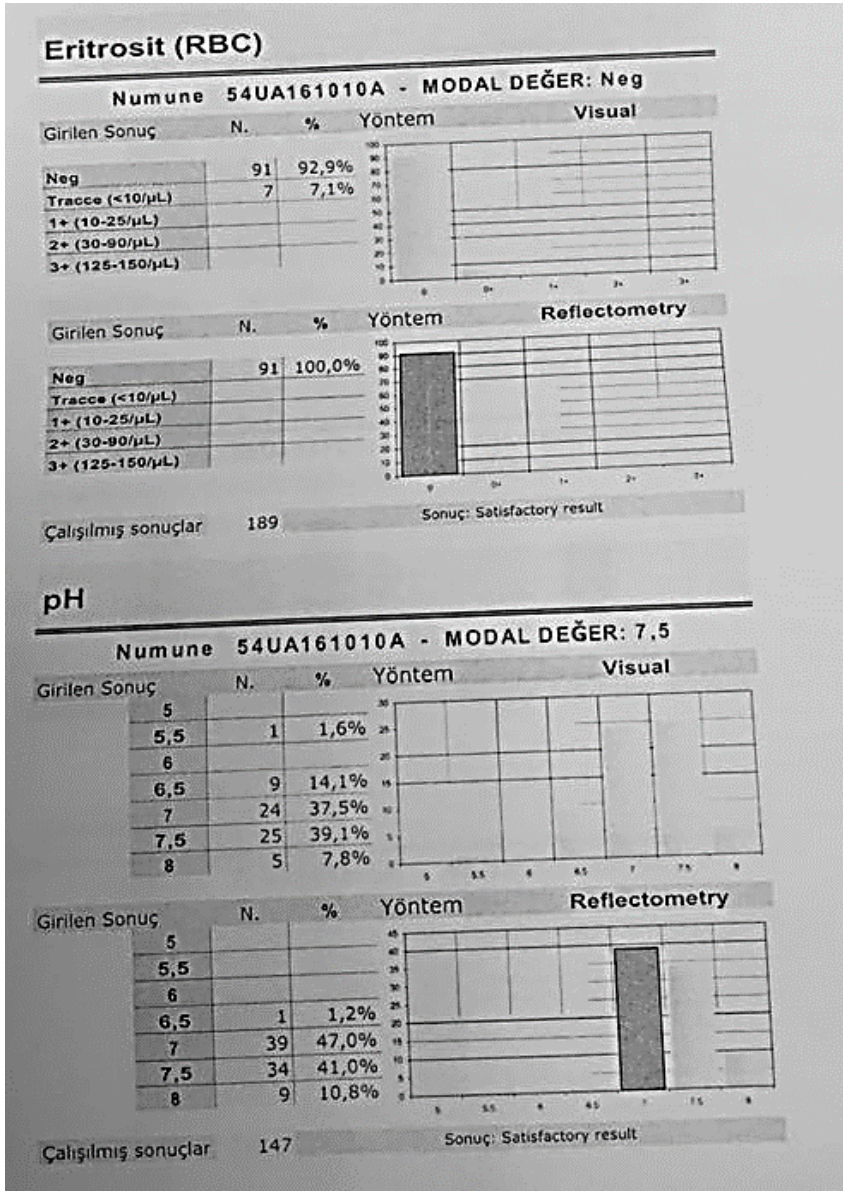
The following fractions describe the trueness of measurements:

1. The fraction of false positives at the detection limit $(L_D) = FP_D = b/(a+b)$ (in the example: 80/280 = 0.29 or 29%).
2. The fraction of false negatives at the grey zone area $= FN_G = c/(c+d)$ (in the example: 25/125 = 0.20 or 20%).
3. The fraction of false negatives at the confirmation limit $(L_C) = FN_C = e/(e+f)$ (in the example: 5/45 = 0.11 or 11%).

Scand J Clin Lab Invest 2000; 60: 1–96

European Urinalysis Guidelines

DKD materyalleri ve değerlendirmeleri sınırlı



Eritrosit (RBC)

Numune 54UA161010A - MODAL DEĞER: Neg

Girilen Sonuç	N.	%	Yöntem: Visual
Neg	91	92,9%	
Tracce (<10/µL)	7	7,1%	
1+ (10-25/µL)			
2+ (30-90/µL)			
3+ (125-150/µL)			

Girilen Sonuç	N.	%	Yöntem: Reflectometry
Neg	91	100,0%	
Tracce (<10/µL)			
1+ (10-25/µL)			
2+ (30-90/µL)			
3+ (125-150/µL)			

Çalışılmış sonuçlar 189

Sonuç: Satisfactory result

pH

Numune 54UA161010A - MODAL DEĞER: 7,5

Girilen Sonuç	N.	%	Yöntem: Visual
5			
5,5	1	1,6%	
6			
6,5	9	14,1%	
7	24	37,5%	
7,5	25	39,1%	
8	5	7,8%	

Girilen Sonuç	N.	%	Yöntem: Reflectometry
5			
5,5			
6			
6,5	1	1,2%	
7	39	47,0%	
7,5	34	41,0%	
8	9	10,8%	

Çalışılmış sonuçlar 147

Sonuç: Satisfactory result

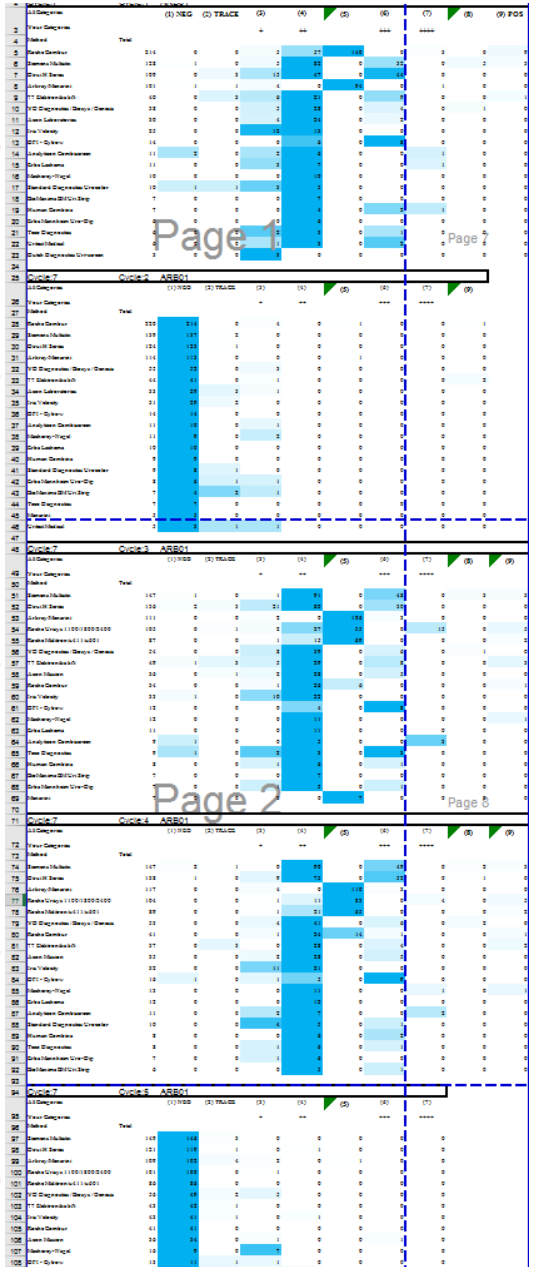
1.

2.

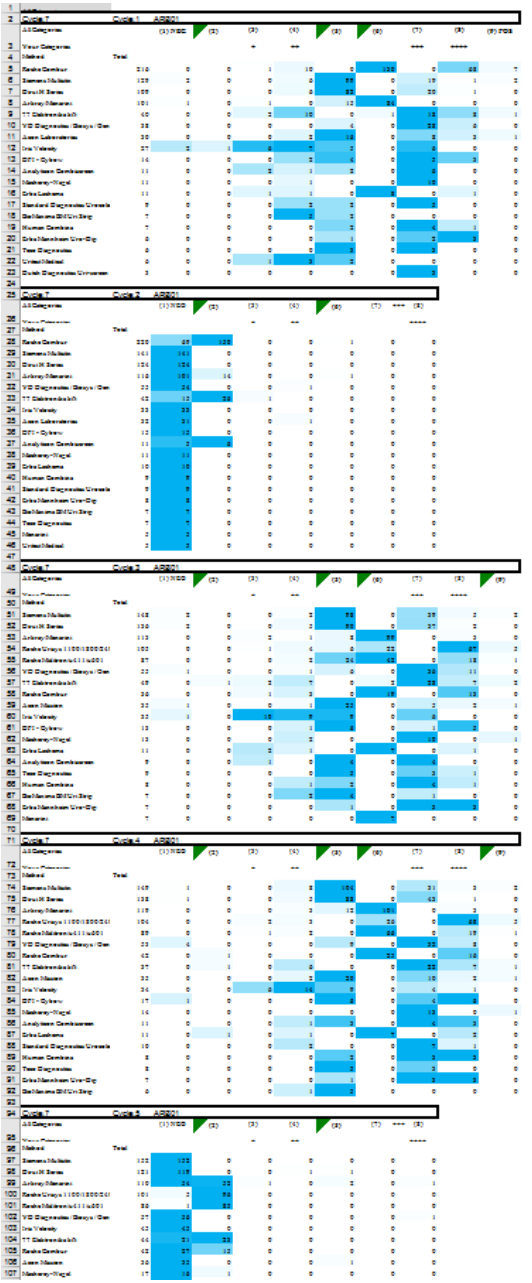
3.

4.

5.



Protein



Glukoz

DKD

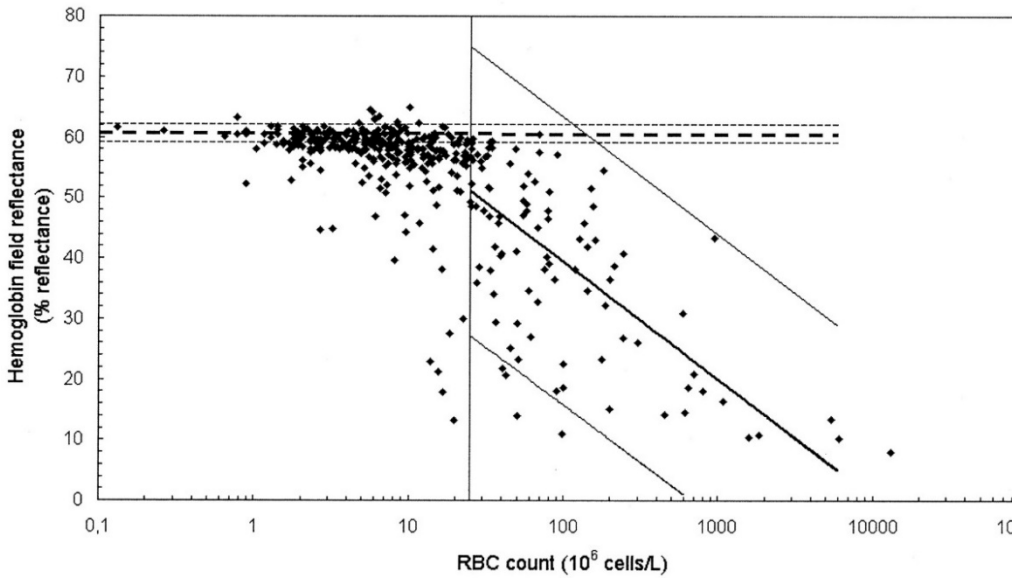
Kalitatif ve semikantitatif değerlendirme

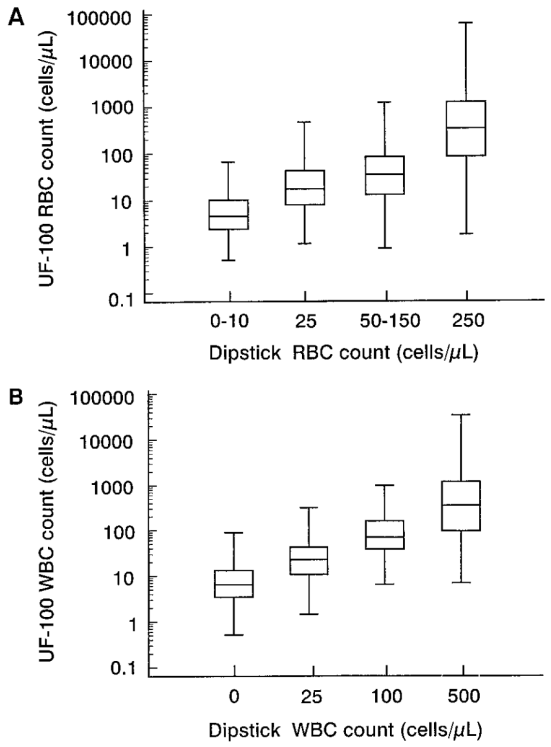
Nitrite, ARB01

All Categories		(1)	(3)	(4)	(5)	(9)
Your Categories		NEG	+	++		
	Total					
Iris Velocity	34	1	29	4		
All Methods (Your Categories)	227	35	83	109		
All Methods (All Categories)	1066	35	83	109	7	832

All Categories		(1)	(3)	(4)	(5)	(9)
Your Categories		NEG	+	++		
Method	**Total**					
Siemens Multistix	172	2	18	11	0	141
Arkray/Menarini	131	2	5	71	0	53
Dirui H Series	123	3	13	0	0	107
Roche Urisys 1100/1800/2400	100	0	0	0	0	100
Roche Miditron/u411/u601	90	0	0	0	0	90
Roche Combur	59	1	0	0	0	58
YD Diagnostics / Biosys / Genesis	55	2	0	0	7	46
Iris Velocity	49	1	29	4	0	15
77 Elektronika kft	48	6	0	0	0	42
Acon Mission	48	0	0	0	0	48
Standard Diagnostics Urocolor	25	0	5	0	0	20
Erba Lachema	23	0	9	14	0	0
DFI - Cybow	16	0	0	0	0	16
Teco Diagnostics	16	3	0	0	0	13
Analyticon Combiscreen	13	2	0	0	0	11
Erba Mannheim Uro-Dip	11	2	0	0	0	9
Human Combina	9	1	0	0	0	8
Uritest Medical	9	2	0	0	0	7
Siemens Clinitek Novus	8	0	0	0	0	8

Kimyasal test ile mikroskobik karşılaştırılması önemli bir hasta temelli kalite kontrol çalışmasıdır





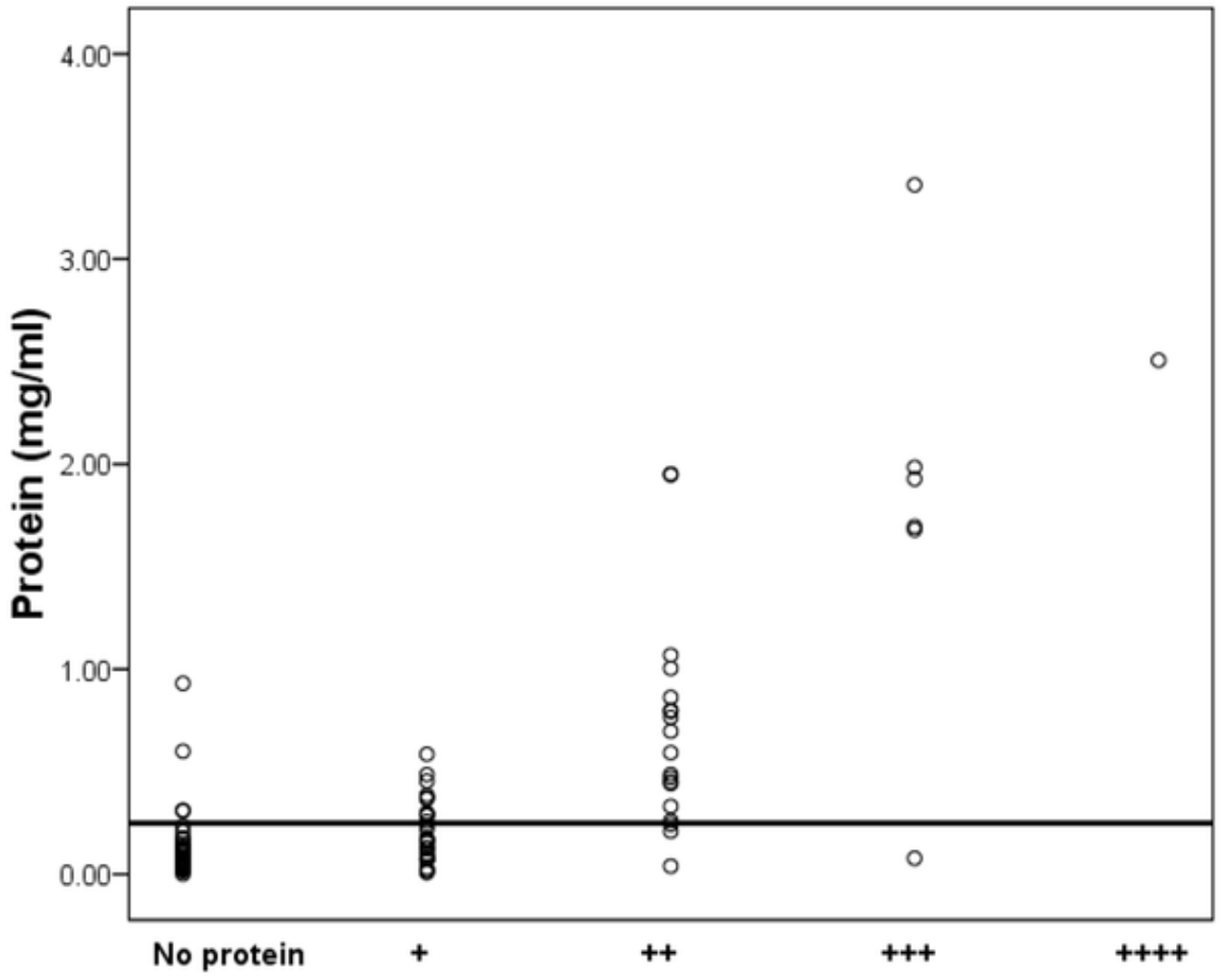
Clinical Chemistry 45:1 118–122 (1999)

Table 6–2 Routine Urinalysis Correlations

Microscopic Elements	Physical	Chemical	Exceptions
RBCs	Turbidity Red color	+ Blood	Number Hemolysis
WBCs	Turbidity	+ Protein + Nitrite + Leukocytes	Number Lysis
Epithelial cells	Turbidity		Number
Casts		+ Protein	Number
Bacteria	Turbidity	pH + Nitrite + Leukocytes	Number and type
Crystals	Turbidity Color	pH	Number and type

Örnek

Protein ölçümleri



Reid CN, Stevenson M, Abogunrin F, Ruddock MW, Emmert-Streib F, et al. (2012) Standardization of Diagnostic Biomarker Concentrations in Urine: The Hematuria Caveat. PLoS ONE 7(12): e53354. doi:10.1371/journal.pone.0053354
http://journals.plos.org/plosone/article?id=info:doi/10.1371/journal.pone.0053354

PLOS | ONE

Diğer testler

- İdrar kimyasal ve immünolojik testleri (kreatinin, albuminüri, hafif zincir analizleri, hCG)
- İlaç ve toksikoloji testleri (immünolojik veya kromatografik)
- İdrar metabolik testleri (taramalar, amino asit ve organik asit)

İdrar kreatinin ölçümü

LOD, LOQ, Linerite

İdrar 5-400 mg/dL

Serum 0.15-20 mg/dL

Otomatik Dilusyon (1/20)

Table 1: Creatinine Methods Summary Table

Method 1: Jaffe; spectrophotometric, end point, quantitative
Principle of analysis: Creatinine + alkaline picrate → Janovski complex *(red)*
Comments: Serum, plasma, diluted urine; described by Jaffe, 1886. Significant interference from noncreatinine chromogens.

Method 2: Jaffe/Fuller's earth; same as Method 1; creatinine isolated before analysis; can be removed with buffer or picrate reagent added directly to creatinine adsorbent suspension
Principle of analysis: Same as Method 1
Comments: Serum, plasma, diluted urine; alternatively cation exchangers used as adsorbent. Interference from noncreatinine chromogens reduced. No longer in routine use.

Method 3: Jaffe, kinetic; spectrophotometric, quantitative, kinetic analysis during early color formation
Principle of analysis: Same as Method 1
Comments: Serum, plasma, diluted urine; requires automated equipment for accurately timed and precise absorbance measurements. Precise conditions vary between instruments. Interference from noncreatinine chromogens reduced. This is currently the most popular method in diagnostic laboratories.

Method 4: Creatininase (creatinine amidohydrolase); enzymatic hydrolysis to creatine, which reacts in indicator reactions monitored spectrophotometrically at 340 nm
Principle of analysis:

$$\text{Creatinine} + H_2O \xrightarrow{\text{creatinine amidohydrolase}} \text{creatine}$$

$$\text{Creatine} + \text{ATP} \xrightarrow{CK} \text{creatine phosphate} + \text{ADP}$$

$$\text{ADP} + \text{phosphoenolpyruvate} \xrightarrow{\text{pyruvate kinase}} \text{ATP} + \text{pyruvate}$$

$$\text{Pyruvate} + \text{NADH} + H^+ \xrightarrow{LD} NAD^+ + \text{lactate}$$

(*CK,* creatine kinase; *LD,* lactate dehydrogenase)
Comments: Poor sensitivity and precision, not widely used.

Method 5: Creatininase (creatinine amidohydrolase) is coupled with creatinase, generating creatine and sarcosine sequentially. A further reaction with sarcosine oxidase leads to the production of hydrogen peroxide, which can be detected by several indicator reactions.
Principle of analysis:

$$\text{Creatinine} + H_2O \xrightarrow{\text{creatinine amidohydrolase}} \text{creatine}$$

$$\text{Creatine} + H_2O \xrightarrow{\text{creatinase}} \text{sarcosine} + \text{urea}$$

$$\text{Sarcosine} + O_2 + H_2O \xrightarrow{\text{sarcosine oxidase}} \text{formaldehyde} + \text{glycine} + H_2O_2$$

$$\text{Indicator (reduced)} + H_2O_2 \xrightarrow{\text{peroxidase}} \text{indicator (oxidized)} + 2H_2O$$

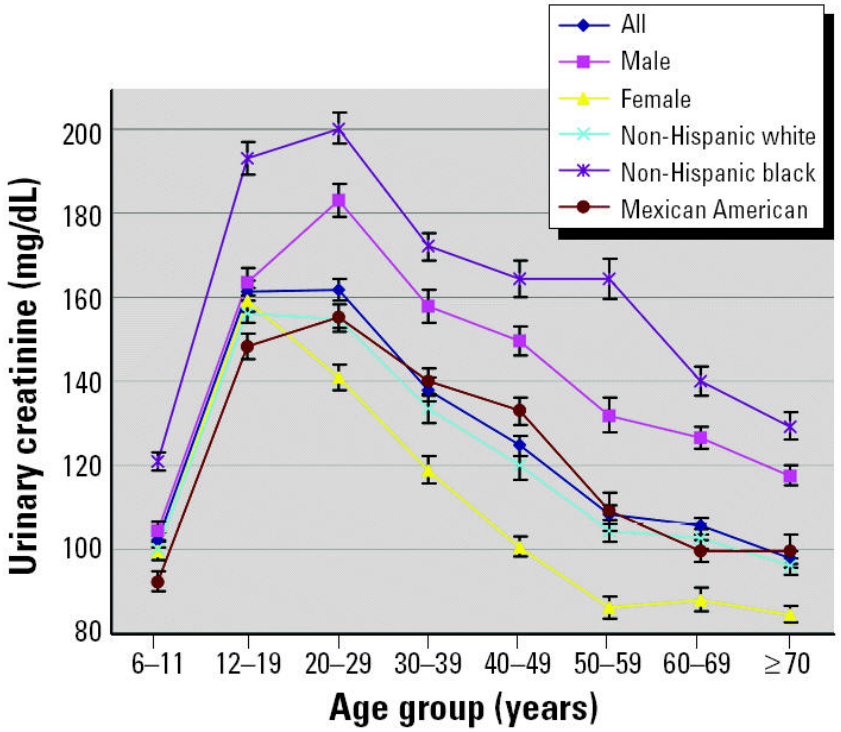
Comments: Widely used specific method. Bilirubin interference remains a problem.

Method 6: Creatinine iminohydrolase; enzymatic hydrolysis of creatinine with formation of ammonia, which can be quantitated spectrophotometrically or electrometrically
Principle of analysis:

$$\text{Creatinine} \xrightarrow{\text{creatinine iminohydrolase}} \textit{N}\text{-methylhydantoin} + NH_3$$

Method 3: Jaffe, kinetic; spectrophotometric, quantitative, kinetic analysis during early color formation
Principle of analysis: Same as Method 1
Comments: Serum, plasma, diluted urine; requires automated equipment for accurately timed and precise absorbance measurements. Precise conditions vary between instruments. Interference from noncreatinine chromogens reduced. This is currently the most popular method in diagnostic laboratories.

Kreatinin biyolojik varyasyonu



Calibration. A known reference material for serum creatinine is SRM 914a [257]. Weighed out creatinine solution may serve as an approximate estimate.

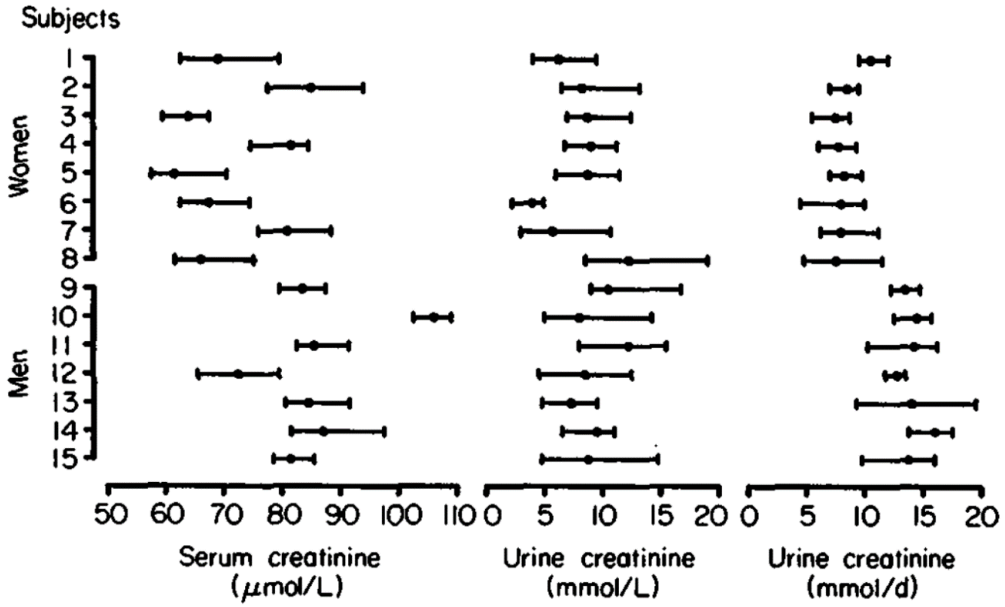


TABLE 1. Components of variance: analytical (CV_A), intra-individual (CV_I), and inter-individual (CV_G)

Quantity	Units	Group	Mean	Coefficients of variation CV_A	CV_I	CV_G	Index of* individuality	Critical† difference
Serum creatinine	μmol/L	Whole	77·9	3·4	4·1	14·1	0·29	11·4
		Female	71·4	2·9	4·9	11·8	0·41	11·2
		Male	83·9	3·8	3·4	6·8	0·54	11·8
Urine creatinine	mmol/L	Whole	8·3	0·9	23·8	24·5	0·97	5·4
Urine creatinine	mmol/d	Whole	10·7	1·2	13·0	28·2	0·46	3·9
		Female	8·0	0·7	15·7	11·0	1·42	3·5
		Male	13·9	1·3	11·0	6·0	1·83	4·3
Creatinine clearance	mL/s	Whole	1·59	4·2	13·2	21·0	0·63	0·56
		Female	1·33	3·0	16·1	16·1	1·00	0·60
		Male	1·89	3·6	11·2	7·1	1·58	0·62
Creatinine clearance corrected to 1·73 m^2 surface area	mL/s	Whole	1·57	4·3	13·6	13·5	1·01	0·62

*Index of individuality = SD_I/SD_G.
†Critical difference = $2·77\ (SD_A^2+SD_I^2)^{½}$.

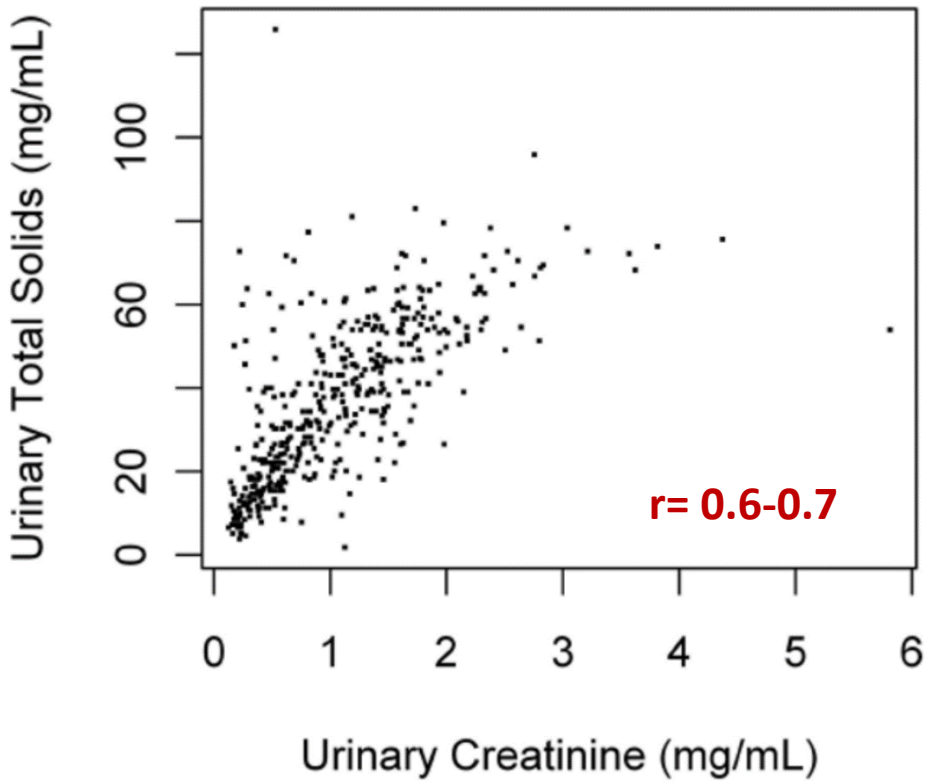
Kreatinin düzeltmeleri ne kadar etkin ?

Biomarkers. 2011 May ; 16(3): 206–211. doi:10.3109/1354750X.2010.538084.

A comparison of creatinine vs. specific gravity to correct for urinary dilution of cotinine

Subject characteristics and biomarker concentrations of 431 cigarette smokers, 1994–2004

	All subject	Black men	Black Women	P-value	White men	White women	P-value
	N=431	N= 105	N=98		N=110	N=118	
Age	34.6 ± 9.9	35.8 ± 9.2	35.4 ± 8.0	0.73	33.1 ± 10.0	34.2 ± 11.6	0.46
Years of education	13.6 ± 2.4	12.8 ± 2.3	13.6 ± 2.4	0.03	13.8 ± 2.5	14.0 ± 2.1	0.61
Age started smoking	16.6 ± 4.1	17.2 ± 4.3	16.9 ± 4.6	0.66	15.9 ± 3.7	16.4 ± 3.8	0.34
Cigarettes/day	18.3 ± 10.5	14.7 ± 8.2	13.4 ± 7.1	0.25	23.5 ± 12.6	20.8 ± 9.4	0.07
Weight (lbs)	164.8 ± 34.1	183.4 ± 30.5	156.4 ± 26.0	<0.01	180.7 ± 30.9	140.1 ± 28.1	<0.01
Body mass index	25.2 ± 4.0	26.1 ± 3.5	26.0 ± 3.8	0.87	25.7 ± 4.0	23.5 ± 4.0	<0.01
Blood cotinine (ng/mL)	346.2 ± 250.4	382.3 ± 267.3	356.3 ± 256.0	0.45	344.7 ± 253.3	310.0 ± 225.4	0.23
Urinary cotinine (ng/mL)	3396 ± 0.3081	3762 ± 3060	3812 ± 3639	0.90	3265 ± 2989	2846 ± 2587	0.21
Urinary creatinine (mg/mL)	1.07 ± 0.73	1.29 ± 0.81	1.08 ± 0.81	0.01	1.13 ± 0.67	0.82 ± 0.57	<0.01
Creatinine clearance (mL/min)	102.3 ± 0.26.1	109.3 ± 26.6	88.9 ± 22.8	<0.01	112.6 ± 20.3	88.9 ± 22.8	<0.01
Urinary total solids (mg/mL)	36.6 ± 19.3	38.4 ± 19.6	35.7 ± 18.0	0.36	39.7 ± 19.9	32.8 ± 19.2	<0.01



Aynı bireyde kreatinin değişimi ile test sonuçları değişir mi?

Cd and β_2-MG by creatinine concentration in urine

Cr range[a] (g/l)	No. (%)	M[b] and SD[b]	Age (years)	Factor G[a]	Cd_{ob} (μg/l)	Cd_{cr} (μg/g)	Cd_{sg} (μg/l)	β_2-MG_{ob}[c] (μg/l)	β_2-MG_{cr}[c] (μg/g)	β_2-MG_{sg}[c] (μg/l)
<0.5	1628	*M*	50.1	8.5	0.44	1.43	0.90	49.2	161.7	101.9
	18.1%	SD	7.5	3.4	1.99	1.92	1.94	1.96	1.80	1.76
0.5 to <1.0	3251	*M*	49.9	15.9	1.00	1.37	1.04	96.4	131.8	99.5
	36.2%	SD	7.5	3.6	2.23	2.18	2.17	1.71	1.70	1.67
1.0 to <1.5	2405	*M*	48.0	21.0	1.49	1.23	1.15	123.1	101.5	95.1
	26.8%	SD	7.6	3.2	2.10	2.09	2.12	1.67	1.67	1.69
1.5 to <2.0	1163	*M*	46.0	24.3	1.75	1.03	1.16	145.2	85.4	96.4
	13.0%	SD	7.3	3.1	2.01	2.01	2.05	1.72	1.72	1.75
2.0 to <2.5	387	*M*	43.6	26.8	1.89	0.86	1.14	159.4	72.4	95.9
	4.3%	SD	6.7	3.1	2.01	2.02	2.05	1.68	1.69	1.71
2.5 to <3.0	106	*M*	43.5	28.2	2.59	0.96	1.48	189.3	70.3	108.4
	1.2%	SD	7.1	4.2	1.84	1.85	1.92	1.64	1.63	1.69
≥3.0	35	*M*	43.9	29.6	2.87	0.84	1.57	201.8	58.8	110.0
	0.4%	SD	6.3	4.1	2.03	2.08	2.04	1.95	1.93	1.96
All	8975	*M*	48.5	17.7	1.08	1.26	1.06	99.3	116.2	98.3
	100%	SD	7.7	6.5	2.43	2.10	2.11	1.95	1.80	1.71

[a] CR, creatinine; SG, specific gravity (1.016); OB, as observed. Factor G = (specific gravity − 1.000) × 1000.
[b] AM and ASD for age and Factor G, and GM and GSD for Cd and β_2-MG.
[c] In μg/g cr for β_2-MG_{cr}, and μg/l for β_2-MG_{sg} and β_2-MG_{ob}.

1.5-2 kat

3 kat

Toxicology Letters 145 (2003) 197–207

Kreatinin ve Osmololalite düzeltmesi

Demographic data of never-smoking women by urine density

Item	Unit	Women with				*P* for difference[a]
		Various urine density[b]		Adequate urine density[c]		
		M[d]	S.D.[d]	*M*[d]	S.D.[d]	
Number		8975		7081		
Percentage	%	83.5[e]	72.8–90.5[g]	78.9[f]	57.3–89.6[g]	
Age	Years	48.5	7.7	48.3	7.6	>0.05, <0.10
CR	g/l	1.02	0.57	1.15	0.47	<0.01
Factor *G*[h]		17.7	6.5	19.6	4.6	<0.01
Cd_{ob}	μg/l	1.07	2.432	1.32	2.213	<0.01
Cd_{cr}	μg/g cr	1.26	2.104	1.24	2.133	>0.10
Cd_{sg}	μg/l	1.06	2.104	1.11	2.128	<0.01
Mg_{ob}	mg/l	61	38	68	35	<0.01
Ca_{ob}	mg/l	111	70	124	67	<0.01
Zn_{ob}	μg/l	356	294	397	284	<0.01
β_2-Mg_{ob}	μg/l	99.3	1.950	116.1	1.738	<0.01
β_2-MG_{cr}	μg/g cr	116.1	1.803	109.1	1.750	<0.01
β_2-MG_{sg}	μg/l	98.4	1.702	97.9	1.687	>0.10

[a] No selection in terms of urine density.
[b] $0.5 \leqq CR \leqq 3.0$ g/l and $1.010 \leqq SG \leqq 1.030$.
[c] AM and A.S.D. for age, CR, Factor *G*, Mg_{ob}, Ca_{ob} and Zn_{ob}, and GM and G.S.D. for Cd_{sg}, Cd_{cr} and Cd_{ob}.
[d] The percentage of the never-smokers (with various urine density) over total women in the database.
[e] The percentage of the never-smoking women (with adequate urine density) over total never-smoking women (with various urine density).
[f] The minimum and the maximum in percentage among the 10 areas studied.
[g] By unpaired *t*-test, after logarithmic conversion in cases of Cd and β_2-MG.
[h] Factor $G = (SG - 1.000) \times 1000$.

Clinical Chemistry 50:5
924–932 (2004)

General Clinical Chemistry

Comparison of Specific Gravity and Creatinine for Normalizing Urinary Reproductive Hormone Concentrations

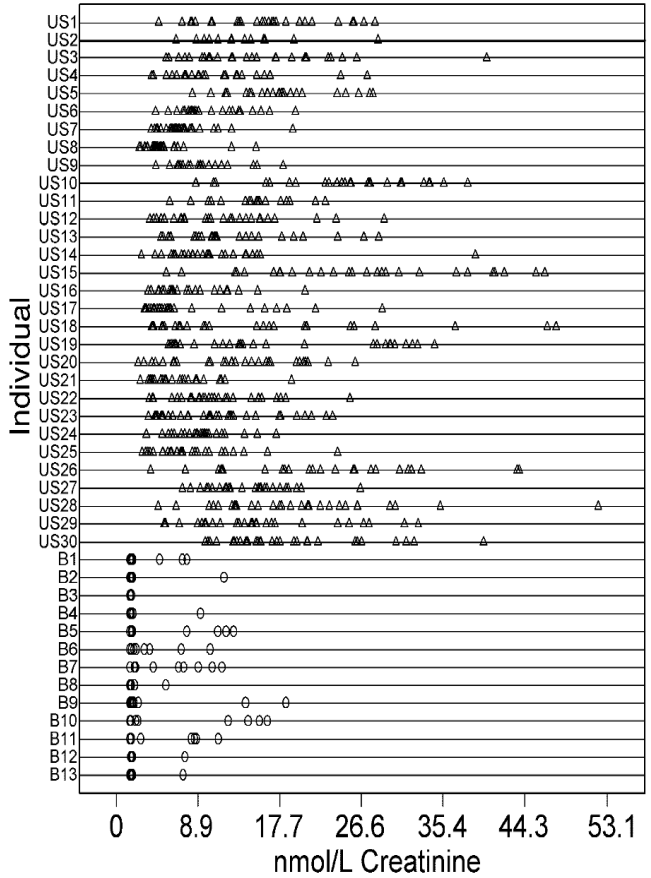


Fig. 1. Distribution of CR values from one menstrual cycle for 30 US (△) and 13 Bangladeshi (*B*; ○) participants.
Each *line* shows all CR measurements for one participant from one menstrual cycle with CR concentration plotted on the *x axis*.

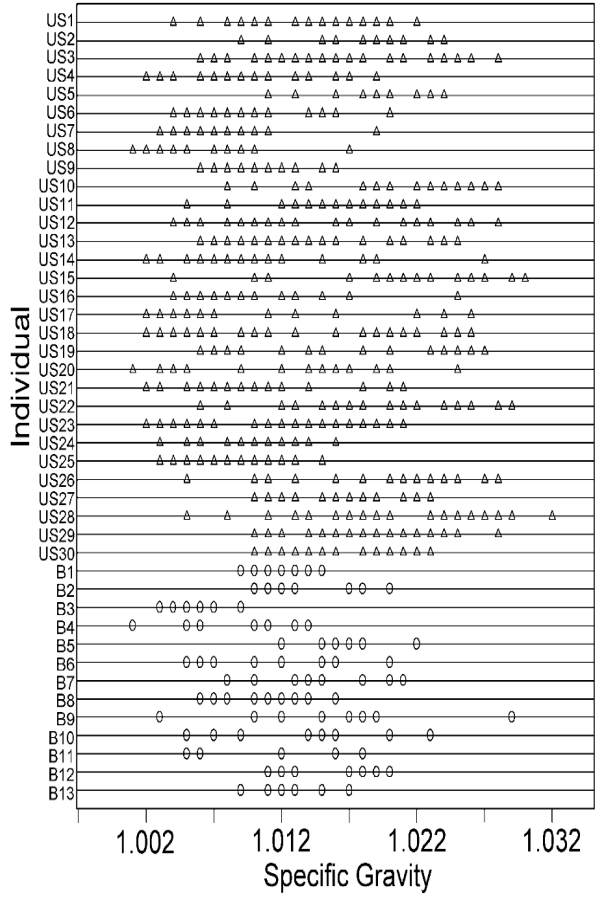
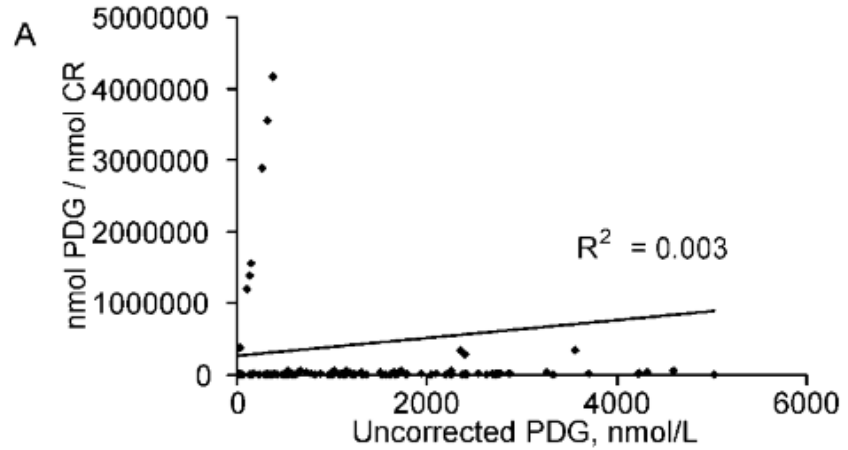
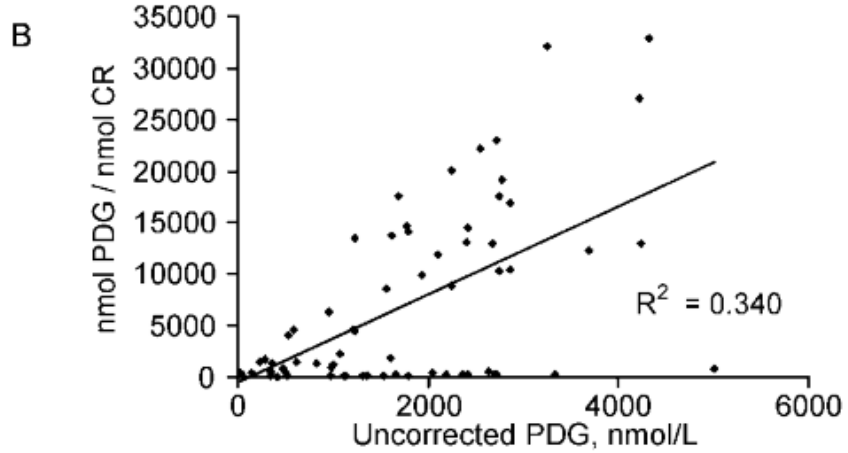
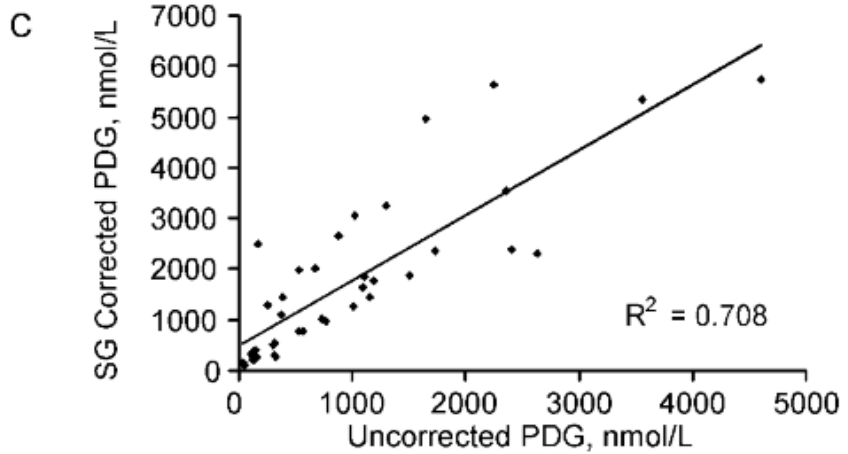


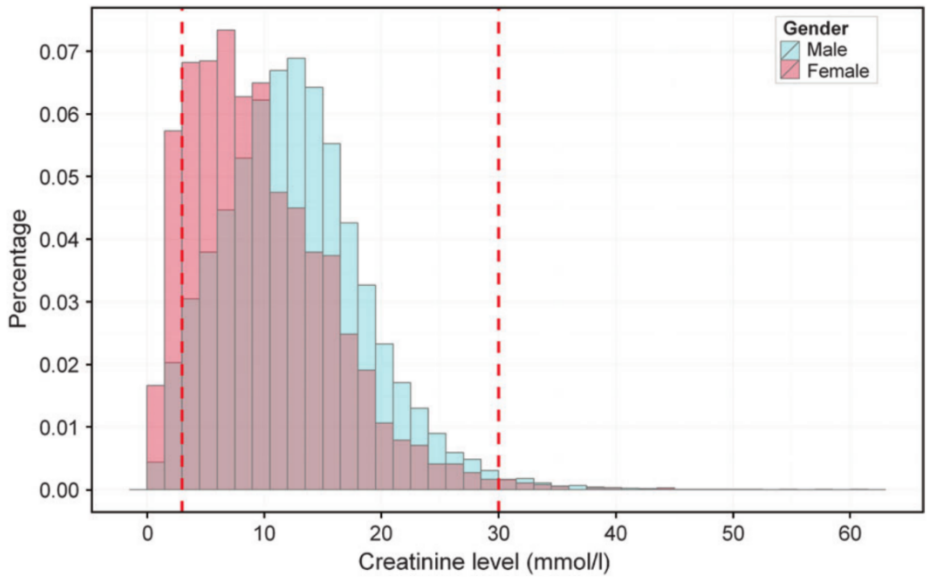
Fig. 4. Distribution of SG values from one menstrual cycle for 30 US (△) and 13 Bangladeshi (*B*; ○) participants.
Each *line* shows all SG measurements for one participant from one menstrual cycle with SG plotted on the *x axis*.







Creatinine adjustment of biological monitoring results



Key points

- The mean and median creatinine concentrations of 12 mmol/l for all 49 506 samples from adults in this study correspond to 1.36 g/l and this value should be used instead of 1 g/l for conversion calculations.
- The range of 0.3 and 3.0 g/l (2.653 and 26.53 mol/l) traditionally used for confirming acceptability of the sample corresponded to the 2.5th and 97.4th percentiles and the 8.7th and 98.4th percentiles, respectively, of the male and female creatinine distributions in this study. In practice this means that 2.5% of samples from men and 9% of samples from women result in a repeat sample request.
- Health and Safety Laboratory uses the acceptable range of 0.3–3 g/l and rounds the values in SI units to give a range of 3–30 mmol/l and this results in 5% of all samples from workers being flagged as low creatinine and 1% flagged as high creatinine.

0.3-3 g/L

Occupational Medicine 2011;**61**:349–353

Weekly Biological Variability of Urinary Organic Acids

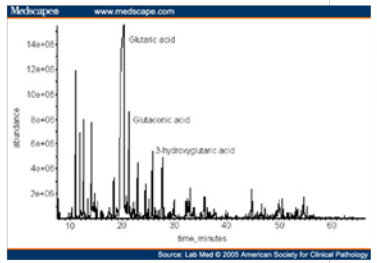
Analyte	CVT	CVa	CVb	Average Concentration (Biol. Var. Range)	Laboratory 95% Reference Range	SD v. Conc. Slope
Picolinic acid	16	9.7	12.3	6.1 (5.7-6.5)	1.8 – 11.2	0.14
Isocitric acid	18	3.9	17.5	74.7 (68.2-81.2)	1.0 – 110	0.41
Quinolinic acid	21	10.4	17.8	2.8 (2.6-3)	< 5.8	0.16
Ethylmalonic acid	20	9.2	18.3	2.1 (1.9-2.3)	< 4.4	0.43
cis-Aconitic acid	19	3.9	19.1	37.2 (33.6-40.8)	1.0 – 74	0.29
Methylmalonic acid	22	9.7	19.4	1.1 (1.0-1.2)	< 2.0	0.24
Vanilmandelic acid	21	3.4	20.9	2.7 (2.4-3)	1.0 – 5.7	0.23
Sulfuric acid	22	2.5	21.8	1380 (1230-1530)	762 – 2778	0.25
8-Hydroxy-2-deoxyguanosine	26	4.4	25.5	3.6 (3.1-4.1)	< 7.6	0.25
Glucaric acid	31	16.4	25.9	4.3 (3.7-4.9)	< 14.9	0.21
Hydroxymethylglutaric acid	28	5	27.6	3.4 (2.9-3.9)	< 5.2	0.15
3-Hydroxyisovaleric acid	29	7.9	28.1	6.4 (5.5-7.3)	< 7.9	0.35
2-Methylhippuric acid	35	19.2	29.3	0.04 (0.03-0.05)	< 0.073	—
Citric acid	34	5.7	29.5	386 (329-443)	9.0 – 670	0.16
Homovanillic acid	30	3.7	30.1	3.6 (3.1-4.1)	0.8 – 13	0.01
Pyruvic acid*	34	14	30.6	3.2 (2.7-3.7)	< 4.9	0.21
L-Lactic acid	37	15.2	33.5	9.4 (7.8-11.0)	3.0 – 47	0.74
Pyroglutamic acid	34	3.5	33.5	25.5 (21.2-29.8)	29 – 85	1.04
2-Ketoglutaric acid	49	34.3	35.2	14.5 (11.9-17.1)	< 35	0.17
3-Hydroxybutyric acid	40	17	36.2	1.7 (1.4-2.0)	< 9.9	0.04
4-Hydroxyphenyllactic acid	37	6	36.7	0.6 (0.49-0.71)	< 1.5	0.22
Xanthurenic acid	37	5.4	36.9	0.7 (0.57-0.83)	< 0.74	0.51
Malic acid	50	32.7	38.2	0.53 (0.43-0.63)	< 3.1	0.41
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
Orotic acid	72	24.9	67.2	0.44 (0.29-0.59)	< 1.01	0
Fumaric acid	82	36.4	74.3	0.34 (0.21-0.47)	< 1.35	0.01

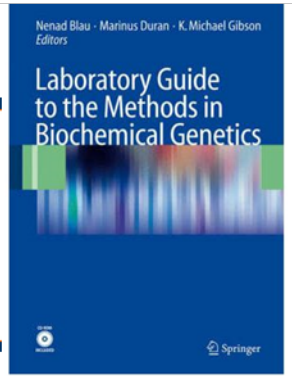
Sample Preparation Procedure

GC-MS TIC Analysis

1. Obtain the creatinine concentration (mg/dl) on the specimen to be analyzed. Determine the amount of urine equivalent to 0.25 mg creatinine. If the creatinine value is <8 mg/dl, extract 3.0 ml of urine.

Organic acid





N A J Med Sci. 2012;5(3): 148-156.]

Referans aralık

TABLE XXVIII. Upper 95% reference limits (URL) for protein-creatinine ratios in urines from healthy individuals. SI units are favoured over conventional units.

Protein	Type of specimen	Upper 95% reference limit (g/mol creatinine; SI unit)	Upper 95% reference limit (mg/g creatinine; conventional unit)
Total protein	Second morning	8[a]	70[a]
Albumin	First morning	3.0	27
	Random	5.3	47
IgG	First morning	0.7	6
	Random	1.0	9
Protein HC	First morning	0.5	4
(α_1-microglobulin)	Random	0.7	6
κ-immuno-reactivity	First morning	0.4	4
	Random	0.7	6
λ-immuno-reactivity	First morning	Below detection limit	Below detection limit
	Random	0.7	6

[a] Turbidometric trichloroacetic acid precipitation method (see below).

Scand J Clin Lab Invest 2000; 60: 1–96

European Urinalysis Guidelines

İdrar Proteinleri ilave bilgiler verebilir

Hasta temelli değerlendirme

TABLE XXIX. Concentration ratios of proteins used for differentiation of proteinuria.

Concentration ratio	Decision limit	Suggested pathological condition
α_2-macroglobulin/albumin	<0.02	Renal haematuria
	>0.02	Postrenal haematuria
IgG/albumin	<0.03	Selective glomerular proteinuria
	>0.03	Non-selective glomerular proteinuria
α_1-microglobulin/albumin	>0.1	Mixed proteinuria
	<0.1	Glomerular proteinuria
CRP (serum)/CRP (urine)	>1.0	Bacterial infection
	<1.0	Rejection of renal transplant
(Albumin + IgG + α_1-microglobulin)/total protein)	>0.6	Renal proteinuria
	<0.6	Suspicion of Bence-Jones proteinuria
Immunoglobulin light chain κ/λ ratio	<1	Monoclonal lambda chain
	$1-5.2$	Polyclonal light chains
	>5.2	Monoclonal kappa chain

Scand J Clin Lab Invest 2000; 60: 1–96

European Urinalysis Guidelines

Kromatografik testler

Çok test kendimizin geliştirdiği tekniklerdir

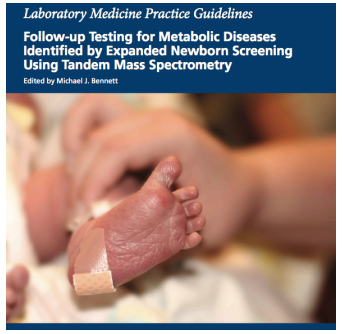
Pre-Validation	• Metod geliştirme • Pre- validasyon (e.g. CLSI EP10)
Validasyon	• Tekrarlanabilirlik • Geri kaznım • Doğruluk, method karşılaştırma • Linearite • Sensitivite (LOQ, LOD) • Spesifisite, interferans • Örnek tipi, matriks çalışmaları • …….
Post Validasyon Süreci	• İç Kalite kontrol uygulamaları • Yeterlilik Testleri • Sistem performans monitorizasyon

System Performance Monitoring

- System Suitability Samples
- Retention Time Monitoring
- Calibrator and Internal Standard Signal Monitoring
- Calibration Slope Monitoring
- Ion Ratio Monitoring
- Carry over
- Maintenance and data log
  - Argon, outlet pressure, regulation pressure etc
  - Tuning data
  - Cone cleaning
  - Reboot HPLC and computer

İdrar metabolik testleri

METBIONET GUIDELINES FOR AMINO ACID ANALYSIS.



Appendix 4. Disorders in which amino acid abnormalities are predominantly found in urine

Condition	Quantitative Urine
Aspartylglycosaminuria	Aspartylglucosamine
Cystinosis	Generalised Aminoaciduria
Cystinuria	↑Cys, ↑Orn, ↑Arg, ↑Lys
Dicarboxylic Aminoaciduria	↑Glu, ↑Asp
Fanconi Syndrome	Generalised Aminoaciduria
Fructose Intolerance	Generalised Aminoaciduria
Galactosaemia (Classical)	Generalised Aminoaciduria
Glutamylcysteine Synthase Deficiency	Generalised Aminoaciduria
Hartnup's Disorder	↑Neutral Amino Acids
Lowe Syndrome	Generalised Aminoaciduria
Lysinuric Protein Intolerance	↑Lys, ↑Arg, ↑Orn, ↑Gln, (↑Cys)
Prolidase Deficiency	Proline containing di- and tri-peptides
Renal Iminoglycinuria	↑Pro, ↑Hyp, ↑Gly
Rickets (Vitamin D Dependent)	Generalised Aminoaciduria
Wilson's Disease	Generalised Aminoaciduria

E.4 Internal Quality Control

- QC material should be of a comparable matrix (plasma, urine, CSF) and concentration to the samples being analysed.
- QC samples should be analysed regularly and after any maintenance changes e.g. with each bottle of ninhydrin.
- Results should be recorded and any falling outside 2 standard deviations should be investigated.
- QC samples may be a commercial product where available or pooled patient samples which may be enriched with other amino acids. Material may be obtained from ERNDIM.

E.5 External Quality Control

- Laboratories should participate in external quality assurance programmes
  E.g. ERNDIM www.erndimqa.nl or UKNEQAS www.uknegas.org.uk

E.6 Precision

- An inter assay CV of <10% should be achievable for most amino acids.

PRİMER AMİNO ASİT METABOLİZMA BOZUKLUKLARI-PLAZMA VE İDRAR

		Fosfoserin	Taurin	Fosfoetanolamin	Aspartik asit	Hidroksiprolin	Treonin	Serin	Asparajin	Glutamik asit	Glutamin	Sarkozin	α-Aminoadipik asit	Prolin	Glisin	Alanin	Sitrüllin	α-Amino-N-Bütirik asit	Valin	Sistin	Metionin	Alloizolösin	Sistatiyonin	İzolösin	Lösin	Tirozin	Arjininosüksinik asit	Fenilalanin	β-Alanin	β-Aminoizobütirik asit	Homosistin	γ-Aminobütirik asit	Triptofan	Hidroksilizin	Ornitin	Lizin	Histidin	L-1-Metilhistidin	L-3-Metilhistidin	Anserin	Karnozin	Amino-β-guanidopropionat	Arjinin
Arjininosüksinik asidüri	P										⇑			⇑	⇑		⇑⇑										⇑								⇓								⇓
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Karbamil fosfat sentetaz eksikliği	P									⇑	⇑				⇑	⇑																				⇑							
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Karnozinemi	P																																					⇑		⇑	⇑		
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Sitrüllinemi	P										⇑						⇑																										⇓
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Sistinüri	P																																										
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Dikarboksilik aminoasidüri	P																																										
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Gyrate(jirat) atrofisi	P																																		⇑								
	İ																																		⇑								
Hartnup hastalığı	P						N,⇓	N,⇓			N,⇓					N,⇓	N,⇓		N,⇓					N,⇓	N,⇓	N,⇓											⇑						
	İ						⇑	⇑			⇑					⇑	⇑		⇑					⇑	⇑	⇑		⇑				⇑	⇑				⇑						
Histidinemi	P															N, ⇑																				⇑							
	İ															N, ⇑																					⇑						
Homosistinüri	P																				⇑										⇑												
	İ																				⇑										⇑												
Hidroksilizinüri	P																																	⇓									
	İ																																	⇑									
Hidroksiprolinemi	P					⇑																																				
	İ					⇑																																				
Hiper-β-alaninemi	P																												⇑														
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Hiperarjininemi(Arjinaz eksikliği)	P																																										⇑
	İ																																										⇑
Hiperdibazik aminoasidüri	P																																										
	İ																																		⇑	⇑						⇑
Lizinürik protein intoleransı	P							⇑			⇑			⇑	⇑																				⇓	⇓							
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Hiperlizinemi	P																																		N, ⇑	⇑⇑						N,
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HHH Sendromu	P																																		⇑								
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Hiperprolinemi	P													⇑	N, ⇑	N, ⇑																			N, ⇑							
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Amino Asit DKD Sonuçları
ERNDIM-EQAS

241 Laboratuvar katılmıştır
211 Yeterli performans göstermiştir
8 laboratuvar yetersiz
22 laboratuvar sonuç göndermemiştir
Alanine: tekrarlanabilirlik (% 4.3), recovery (93%) and interlab CV %8.27
Argininosuksinik asit: tekrarlanabilirlik (%12.8), recovery (84%) and interlab CV %32 (128 lab).
Sistin geri kazanım (49%)
Fenilalanin (347 µmol/l)
laboratuvar içi 4.0%
laboratuvarlar arası 12.8% (6.4–32.7 arasında)

Biray içi varyasyon	%9.5 - 46.4
Bireyler arası varyasyon	%46.6
Referans değişim değeri	%30.9 - 128.4
Total Hata	%.15.2 - 61.0

Clin Chem Lab Med. 2010;48(1):99-104.

ERNDIMQA - ANNUAL REPORT

Amino acids 2013

	Accuracy (mean)		Precision (CV% duplicates)		Linearity (r)		Recovery (%added analyte)		Data All Labs	
Analyte	Your Lab	All Labs	Your Lab	All Labs	Your Lab	All Labs	Your Lab	All Labs	n	Interlab CV
2-Aminobutyric acid		33.4		6.5%		0.994		104%	213	9.94%
Alanine	370	371	4.3%	4.2%	0.999	0.999	97%	96%	259	8.59%
Arginine	298	316	18.2%	5.1%	0.993	0.999	86%	94%	257	11.3%
Asparagine	107	116	14.7%	6.3%	0.974	0.991	101%	108%	239	21.4%
Aspartic Acid	45.6	47.9	5.9%	5.6%	0.961	0.967	84%	86%	252	18.0%
Aspartyl glucosamine		7.36		19.7%		0.944		73%	47	34.7%
Citrulline	115	120	2.0%	5.4%	1.000	0.999	90%	95%	253	10.3%
Cystathionine	33.4	32.9	2.7%	7.8%	0.999	0.996	99%	99%	186	18.0%
Cystine	41.9	41.4	3.7%	9.0%	0.996	0.992	70%	74%	232	13.9%
Glutamic acid	82.3	93.5	25.3%	6.5%	0.934	0.993	81%	99%	259	10.9%
Glutamine		785		5.6%		0.996		95%	246	10.2%
Glycine	507	511	4.1%	4.3%	0.999	0.999	97%	94%	259	10.1%
Histidine	155	154	4.0%	6.1%	0.997	0.996	94%	91%	255	9.85%
Histidine 1-Methyl		28.1		6.1%		0.995		86%	193	12.9%
Histidine 3-Methyl	31.2	32.4	10.7%	7.3%	0.988	0.994	74%	79%	193	14.6%
Hydroxyproline	57.0	60.6	20.0%	8.8%	0.915	0.985	73%	93%	218	13.3%
Isoleucine	250	255	3.6%	4.6%	1.000	0.999	93%	93%	262	10.5%
Leucine	406	396	12.8%	4.8%	0.997	0.999	99%	92%	262	10.3%
Lysine	169	171	2.0%	4.3%	1.000	0.998	87%	85%	257	7.48%
Methionine	264	273	8.4%	4.5%	0.999	1.000	88%	91%	262	10.3%
Ornithine	326	327	2.1%	4.3%	1.000	0.999	96%	95%	260	9.28%
Phenylalanine	350	350	1.4%	4.2%	1.000	0.999	91%	91%	264	9.79%
Pipecolic acid		69.4		10.8%		0.974		99%	56	27.0%
Proline	234	243	12.2%	5.1%	0.988	0.998	79%	85%	240	9.58%
Sarcosine		79.2		10.9%		0.988		98%	171	17.5%
Serine	147	150	9.0%	4.9%	0.998	0.999	94%	96%	258	9.29%
Taurine	144	140	7.3%	4.8%	0.997	0.999	92%	96%	238	8.90%
Threonine	158	160	7.2%	3.9%	0.993	0.998	94%	96%	258	7.03%
Tyrosine	79.4	82.6	4.9%	4.8%	0.998	0.997	93%	97%	265	8.86%
Valine	376	389	3.8%	4.0%	0.998	0.998	99%	95%	264	7.29%
Overall	198	195	7.8%	6.3%	0.988	0.993	90%	93%	229	12.7%

ERNDIMQA - CYCLE REVIEW

Amino acids 2013

Analyte	Your Lab	Med All Labs	n	10%	20%	30%	40%	50%	60%	70%	80%	90%	100%
2-Aminobutyric acid		5.35	176										
Alanine	102	105	234	2 4			1		5 6	7			3
Arginine	26.0	25.0	230	1	4		2	7	5 6		3		
Asparagine	82.0	81.2	210		1 2 3 4			5 7	6				
Aspartic Acid	37.0	38.0	224		4		2 3	1 5 6 7					
Aspartyl glucosamine		2.20	43										
Citrulline	328	347	227	1 2	4	3	7	5 6					
Cystathionine	8.00	7.40	159				1	2	4 6 7	5			3
Cystine	75.0	76.0	205				4	1		5 6 7			2 3
Glutamic acid	66.0	70.4	233	3 4	5	2	7	6		1			
Glutamine		569	225										
Glycine	483	490	235	1 3	6			4	5 7	2			
Histidine	187	189	232			1 4			6 7	3 5	2		
Histidine 1-Methyl		17.8	162										
Histidine 3-Methyl	42.0	40.0	163		3	1 4	6	7		5		2	
Hydroxyproline	72.0	72.6	191	4	1 2				5 6 7				3
Isoleucine	237	239	237	3	4	6	1 2	7	5				
Leucine	104	119	237	4	1	2		5 6 7				3	
Lysine	87.0	95.0	233	1	4		2	6 7	3 5				
Methionine	31.0	31.0	237	4	1 2 3	7		5	6				
Ornithine	100	100	235	4	1		2	7	3 5 6				
Phenylalanine	73.0	74.5	237			4	2	5 6 7	3	1			
Pipecolic acid		25.4	46										
Proline	60.0	66.0	214	1	2	4		5	6 7			3	
Sarcosine		94.9	133										
Serine	12.0	15.0	231	4	1		2	6	3	5 7			
Taurine	33.0	32.0	216				1	6 7		5		2 4	3
Threonine	296	293	233	1				4 5	2 6 7	3			
Tyrosine	97.0	100	236		1 4	2		3 5 7	6				
Valine	217	244	238	1 4	2			7	3 5 6				

	Score		Cumulative Score
< 10%	17%	< 10%	12%
10% - 90 %	83%	10% - 90 %	84%
> 90 %	0%	> 90 %	3%

Bizim deneyimlerimiz

Amino asit

Instand e.V.
EQAS

Assessment May - 2016
Individual results

Ubier - Str. 20 / PF 250211
40223 / 40093 Düsseldorf
Tel (0211) 159213 - 0
FAX (0211) 159213 - 30

4423 Dr Ibrahim UNSAL Acibadem Labmed Clinic Laboratories 24.6.2016

Amino acid analysis (710) (Prof. Dr. rer. nat. Peter Schadewaldt)		sample	your result	target	range	dev. (%)	
Alanine	umol/L	31	451.0	409	348 - 470	10	+
Meth.0-9999		32	357.0	346	294 - 398	3	
b-Alanine	umol/L	31	2.00	0.00	0.00 - 5.00		+
Meth.0-9999		32	1.00	0.00	0.00 - 5.00		
a-Aminoadipic acid	umol/L	31	1.00	2.00	0.00 - 5.00	-50	-
Meth.0-9999		32					
Arginine	umol/L	31	36.00	36.0	25.0 - 47.0	0	+
Meth.0-9999		32	22.00	24.0	16.0 - 32.0	-8	
Asparagine		31	1	1, Analyt vorhanden			+
Meth.0-9999		32	1	1, Analyt vorhanden			
Aspartic acid	umol/L	31	14.00	12.0	6.00 - 18.0	17	+
Meth.0-9999		32	7.00	6.00	3.00 - 10.0	17	
Citrulline	umol/L	31	22.00	22.0	15.0 - 29.0	0	+
Meth.0-9999		32	24.00	25.0	17.0 - 33.0	-4	
Cystine	umol/L	31	1.00	2.00	0.00 - 10.0	-50	+
Meth.0-9999		32	3.00	5.00	0.00 - 10.0	-40	
Glutamine	umol/L	31	379.0	376	320 - 432	1	+
Meth.0-9999		32	440.0	460	391 - 529	-4	
Glutamic acid	umol/L	31	118.0	123	105 - 141	-4	+
Meth.0-9999		32	57.00	54.0	45.0 - 62.0	6	
Glycine	umol/L	31	210.0	184	156 - 212	14	+
Meth.0-9999		32	198.0	181	154 - 208	9	
Histidine	umol/L	31	79.00	75.0	63.0 - 87.0	5	+
Meth.0-9999		32	66.00	64.0	54.0 - 74.0	3	
4-Hydroxyproline	umol/L	31	15.00	11.0	0.00 - 20.0	36	+
Meth.0-9999		32	6.00	3.00	0.00 - 20.0	100	

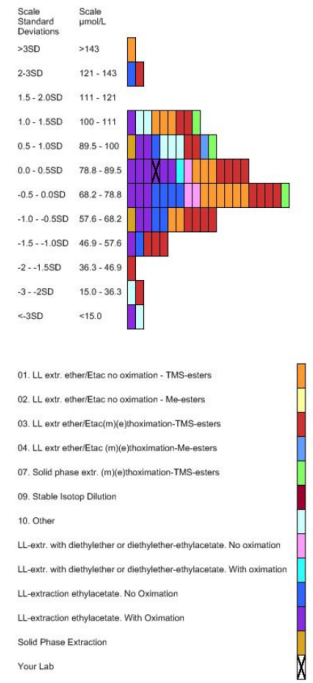
Organik asit

ERNDIM
QUALITY ASSURANCE IN LABORATORY TESTING FOR IEM

ERNDIMQA - ANALYTE IN DETAIL
Quant.org.acids 2016

Analyte : 2-OH Glutaric acid
Deadline : 28/10/2016
Unit : µmol/L
Your Method : LL-extraction ethylacetate. With Oximation
Your Result : 86.4

Parameter	Method Results	All Labs Results
n :	16	79
Mean :	84.3	78.8
Median :	85.0	77.7
SD :	11.6	21.3



Yeterlilik Testlerini klinik durum temelli olması önemlidir

Disorder	Proportion of laboratories giving the correct diagnosis	Disorder	Proportion of laboratories giving the correct diagnosis
Methylmalonic aciduria	100%	2-OH glutaric aciduria	92%
Medium-chain acyl CoA dehydrogenase deficiency	100%	Malonic aciduria	92%
Isovaleric aciduria	100%	Morquio disease	92%
Ornithine aminotransferase deficiency	100%	4-hydroxybutyric aciduria	91%
Hunter disease	100%	Tyrosinaemia type 1	89%
Alkaptonuria	100%	Multiple acyl CoA dehydrogenase deficiency	88%
Ethylene glycol ingestion	96%	Hurler disease	87%
Tyrosinaemia type 2	96%	Homocystinuria	82%
Mevalonic aciduria	96%	Biotinidase deficiency	82%
Maple syrup urine disease	96%	Hypophosphatasia	69%
Glutaric aciduria type 1	94%	Fumarase deficiency	53%
Cystinuria	93%	Peroxisomal disorder	46%
D-glyceric aciduria	93%	Prolidase deficiency	38%
Phenylketonuria	92%	Sialidosis	27%

Laboratory Measurement of Urine Albumin and Urine Total Protein in Screening for Proteinuria in Chronic Kidney Disease

DKK değerlendirme sonuçlarını değerlendiriken dikkatli olunmalıdır

Instrument	No. Labs	SD	CV (%)	Low 8.1	High 132.0
Beckman Coulter LX20/LX40	1	1.24	1.8	8.4	130.7
Roche Diagnostics Hitachi Cobas c501/c502	22	1.85	2.7	9.7	129.2
Siemens Healthcare Diagnostics	1	2.20	2.8	8.1	151.6
Roche Diagnostics Hitachi Modular	15	2.30	3.2	10.5	132.5
INTEGRA 400/400+	7	2.23	3.2	7.7	132.0
ADVIA 1650/1800	5	2.49	3.4	5.7	148.9
Roche Diagnostics Hitachi 912	1	2.46	3.5	7.0	132.4
Abbott ARCHITECT c8000	11	2.63	3.5	7.5	143.3
Beckman Coulter AU2700/AU5421/AU5432	7	2.25	3.6	7.6	117.9
BN ProSpec	1	2.87	3.7	8.9	144.6
Beckman Coulter UniCel DxC 600/601i	13	2.75	3.7	8.2	140.5
Beckman coulter AU400	1	2.31	3.8	5.7	117.1
ADVIA 2400	13	2.97	4.0	6.1	140.8
Beckman Coulter AU600/640	9	2.63	4.1	7.7	118.6
Abbott ARCHITECT c4000/c16000	5	3.13	4.2	8.4	138.6
Roche Diagnostics Hitachi 917	2	2.97	4.2	10.1	129.9
Beckman Coulter Immage/Immage 800	10	2.75	4.4	6.8	121.8
Roche Diagnostics Hitachi Cobas c701/c702	1	3.6	5.1	11.0	133.4
Beckman Coulter UniCel DxC 800	7	4.05	5.7	8.6	138.0
INTEGRA 700/800	23	4.08	5.9	5.8	132.3
DCA Vantage	2	4.38	6.2	4.9	133.9
Siemens Healthcare Diagnostics DCA 2000	2	4.32	6.4	6.0	128.6
VITROS 5,1 F S/5600 (c)	6	6.11	8.3	8.1	134.8
Immulite 2000/2000 XPi	1	6.22	8.8	8.8	131.9
Immulite/Immulite 1000	2	8.69	11.4	5.1	147.1
Dimension Vista	2	9.62	11.4	11.9	157.5
Dimension XL/RXL/RXL MAX	14	7.95	13.9	6.1	112.6

Genel olarak İç Kalite Kontrol Materyali Nerden temin edebilirim?

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Nicotine and Metabolites	CDT
Parameters for Occupational Medicine	Drugfree
Parameters for Environmental Medicine	Ethylglucuronide, Ethylsulfate
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Porphyrins	Metanephrines
Trace Elements	Methylmalonic Acid

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« Back

CLINICAL CHEMISTRY 9: URINE ANALYSIS

Urine, strip tests A

External quality assessment (EQA) for Urine, strip test

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Human urine controls containing a large panel of drugs of abuse at various levels for monitoring the precision of confirmatory test methods

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- **CAP** (College of American Pathologist)
  - Yılda 4 kez. 60'ın üzerinde 5000 üzerine katılımcı
- **CDC Newborn and LAMP** (Lead and Multielement Proficiency Program)
- **BİO-RAD EQAS** (External Quality Assurance Services)
  - (Genel biyokimya,TDM,Tümör markırları,Immunoassay)
  - 12 ayda 24 örnek, 50 ülkeden fazla katılımcı
- **LABQUALITY**
  - Yılda 1-6 kez. 32 ülkeden 2280 laboratuvar
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- **Oneworld**
  - Canada
- **Bio-Dev**
  - Italy
- **ERNDIM** (European Research Network for evaluation and improvement of screening, Diagnosis and treatment of Inherited disorders of Metabolism)

Sınırlıdır!

- Aslında kullanımında **klinik bulgular çok** önemlidir. (Üriner enfeksiyon, diabetik nefropati, idrar katekolaminler, organik asidüri ve aminoasidüri, toksikoloji ve ilaç analizleri). Gereksiz test isteği yapılan tesler arasındadır.
- İdrar diğer biyolojik sıvılarından **farklıdır ve biyolojik varyasyonu yüksektir**
- İdrar analizleri çoğunlukla **kalitatif ve semi-kantitatif** test grubundadır
- **Kreatinin düzeltmeleri** konusunda sınırlılıklar bilinmelidir
- Uygulamalarda **İKK ve DKD** çalışmaları daha sınırlıdır. **Hasta temelli kalite kontrol (diğer testler, klinik durum vs)** önemlidir.
- KK materyali temini ve standardizasyonu sınırlıdır. Çoğunlukla **firma üreticilerinin materyalleri** kullanılmaktadır. Referans materyal ve referans metot sınırlıdır.
- **Test üreticiler arasında standardizasyon iş birlikteliği** sınırlıdır ve uyumluluk test sonuçları diğer laboratuvar testlerine göre sınırlıdır
- İdrar testlerinin **yeterliliğinin değerlendirilmesinde** eğitim eksikliklerimiz vardır

Yanıt bekleyen sorular

1. İdrar materyali diğer biyolojik sıvılardan **farklı mıdır**?
2. İdrar testlerinin **yeterlilik değerlendirmeleri hangi kriterlere** göre yapılacaktır?
    1. İdrar kimyasal ve mikroskobi analizleri
    2. Kromatografik idrar testleri
        1. İlaç analizleri
        2. Toksikoloji testleri
        3. Metabolik testleri
3. Kalite kontrol uygulamaları, kuralları, sıklıkları ve değerlendirme prosedürleri nasıl uygulanacaktır?
4. **Nasıl bir ürün istiyorsunuz, nasıl değerlendireceksiniz ve uygunsuz ürün ile karşılaştırıldığında neler yapacaksınız?**

Tarama Testleri

Silver Nitroprusside Test

1. Place 1 mL of urine in a tube.
2. Add two drops concentrated NH_4OH.
3. Add 0.5 mL 5% silver nitrate.
4. Wait 10 minutes.
5. Add five drops sodium nitroprussi
6. Observe for red-purple color.

2,4-Dinitrophenylhydrazine (DNPH) Test

1. Place 1 mL of urine in a tube.
2. Add 10 drops of 0.2% 2,4-DNPH in 2N HCl.
3. Wait 10 minutes.
4. Observe for yellow or white precipitate.

Cyanide-Nitroprusside Test

1. Place 3 mL of urine in a tul
2. Add 2 mL sodium cyanide.
. Wait 10 minutes.
. Add five drops 5% sodium
. Observe for red-purple colc

Ferric Chloride Tube Test

1. Place 1 mL of urine in a tube.
2. Slowly add five drops of 10% ferric chloric
3. Observe color.

Mucopolysaccharide (MPS) Paper Test

1. Dip filter paper into 0.59% azure A dye in 2% acetic acid.
2. Dry.
3. Add one drop of urine to paper.
4. Wash with 1 mL acetic acid + 200 mL methanol diluted to a liter.
5. Observe for blue color.

Nitroso-Napthol Test

1. Place five drops of urine in a tube.
2. Add 1 mL of 2.63N nitric acid.
3. Add one drop of 21.5% sodium nitrite.
4. Add 0.1 mL 1-nitroso-2-napthol.
5. Mix.
6. Wait 5 minutes.
7. Observe color.

Fructose Screening Test

1. Place 5 mL of urine in a tube.
2. Add 5 mL of 25% HCl.
3. Boil 5 minutes.
4. Add 5 mg resorcinol.
5. Boil 10 seconds.
6. Observe for a red precipitate.

p-Nitroaniline Test

1. Place one drop of urine in a tu
2. Add 15 drops of 0.1% *p*-nitro
3. Add five drops of 0.5% sodiu
4. Mix.
5. Add 1 mL of 1 M sodium acetate buffer at pH 4.3.
6. Boil for 1 minute.
7. Add five drops of 8N NaOH.
8. Observe for emerald green color.

Test	Disorder	Observation
	Cystinuria	Sulphur
	Cystinosis	Sulphur
	Homocystinuria	Sulphur
Crystals	Tyrosyluria	Sheaths of fine needles
	Cystinuria	Colorless hexagonal plates
	Lesch-Nyhan disease	Yellow-brown crystals
Ferric chloride tube test	Phenylketonuria	Blue-green
	Tyrosyluria	Transient green
	Alkaptonuria	Transient blue
	Melanuria	Gray-black
	Maple syrup urine disease	Green-gray
	Indicanuria	Violet-blue with chloroform
	5-HIAA	Blue-green
Nitroso-naphthol	Tyrosyluria	Red
	Maple syrup urine disease	Red
	5-HIAA	Violet with nitric acid
2,4-Dinitrophenylhydrazine	Phenylketonuria	Yellow
	Tyrosyluria	Yellow
	Maple syrup urine disease	Yellow
	Isovaleric acidemia	Yellow
	Propionic acidemia	Yellow
	Methylmalonic acidemia	Yellow
Acetest	Maple syrup urine disease	Purple
	Isovaleric acidemia	Purple
	Propionic acidemia	Purple
	Methylmalonic acidemia	Purple
	Melanuria	Red
p-Nitroaniline	Methylmalonic acidemia	Emerald green
Cyanide-nitroprusside	Cystinuria	Red-purple
	Cystinosis	Red-purple
	Homocystinuria	Red-purple
Silver nitroprusside	Homocystinuria	Red-purple
	Alkaptonuria	Black
Ehrlich reaction	Porphyrinuria	Red
	Melanuria	Red
Cetytrimethylammonium bromide	Mucopolysaccharidoses	White turbidity
Mucopolysaccharide paper	Mucopolysaccharidoses	Blue spot
Clinitest	Melituria	Orange-red
	Cystinosis	Orange-red
	Alkaptonuria	Orange-red

Table 3–4 Types of Urine Specimens

Type of Specimen	Purpose
Random	Routine screening
First morning	Routine screening Pregnancy tests Orthostatic protein
Fasting (second morning)	Diabetic screening/monitoring
2-hour postprandial	Diabetic monitoring
Glucose tolerance test	Optional with blood samples in glucose tolerance test
24-h (or timed)	Quantitative chemical tests
Catheterized	Bacterial culture
Midstream clean-catch	Routine screening Bacterial culture
Suprapubic aspiration	Bladder urine for bacterial culture Cytology
Three-glass collection	Prostatic infection

MICROSCOPIC QUANTITATIONS

Quantitate an average of 10 representative fields. Do not quantitate budding yeast, mycelial elements, trichomonas, or sperm, but do note their presence with the appropriate LIS code.

Epithelial cells/LPF		
	None:	0
	Rare:	0–5
	Few:	5–20
	Moderate:	20–100
	Many:	>100
Casts/LPF		
	None:	0
	Numerical ranges:	0–2, 2–5, 5–10, >10
RBCs/HPF		
	None:	0
	Numerical ranges:	0–2, 2–5, 5–10, 10–25, 25–50, 50–100, >100
WBCs/HPF		
	None:	0
	Numerical ranges:	0–2, 2–5, 5–10, 10–25, 25–50, 50–100, >100
Crystals/HPF		
	None:	0
	Rare:	0–2
	Few:	2–5
	Moderate:	5–20
	Many:	>20
Bacteria/HPF		
	None:	0
	Rare:	0–10
	Few:	10–50
	Moderate:	50–200
	Many:	>200
Mucous threads		
	Rare:	0–1
	Few:	1–3
	Moderate:	3–10
	Many:	>10

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Urinalysis: Current Status and Prospects for the Future*

ABSTRACT

More than 300 million routine clinical analyses are performed annually in the United States. Methods for routine clinical urine examination, including detection of bacteriuria, are briefly reviewed. Prospects of some newer, better techniques to carry out such analyses are introduced. A preliminary report is presented on the use of supravital microscopic fluorescence technique (SMFT), employing acridine orange as a non-specific staining fluorochrome. Results of examining 218 unspun urine specimens by SMFT are compared to traditional bacteriologic culture at a large pediatric hospital reference laboratory.

Assessment of the Diurnal Variations in Urinary Homovanillic and Vanillylmandelic Acid Excretion for the Diagnosis and Follow-Up of Patients with Neuroblastoma

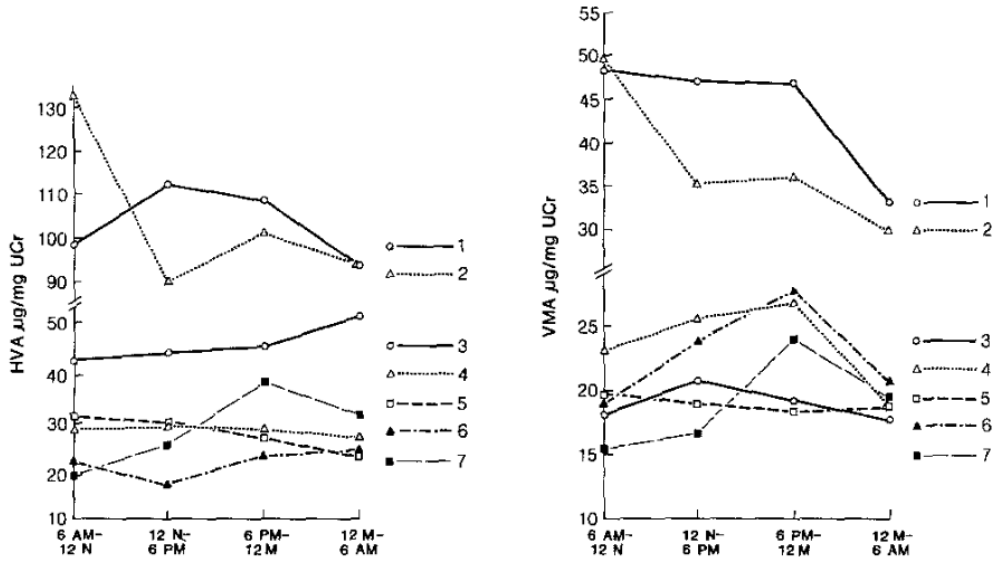

Figure 2 — Urinary HVA and VMA levels (in µg/mg UCr) obtained from seven studies in a patient with neuroblastoma. The studies were performed at one-month intervals and they are numbered according to their chronological order.

Value of Random Urinary Homovanillic Acid and Vanillylmandelic Acid Levels in the Diagnosis and Management of Patients with Neuroblastoma: Comparison with 24-Hour Urine Collections

DISCUSSION

Increased urinary excretion of catecholamines and their metabolites in patients with neuroblastoma was first reported by Voorhess and Gardner.[18,19] The diagnostic value of VMA in neuroblastoma has been emphasized because this acid is the metabolite of epinephrine and norepinephrine.[20]

The diagnostic value of HVA, the dopamine me-

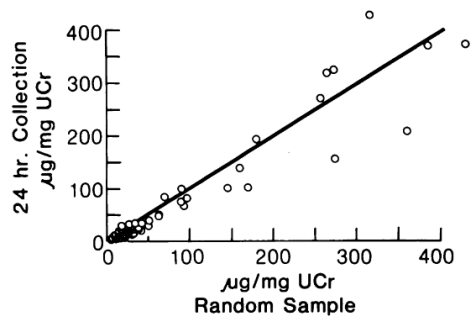

Fig 1. Homovanillic acid levels in random urinary samples *v* 24-hour urine collections. A total of 59 determinations were compared. Correlation coefficient was 0.951 ($P < .001$). Abbreviation used is: UCr, urinary creatinine.

of catecholamine metabolite excretion as well as information on the circadian rhythm and seasonal variations of catecholamine excretion.[25–30]

The effects of different diets containing increased

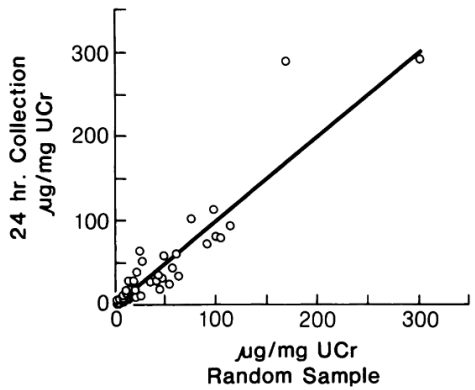

Fig 2. Vanillylmandelic acid levels in random urinary samples *v* 24-hour urine collections. A total of 52 determinations were compared. Correlation coefficient was .929 ($P < .001$). Abbreviation used is: UCr, urinary creatinine.