IR-1 – Industrijom sponzorirana radionica
ROCHE, IR1-1

Analitička procjena imunokemijskog analizatora Modular-E170 tvrtke Roche Diagnostics

Dvornik Štefica

Klinički bolnički centar Rijeka, Rijeka, Hrvatska

Analitička procjena imunokemijskog analizatora MODULAR E – 170 provedena je prema preporukama ECCLS – a za određivanje koncentracije Ca-125, CEA, Ca-19-9, α-fetoprotein i PSA.
Procjena je obuhvatila nepreciznost u seriji i iz dana u dan, netočnost, te usporedna određivanja. Sva ispitivanja napravljena su za obje ćelije MODULARA E – 170.
Nepreciznost u seriji određena je na 10 uzoraka istog seruma pacijenta sa normalnim vrijednostima i na 10 uzoraka istog seruma pacijenta sa visokim vrijednostima. Za sve ispitivane analite dobiveni su zadovoljavajući koeficijenti varijacije. Prosječno za Ca-125 koeficijent varijacije bio je 1,1%, za CEA 0,86%, za Ca-19-9 iznosio je 0,9%, za α-fetoprotein 1,1% i za PSA 0,43%.
Nepreciznost iz dana u dan određivana je u 2 kontrolna seruma (niski i visoki nivo) kroz 10 dana. Prosječno za Ca-125 nepreciznost je iznosila 4,4%, za CEA 3,7%, za Ca-19-9 3,1 % za α-fetoprotein 2,9% i za PSA 4,1% što nam pokazuje da su koeficijenti varijacije iz dana u dan za sve analite zadovoljavajući. Netočnost mjerenja izračunata je kao % odstupanja (R%) srednje izmjerene vrijednosti od srednje deklarirane vrijednosti kontrolnih seruma. U izračunu su korištene srednje izmjerene vrijednosti dobivene pri određivanju nepreciznosti iz dana u dan. Vrijednost za "R" prihvatljiva je za sve analite u oba kontrolna seruma i na obje ćelije i prosječno je iznosila 1,03% za Ca-125 za CEA 4,8%, za Ca-19-9 bila je 6,9%, za α-fetoprotein 2,5 % i za PSA 1,8%.
Linearnost je za sve ispitivane parametre bila unutar dozvoljene analitičke pogreške.
Rezultati usporednih ispitivanja analizirani su u odnosu na rezultate dobivene na Architectu tvrtke Abbott te su pokazali visok stupanj korelacije.
Prikazani rezultati provedene analitičke procjene imunokemijskog analizatora MODULAR E – 170 za određivanje koncentracije navedenih tumorskih biljega pokazuju da se aparat i reagensi mogu koristiti u laboratoriju.

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IR-1 – Industry sponsored workshop
ROCHE, IR1-1

Analytical estimation of Roche immunochemistry analyzer Modular E-170

Dvornik Štefica

Clinical Hospital Center Rijeka, Rijeka , Croatia

We estimate analytical performance of Roche immunochemistry analyzer according to ECCLS recommendations by determination of tumor marker concentrations of CA-125, CEA, CA 19-9, a-fetoprotein and PSA. Imprecision within-run, imprecision between-run and accuracy were determined for both Modular E-170 photometric cells. Imprecision within-run was analyzed on ten replicates of same serum samples for two different concentrations (normal and high) and mean CVs were 1,1% for CA-125, 0,86% for CEA, 0,9% for CA 19-9, for a-fetoprotein 1,1% and 0,43% for PSA.
Imprecision between-run (for two control samples measured ten days) showed a little bit higher but acceptable CVs: 4,4 % for Ca-125, 3,7% for CEA, 3,1 % for CA 19-9, for a-fetoprotein 2,9% and for PSA it was 4,1%.
Inaccuracy was tested using two different control materials (normal and high) for 10 days. Mean biases from target values were acceptable: 1,0 3% for CA-125, for CEA it was 4,8%, 6,9% for CA 19-9, for a-fetoprotein 2,5 % and 1,8% for PSA.
Linearity was also determined and was satisfactory for all tests. Comparison with Abbott Architect results were assessed and results of the comparison study showed no statistical difference according to the Passing & Bablok regression analysis. Results of the study indicate that determination of tumor marker concentrations on Roche Modular E-170 provides precise and accurate results and are convenient for use in routine laboratory.

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IR1-2

Roche/Hitachi Modular – Analytics E170

Vuletić Ana

Opća bolnica Zadar, Odjel za laboratorijsku dijagnostiku, Zadar

Ovaj potpuno automatizirani instrument za imunokemijska određivanja dio je MODULAR – ANALYTICS sustava te može funkcionirati kao njegov sastavni dio, ali i kao samostalni analizator, vrlo prihvatljiv za rutinski rad. Nakon vrlo dobrog iskustva na ELECSYS-u 2010, Modular – Analytics E170 ponudio nam je rješenje za brži protok uzoraka i veći broj parametara "on board" u našem laboratoriju. "Family" koncept reagenasa otvorio nam je mogućnost usporedbe rezultata na oba instrumenta, a Elecsys 2010 stavio u funkciju "back up" uređaja (R. V. su u oba slučaja identične, štoviše koriste se identični reagensi).
Dnevni protok u našem laboratoriju je 700 do 800 različitih testova (reproduktivni hormoni, hormoni štitnjače, tumorski biljezi, koštani biljezi, kortizol, PTH, feritin, B-12, ukupni IgE). Uređaj je umrežen na LIS. Rađena je skraćena evaluacija na 200 različitih uzoraka/10 različitih testova i dobiveni rezultati su u skladu s deklariranim C. V.
Prednosti uređaja:

- Kapacitet 170 testova/sat, uz mogućnost povećanja (dogradnja modula)
- Mogućnost kontinuiranog dodavanja uzoraka i potrošnog materijala bez zaustavljanja aparata
- Automatski rerun i dilucija
- Vrlo dobra "lot to lot" varijabilnost i stabilnost kalibracijskih krivulja

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IR1-2

Roche/Hitachi Modular – Analytics E170

Vuletić Ana

General hospital Zadar, Department for lab. diagnostics

This entirely automatized instrument for immunological tests is a part of MODULAR - ANALYTICS system and is capable of working as one of its parts, but also as an individual analyser, well established for routine use. After indeed positive experience with ELECSYS 2010, Modular – Analytics E 170 offers a solution for the higher samples throughput and greater number of "on board" parameters in our lab. "Family concept" in the heterogenous immunology reagent enables us to obtain comparable results on both instruments, while it sets up Elecsys as a "back up" device (reference values are identical in both cases, moreover the same reagents are used).
Daily throughput in our lab is 700 – 800 different tests (reproductive hormons, thyroid hormons, tumor markers, bone markers, cortizol, PTH, ferritin, B-12, total IgE). The analyser is integrated in LIS. Shortened evaluation was made with 200 heterogenous samples/10 heterogenous tests. The results obtained were compatible with declarated C.V.
Advantages of E 170:

- Test throughput: 170 tests/hour, with the increase possibility (on-site modul extendability)
- Continuous reloading of samples and disposable materials during routine operation possible without interruptions
- Automatical rerun and dilution
- Very good «lot to lot» variability and stability of calibration curves

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IR1-3

Biljezi koštane pregradnje na imunokemijskom analizatoru Modular Analytics <E> tvrtke Roche Diagnostics

Horvat V, Mandić S

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Osteoporoza je metabolička koštana bolest karakterizirana smanjenom mineralnom gustoćom, promjenama

IR1-3

Bone turnover markers on immunochemistry analyzer Modular analytics <E> by Roche Diagnostics

Horvat V, Mandić S

Cinical Hospital Osijek, Department for Clinical Chemistry, Osijek, Croatia

Osteoporosis is metabolic bone disease characterized with decreased mineral density, michroarhitetural de-

mikroarhitekture i smanjenim biomehaničkim svojstvima kosti koji mogu imati za posljedicu prijelome i deformitete. Najviše pogađa starije ljude, a žene u postmenopauzi, predstavljaju najrizičniju skupinu.
Trenutni standard u dijagnozi osteoporoze je mineralna gustoća kostiju (BMD). Međutim, ona nije prediktor gustoće kostiju u budućnosti, pokazalo se i da smanjenje rizika loma često ne korelira s odgovarajućim BMD porastom.
Biokemijski biljezi koštane pregradnje su molekule koje izravno proizlaze iz strukture i funkcije koštanog tkiva. Iako nisu specifični za određenu bolest, njihovo je uvođenje u kliničku praksu značajno poboljšalo dijagnostički potecijal jer se pokazalo da dobro koreliraju sa učestalošću prijeloma, pa primjenjeni zajedno s DXA, značajno olakšavaju odluku o tome kada početi liječenje. Dijelimo ih na:

1. biljege koštane izgradnje (ALP, BAP, osteocalcin, P1NP, P1CP)
2. biljege koštane razgradnje (β-CrossLaps, NTX, DPD, PYD).

International Osteoporosis Foundation (IOF) preporuča uporabu koštanih markera u predviđanju prijeloma i deformiteta kostiju, te u praćenju terapije. Prije davanja terapije preporuča se inicijalno određivanje β-crosslapsa i P1NP.
Oba markera se nalaze u programu imunokemijskog analizatora MODULAR ANALYTICS <E> firme ROCHE DIAGNOSTICS. To su potpuno automatizirani testovi za određivanje u serumu. Vrijednosti β-crosslapsa mjerene Elecsys® β-CrossLaps setom vrlo dobro koreliraju s određivanjem u urinu. Osim toga β-crosslaps i P1NP antigeni su vrlo stabilni na 4°C pa su uzorci stabilni i do dva dana na sobnoj tempetaturi.

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terioration of bone tissue and decreased biomehanical properties of bone, which can lead to a bone fractures and deformations. Elderly are most troubeld, and postmenopauzal women are in greatest risk.
Bone mineral densitometry (BMD) is the current standard for diagnosis of osteoporosis. But, BMD is not a predictor of future bone density and a reduction in the fracture risk does not always correlate with corresponding BMD increase.
Biochemical markers of bone turnover are related primarily to bone structure and function. Although not related specifically to any disease, they enhanced significitanly diagnostic potential in clinical praxis. In combination with DEX, they are of great help to physician in decision when to start terapy. They are divided into:

1. bone formation markers (ALP, BAP, Osteocalcin, P1NP, P1CP)
2. bone resorption markers (β-CrossLaps, NTX, DPD, PYD).

International Osteoporosis Foundation (IOF) recommends bone markers for use in therapy monitoring and prediction of fragility fractures in their guidelines. For the initial assessment before treatment selection P1NP and β-CrossLaps should be measured.
Both assays are fully automated serum assays available on MODULAR ANALYTICS <E> SYSTEM from ROCHE DIAGNOSTICS. Serum values measured with Elecsys® β-CrossLaps very vell correlate with urine samples. Beside that β-CrossLaps and P1NP antigens are very stabile at 4°C so samples can be stored at room temperature for up to 2 days.

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IR2 – Industrijom sponzorirana radionica 2 – MDLAB, IR2-1

Rutinske koagulacijske analize na koagulacijskom analizatoru ACL TOP

Miloš M, Coen-Herak D, Kačkov S, Zadro R

Klinički zavod za laboratorijsku dijagnostiku, KBC Zagreb, Zagreb, Hrvatska

ACL TOP (Instrumentation Laboratory, Italija) je potpuno automatizirani koagulacijski analizator za istodobno mjerenje rutinskih i specijalnih analiza uporabom koagulacijskih, kromogenih i imunokemijskih metoda. U ovom smo radu ispitivali svojstva analizatora u izvođenju rutin-

IR2 – Industry sponsored workshop 2 – MDLAB, IR2-1

ACL TOP performance in routine coagulation testing

Miloš M, Coen-Herak D, Kačkov S, Zadro R

Clinical Institute of Laboratory Diagnosis, Zagreb University Hospital Center, Zagreb, Croatia

ACL TOP (Instrumentation Laboratory, Italy) is a fully automated coagulation analyzer, designed for simultaneous measurement of routine and special coagulation parameters by using clotting, chromogenic and immunological methods. In the present study we evaluated its

skih koagulacijskih analiza: protrombinskog vremena (PV, RecombiPlasTin), aktiviranoga parcijalnog tromboplastinskog vremena (APTV, SynthASil i APTT-SP) i aktivnosti fibrinogena (FIB, Fibrinogen-C XL) ispitivanjem nepreciznosti u seriji, nepreciznosti iz dana u dan i nepreciznosti kalibracijske krivulje za PV i FIB. Napravljena je i korelacija s Behring Coagulation System (BCS; Dade Behring, Njemačka) za sva 3 testa na najmanje 100 uzoraka plazme sa širokim rasponima vrijednosti uporabom slijedećih reagensa: Innovin za PV, ActinFS za APTV, Multibren U za FIB. Za nepreciznost u seriji dobiveni su koeficijenti varijacije (CV) od 1% (PV INR u terapijskom rasponu) do 7,7% (FIB u patološkom području), a za nepreciznost iz dana u dan od 2,7% (APTV u Low Abnormal Control) do 7,7% (PV u Normal Control). Dobiveni su slijedeći CV za nepreciznost standardne krivulje: PV 1,3-2,3%; FIB 4,8-7,0%. Ispitivanjem korelacije dobiveni su zadovoljavajući koeficijenti korelacije: r=0,936 za PV%, 0,944 za PV INR, 0,863 za APTV sa SynthASilom, 0,922 za APTV s reagensom APTT-SP, 0,960 za FIB, dok su prema analizi prema Blandu i Altmanu dobivene određene razlike između vrijednosti dobivene na BCS i ACL TOP. Srednja razlika za PV za sve ispitivane uzorke bila je 0,19, dok je za uzorke u terapijskom rasponu (INR-BCS=2,00-3,50) bila 0,25, a za uzorke s INR-BCS >3,50 iznosila je 1,05, što može dovesti do različitih odluka o doziranju oralnih antikoagulanata. Srednja razlika za APTV bila je manja za SynthASil (1,3) nego za APTT-SP (-4,0). Nadalje, prema referentnom intervalu preporučenom od proizvođača za SynthASil, od 63 normalna rezultata za APTV dobivena na BCS samo 31 (49%) normalan rezultat je dobiven na ACL TOP, a od 39 patoloških rezultata na BCS dobivena su 24 (66%) patološka rezultata na ACL TOP. Srednja razlika za FIB bila je -0,44 za sve ispitivane uzorke, dok je u skupini normalnih rezultata bila nešto viša (-0,7). Prema navedenim rezultatima i nakon usklađivanja s dokumentom Hrvatske komore medicinskih biokemičara o harmonizaciji laboratorijskih nalaza u koagulaciji, ACL TOP može biti pogodan analizator za koagulacijski laboratorij srednje veličine.

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performance in routine coagulation testing: prothrombin time (PT, RecombiPlasTin), activated partial thromboplastin time (aPTT, SynthASil and APTT-SP) and fibrinogen activity (FIB, Fibrinogen-C XL), by determining within-run and between-run imprecision and imprecision of the standard curve for PT and FIB. Additionally, the correlation to Behring Coagulation System (BCS; Dade Behring, Germany) was performed with the following reagents: Innovin for PT, Actin FS for aPTT and Multifibren U for FIB, by using at least 100 plasma samples in normal and pathological range for all tested parameters. Within-run coefficients of variation (CVs) ranged from 1.0% (PT INR in the therapeutic range) to 7.7% (FIB in the pathological range), and between-run from 2.7% (aPTT in the Low Abnormal Control) to 7.7% (PT in the Normal Control). The obtained CVs for standard curve imprecision were 1.3-2.3% for PT, and 4.8-7.0% for FIB. In the correlation study satisfactory correlation coefficients were obtained: r=0.936 for PT%, 0.944 for PT INR, 0.863 for aPTT with SynthASil, 0.922 for aPTT with APTT-SP, 0.960 for FIB, while according to Bland and Altman analysis we found some differences between the values obtained on BCS and ACL TOP. The mean difference for PT INR was 0.19 for all tested samples, being higher for samples in the therapeutic range (INR-BCS=2.00-3.50) and for samples with INR-BCS >3.50 (0.25 and 1.05, respectively); these differences may lead to different anticoagulant dosage decisions. The mean difference for aPTT was lower with SynthASil (1.3) than with APTT-SP (-4.0). Additionally, according to the reference interval recommended by the manufacturer for SynthASil, only 49% (31/63) of normal aPTT results on BCS were normal on ACL TOP, and 66% (24/39) of pathological results on BCS were pathological on ACL TOP. The mean difference for FIB was -0.44 for all tested samples, being greater in the group with normal FIB activity (-0.70). According to the above results and after adjustment to the document of the Croatian Chamber of Medical Biochemists on harmonization of coagulation laboratory reports, ACL TOP could be a suitable analyzer for mid-size coagulation laboratories.

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Course program…

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3. Genetic susceptibility to the Metabolic syndrome

RISK ASSESMENT — **SATURDAY: 15^{00}-18^{30}**

4. Dislipidemia and MS
5. Coronary disease and MS
6. Insulin resistance and MS
7. Hypertension and MS

DIAGNOSTIC EXACTNESS OF BIOCHEMICAL MARKERS — **SUNDAY: 8^{00}-12^{00}**

8. Evidence based laboratory medicine
9. Pro-inflammatory and thrombotic factors
10. Approach to the treatment of MS

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Sestre milosrdnice University Hospital
Vinogradska 29, 10 000 Zagreb
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Elizabeta Topić, Dragan Primorac, Stipan Janković

Medicinskobiokemijska dijagnostika u kliničkoj praksi

Ovaj suvremeni i sveobuhvatni udžbenik prikazuje primjenu medicinske biokemijske dijagnostike u kliničkoj praksi i time premošćuje edukacijsku prazninu između medicinske biokemijske dijagnostike i kliničkih disciplina. Udžbenik je podijeljen na dva glavna dijela: Uvodni dio obuhvaća značajke medicinske biokemije kao dijela znanstvene skrbi, osvrt na biološke varijacije biokemijskih i hematoloških sastojaka krvi te utjecaj različitih čimbenika na interpretaciju laboratorijskog nalaza.
Posebni dio uključuje medicinskobiokemijsku dijagnostiku hitnih stanja, bolesti srca i krvnih žila, gastrointestinalnoga sustava, urološkoga sustava, endokrinološkoga sustava, hematoloških bolesti i bolesti zgrušavanja, neuroloških bolesti i ostalih medicinskih područja. Knjiga je namijenjena studentima, odnosno dodiplomskoj nastavi iz medicinske biokemije i poslijediplomskoj nastavi različitih predmeta iz područja biomedicinskih znanosti te specijalizantima različitih medicinskih struka (interna medicina, pedijatrija, neurologija), a posebice medicinske biokemije.

Elizabeta Topić, Dragan Primorac, Stipan Janković

Medical biochemistry diagnosis in clinical practice

This modern and comprehensive textbook presents the use of medical biochemistry diagnosis in clinical practice, thereby bridging the educational gap between medical biochemistry diagnosis and clinical disciplines. The textbook is divided into two main parts. The introductory section presents the characteristics of medical biochemistry as part of the health care system, and provides a review of biological variation in biochemical and hematological blood components, along with an account of the effect of different factors on the result interpretation.
A special section is dedicated to medical biochemistry diagnosis of emergency states, cardiovascular diseases and diseases of the gastrointestinal, urinary and endocrine systems, hematological and coagulation disorders, neurological diseases, etc. The book is intended for undergraduate students of medical biochemistry, postgraduate students in various fields of biomedical sciences, and residents in different medical professions (internal medicine, pediatrics, and neurology), medical biochemistry in particular.

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Ivana Čepelak, Slavica Dodig, Boris Labar, Božidar Štraus

Medicinsko-biokemijske smjernice

Naglasak u ovom udžbeniku stavljen je na racionalni odabir laboratorijskih pretraga u kliničkom odlučivanju i na njihovu dijagnostičku pouzdanost. Gradivo je podijeljeno na 4 poglavlja. U prvom se poglavlju (*Uvod*) opisuju osnovne karakteristike laboratorijskih pretraga i njihovo korištenje u kliničkom odlučivanju te načela racionalnog odabira laboratorijskih pretraga. U drugom poglavlju, *Probiranje*, opisana su načela općeg i ciljanog probiranja. U drugom dijelu knjige, možda najvažnijem, obrađene su bolesti i patološka stanja pojedinih organa i organskih sustava. Opisane su najučestalije bolesti, navedene su dijagnostičke smjernice za njihovu dijagnozu te interpretacija laboratorijskih nalaza. Zadnje poglavlje, *Prilozi*, sadrži korisne tablice s podatcima o referentnim rasponima, kritičnim vrijednostima, terapijskim i toksičnim koncentracijama lijekova, indikacijama za laboratorijske pretrage, stabilnosti te biološkim i interferirajućim čimbenicima i kritičnim razlikama.

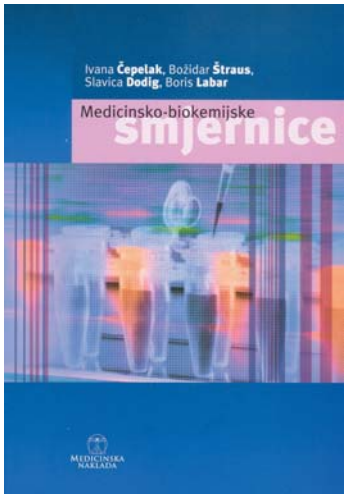
Ukratko, ovaj udžbenik sadrži najnovija saznanja iz područja kliničke biokemije i laboratorijske hematologije. Namijenjen je studentima medicine, medicinske biokemije i farmacije, općenito liječnicima i stručnjacima koji dolaze u kontakt s laboratorijskom dijagnostikom.

Ivana Čepelak, Slavica Dodig, Boris Labar, Božidar Štraus

Medical biochemistry guidelines

This textbook is focused on the rational selection of laboratory tests in clinical decision making and their diagnostic reliability. The material is divided into four chapters. Chapter one (Introduction) describes basic characteristics of laboratory tests and their use in clinical decision making, and presents the principles of rational choice of laboratory tests. Chapter two (Screening) is dedicated to the principles of general and target screening. The second and probably the most important part of the book brings a thorough account of the diseases and pathological states of particular organs and organ systems, describing the most common diseases, respective diagnostic guidelines and interpretation of test results. The last chapter (Appendices) contains useful tables providing data on reference intervals, critical values, therapeutic and toxic drug concentrations, indications for laboratory testing, stability, and biological and interfering factors and critical variations.

In brief, the textbook offers the latest state-of-the-art in the field of clinical biochemistry and laboratory hematology. It is intended for undergraduate students of medicine, medical biochemistry and pharmacy, physicians and all professionals engaged in laboratory diagnosis.



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