P12 – Procjena analitičkih sustava

P12-1 (Usmeno priopćenje)

Prednosti određivanja takrolimusa na Abbott Architect analizatoru

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Uvod: Doživotna imunosupresivna terapija u transplantiranih bolesnika zahtijeva intra- i interindividualno terapijsko titriranje. Niža terapijska doza lijeka smanjuje toksične nuspojave. Preporuka je European Consensus Recommendation from the Committee on Tacrolimus Optimization da se za određivanje takrolimusa treba koristiti specifične metode s funkcionalnom osjetljivošću na razini 1 ug/L.
Materijali i metode: Analitička validacija takrolimusa metodom kemiluminiscentnog određivanja (CMIA) na Abbott Architect analizatoru obuhvaćala je: nepreciznost u seriji na humanom uzorku i na komercijalnim kontrolnim uzorcima(N = 5); nepreciznost iz dana u dan na komercijalnim kontrolnim uzorcima (N = 15); netočnost na komercijalnim kontrolnim uzorcima (N = 15) i usporedno određivanje na humanim uzorcima (N = 20) na IMx analizatoru MEIA metodom i CMIA metodom na Architect analizatoru.
Rezultati: Nepreciznost u seriji na humanom uzorku iznosi 1,69%, dok na komercijalnom kontrolnom uzorku za L1 iznosi 1,24%, za L2 3,61% i za L3 2,38%; nepreciznost iz dana u dan na komercijalnim uzorcima iznosi za L1 4,01%, za L2 4,49% i za L3 3,38%; netočnost na komercijalnim uzorcima za L1 -4,95%, za L2 0,39% i L3 -2,23%. Rezultati su unutar ciljnih dometa proizvođača i iznose za nepreciznost i netočnost ≤ 10%. Linearnost je potvrđena kalibracijskom krivuljom u 6 točaka u rasponu od 0 do 30 ug/L. Preliminarni podaci usporedbe humanih uzoraka (N = 20) u području linearnosti metode pokazuju koeficijent korelacije od 0,957.
Zaključak: CMIA metoda za određivanje takrolimusa na Abbott Architect analizatoru je osjetljiv i precizan test. Metoda ima nisku funkcionalna osjetljivost i eliminaciju interferencija: hematokrita, visokih vrijednosti kolesterola, triglicerida, bilirubina, ukupnih proteina i urata, te je specifičnija u odnosu na druge rutinske metode.

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P12 – Evaluation of analytical systems

P12-1 (Oral presentation)

Advantage of tacrolimus determination on Abbott Architect analyzer

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Introduction: Long life immunosuppressive therapy in transplant patients requiring intra- and interindividual therapeutic titrate. Lower therapeutic dose of drug reduces the toxic side effects. European Consensus Recommendation from the Committee on Tacrolimus Optimization recommended for the tacrolimus determination to use method which requires detection of functional sensitivity of 1 µg/L.
Materials and methods: Analytical validation of tacrolimus determination by chemiluminescent immunoassay (CMIA) on Abbott Architect system included: within-run imprecision on the human samples and commercially controls (N = 5); between-day imprecision on commercially controls (N = 15); inaccuracy on commercially controls (N = 15) and comparation determination on the human samples (N = 20) on 2 systems: IMX (MEIA) and Architect (CMIA) methods.
Results: Within-run imprecision on the human sample is 1.69% and on commercially controls for L1 is 1.24%, L2 is 3.61% and L3 is 2.38%; between-day imprecision on commercially controls is 4.01%; 4.49%; 3.38% for L1, L2, L3 respectively; inaccuracy on commercially controls for L1 is -4.95%, L2 is 0.39 and L3% is -2.23%. The results are within the target range of the Architect Tacrolims assay data and they are for imprecision and inaccuracy ≤ 10%. Linearity was confirmed with calibration curve in 6 points in concentration range from 0 to 30 ug/L. Preliminary data of method comparison on human samples (N = 20) show in the range of method linearity correlation coefficient from 0.957.
Conclusion: CMIA method for tacrolimus determination on the Abbott Architect system is sensitive and accurate test. Method has low functional sensitivity and elimination of interferences: hematocrit, high values of cholesterol, triglycerides, bilirubin, total protein and uric acid, what means that this method is more specific in comparison to other routine methods.

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P12-2

Usporedba kolorimetrijske i turbidimetrijske metode za određivanje koncentracije ukupnih proteina u mokraći

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Uvod: Najčešće upotrebljavane automatizirane metode za određivanje koncentracije ukupnih proteina u mokraći su kolorimetrijske metode temeljena na vezivanju boje (crveni pirogalol) i turbidimetrijske metode temeljene na precipitaciji (benzetonijev klorid) za koje se pokazalo da imaju različitu osjetljivost prema različitim vrstama proteina. Cilj ovog istraživanja je bila analitička usporedba dviju metoda za određivanje koncentracije ukupnih proteina u mokraći te procjena njihovih dijagnostičkih točnosti u otkrivanju albuminurije.
Materijali i metode: U istraživanje je bilo uključeno 57 ispitanika kojima je određena koncentracija ukupnih proteina i albumina u uzorku 24-satne mokraće. Ukupni proteini su određivani na biokemijskom analizatoru Olympus AU 2700 (reagensi Olympus Urinary/CSF Reagent i Roche Diagnostics GmbH Urinary/CSF Protein), kalibracija za obje metode je učinjena istim standardom proteina iz paketa reagensa Olympus Urinary/CSF reagent, a za provjeru točnosti koristili smo komercijalne kontrole Bio-Rad Liquichek Urine Controls u dvije razine. Albumin je određen nefelometrijskom metodom na nefelometru Behring Nephelometer analyzer II.
Rezultati: Nepreciznost iz dana u dan, nepreciznost u seriji i netočnost za metodu s pirogalol-crvenilom iznosili su 3,1%; 2,6% i 9,4%, a za metodu s benzetonijevim kloridom 5,4%; 3,1% i 8,9%. Statistička analiza usporedivosti metoda po Bland i Altman-u pokazala je neslaganje između dviju metoda (prosječni otklon = -43,9%; 95% CI = -57,3 do -30,5 što je posebito izraženo u rasponu nižih koncentracija. Dijagnostička točnost u otkrivanju albuminurije procijenjena je pomoću ROC analize. Dijagnostički kriterij za albuminuriju je bila koncentracija albumina ≥ 0,030 g/dU. Za kolorimetrijsku metodu površina ispod krivulje (AUC) iznosila je 0,867 (95% CI = 0,751-0,942) uz izračunanu optimalnu graničnu vrijednost 0,131 g/dU, a za turbidimetrijsku metodu AUC = 0,920 (95% CI = 0,817-0,975) uz izračunanu optimalnu graničnu vrijednost 0,069 g/dU. Usporedbom površina ispod krivulje nije dobivena statistički značajna razlika između ispitivanih metoda.

P12-2

Comparison of colorimetric and turbidimetric method for total protein determination in urine

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Background: The most frequently used automated methods for quantitative determination of total urinary proteins are colorimetric, dye binding methods (pyrogallol red) and turbidimetric, precipitation methods (benzethonium-chloride) which exhibit different sensitivities to various proteins. The aim of this study was analytical comparison of two methods for urine protein determination and evaluation of their diagnostic accuracy for determination of albuminuria.
Materials and methods: We examined 55 participants and determined total protein and albumin concentration in 24-hour urine collection. Total urine protein assays were performed on biochemical analyzer Olympus 2700 (reagents Olympus Urinary/CSF Reagent and Roche Diagnostics GmbH Urinary/CSF Protein), we calibrated both tests with the same protein standard from Olympus kit, commercial controls Bio-Rad Liquichek Urine Controls at two levels were used for inaccuracy control. Albumin was determined by nephelometric method on Behring Nephelometer analyzer II.
Results: Bland and Altman statistical method showed disagreement between two methods (mean amount of disagreement = -43.9%; 95% CI= -57.3 to -30.5) which is specifically expressed in the lower concentration range. Inter-assay imprecision, intra-assay imprecision and inaccuracy for pyrogallol and benzethonium-chloride were: 3.1%, 2.6%, 9.4% and 5.4%, 3.1% and 8.9%, respectively. Receiver operating characteristic (ROC) analysis was used to assess diagnostic accuracy. Decision criteria for albuminuria was albumin concentration ≥ 0.030 g/24h. The area under the ROC curve for colorimetric method was 0.867 (95% CI = 0.751-0.942) with the optimal calculated cut-off value 0.131 g/24 h, and for the turbidimetric AUC = 0.920 (95% CI = 0.817-0.975) with the optimal cut-off value 0.069 g/24h. Comparison of areas under the ROC curve showed no statistically significant difference.
Conclusion: Imprecision and inaccuracy are acceptable for both methods according to the Westgard specification, but quantification of total urine protein was not

Zaključak: Nepreciznost i netočnost za obje metode je prihvatljiva prema Westgard-ovim pravilima,međutim kvantificiranje ukupnih proteina u uzorcima mokraće nije usporedivo, posebito u području nižih koncentracija. Navedene metode su pokazale sličnu dijagnostičku točnost u otkrivanju albuminurije, ali uz različite granične vrijednosti pa se klinička odluka treba temeljiti na optimalnim graničnim vrijednostima za pojedinu metodu.

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P12-3

Analitičko ispitivanje Gem® Premier TM4000 analizatora - komparativna studija

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Cilj: Cilj studije je bio usporediti kvantitativne rezultate na novom Gem® PremierTM4000 kao POCT (engl. *point of care testing*) analizatoru s referentnim analizatorima. Posebna pažnja je posvećena tehnologiji mjerenja koncentracije hemoglobina i hematokrita na POCT analizatorima.
Materijali i metode: Rezultati dobiveni na Gem® PremierTM4000 su bili uspoređivani s Ciba Corning 865, Gem Premier 3000 i Dimenzija RxL analizatorima za pH/pCO2, pO2/elektrolite/metabolite i za hemoglobin/hematokrit. Nepreciznost u seriji i nepreciznost iz dana u dan su analizirani na Gem® PremierTM4000 analizatoru. Analizirano je 200 uzoraka pune krvi (arterijska krv) u razdoblju od 30 dana.
Rezultati: Dobiveni su zadovoljavajući rezultati ispitivanja nepreciznosti u seriji kod svih analita (CV ≤ 4,89%), osim za pO2 (CV = 14,66%). Rezultati ispitivanja nepreciznosti iz dana u dan su bili zadovoljavajući (CV ≤ 4,41%), osim za laktat (razina I: CV = 8%, razina II: CV = 6,59%). Koeficijenti korelacije usporednih metoda su bili zadovoljavajući za većinu parametara (r = 0,9458-0,9948), osim za natrij (r = 0,8635). Koeficijenti korelacije za hemoglobin su bili izvrsni, r = 0,9923 (Gem® PremierTM4000 *vs*. Ciba Corning 865) i r = 0,9759 (Gem® PremierTM4000 vs Gem® PremierTM 3000). Regresijska analiza po Passing Babloku pokazuje dobru kompatibilnost između rezulta dobivenih usporedbom ispitivanog analizatora i referentnih analizatora, osim natrija (Gem® PremierTM4000 *vs*. Ciba Corning 865; y = 34,7500 + 0,7500x) i hemoglobina (Gem® PremierTM4000 *vs*. Gem Premier 3000; y = 23,6923 + 0,8308x).
Zaključak: Rezultati dobiveni usporednim mjerenjem analita između ispitivanog i referentnih analizatora su bili kompatibilni. Naši rezultati prikazuju da CO-oximetrija je točnija i pouzdanija metoda određivanja koncentracije hemoglobina u sustavu POCT-a.

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comparable, specifically at the lower concentration range. The two examined methods showed similar diagnostic accuracy, but with different cut-off values, so clinical decisions should be made according to the optimal cut-off value for the certain method.

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P12-3

Analytical performance of the Gem® Premier TM4000 – comparative study

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Objective: The aim of this study was to compare quantitative data on a new point-of-care testing (POCT) Gem® PremierTM4000 analyzer with reference analyzers. Special attention was given to technology of measurement concentration of hemoglobin and hematocrit on the POCT analyzers.
Materials and methods: Analytical performance of the Gem® PremierTM4000 was compared with Ciba Corning 865, Gem Premier 3000 and Dimension RxL analyzers for pH/pCO2, pO2/electrolytes/metabolites and for hemoglobin/hematocrit. Within-run and between-run imprecisions have been done for the Gem® PremierTM4000 analyzer. In the period of 30 days, 200 whole blood samples were analyzed.
Results: Satisfactory results were obtained on within-run imprecision for all study analytes (CV ≤ 4.89%), except for pO2 (CV = 14.66%) and on between-run imprecision for all parameters (CV ≤ 4.41%), except for lactate (Level I: CV = 8%, Level II: CV = 6.59%). The correlation with the comparative methods was satisfactory, correlation coefficients were between 0.9458-0.9948, for most parameters, except for sodium r = 0.8635. For hemoglobin correlation coefficients were excellent, r = 0.9923 (Gem® PremierTM4000 *vs*. Ciba Corning 865) and r = 0.9759 (Gem® PremierTM4000 *vs*. Gem® PremierTM 3000). Passing Bablok regression analysis of analytes concentrations showed good compatibility, except for sodium (Gem® PremierTM4000 *vs*. Ciba Corning 865; y = 34.7500 + 0.7500x) and hemoglobin (Gem® PremierTM4000 *vs*. Gem Premier 3000; y = 23.6923 + 0,8308x).
Conclusions: Results of analyses obtained by the comparative measurement analytes between study and reference analyzers were compatible. Our results present that co-oximetry is the only accurate and reliable method of hemoglobin determination.

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P12-4

Skraćena validacija analizatora Capillarys 2 - Sebia

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Uvod: Skraćena validacija analizatora za kapilarnu elektroforezu Capillarys 2 - Sebia, provedena je prema preporukama Europskog odbora za kliničko-laboratorijske standarde (ECCLS).
Materijali i metode: Procjena analitičkih značajki analizatora provedena je određivanjem nepreciznosti u seriji, nepreciznosti iz dana u dan, netočnosti i usporednim određivanjem uzoraka seruma na analizatoru Capillarys 2 Sebia i Olympus HITE 320. Nepreciznost u seriji određena je na 10 uzastopnih mjerenja dva kontrolna seruma tijekom 3 dana. Nepreciznost iz dana u dan određena je mjerenjem koncentracije analita u duplikatu kroz 10 dana u 2 kontrolna seruma. Netočnost je izražena kao postotak odstupanja srednje izmjerene vrijednosti od deklarirane vrijednosti kontrolnih seruma. Usporedna određivanja provedena su pomoću 40 uzoraka seruma.
Rezultati: Nepreciznost u seriji pokazala je koeficijent varijacije < 4,64% za sve frakcije. Nepreciznost iz dana u dan pokazala je koeficijent varijacije < 5,92% za sve frakcije. Rezultati ispitivanja netočnosti pokazali su odstupanje < 8,32% za sve frakcije osim za alfa 2-globuline u Hipergama kontroli gdje je odstupanje bilo 12,60%. Rezultati usporednih ispitivanja pokazali su koeficijent korelacije od 0,8873 do 0,9665 za sve frakcije. Regresijska analiza po Passingu i Babloku pokazala je da nije bilo značajnog odstupanja od linearnosti.
Zaključak: Rezultati skraćene validacije pokazali su da je sustav Capillarys 2 Sebia precizan, točan i pouzdan analizator koji je pokazao visoki stupanj podudarnosti s analizatorom Olympus HITE 320. Potpuna automatizacija, visoki stupanj razlučivosti, velika brzina, visoka osjetljivost i reproducibilnost te mogućnost priključivanja na laboratorijski informacijski sustav značajno su proširili domet primjene samog analizatora te ubrzali i olakšali rutinski rad.

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P12-4

Short validation of the Sebia Capillarys 2 analyzer

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Introduction: Short validation of the Sebia Capillarys 2 analyzer for capillary electrophoresis was performed according to the guidelines of the European Committee for Laboratory Standards (ECCLS).
Materials and method: Analytical properties of the analyzer were evaluated by determination of within-run imprecision, between-run imprecision, inaccuracy, and comparative determination serum samples on Sebia Capillarys 2 and Olympus HITE 320 analyzers. Within-run imprecision was examined in 10 consecutive measurements of two control sera during 3 days. Between-run imprecision was examined in duplicate in two control sera during 10 days. Inaccuracy was calculated as a percentage of deviation of mean determined value from the mean value declared for control sera. Comparative determinations was made using 40 serum samples.
Results: Within-run imprecision showed coefficients of variation < 4.64% for all fractions. Between-run imprecision showed coefficients of variation < 5.92% for all fractions. Inaccuracy testing showed bias < 8.32% for all fractions except alfa 2-globulin in Hipergamma Control where bias was 12.60%. Results of the comparison showed correlation coefficients to range from 0.8873 to 0.9665 for all fractions. Passing Bablok regression analysis showed that there was no significant deviation from linearity.
Conclusion: Results of the short validation showed the Sebia Capillarys 2 analyzer to be a precise, accurate and reliable instrument with high degree of correlation to Olympus HITE 320 analyzer. Full automatization, high resolution, high speed, high sensitivity and reproducibility and possible connection of the analyzer to laboratory information system have significantly broadened the possibilities for its application, making the routine work faster and easier than before.

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P12-5

Analitička procjena biokemijskog analizatora Pentra400 tvrtke Horiba ABX

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Cilj: Analitička procjena biokemijskog analizatora Pentra400 tvrtke Horiba ABX, Francuska, prema preporukama ECCLS, određivanjem koncentracije glukoze, kolesterola, kreatinina, ALP, AST, CRP, natrija i kalija reagensima iste tvrtke.
Materijal i metode: Analitička procjena obuhvatila je nepreciznosti u seriji i iz dana u dan, te netočnost. Nepreciznost u seriji određena je višekratnim (10x) mjerenjem komercijalnih kontrolnih uzoraka (N/P) i svježeg humanog seruma, i izražena kao koeficijent varijacije (KV). Nepreciznost iz dana u dan određena je mjerenjem u duplikatu tijekom 15 dana na kontrolnim uzorcima i pool seruma. Netočnost je izračunata kao odstupanje (R%) srednje izmjerene vrijednosti u odnosu na deklariranu vrijednost kontrolnih seruma tijekom provjere nepreciznosti iz dana u dan.
Rezultati: Zadovoljavajući rezultati za nepreciznost u seriji dobiveni su za kreatinin, kolesterol, glukozu, AST, CRP natrij i kalij. Nešto slabiji rezultati na kontrolnom uzorku P dobiveni su za ALP (KV 4,1%). Zadovoljavajući rezultati za nepreciznost iz dana u dan dobiveni su za glukozu, kolesterol, AST, CRP i kalij. Nešto slabiji rezultati na kontrolnom uzorku P dobiveni su za kreatinin (KV 3,1%) i ALP (KV 4,5%). Za natrij nisu dobiveni zadovoljavajući rezultati nepreciznosti iz dana u dan (KV 1,7% za kontrolu N, KV 1,9% za kontrolu P i KV 1,0% za *pool* seruma). Odstupanja od deklariranih vrijednosti pokazala su prihvatljiv stupanj točnosti za sve ispitivane analite.
Zaključak: Prikazani rezultati provedene analitičke procjene analizatora Pentra400 tvrtke Horiba ABX za određivanje koncentracije glukoze, kolesterola, kreatinina, ALP, AST, CRP, natrija i kalija pokazuju da se analizator i reagensi mogu koristiti u laboratoriju.

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P12-5

Analytical evaluation of biochemistry analyzer Pentra400 (Horiba ABX)

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Aim: To estimate analytical performance of biochemistry analyzer Pentra400, Horiba ABX, France, according to the ECCLS protocol by determination of creatinine, cholesterol, glucose, ALP, AST, CRP, sodium and potassium concentrations using reagents of same manufacturer.
Material and methods: Analytical assessment comprised within-run as well as between-run imprecision and inaccuracy. Within-run imprecision was determined by multiple (10x) measurements of commercial control samples (N/P) and human sera, and expressed as a coefficient of variation (CV). Between-run imprecision was determined on N/P control samples and pool sera during 15 days on two replicates. Inaccuracy was expressed as a percentage of bias (R%) of the determinated mean value from the declared mean value. Inaccuracy was evaluated using data from between-run imprecision measurement on control samples.
Results: Satisfactory results were achieved for within-run imprecision for creatinine, glucose, cholesterol, AST, CRP, sodium and potassium. Poorer result for the control sample P was obtained for ALP (CV 4.1%). Satisfactory results were achieved for between-run imprecision for glucose, cholesterol, AST, CRP and potassium. Poorer but acceptable results of control sample P were obtained for creatinine (CV 3.1%) and ALP (CV 4.5%). The results of between-run imprecision for sodium were not satisfactory (CV 1.7% for control N; CV 1.9% for control P; CV 1.0% for human sera, respectively). Deviation from declared control sample values showed a satisfactory level of accuracy for all tested parameters.
Conclusion: Results of the study indicate that biochemistry analyzer Pentra400 provides accurate and precise results and is convenient for use in routine laboratory.

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P12-6

Usklađivanje različitih analitičkih sustava u svakodnevnom laboratorijskom radu

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Uvod: U skladu s pravilima dobre laboratorijske prakse i uvođenjem harmonizacije laboratorijskih nalaza, u svakodnevnoj praksi suočavamo se s problemom usklađivanja različitih analitičkih sustava. Cilj rada bio je usporediti izmjerene koncentracije ukupnog i konjugiranog bilirubina koje su određivane različitim modifikacijama metoda s diazo-reagensom na biokemijskim analizatorima Architect c8000 i Olympus AU400, te razmotriti kliničku opravdanost uvođenja jedinstvenih referentnih intervala (Harmonizacija laboratorijskih nalaza iz medicinske biokemije; HKMB, 2004.).

Materijali i metode: Koncentracija ukupnog i konjugiranog bilirubina određena je u 41 uzorku. Usporedba metoda učinjena je statističkim programom MedCalc 9.2.1.0 regresijom po Passing-Bablok-u i Bland-Altman prikazom.

Rezultati: Izmjerene koncentracije ukupnog bilirubina prosječno su 14,6% (95% CI= -19,0 do -10,1) niže na Architectu c8000. Metode za određivanje ukupnog bilirubina na Architectu c8000 i Olympusu AU400 moguće je uskladiti pomoću pripadne jednadžbe pravca regresije po Passing-Bablok-u: y (uk.bil.Arch) = 0,934 x (uk.bil.Oly) - 1,906. Izmjerene koncentracije konjugiranog bilirubina prosječno su 51,6% (95% CI = 42,4 do 60,9) više na Architectu c8000. Metode za određivanje konjugiranog bilirubina na Architectu c8000 i Olympusu AU400 nije moguće primjereno uskladiti zbog značajnog odstupanja od linearnosti. Analitički otklon izmjerenih koncentracija ukupnog i konjugiranog bilirubina izraženiji je u području nižih koncentracija.

Zaključak: S obzirom na značajna neslaganja između različitih metoda s diazo-reagensom za određivanje konjugiranog bilirubina na dva analitička sustava, upitna je opravdanost uvođenja jedinstvenih referentnih intervala po Harmonizaciji.

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P12-6

Harmonization of different analytical systems in everyday laboratory practice

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Background: In accordance with the rules of good laboratory practice and with the introduction of harmonization of laboratory test results, in everyday practice we face the problem of harmonizing various analytical systems. The aim was to compare the measured concentrations of total and conjugated bilirubin obtained by various modifications of methods with diazo-reagent on biochemical analyzers Architect c8000 and Olympus AU400. Also, we consider the clinical justification of introduction of unique reference interval (Harmonization of laboratory test results in medical biochemistry; CCMB, 2004.).

Materials and methods: Concentration of total and conjugated bilirubin was determined in 41 sample. Comparison of methods was performed with MedCalc 9.2.1.0 statistical software using Passing-Bablok regression and Bland-Altman plot.

Results: Measured concentrations of total bilirubin were on average 14.6% (95% CI = -19.0 to -10.1) lower on Architect c8000. Methods for determination of total bilirubin on Architect c8000 and Olympus AU400 can be harmonized with the direction of Passing-Bablok regression equation: y (tot.bil.Arch) = 0.934 x (tot.bil.Oly) – 1.906. Measured concentrations of conjugated bilirubin were on average 51.6% (95% CI = 42.4 to 60.9) higher on Architect c8000. Methods for determination of conjugated bilirubin on Architect c8000 and Olympus AU400 can not be properly harmonized because of significant deviation from linearity. Analytical deflection of total and conjugated bilirubin concentrations was more visible in the area of lower concentrations.

Conclusion: Considering significant disagreement between different methods with diazo-reagent for determination of conjugated bilirubin on two analytical systems, the legitimacy of the introduction of unique reference interval by Harmonization is questionable.

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P12-7

Usporedba metoda za određivanje tumorskih biljega

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Uvod: Za određivanje tumorskih biljega (TM) u serumu pacijenata koriste se imunokemijski testovi i analitički instrumenti različitih proizvođača. U provedbi validacije imunokemijskih testova usporedba metoda je iznimno značajna. Cilj je bio usporediti vrijednosti pet TM dobivenih dvijema različitim metodama.
Materijali i metode: Analizirani su serumi pacijenata s kliničkom sumnjom na malignu bolest ili potvrđenom malignom bolesti. Uspoređivani su rezultati za CEA, CA 19-9, CA 15-3, PSA, i fPSA dobiveni na analizatorima Elecsys 2010 (Roche) i Olympus AU 3000i (Olympus). Na analizatoru Elecsys 2010 TM su se određivali elektrokemiluminiscentnom metodom a na AU 3000i kemiluminiscentnom metodom. Statistička obradba rezultata učinjena je pomoću statističke programske potpore. (MedCalc Software).
Rezultati: Koeficijent korelacije (r) između Elecsys 2010 and AU 3000i za: CEA (N = 180, r = 0,993), CA 19-9 (N = 131, r = 0,979), CA 15-3 (N = 105, r = 0,826), PSA (N = 148, r = 0,986) i fPSA (N = 61, r = 0,976). Uvjeti Passing-Bablok regresije nisu zadovoljeni za: CEA (95% CI, a = - 0,701 do – 0,470; b = 0.869 do 0.948), CA 19-9 (95% CI, a = 1,533 do 2,476; b = 0,890 do 0,970), PSA (95% CI, b = 0,916 do 0,966), fPSA (95% CI, b = 0,735 do 0,829), a zadovoljeni su za CA 15-3 (95% CI, a = -1,233 do 2,327, b = 0,867 do 1,074). Na Bland-Altmanovom prikazu 95% granice podudaranja srednjih razlika bile su: CEA Elecsys-AU3000i (95% CI = -50,4 do 43,2), CA 19-9 Elecsys-AU3000i (95% CI = -111,1 do 87,6), CA 15-3 Elecsys-AU3000i (95% CI = -727 do 817,8), PSA Elecsys-AU3000i (95% CI = -11,1 do 8,9) i fPSA Elecsys-AU3000i (95% CI = -1,13 do 0,49).
Zaključak: Rezultati određivanja TM sa dva analizatora ne mogu se koristiti istovremeno. Kod zamjene postojeće metode potrebno je izvjesno vrijeme TM određivati na oba analizatora.

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P12-7

Comparison of different immunoassays for tumor marker

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Background: The comparability of immunoassay tests on different analyzer is extremly important during the assay validation process. In this study, we investigated the interchangeability of tumor markers (TM) on two different analyzer.
Methods: We tested patient samples for CEA, CA 19-9, CA 15-3, PSA and fPSA. We used Elecsys 2010 (Roche) with electrochemiluminescence detection and AU 3000i (Olympus) with chemiluminescent detection. We performed statistical comparative analysis using commercially available program MedCalc Software.
Results: The correlation coefficient (r) between Elecsys 2010 and AU 3000i were: CEA (N = 180, r = 0.993), CA 19-9 (N = 131, r = 0.979), CA 15-3 (N = 105, r = 0.826), PSA (N = 148, r = 0.986) and fPSA (N = 61, r = 0.976). The parameters of Passing-Bablok regression show significant systematic differences among analytical systems for: CEA (95% CI, a = -0.701 to -0.470; b = 0.869 to 0.948), CA 19-9 (95% CI, a = 1.533 to 2.476; b = 0.890 to 0.970), PSA (95% CI, b = 0.916 to 0.966), fPSA (95% CI, b = 0.735 to 0.829) not for CA 15-3 (95% CI, a = -1.233 to 2.327, b = 0.867 to 1.074). Systematic differences between tested analytical systems evaluated by Bland-Altman method were: CEA Elecsys-AU3000i (95% CI = -50.4 to 43.2), CA 19-9 Elecsys-AU3000i (95% CI = -111.1 to 87.6), CA 15-3 Elecsys-AU3000i (95% CI = -727 to 817.8), PSA Elecsys-AU3000i (95% CI= -11.1 to 8.9) and fPSA Elecsys-AU3000i (95% CI = -1.13 to 0.49).
Conclusion: The results of determining TM cannot be substitute for one analytical system to another. If TM method is changed, parallel measurements of TM with both methods for an appropiate time span strongly recommended.

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P12-8

Biokemijski pokazatelji statusa željeza i načini izračuna zasićenja transferina

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Uvod: Procjena i razlikovanje funkcionalnog naspram stvarnog nedostatka željeza te toksičnosti željeza u kliničkoj praksi temelji se na biokemijskim pokazateljima statusa željeza, primjerice, na zasićenju transferina i koncentraciji feritina. Odabir dijagnostičkih pretraga u procjeni statusa željeza izrazito je važan s obzirom da se odluka o vrsti i načinu liječenja bolesnika temelji na rezultatima tih pretraga.
Materijali i metode: Uzorci krvi prikupljeni su od bolesnika (N = 34) s dijagnosticiranom bolešću jetre. Na zahtjev liječnika, određivani su biokemijski pokazatelji statusa željeza: koncentracija željeza (Fe), nezasićeni kapacitet vezanja željeza (UIBC) i ukupni kapacitet vezanja željeza (TIBC). U ostatnim uzorcima seruma dodatno je određivana koncentracija transferina (Tf). Nadalje, pomoću opće prihvaćenih empirijskih jednadžbi izračunano je zasićenje transferina željezom (TSAT) na dva različita načina: Jednadžba I (Fe&UIBC): TSAT% = 100 x Fe/(UIBC + Fe) i Jednadžba II (Fe&Tf): Tsat% = 3,98 x Fe/Tf.
Rezultati: Ukupna pogreška izračunske vrijednosti TSAT objedinjuje analitičke pogreške mjerenih parametara koji su dio jednadžbe za izračun. Računske izvedenice TSAT% i Tsat% uspoređene su statističkim analizama po Passing&Babloku i Bland&Altmanu (MedCalc, v10.1.8). Nije nađeno značajno odstupanje od linearnosti (P > 0,10), a pripadna regresijska jednadžba pravca je: TSAT% = 1,084 x Tsat% + 0,774. Zasićenje transferina koje je izračunano pomoću prve jednadžbe (Tsat%) bilo je 11,4% (95% CI = 9,4-13,3) više u usporedbi s TSAT koji je izračunan pomoću druge jednadžbe (TSAT%).
Zaključak: Uputno je učiniti vrednovanje i ocjenu novih metoda ili poboljšanih inačica za izravno spektrofotometrijsko određivanje UIBC. Izračun zasićenja transferina pomoću druge jednadžbe je točnije u usporedbi s drugim zamjenskim metodama izračuna TSAT.

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P12-8

Biochemical indicators of iron status and modalities for calculation of transferrin saturation

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Background: Estimation and differentiation of functional versus absolute iron deficiency as well as iron toxicity in clinical praxis is based on biochemical indicators of iron status such as transferrin saturation or feritin concentration. Selection of diagnostic tests for iron status estimation is very important because therapy strategy is based on these results.
Materials and methods: Blood samples (N = 34) had been collected from the patients with liver disease. At the request of the physician, blood samples were analyzed for the biochemical indicators of iron status: iron concentration (Fe), unsaturated iron binding capacity (UIBC) and total iron binding capacity (TIBC). Transferrin concentration (Tf) was additionally determined in the residual samples. Furthermore, transferrin saturation (TSAT) was calculated by using the widely accepted two different empirical equations: Equation I (Fe&UIBC): TSAT% = 100 x Fe/(UIBC + Fe) and Equation II (Fe&Tf): Tsat% = 3.98 x Fe/Tf.
Results: Total error of the calculated TSAT value summarizes analytical errors of the measured parameters that participate in equations. Derived parameters TSAT% and Tsat% were compared by Passing&Bablok and Bland&Altman statistical methods (MedCalc, v10.1.8). There was no significant deviations from linearity (P > 0.10) and the computed linear regression equation was: TSAT% = 1.084 x Tsat% + 0.774. Transferrin saturation that has been computed by the first equation (Tsat%) was 11.4% (95% CI = 9.4-13.3) higher in comparison with the TSAT that has been computed by the second equation (TSAT%).
Conclusion: Therefore, method evaluation is recommended before applying a new or improved assay for direct spectrophotometric determination of UIBC. Transferrin saturation calculated by second equation is more accurate method in comparison with the other alternative methods to assess TSAT.

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P12-9

Usporedba CA19-9, CEA i AFP na analizatorima Vitros ECI i Cobas e411

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Uvod: Uspoređivane su vrijednosti tri tumorska biljega, CA19-9, CEA i AFP, dobivene na analizatorima Vitros ECi (Ortho Clinical Diagnostics, Johnson and Johnson, UK) te Cobas e 411 (Roche Diagnostics, Japan), u svrhu validacije metode radi uvođenja novog analizatora. Cilj rada bio je ispitati odnos dviju metoda pri određivanju tumorskih biljega.
Materijali i metode: U ispitivanje je uključeno 26 uzoraka seruma za usporedbu CA 19-9, 20 uzoraka za CEA i 18 za AFP. Vitros Eci je imunokemijski analizator koji radi na principu kemiluminiscencije, a Cobas e 411 na principu elektrokemiluminiscencije. Metode su uspoređene Passing-Bablok regresijom.
Rezultati: Passing-Bablok regresijom dobiveni su sljedeće vrijednosti odsječka na osi y te nagiba pravca i pripadajući 95% intervali pouzdanosti: za CA19-9 0,8418 (-0,1021-2,9266) i 0,9977 (0,7793-1,0639); za CEA 1,0289 (0,8478-1,1875) i 0,9016 (0,8388-0,9979); za AFP 0,7081 (0,5436-0,8375) i 0,7932 (0,7357-0,8515). U sklopu Passing-Bablok regresije učinjen je Cusum test linearnosti koji je za sve gore navedene kombinacije tumorskih biljega pokazao da nema značajnog odstupanja od linearnosti (P > 0,10).
Zaključak: Iz podataka dobivenih Passing-Bablok regresijom vidljivo je da nisu svi rezulati usporedbe u potpunosti usklađeni i ne slijede jednaku linearnost (nagib i odsječak na osi y ne obuhvaćaju 1 odnosno 0). Jedino CA19-9 zadovaljava sve postavke Passing-Bablok regresije. CEA je pokazao dobru usklađenost, ali ne slijedi jednaku linearnost. AFP nije zadovoljio uvijet usklađenosti niti linearnosti. Ovi rezulati potvrđuju važnost preporuke o praćenju vrijednosti tumorskih biljega na istom analizatoru istom metodom.

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P12-9

Comparison of CA19-9, CEA and AFP on Vitros ECI and Cobas e411 analyzers

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Background: We compared the values of three tumor markers, CA19-9, CEA and AFP, obtained on Vitros ECi (Ortho Clinical Diagnostics, Johnson and Johnson, UK) and Cobas e411 analyzer (Roche Diagnostics, Japan), as a part of method validation for the new analyzer. The aim of the study was to examine the relationship between two methods for determinating tumor markers concetrations.
Materials and methods: The study included 26 sera for CA19-9, 20 for CEA and 18 for AFP. Vitros ECi is immunochemical analyzer that works on chemiluminiscence and Cobas e411 on electrochemiluminiscence principle. Methods were compared using Passing-Bablok regression.
Results: The values of the intercept and slope with 95% confidence interval obtained with Passing-Bablok regression were as follows: for CA19-9 0.8418 (-0.1021-2.9266) and 0.9977 (0.7793-1.0639); for CEA 1.0289 (0.8478-1.1875) and 0.9016 (0.8388-0.9979); for AFP 0.7081 (0.5436-0.8375) and 0.7932 (0.7357-0.8515). The Cusum linearity test performed on Passing-Bablok regression showed that there was no significant deviation from linearity for any of the above tumor markers combinations(P > 0.10).
Conclusion: Data obtained by Passing-Bablok regression showed that the results are not completely comparable and they do not follow the same linearity (slope and intercept on the y axis does not include 1 or 0). Only CA19-9 fulfilled settings of Passing-Bablok regression. CEA showed good comparability, but does not follow the same linearity. AFP did not meet the requirement of comparability, nor linearity. These results confirm the importance of recommendations on monitoring the values of tumor markers on the same analyzer with the same method.

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P12-10

Usporedba brojanja eritrocita i leukocita manualnom mikroskopijom sa dva analizatora za čitanje test traka u mokraći: LabUMat i Clinitek 500

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Uvod: Analiza mokraće test trakama ima važnu ulogu u kompletnoj analizi mokraće. Automatizacijom čitača test traka omogućeno je da dobivene nalaze izražavamo semikvantitativno. U ovom radu smo željeli usporediti rezultate dobivene reflektometrijom i manualnom mikroskopijom.
Materijali i metode: Ispitivali smo razinu slaganja između dva analizatora za čitanje test traka u mokraći: LabUMat 77Elektronika Kft., Hungary i Clinitek 500, Bayer Corporation, Diagnostics Division, Tarrytown,NY sa manualnom mikroskopijom supravitalno obojenog sedimenta u detekciji i brojanju eritrocita (Erc) i leukocita (Lkc). Analizirali smo 165 uzoraka mokraće bez centrifugiranja za brojanje Erc i Lkc na dva analizatora za čitanje test traka: Clinitek 500 i LabUMat dobivene reflektometrijskim mjerenjem sa manualnom mikroskopijom priređenom prema preporukama europske grupe za analizu mokraće(ELM - European Urinalysis Group).
Rezultati: Rezultate smo grupirali u četri kategorije i izračunali razinu slaganja izraženu kao postotak (%). Slaganje u brojanju Erc i Lkc između dva analizatora Clinitek 500 prema LabUMat pokazuje razinu slaganja od 90% odnosno 84%; između Clinitek 500 i manualne mikroskopije 83% odnosno 81% i između analizatora LabUMat i manualne mikroskopije ta razina slaganja je 80% odnosno 78%.
Zaključak: Dobiveni rezultati na oba analizatora pokazuju slične rezultate koji osiguravaju kliničku prihvatljivost dobivenih rezultata. Razlike u rezutlatima dobivenim između rezultata za brojanje Erc i Lkc na analizatorima za čitanje test traka sa onima dobivenim manualnom mikroskopijim suprevitalno obojenog uzorka su temeljene na različitim metodologijama. Analizatori za čitanje test traka mjere enzimsku aktivnost, a ne broje stanice. Zbog toga svaki pozitivan rezultat treba biti potvrđen mikroskopskim pregledom.

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P12-10

Comparison betweeen manual count erithrocytes and leukocytes with two test strips urine analyzers: LabUMat and Clinitek 500

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Introduction: Test strip analisys plays an important role in urinalysis. Automated test strips urine analyzers are now available to report semiquantitative data. In this study, we wanted to compare the reflectance readings with manual microscopy.
Materials and methods: We evalated concordance level between two automated test strips urine analyzers: LabUMat 77Elektronika Kft., Hungary and Clinitek 500, Bayer Corporation, Diagnostics Division, Tarrytown,NY with manual microscopy of supravitally stained specimens in detecting and counting erithrocytes (RBC) and leukocytes (WBC). We analyzed 165 urine specimens whithout centrifgation for RBC and WBC counting by two urine analyzers, Clinitek 500 and LabUMat based on reflectance masurement with manual microscopy performed according the European Urinalysis Guidelines (ELM - European Urinalysis Group)) recommendations.
Results: The results have been categorized into four ranges and calculated concordance level expressed as percent (%). The agreement for RBC and WBC made by two urine analyzers Clinitek 500 versus LabUMat showed a concordance level of 90% and 84% respectivly; between Clinitek 500 with manual microscopy of 83% and 81% and between urine analyzer LabUMat with manual microscopy showed a concordance level of 80% and 78% respectivly.
Conclusion: Both test strip analyzers showed similar results provides clinically acceptable results. The differences observed between the results obtained for RBC and WBC with test strip urine analyzers with those obtained with manual microscopy of supravitally stained specimens are based on the different methodology. The strip test analyzers measure enzymatic activity and do not count cell units.Therefore each positive results mast be confirmation by microscopy.

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P12-11

Procjena testa za određivanje fruktozamina na analizatoru Vitalab

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Uvod: Fruktozamin je glikirani protein i indikator prosječne (vremenski) koncentracije glukoze u krvi te se rabi za procjenu glikemijskog statusa šećerne boelsti.
Materijali imetode: Procjenili smo metodu fruktazaminom na Vitalab analizatoru. Fruktozamin u svom ketoaminskom obliku u lužnatim uvjetima reducira tetrazolijevu sol NBT u formazan. Brzina reagiranja izmjerena fotometrijski na 550 nm, izravno je poporcionalna s koncentracijom fruktozamina u uzorku.
Rezultati: Osjetljivost metode bila je 10 umol/L. Preciznost unutar serije (N = 20) iznosila je 1-2,3% (CV) za uzorke s koncentracijom fruktozamina od 197-587 umol/L. Preciznost iz serije u seriju (N = 20) iznosila je 2,2% za uzorke sa srednjom vrijednosti koncentracije od 552 umol/L i 4,7% za uzorke sa srednjom vrijednosti koncentracije od 217 umol/L. Proširenri raspon mjerenja iznosio je do 2000 umol/L s automatskim razrjeđenjem. Regresijskom analizom usporedbe Vitalab metode (y) i Abbottove metode (x) dobivena je sljedeća jednadžba: y = 1,10x - 21,1 i koeficijent korelacije (r) od 0,98.
Zaključak: Metoda fruktozaminom na Vitalab analizatoru je točna i precizna.

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P12-11

Evaluation of fructosamine assay on the Vitalab analyzer

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Introduction: Fructosamine is a glycated protein and a time-averaged indicator of blood glucose level, that is used to assess the glycaemic status of diabetes.
Material and methods: We evaluated a fructosamine method on Vitalab analyzer. Fructosamine, in its ketoaminic form, reduces in an alkaline medium, with nitroblue tetrazolium, to formazan. The reaction rate, measured photometrically at 550 nm, is directly proportional to the concentration of fructosamine present in the sample.
Results: The sensitivity of the assay was 10 umol/L. The within-run precision (N = 20) was frim 1-2.3% (CV) for samples with fructosamine concentrations from 197-587 umol/L. The between-day precision (N = 20) was 2.2 % for a sample with a mean concentrations of 552 umol/L and 4.7% for a sample with a mean concentrations of 217 umol/L. The extended measurement range is up to 2000 umol/L with automatic dilution. Regression analysis comparing the Vitalab assay (y) and Abbott method (x) yielded the following equation: y = 1.10x – 21.1 and correlation coefficient (r) of 0.98.
Conclusion: The fructosamine method on Vitalab analyzer is accurate and precise.

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P12-12

Usporedba vrijednosti koncentracije glukoze, ureje i kreatinina iz pune krvi (EDTA) i seruma kao uzorka na različitim analizatorima

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Uvod: Jedan od načina skraćivanja TATa (engl. *turn around time*, vrijeme od vađenja uzorka do izdavanja nalaza) u hitnim laboratorijima je izvođenje testova iz pune krvi. Cilj je ovoga rada bila usporedba dobivenih vrijednos-

P12-12

Comparison of the values of metabolites glucose, urea and creatinine using whole blood (EDTA) and serum as a sample on different analyzers

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Background: One way to make TAT (turn around time) shorter in emergency laboratories is performing the tests using whole blood as a sample. The purpose of this work was to compare the obtained values of glucose, BUN

ti glukoze, ureje (BUN) i kreatinina iz pune krvi (EDTA) na acidobaznom analizatoru Stat Profile Critical Care Xpress CCX (Nova Biomedical) i vrijednosti istih metabolita iz seruma kao uzorka na biokemijskom analizatoru Olympus AU 400.

Materijali i metode: Kao uzorci korištene su pune krvi (EDTA) i serumi ležećih pacijenata. Ponovljivost u seriji i ponovljivost iz dana u dan na acido-baznom analizatoru CCX određena je korištenjem kontrola proizvođača.

Rezultati: Ponovljivost u seriji za glukozu izražena preko koeficijenta varijacije iznosila je KV = 0,6%, za BUN KV = 2,7%, za kreatinin KV = 1%. Ponovljivost iz dana u dan za glukozu KV = 0,5%, BUN KV = 4,6%, kreatinin KV = 4%. Podaci dobiveni usporednim određivanjem glukoze iz seruma na OLY AU 400, te glukoze iz pune krvi (EDTA) na CCX-u (N = 88) statistički su obrađeni te je dobivena zadovoljavajuća korelacija uz R^2 = 0,8919. Za kreatinin (N = 84) koeficijent korelacije je iznosio R^2 = 0,9819, dok je za BUN (N = 60) koeficijent iznosio 0,964.

Zaključak: Iz dobivenih je rezultata vidljivo da postoji značajna korelacija dobivenih rezultata za metabolite glukozu, BUN i kreatinin određenih iz seruma na analizatoru Olympus AU 400 sa rezultatima iz pune krvi kao uzorka na acido-baznom analizatoru CCX. Može se donijeti zaključak da je moguće glukozu, BUN i kreatinin kao najznačajnije metabolite odrediti iz pune krvi (EDTA) i tako značajno smanjiti TAT.

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and creatinine using whole blood (EDTA) as a sample on a blood gas analyzer Stat Profile Critical Care Xpress CCX (Nova Biomedical) and the values of metabolites using serum as a sample on the Olympus AU 400 biochemistry analyzer.

Materials and methods: As samples we used whole blood (EDTA) and serums of hospital patients. Repeatability of serial sampling and day by day repeatability of the given metabolites was determined using quality control samples.

Results: Repeatability of serial sampling for glucose described by coefficient of variation was CV = 0.6%, for BUN CV = 2.7% and for creatinine 1%. Day by day repeatability is for glucose CV = 0.5%, for BUN CV = 4.6% and for creatinine CV = 4%. The obtained results were statistically processed the correlation coefficient between the two analyzers and two different samples for glucose (N = 88) was R^2 = 0.8919, for BUN (N = 60) was R^2 = 0.964 nad for creatinine (N = 84) R^2 = 0.9819.

Conclusions: From the obtained results it can be seen that the correlation of the results for the metabolites glucose, BUN and creatinine using serum as a sample on the biochemistry analyzer Oympus AU 400 and the results for the same metabolites using whole blood as a sample on the blood gas analyzer CCX is significant. Also using whole blood as a sample we can make TAT considerably shorter.

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P12-13

Procjena Nova StatStrip glukometra u odnosu na točnost, preciznost i interferencije

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Cilj: Poznato je, da biokemijski sastav i matriks pune krvi mogu značajno utjecati na mjerenje glukoze glukometrima. Nova generacija StatStrip (Nova Biomedical Waltman, SAD) glukometara konstruirana je tako da uklanja interferencije.

Materijali i metode: Ispitivanje korelacije provedeno je ispitivanjem uzoraka venske krvi kod bolesnika u intenzivnoj jedinici i kod bolesnika na kroničnoj dijalizi. Korelacija je provedena analizom uzoraka na dva glukometra koji su do sada korišteni i na StatStrip glukometru. Kao referenzna metoda korištena je metoda sa heksokinazom

P12-13

Assessment of Nova StatStrip blood glucose meter for accuracy, preecision and interferences

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Aim: It is now recognized that the accuracy of commonly used hospital glucose meters is adversely affected by the biochemical composition and matrix of blood in critical ill patients. The aim of the study is to evaluate a new generation meter (StatStrip Glucose Nova Biomedical Waltham, MA) that has been designed to compensate for these interference effects.

Material and methods: Whole blood venous samples were collected from patients admitted to ICU and from patients attending for dialysis treatment. Correlation studies were performed by analyzing the venous whole

(Olympus AU 400). Vrijednosti hematokrita određene su na hematološkom analizatoru Sysmex KX 2100. Korelacija je učinjena metodom linearne regresije, a klinička točnost i preciznost usporedbom rezultata prema kriterijima standarda ISO15197 za procjenu glukometra.
Rezultati: Linearna regresijska analiza pokazala je dobru korelaciju za sve ispitivane glukometre. Srednje odstupanje za referentnu metodu bilo je niže za StatStrip glukometar u odnosu na Roche Acu chek Performa i Roche Accu chek active glukometre. Kod bolesnika na kroničnoj dijalizi StatStrip glukometar je pokazao podudarnost sa kriterijima prema ISO15197, dok Roche Accu chek Performa i Roche Accu chek Active nisu. Kod bolesnika u intenzivnoj jedinici utvrđen je negativan bias praćen povećanjem vrijednosti hematokrita kod Roche Accu chek glukometra. Vrijednosti hematokrita nisu utjecale na vrijednosti glukoze izmjerene StatStrip glukometrom
Zaključak: Iz dobivenih rezultata proizlazi prednost StatStrip glukometra u povećanju točnosti mjerenja glukoze.

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blood samples on two commonly used glucose meters and StatStrip Glucose. Serum samples prepared from the whole blood sample were tested using a reference plasma hexokinase method (Olympus AU 400). Hematocrit values were measured using a Sysmex KX 2100. Method correlation was assessed by linear regression analysis and the clinical accuracy was assessed by comparing the pattern of results to the ISO15197 criteria for blood glucose monitoring.
Results: Linear regression analysis showed good correlations for all tested meters. Median bias from the reference method was lower for the StatStrip than for either Roche Accu-chek Performa or Roche Accu-chek Active. For the Dialysis patient population StatStrip Glucose met the accuracy acceptance criteria of ISO 15197 but Roche Accu-chek Performa did not. For the ICU patients there is a negative bias associated with increasing hematocrit for the Roche Accu chek Active meter. StatStrip Glucose was unaffected by hematocrit.
Conclusions: StatStrip Glucose offers the potential for improved accuracy of glucose monitoring in hospitalized patients.

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P12-14

Analitička procjena metoda za TSH, tT3 i tT4

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Uvod: Proveden je kratki evaluacijski postupak analitičkog sustava sukladno CLSI preporukama sa statističkim modelom EP-Evaluator® za procjenu metoda i to za: EP5-protokol – nepreciznost (SD i CV unutar serije, između serije, ukupni CV); EP10-protokol – preliminarna evaluacija novih metoda za linearnost, test iskorištenja, nepreciznost, bias,"carryover"; EP9-protokol – usporedba metoda. Valjanost metoda je utvrđena u odnosu na tri kriterija: prema proizvođačevim kriterijima (SDP unutar serije i CVP unutar serije); prema kriterijima državne vanjske kontrole rezultata za bias (B%DK) i prema biološkoj bazi podataka za TE%B, CV%B i B%B.
Materijali i metode: 1. metoda – Analizator Elysis Uno ELISA test za TSH (test druge gen., analitička osjetljivost manja od 0,10 mIU/L), T3 i T4; 2. metoda – Analizator Vitros ECI CLIA metoda za TSH (test treće gen., analitička osjetljivost manja od 0,02 mIU/L), T3 i T4. Za uzorke su ko-

P12-14

Analytical evaluation of TSH, tT3 and tT4 assays

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Introduction: The short evaluation for analytical system was performed according to CLSI protocols. Statistical analysis was performed using EP-Evaluator®: EP5-protocol – imprecision (SD and CV within- and between run, total CV); EP10-protocol – preliminary evaluation for linearity, recovery, precision, bias, carryover and drift; EP9-protocol – method comparison. Interpretations of results were performed according to three criteria: vendor's claimed for SDP within run and CVP within run; national periodic proficiency testing surveys for bias (B%DK) and european biologic goals and calculated biological allowable total errors TE%B, CV%B and B%B.
Materials and methods: 1. method – Analyzer Elisys Uno ELISA assay for TSH (2nd gen., analytic sensitivity lower than 0.10 mIU/L), T3 and T4; 2. method – Analyzer Victors ECI CLIA method for TSH (3rd gen., analytic sensitivity

rišteni: a) Biorad kontrolni serum (L1,L2, L3) za EP5 i EP10 protokol i b) 92 seruma ispitanika za usporedbu metoda prema EP9-protokolu.
Rezultati: EP5 protokol: a) korisnikov SDE i CV%E manji od SDP unutar serije i CVP unutar serije za TSH, T3 i T4; b) korisnikov CV%ukE veći od CV%B za TSH, T3 i T4. EP10 protokol: a) korisnikov CV%ukE veći od CV%B za TSH, T3 i T4; b) korisnikov bias B%E manji od B%DKza TSH, T3 i T4; c) t-vrijednost manja od 4,6 za odsječak, nagib, %"carryover", test iskorištenja, linearnost, osim za vrijednost za nagib za TSH (t = 16,6). EP9 protokol: a) koeficijent korelacije veći od 0,975 (r = 0,9775, B% = -1,4) za TSH, r je manji od 0,975 za T3 (r = 0,8360, B% = 0,16) i T4 (r = 0,8070, B% = 1,8%); b) TE% između metoda veći od TE%B.
Zaključak: Metode za određivanje hormona štitnjače zadovoljavaju nepreciznost prema proizvođačevim zahtjevima, ali ne prema biološkim kriterijima. Metode zadovoljavaju bias prema kriterijima vanjske procjene kvaltete. Metode se ne mogu ekvivalentno upotrebljavati za praćenje rezultata bolesnika.

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lower than 0.02 mIU/L), T3 and T4. For samples we have used: a) Biorad control serum L1, L2, L3 for EP5 and EP10 protocol and b) 92 patient's serum samples for method comparison according EP9-protocol.
Results: EP5-protocol: a) users SDE and CV%E lower than SDP within run and CVP within run for TSH, T3 and T4; b) users CV%totE higher than CV%B for TSH, T3 and T4. EP10-protocol: a) users CV%totE higher than CV%B for TSH, T3 and T4; b) users bias B%E lower than B%DK for TSH, T3 and T4 and c) t-value lower than 4.6 for intercept, slope, %carryover, recovery, linearity, except for TSH slope (t = 16.6). EP9-protocol: a) correlation coefficient higher than 0.975 for TSH (r = 0.9775, B% = -1.4), r lower than 0.975 for T3 (r = 0.8360, B% = 0.16) and T4 (r = 0.8070, B% = 1.8%); b) TE% between method higher than allowable TE%B.
Conclusion: Methods for determination of TSH, T3 and T4 met allowable vendor's claimed for imprecision but did not met european biologic goals for CV%B. Methods met allowable bias (B%DK) according to national periodic proficiency testing surveys. Methods comparisons show that these two methods should not be used like equivalence.

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P12-15

Analitička validacija biokemijskog analizatora Cobas 6000 analyzer series modul C501

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Uvod: Cobas 6000 (Hitachi, Japan) je biokemijski analizator koji spektrofotometrijski, imunoturbidimetrijski te ion selektivnim elektrodama mjeri biokemijske analite. Prikazan je dio rezultata opsežne validacije analizatora.
Materijali i metode: Validacija je učinjena za 12 analita, predstavnika metabolita, enzima, elemenata u tragovima, specifičnih proteina i elektrolita. Ispitana je nepreciznost u seriji (N = 20), nepreciznost iz dana u dan (N = 30) i usporedba s analizatorom korištenim u rutinskom radu (Olympus AU640) (N = 50).
Rezultati: Koeficijenti varijacije za nepreciznost u seriji: glukoza = 2,8%, ureja = 0,8%, kreatinin = 4,0%, GGT = 0,8%, AST = 0,6%, ALT = 0,8%, IgG = 3,2%, IgA = 1,1%, IgM = 1,5%, Fe = 0,9%, Na = 0,4% i K = 0,6%, a za nepreciznost između serija: glukoza = 1,6%, ureja = 2,0%, kreatinin = 2,6%, GGT = 1,9%, AST = 2,7%, ALT = 1,7%, IgG = 2,5%, IgA = 3,2%, IgM = 7,9%, Fe = 3,2%, Na = 1,3%, K = 2,0%.

P12-15

Analytic validation of biochemistry analyzer Cobas 6000 analyzer series modul C501

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Introduction: Cobas 6000 (Hitachi, Japan) is biochemistry analyzer for spectrophotometric, immunoturbidimetric and ion-selective determination of biochemical analytes. Here we present part of comprehensive analyzer validation.
Materials and methods: Validation was made for 12 analytes which represent following groups: metabolites, enzymes, trace elements, specific proteins and electrolytes. Research included determination of within-run imprecision (N = 20), between-run imprecision (N = 30), and method comparison with routine biochemistry analyzer (Olympus AU640) (N = 50).
Results: Within-run imprecision coefficients of variations are: glucose = 2.8%, urea = 0.8%, creatinine = 4.0%, GGT = 0.8%, AST = 0.6%, ALT = 0.8%, IgG = 3.2%, IgA = 1.1%, IgM = 1.5%, Fe = 0.9%, Na = 0.4% i K = 0.6%, and between-run imprecision coefficients of variations are: glucose =

Pri usporedbi dvaju analizatora koeficijent korelacije za sve ispitivane analite iznosi r > 0,99 osim za Na (r = 0,97). Usporedba metoda učinjena je s pomoću Passing-Bablok regresije i izračunate su jednadžbe pravca za sve analite te 95% interval pouzdanosti za odsječak i nagib pravca. Za ureju, Na i K interval pouzdanosti za odsječak obuhvaća vrijednost nula, a za nagib vrijednost jedan pa su sasvim suglasni s rutinski korištenom metodom. Usporedba za AST, ALT, IgM i Fe ukazuje na postojanje male konstantne pogrješke (CI odsječka ne obuhvaća vrijednost nula), a za IgG postojanje male proporcionalne pogrješke (CI za nagib ne obuhvaća vrijednost jedan). Male vrijednosti konstantne i proporcionalne pogrješke pronađene su za glukozu, kreatinin, GGT i IgA.
Zaključak: S obzirom na niske vrijednosti CV instrument je zadovoljavajuće točnosti i preciznosti. Većina analita je usklađena na oba analizatora dok su za dio potrebna podešenja nagiba i odsječka pravca za potpunu usklađenost.

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1.6%, urea = 2.0%, creatinine = 2.6%, GGT = 1.9%, AST = 2.7%, ALT = 1.7%, IgG = 2.5%, IgA = 3.2%, IgM = 7.9%, Fe = 3.2%, Na = 1.3%, K = 2.0%. Method comparison study showed correlation coefficient r > 0.99 regarding all tested analytes accept for Na r = 0.97. Passing-Bablok regression analysis provided linear equation for tested analytes as well as 95% confidence interval for intercept and slope. Intercept confidence interval for urea, Na and K includes zero as value, and slope confidence interval includes one as value which makes these analytes in accordance with routine method. Method comparison regression analysis for AST, ALT, IgM and Fe shows small constant difference (intercept CI does not include zero), and for IgG small proportional difference (slope CI does not include one). Both, small constant and proportional differences, are found for glucose, creatinine, GGT and IgA.
Conclusion: Regarding low CV values tested analyzer has satisfactory accuracy and precision. Most analytes are coherent on both analyzers whereas a part of them require adjustments of slope and intercept for complete accordance.

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P13 – Plućne bolesti

P13-1

Hematološki pokazatelji anemije i C-reaktivni protein (CRP) u bolesnika sa stabilnom opstruktivnom plućnom bolesti

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Uvod: Cilj istraživanja bio je odrediti vrijednosti hematoloških pokazatelja anemije i CRP u bolesnika sa stabilnom KOPB kako bi se utvrdio relativni udio prisutnosti anemije, stupanj sistemske upale te eventualne korelacije navedenih analita u ovih bolesnika.
Materijali i metode: U ispitivanje je bilo uključeno 109 bolesnika s KOPB (forsirani ekspiratorni volumen u 1 sekundi izdisaja, FEV1 = 41 ± 14%), te 51 zdravi ispitanik, FEV1 = 106 ± 15%). U skladu s GOLD smjernicama, bolesnici su podijeljeni u 3 podskupine: II, III i IV, a prema kriteriju SZO za anemiju (Htc < 0,36 L/L za žene i < 0,39 L/L

P13 – Lung diseases

P13-1

Hematologic markers of anemia and C-reactive protein (CRP) in patients with stable chronic obstructive pulmonary disease

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Introduction: The goal of this investigation was to determine the value of hematologic markers of anemia and CRP in patients with stable chronic obstructive pulmonary disease, in purpose to define the relative portion of anemia, degree of systemic inflammation, and occasional correlation of cited data in these patients.
Material and methods: The investigation included 109 patients with COPD (forced expiratory volume in 1 sec. of expiration, FEV1 = 41 ± 14%) and 51 healthy examinee (FEV1 = 106 ± 15%). In accordance with GOLD guidelines, the patients were divided in three subgroups: II, III, IV,