Russian Federal Agency for High-Tech Medical Aid (Rosmedtehnologiy)
Federal State Institution "P. A. Gertsen Oncological Research Institute of Moscow"

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<Seal of Federal State Institution "P. A. Gertsen Oncological Research Institute of Moscow" under Federal Agency for High-Tech Medical Aid>

REPORT
of Clinical Trial
# of A2MP Noninvasive Hemogram Analyzer
under Agreement No. 4/07-A2МП dated August 13, 2007

1. In the period from August 13 to September 17, 2007, the Clinicodiagnostic Laboratory of the Federal State Institution "P. A. Gertsen Oncological Research Institute of Moscow" under the Russian Federal Agency for High-Tech Medical Aid (Rosmedtehnologiy) performed scientific research relating to clinical trial of A2MP Noninvasive Hemogram Analyzer manufactured by Scientific and Production Complex "Biopromin" Ltd, Ukraine.
2. The purpose of the research was to evaluate the possibility of use of the above item in medical practice on the territory of the Russian Federation.

The following documents were submitted for the trial:

- Letter of Referral No. 34/07 dated June 18, 2007, issued by the International Institute for Noosphere Technologies related to testing of one AMP Noninvasive Hemogram Analyzer and signed by its General Director, Professor A. N. Nikitin, and a specimen of AMP Noninvasive Hemogram Analyzer, Serial No. 5901, with a delivery set (set of transducers, software, encryption key, instruction);
- Letter of Referral No. 294-05/5820Л-06 dated February 21, 2007 issued by the Department of Registration of Foreign Medical Devices and Medical Purpose Items of the Russian Federal Service for Healthcare and Social Development Supervision (Roszdravnadzor);
- Report of Technical Tests by Research Center "Energy Plus" Ltd. No. 0655 ПТИ/2007 dated April 23, 2007;

- Report of Toxicological Tests by Research Institute of Physicochemical Medicine, Report No. 755.077 dated March 09, 2007

1. Brief Technical Characteristic and Purpose of Item Under Trial

The A2MP Noninvasive Hemogram Analyzer designed in 2001 by Ukrainian and Russian scientists is intended for automatic determination of over one hundred parameters of blood based on the results of measurements at biologically active reference points on the human body surface and processing of those results using special software. The Analyzer transfers measurement results into a computer for subsequent analysis and printing of a report. The instrument uses a number of laboratory and functional indicators to evaluate the condition of some systems of human organism and to determine susceptibility to diseases of central nervous system, cardiovascular system, internal organs, musculoskeletal system, etc.

2. Substance of Report

Parallel studies to determine concentration of a number of laboratory indicators in the blood of healthy people and patients with malignant tumors using automatic analyzers and the A2MP Noninvasive Hemogram Analyzer.

Material and Methods of Study

Clinical testing of the A2MP Noninvasive Hemogram Analyzer at the P. A. Gertsen Oncological Research Institute in Moscow involved examination of 42 patients of different sex, aged 21 through 66 years, of whom 12 patients were practically healthy and the other 30 patients had variously located malignant tumors at various clinical stages. Most examined patients were from the following clinical departments of the Institute: Resuscitation and Anesthesiology Department, Thoracoabdominal Department, Urology Department, General Surgery Department, Chemotherapeutical Department, Radiotherapy Department. The examined patients were at various phases of treatment (surgical treatment, radiotherapy, chemotherapy).

The group of healthy people included men and women without acute infectious inflammatory diseases and serious chronic pathologies.

Blood samples for laboratory analysis were taken into specialized disposable Monovette test tubes, all patients being with an empty stomach. Blood samples were analyzed on the day when they were taken. On the same day, after blood sampling, the patients were examined using the A2MP Noninvasive Hemogram Analyzer. A statistical card was created for each patient containing personal data, date of examination, patient's history number, name of clinical department, verified diagnosis, results of laboratory examination and examination using the A2MP Noninvasive Hemogram Analyzer.

26 indicators of different kinds of laboratory analysis were studied as diagnostic tests:

- hematological indicators: hemoglobin, hematocrit, erythrocytes, thrombocytes, leukocytes, segmented neutrophils, stab neutrophils, eosinophils, lymphocytes, monocytes, erythrocyte sedimentation rate (ESR);

- biochemical indicators: total bilirubin, direct bilirubin, crude protein, cholesterol, aspartate aminotransferase (AST), alanine-aminotransferase (ALT), amylase, urea, creatinine, glucose, potassium, sodium, calcium;
- hemostasis system indicators: prothrombin test, fibrinogen.

The analysis was performed using modern laboratory equipment: Sysmex KX-21 Hematology Analyzer, Roche Hitachi-902 Chemistry Analyzer, Behring Fibrintimer II Coagulation Analyzer. The analysis also used test sets manufactured by leading laboratory diagnostics companies: Roche, Biosystems, Behring. The quality of analysis was controlled by daily laboratory quality control using master materials and by systematic participation in federal program of external quality assessment of clinical laboratory research.

Examination of patients using the A2MP Noninvasive Hemogram Analyzer was performed according to the Operator's Manual using the following algorithm:

- software installation;
- connection and setup of the A2MP Analyzer;
- program customization: program setting, completion of patient's card, connection of external microprocessors to the patient, selection of measurement interval, saving results into the database.

For most patients the measurement interval was 360 seconds. If the summation indicator was not stable, the measurement interval was increased to 720 seconds.

Analysis Results

The research done by the Clinicodiagnostic Laboratory of P. A. Gertsen Oncological Research Institute in Moscow using automated analyzers involved 1092 examinations of which 462 related to hematology, 546 related to biochemistry, and 84 related to coagulation. All resulting data are specified in tables in the supplement to the Report of Clinical Trial. The tables also specify quantitative results of examination of 42 patients using the A2MP Noninvasive Hemogram Analyzer for each laboratory indicator under consideration.

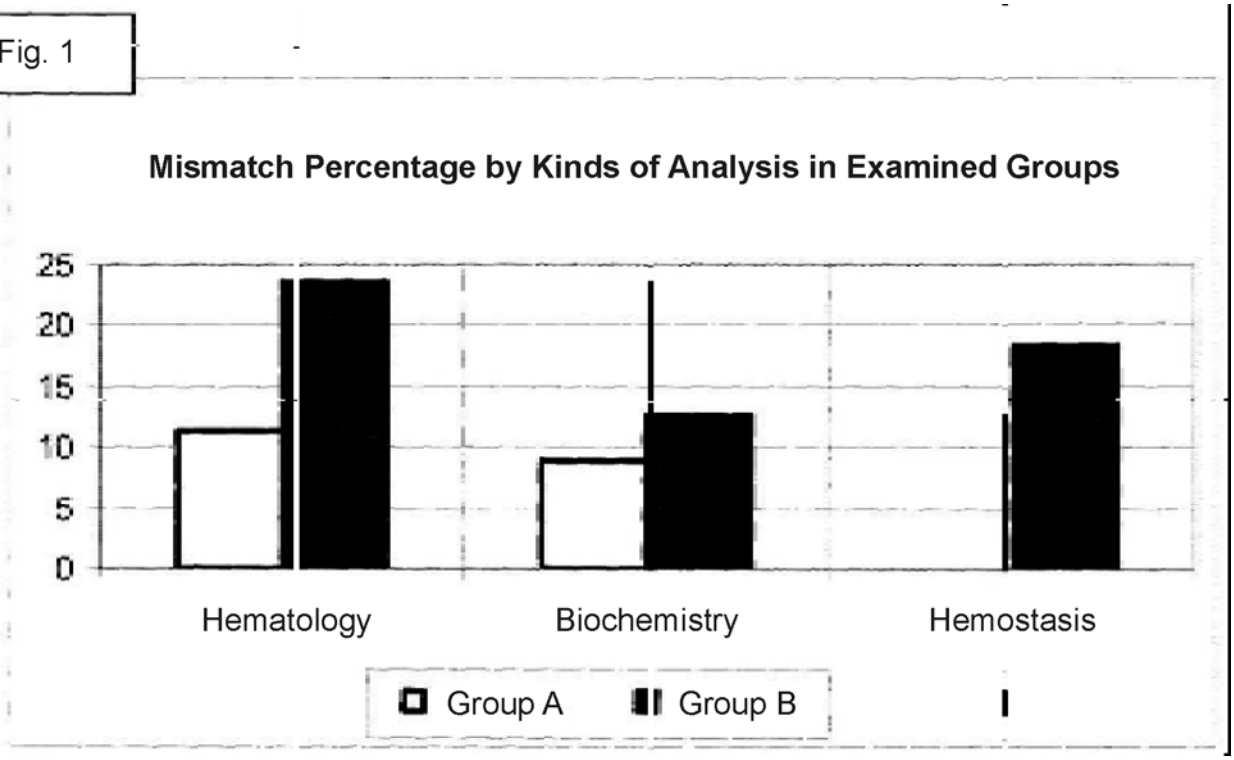
Diagnostic significance of the A2MP Noninvasive Hemogram Analyzer was evaluated by the quantity of analytical data mismatch. Analytical data mismatch meant absence of synchronous dynamics of laboratory indicators under consideration which value was beyond the limits of known reference values for the two analysis means involved: the analyzers available in the Clinicodiagnostic Laboratory and the A2MP Noninvasive Hemogram Analyzer.

Table 1 specifies the analytical mismatch percentage values with respect to the number of corresponding examinations. The number of analytical mismatches within the group of practically healthy people appeared to be smaller than that within the group of sick patients (Fig. 1).

Table 1. Results of Analytical Mismatch of Laboratory Indicators in Test Groups Determined Using Automated Analyzers Available in Clinicodiagnostic Laboratory and A2MP Noninvasive Hemogram Analyzer

Laboratory Indicators	Group A (Healthy), %	Group B (Sick), %
Hematology		
Hemoglobin	8.3	36.7
Erythrocytes	0	33.3
Hematocrit	8.3	23.3
Thrombocytes	8.3	33.3
Leukocytes	16.7	63.3
Stab neutrophils	24.9	27.2
Segmented neutrophils	0	10
Eosinophils	0	0
Lymphocytes	33.3	6.7
Monocytes	8.3	6.7
ESR	16.7	16.7
Biochemistry		
Total bilirubin	0	3.3
Direct bilirubin	0	3.3
Cholesterol	16.7	40
Crude protein	16.7	40
AST	33.3	23.3
ALT	25	30
Amylase	8.3	16.7
Urea	0	16.7
Creatinine	0	20
Glucose	16.7	6.7
Potassium	0	3.3
Sodium	0	0
Calcium	0	0
Hemostasis		
Prothrombin test	0	0
Fibrinogen	0	36.7

Fig. 1



In general, within **the group of healthy people**, 312 examinations produced 29 result mismatches that corresponds to 9.29 %. Assessment of results by kinds of laboratory analysis demonstrated the greatest mismatch percentage in hematology examinations equal to 11.36 %. Biochemical examinations produced an 8.29 % mismatch. Hemostasis system indicators matched completely. As to particular laboratory indicators, the greatest mismatch was detected for leukocytes, lymphocytes, stab neutrophils, enzymes, cholesterol, crude protein, and glucose (Fig. 2, 3).

Within **the group of sick people**, 780 examinations produced 138 analytical mismatches that corresponds to 17.7 %. The greatest number of mismatches equal to 23.6 % was detected for hematological indicators. Table 1 demonstrates the smallest accuracy for such indicators as hemoglobin, erythrocytes, leukocytes (63.3 % mismatches), stab neutrophils. Biochemical indicators produced a 12.6 % mismatch mostly due to mismatch in such indicators as crude protein, cholesterol, enzymes, and fibrinogen (Fig. 2, 3).

Fig. 2

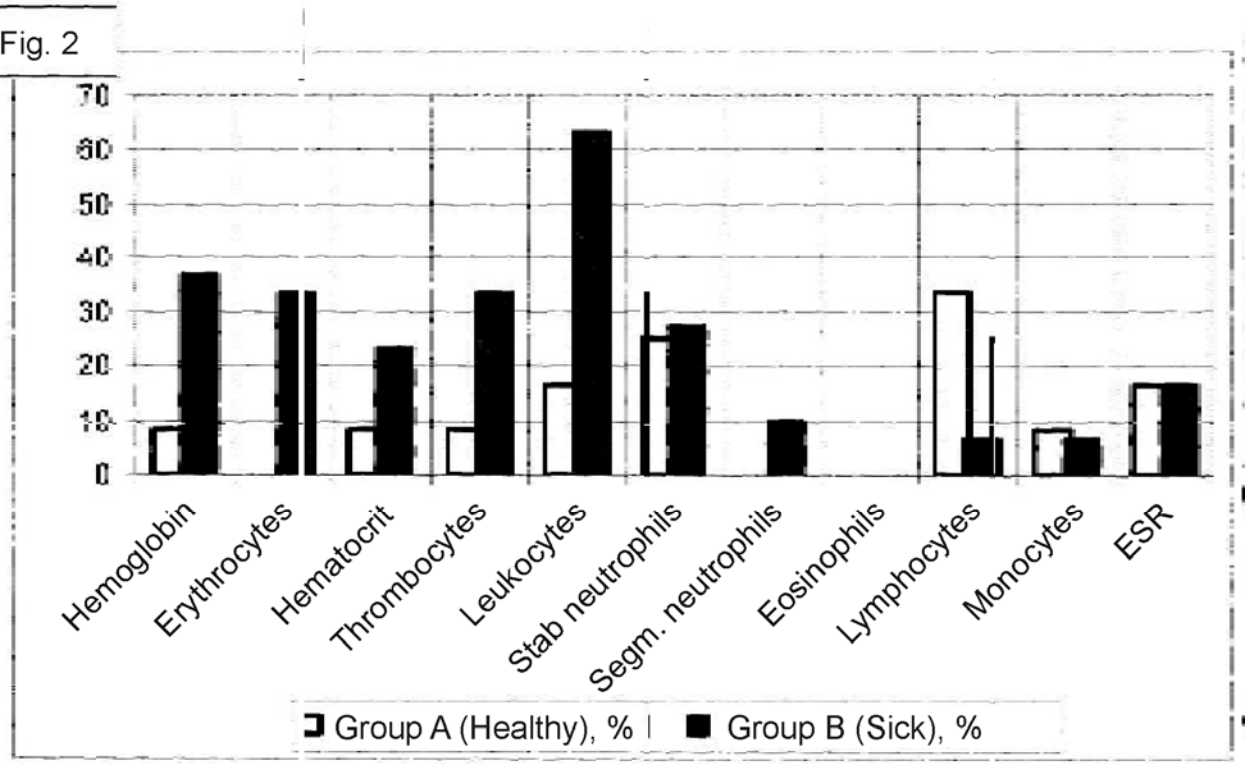
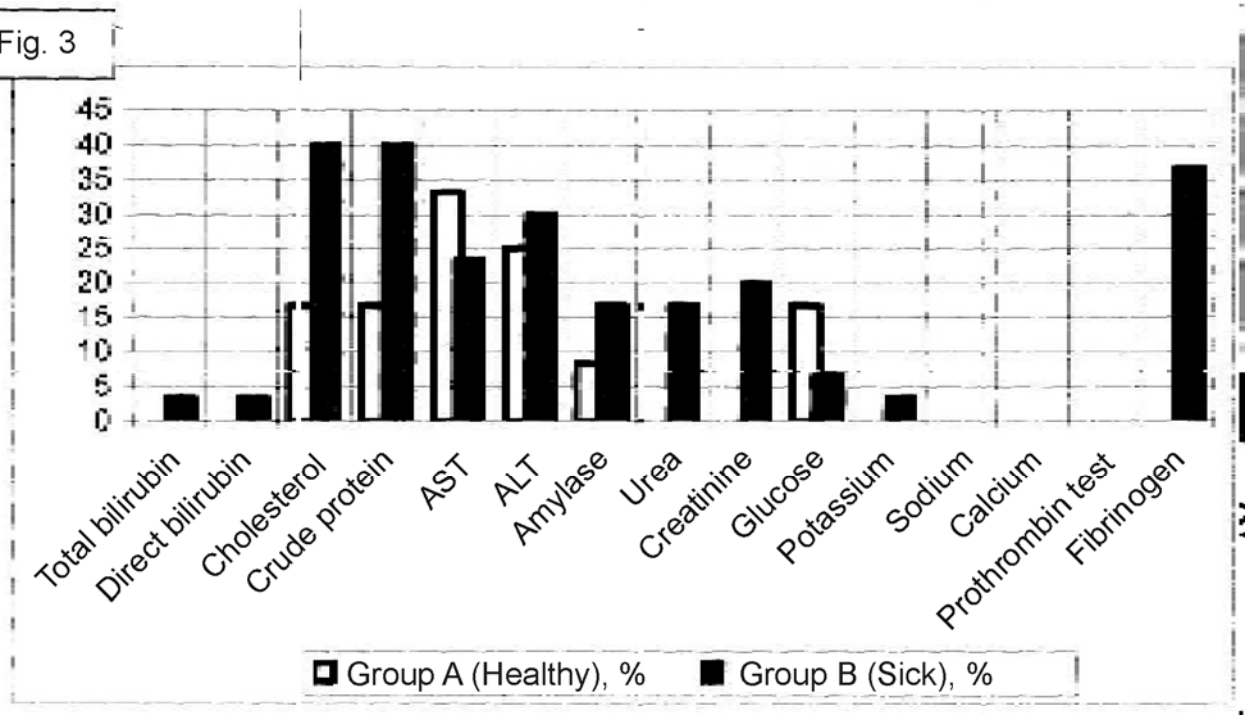


Fig. 3



Supplement 1 hereto contains tables with results of analysis of 26 laboratory indicators within the group of practically healthy people and the group of patients with malignant tumors performed using the analyzers available in the Clinicodiagnostic Laboratory and the A2MP Noninvasive Hemogram Analyzer.

Supplement 2 hereto contains results of examination of healthy people and patients with malignant tumors using the A2MP Noninvasive Hemogram Analyzer with all parameters to be printed out according to the designed program.

CONCLUSION

Activities under Agreement No. 4/07-A2MП dated August 13, 2007 were performed according to the schedule and completed in due time.

The activities involved clinical trial of the A2MP Noninvasive Hemogram Analyzer to determine its suitability for use in medical practice on the territory of the Russian Federation.

For this purpose, 42 practically healthy people (n=12) and patients with malignant tumors (n=30) under treatment at P. A. Gertsen Oncological Research Institute in Moscow were selected for analysis of 26 hematological and biochemical indicators which content in the blood was determined by laboratory methods using automated analyzers and by testing using the A2MP Noninvasive Hemogram Analyzer. 1092 laboratory examinations were performed during the period under consideration. All resulting data were presented in tables in the supplement to the Report of Clinical Trial. The tables also specify quantitative results of examination of all patients using the A2MP Noninvasive Hemogram Analyzer for each laboratory indicator under consideration.

Diagnostic significance of the A2MP Noninvasive Hemogram Analyzer was evaluated by the quantity of analytical data mismatch. Comparative analysis of the results demonstrated mismatches in a number of laboratory indicators in a varying degree. In general, the group of healthy people produced a smaller analytical mismatch (9.26 %) as compared to the group of patients with pathologies in laboratory tests under consideration (17.7 %). Most considerable mismatch was detected within the group of sick people in relation to the content of such indicators as hemoglobin, erythrocytes, leukocytes, crude protein, enzymes, and fibrinogen.

During the trial, some remarks were made that however do not affect the Analyzer operational quality: use of medical adhesive plaster for fastening of temperature transducers, absence of cover for storage and transportation of the instrument. Consideration should be given to fastening of temperature transducers using suction cups or other means.

Thus, the trial results demonstrate that the A2MP Noninvasive Hemogram Analyzer may be used in medical practice for obtaining approximate information about the condition of systems of the human organism.

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