

«Association for mutual help, protection of individual health and the environment - A.M.H.-P.I.H.E.»

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11 january 2021

Dear Mr. Anatolii Pulavskyi, Mr. Artur Lebedynskyi!

Tests and research on the potential of the diagnostic system «Kolibri» (DS «Kolibri») were carried out within the framework of the European project «ONLINE MEDICAL-BIOLOGICAL LABORATORY» over the period 2018-2020.

Clinical test of the diagnostic system «Kolibri».

Scientific staff: MD Auguste Riddley, MD Cyrus Terrani (Lausanne, Switzerland).

The test objective:

1) Analytical reliability of the DS «Kolibri» in the detection and exclusion of non-communicable diseases:

- diseases of the cardiovascular system, in particular chronic heart failure, cardiac arrhythmias, ischemic heart disease, hypertension;
- endocrine diseases, in particular type 1 and type 2 diabetes mellitus;
- diseases of the respiratory system, in particular bronchial asthma, chronic respiratory failure;
- diseases of the gastrointestinal tract, in particular gastric ulcer and duodenal ulcer.

2) the equivalence of the calculated hematological and biochemical blood parameters with the results of laboratory tests.

Results and Conclusions:

1) Analytical reliability of the DS «Kolibri»:

- sensitivity: 73-90%;
- specificity: 91-97%;
- overall accuracy 89-96%.

2) the equivalence of the calculated blood parameters with the results of laboratory tests within the limits of the tolerated error in healthy people and patients with a mild degree of non-infectious disease.

The difference in results between two methods used to test the same value does not exceed 1/3 of the size of the within-individual variation for each analyte.

3) The accuracy of the calculated indicators decreases as the severity of the patient's condition increases and depends on the drugs taken by the patient.

Study of the potential capacities of the DS «Kolibri».

Scientific staff: MD Valery Vinogradov (France).

Subject of study:

- the possibility of using the DS «Kolibri» in the outpatient follow-up of patients with non-communicable diseases;
- Assessment of the feasibility and effectiveness of investments in the project.

Results and conclusions:

1) The possibility of using the DS «Kolibri» in the outpatient follow-up of patients with non-communicable diseases has been proven:

- The increase in the functionality of the DS «Kolibri» is technically possible and justified.
- To solve the problem, it is necessary to change the quantity and composition of the material, develop new analytical programs, modify the structure of the software at all levels.

2) The assessment of the feasibility and effectiveness of investments in the project is positive (Table 1).

Table 1. Criteria and research results.

| Criteria | Results |
|---|--|
| Price trends for this type of service | gradual growth |
| Market trends | growing |
| Number of potential customers | Up to 24% of the population of EU countries |
| Service request | 6.25% of the population of EU countries have a high need for services |
| Competitive service costs | cheaper than functional analogues from 3 to 7 times according to various indicators. |
| Technological efficiency | has advantages over a separate certified diagnostic device. |
| Business scalability | unlimited |
| Human factor dependence | does not depend |
| Profitability of sales of services through net income | 31,2%/year |

Conclusion of the expert commission «A.M.H.-P.I.H.E.»:

- 1) The DS «Kolibri», in its current form, is intended for screening studies. The effectiveness of the DS «Kolibri» system has been clinically confirmed.
- 2) The DS «Kolibri» can be modified for outpatient monitoring of patients with non-communicable diseases.
- 3) The DS «Kolibri» modification project presents an acceptable investment risk.

In view of the above, the management of the «A.M.H.-P.I.H.E.» has decided to finance outpatient and clinical trials to collect the necessary information and build a database.

We look forward to cooperating with you on this new venture.

If you require any further information we shall be happy to let you have this on request.

Yours faithfully



President «A.M.H.-P.I.H.E.» GAFIROV Khalil