EXPERIMENTAL ARTICLES

UDC 616-097.9.578 https://doi.org/10.15407/biotech12.01.058

DIAGNOSTIC CHARACTERISTICS OF THE ELISA TEST FOR THE HEPATITIS B VIRUS SURFACE ANTIGEN DETECTION

E. K. Kiseleva[1]
L. A. Ganova[2]
E. N. Chumak[1]
T. Yu. Trokhymchuk[1]
V. G. Serdyuk[1]
N. Ya. Spivak[1, 2]

[1]PJSC "SPC" Diaproph-Med ", Kyiv, Ukraine

[2]Zabolotny Institute of Microbiology and Virology of the National Academy of Sciences of Ukraine, Kyiv

E-mail: ekiselova26@ukr.net

Received 23.09.2018
Revised 18.12.2018
Accepted 14.01.2019

The aim of the work was to define the diagnostic ability of the enzyme immunoassay test system DIA-HBsAg (PJSC "SPC "Diaprof-Med""), in which the principle of analysis is based on biotin-streptavidin amplification of a specific signal.

The assay performance was studied on WHO Second International Standard for HBsAg, subtype adw2, genotype A (NIBSC code: 00/588) in concentration 0.006 IU/ml; on Capricorn HBsAg standard subtypes ad and ay in concentration 0.006 ng/ml and 0.004 ng/ml respectively. All 14 members of the HBsAg Low Titer Performance Panel PHA 106 (BBI, USA) were detected in DIA-HBsAg with high OD/CO ratio 11.9–40.7.

The DIA-HBsAg sensitivity were similar to the sensitivity of Roche COBAS and Murex HBsAg 3.0 when tested on the HBsAg Mixed Titer Performance Panel PHA 206 (BBI, USA) which consisted of sera with various HBsAg concentrations.

The DIA-HBsAg has correctly detected low reactive members of the HBsAg Verification Panel VHA 601 (BBI, USA) with OD/CO ratio 21.0–40.7 whereas the negative member OD/CO was 0.4.

In the evaluation of 174 cross-reactive serum specimens one false positive result was obtained out of 8 sera reactive for IgM to HSV-1/2. The DIA-HBsAg specificity on 1 177 blood donors` specimens was 99.9%.

Key words: ELISA, diagnostics, hepatitis B, analytical and diagnostic sensitivity, specificity.

Hepatitis B is an infectious liver disease with various clinical manifestations [1]. The infection is characterized by severity, high lethality, chronic forms with the development of cirrhosis and liver carcinoma [2]. The infectious agent is a DNA virus (HBV- hepatitis B virus), which is widely distributed because of its incredible resistance to various physical and chemical factors [3]. The HBV virus has infected approximately 350 million people worldwide, including 1.5 million in Ukraine [4]. Creating new highly sensitive tests for the HBV diagnosis will significantly reduce the spread of the infection.

The surface HBV antigen, HBsAg is a main serological marker in hepatitis diagnostics. Only a small amount of HBsAg takes part in virion formation while the rest persists in the infected organism [5]. In acute hepatitis B, the antigen is found in blood one-two weeks after the infection occurred and disappears one-two months later. If it circulates in the body for more than six months, the illness has become chronic [6, 7]. Since it appears before the clinical symptoms

of the disease and the increase in the activity of aminotransferases, the diagnosis of HBV includes an obligatory blood test for HBsAg [8, 9]. However, most ELISA kits for HBsAg determination can only detect it in concentrations of 0.1–0.05 IU/ml [10, 11]. At lower concentrations of the antigen, for example during early stages of the disease, the analysis can give false negative results before HBsAg is eliminated in the blood or in the cases of concurrent infections.

The aim of our research was to study qualitative parameters of the ELISA kit DIA-HBsAg with sensitivity level of 0.01 IU/ml for the diagnostics of HBsAg HBV. The kit is manufactured by SPC Diaproph-Med (Ukraine).

Materials and Methods

ELISA kits

ELISA kit DIA-HBsAg was constructed as a two-stage sandwich. The immunosorbent and biotinylated conjugate included mouse monoclonal antibodies to various immunodominant HBsAg sites. The specific signal is amplified at the next stage of the reaction, when biotinylated antibodies to HBsAg bind to the streptavidin conjugate labeled with high polymer horseradish peroxidase. To detect the reaction we used mono-component TMB/substrate (3, 3′, 5, 5′-tetramethylbenzidine in citrate buffer with hydrogen peroxide). The reaction was terminated using 0.5 M HCl solution. Analysis of the results is carried out by measuring the optical density of the liquid in the wells in a two-wave mode at 450/620 nm, it's proportional to the HBsAg concentration in the serum/plasma. Immunoassay was performed using thermoshaker according to the Instruction for the DIA-HBsAg kit. Results of ELISA were considered at ratio of optical density (OD) to the cut off value (CO). Serum was considered positive at OD/CO ≥1,0 or negative at OD/CO < 1,0.

To confirm of HBsAg in test sera of the patients with hepatitis B we used ELISA kits — Immunite HBsAg (Diagnostic Products Corporation, USA), ДС-ІФА-HBsAg-0,01 (RPS Diagnostic systems, Russia), Вектоген В-HBs-антиген (RPS Vector-Best, Russia). The assays were carried out according to the instructions for use.

HBsAg standards

Second International standard HBsAg subtype adw2, genotype A (NIBSC, code 00/588) was diluted with blood serum from healthy donors which was previously tested for the absence of HBsAg, to concentrations of 0.02 IU/ml, 0.01 IU/ml, 0.006 IU/ml and 0.004 IU/ml.

Commercial standard ДС-СО-HBsAg (Russia) was diluted by the manufacturer relative to the Second International standard HBsAg (NIBSC) to 20 IU/ml. The antigen was used in concentrations of 0.02 IU/ml, 0.01 IU/ml, 0.006 IU/ml and 0.004 IU/ml.

Standard HBsAg Capricorn, subtypes ad and ay (USA) were diluted by blood serum without HBsAg to concentrations of 0.01 ng/ml, 0.006 ng/ml and 0.004 ng/ml.

Test blood sera

The diagnostic sensitivity of DIA-HBsAg kit was determined using:

– standard serum panel HBsAg Low Titer Performance Panel (Modified) PHA 106 M (BBI), consisting of 15 samples, 14 of which with low concentrations of HBsAg and 1 (sample No. 7) was negative;

– standard serum panel HBsAg Mixed Titer Performance Panel PHA 206 (BBI) including of 25 samples, 23 of which with different HBsAg concentrations and 2 (No.1 and 25) negative;

– standard HBsAg Verification Panel VHA 601 (BBI), in which 5 sera were weakly positive for HBsAg and 1 (sample No.6) was negative;

– 22 blood sera patients with hepatitis B, 8 of which were additionally diluted by blood sera of healthy donors.

The specificity parameter of the test kit was studied using:

– 174 blood sera with cross-reactive components which can lead to false positives in analysis for hepatitis B, including:

30 samples with IgM/IgG to HCV;
32 samples with IgG to HSV1/2;
8 samples with IgM to HSV1/2;
16 samples with IgM/IgG to HSV1/2, IgM/IgG to CMV;
16 samples with IgG to CMV;
24 samples with IgG to CMV, IgG to HSV1/2;
8 samples with IgM to CMV;
8 samples with IgM/IgG to CMV, IgG to HSV1/2;
8 samples with IgM/IgG to CMV;
24 samples from pregnant women,

and 1177 blood sera of nonselective donors.

The test kit specificity was calculated according to the following formula:

$$Specificity = \frac{TN}{TN+FP} \times 100\%, \qquad (1)$$

where TN is the amount of true negative results; FP is the amount of false positive results.

In the tables and pictures the results of typical experiment are presented.

Results and Discussion

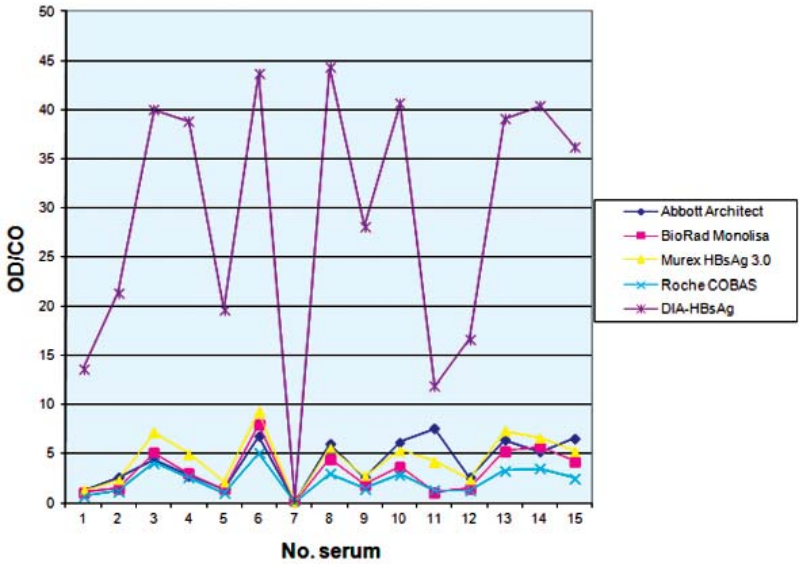
The investigation in the DIA-HBsAg kit different commercial standards of the surface antigen of hepatitis B virus established that it detects Second International standard HBsAg (NIBSC) and Russian standard ДС-СО-HBsAg, diluted by it, in concentration 0.006 IU/ml (Table 1). Test kit was able to detect the standard HBsAg Capricorn subtype ad at 0.006 ng/ml and the subtype ay at 0.004 ng/ml.

To determine diagnostic sensitivity of the DIA-HBsAg kit, we tested samples from serum panel PHA 106 M (BBI) with low concentrations of HBsAg (Figure).

Analysis results in commercial test kits were taken from the passport on the panel. The DIA-HBsAg kit identified all 14 sera with

Table 1. **Performance of DIA-HBsAg kit in tests on various HBsAg standards**

HBsAg standards	HBsAg concentration	ELISA results OD/CO
Second International standard HBsAg (NIBSC, code 00/588)	0.02 IU/ml	3.4
	0.01 IU/ml	1.8
	0.006 IU/ml	1.1
	0.004 IU/ml	0.7
ДС-СО-HBsAg	0.02 IU/ml	3.7
	0.01 IU/ml	1.9
	0.006 IU/ml	1.2
	0.004 IU/ml	0.8
Standard HBsAg Capricorn (USA):		
Subtype ad	0.01 ng/ml	1.7
	0.006 ng/ml	1.0
	0.004 ng/ml	0.7
Subtype ay	0.01 ng/ml	3.0
	0.006 ng/ml	1.9
	0.004 ng/ml	1.2



Comparative analysis results HBsAg Low Titer Performance Panel (Modified) PHA 106 M (BBI) in different ELISA kits ($P < 0.05$)

HBsAg as positive with high OD/CO ratio (11.9–40.7), and the one without HBsAg as negative. The data showed the ability of the DIA-HBsAg kit to identify low concentration of HBsAg to be significantly higher than in test kits comparing leading foreign manufacturers (Abbott Architect, BioRad Monolisa Plus, Murex HBsAg 3.0, Roche COBAS).

Table 2 presents the results for PHA 206 (BBI) serum panel with 25 samples containing various ratios of HBV DNA and HBsAg (23 samples) or negative for HBV (No.1 and 25) according to the panel passport. The data on commercial kits were taken from the panel's passport. The DIA-HBsAg kit revealed the HBV surface antigen in all positive samples not inferior in its diagnostic ability to commercial analogues. A false-negative result was obtained in the analysis of serum No. 22 in the Roche COBAS kit, while Murex HBsAg 3.0 and DIA-HBsAg identified this sample positive with OD/CO ratio of 1.9 and 8.9 respectively.

The qualitative parameters of industrially-manufactured ELISA kits

Table 2. **Results of identification of the antigen in samples of HBsAg Mixed Titer Performance Panel PHA 206 (BBI) using various test systems**

Sample №	Test system			
	HBV DNA PCR Roche Amplicor Monitor	Roche COBAS	Murex HBsAg 3.0	DIA-HBsAg
	results			
	copies/ml	OD/CO		
1	<300	0.1	0.4	0.3
2	$>2\times10^5$	**59.0**	**>max**	**40.9**
3	$>2\times10^5$	**47.4**	**35.9**	**42.5**
4	$>2\times10^5$	**74.5**	>max	42.0
5	$>2\times10^5$	**74.5**	**>max**	**42.3**
6	$>2\times10^5$	**74.5**	**>max**	**41.1**
7	2×10^5	**44.6**	**31.9**	**41.9**
8	1×10^5	**25.3**	26.1	46.4
9	2×10^5	**32.8**	**30.9**	**46.2**
10	4×10^4	**10.8**	**11.5**	**39.5**
11	7×10^4	**9.8**	**11.1**	**38.1**
12	2×10^5	**16.0**	15.3	38.7
13	1×10^5	**10.6**	**13.2**	**40.6**
14	5×10^3	**7.8**	**7.4**	**42.4**
15	5×10^4	**3.6**	**5.6**	**35.6**
16	4×10^3	**4.9**	4.8	36.7
17	<300	**1.2**	**2.0**	**7.4**
18	2×10^4	**2.2**	**3.6**	**43.2**
19	6×10^4	**2.7**	**4.1**	**34.2**
20	2×10^4	**4.6**	5.2	40.0
21	2×10^5	**5.7**	**4.7**	**42.0**
22	<300	0.5	**1.9**	**8.9**
23	5×10^3	**2.1**	**2.3**	**25.6**
24	9×10^2	**1.2**	1.6	16.6
25	<300	0.2	0.5	0.3

Table 3. **Serum panel test results for HBsAg Verification Panel VHA 601 (BBI) using DIA-HBsAg test kit**

№	HBsAg analysis (from the panel passport)	IEA results for DIA-HBsAg kit, OD/CO
1	Weakly positive	45.0
2	Weakly positive	43.5
3	Weakly positive	37.1
4	Weakly positive	35.4
5	Weakly positive	21.0
6	Negative	0.4

designed for diagnostics of various infections are determined using the special commercial verification serum panels. They allow to determine the ability of the ELISA kits to distinguish weakly positive samples from negative ones.

In our study, the diagnostic ability of the DIA-HBsAg kit was tested on the commercial serum verification panel VHA 601 (BBI). The panel included 6 samples of which 5 had low concentration of HBsAg and one was negative for HBV. DIA-HBsAg kit identified the surface antigen of HBV in all weakly positive blood sera with OD/CO 21.0–45.0 (Table 3). Sample No.6, without HBsAg, was identified as negative with OD/CO 0.4.

The high diagnostic capability of DIA-HBsAg for standard serological samples, including the ones with low HBsAg content, was further corroborated by testing clinical material obtained from hepatitis B patients (Table 4). We used 22 blood sera, pre-checked for HBsAg using commercial kits. To lower HBsAg content, 8 samples were diluted with sera of healthy donors after which the HBsAg in them was confirmed again.

In investigating of undiluted sera from hepatitis B patients OD/CO was 35.3–51.2. The value OD/OC barely changed (48.1–39.7) for sample No.1 and secondary samples obtained by its dilution 10 and 1000 times. In the analysis of weakly positive samples obtained after dilution of serum No. 13 in 150–1600 times, the ratio of OD/CO was in the range of 1.2–18.1.

Thus, research of diagnostic sensitivity of the DIA-HBsAg kit on standard serum panels and blood serum samples from patients with hepatitis B patients with different virus surface antigen titers showed the kit's ability to detect HBsAg in low concentrations common for the early stages of the disease.

The diagnostic specificity of the DIA-HBsAg kit was tested on 1177 sera of nonselective donors. The ability of the test kit to correctly analyze sera without HBsAg but with various cross-reactive reagents that can cause false positive results was established by testing the sera with specific antibodies to HCV, HSV1/2, CMV, and sera of blood of pregnant women (Table 5).

One sample was determined positive when investigated in DIA-HBsAg 1177 sera from nonselective donors from various units of the Ukrainian Blood Service. At the same time, ДС-ІФА-HBsAg-0,01 and Вектоген В-HBs-антиген identified it as negative. The kit's specificity, calculated according to formula 1, was 99.9%.

In the investigating of 174 sera with potential cross-reactivity in DIA-HBsAg kit was obtained single false positive result for 1 serum out of 8 studied with antibodies of class M to the herpes simplex virus. The specificity parameter in thise experiment was 99.4%.

Therefore, the DIA-HBsAg kit for detecting the main serological marker of hepatitis B — HBsAg, which appears early in the acute stage and persists in the chronic form, has a sufficiently high analytical and diagnostic ability. The ELISA kit employs amplificatory method of boosting a specific signal combined with high-polymer enzyme label. This construction allows to detect low HBsAg concentration - International standard HBsAg (NIBSC) in concentration 0.006 IU/ml, standard HBsAg Capricorn subtypes ad and ay in concentration 0.006 ng/ml and 0.004 ng/ml, respectively. Comparative research showed that DIA-HBsAg kit was able to detect small HBsAg concentrations more reliably than its leading foreign analogues produced by Abbott Architect, BioRad Monolisa Plus,

Table 4. **Results of testing DIA-HBsAg kit against blood sera of hepatitis B patients with varying HBsAg content**

№	Serum (and dilution)	Test kit	IEA results in the DIA-HBsAg kit (OD/CO)
1	1	Immulite HBsAg	48.1
2	1 (1/10)		47.3
3	1 (1/100)		47.5
4	1 (1/1000)		39.7
5	2		45.2
6	3		48.5
7	4		46.0
8	5		45.5
9	6		47.6
10	7		43.4
11	8		35.3
12	9		37.8
13	10	ДС-ІФА-HBsAg-0,01	48.7
14	11		39.1
15	12		48.2
16	13	Вектореп В-HBs-антиген, ДС-ИФА-HBsAg	38.3
17	13 (1/150)		18.1
18	13 (1/200)		12.7
19	13 (1/400)		3.9
20	13 (1/800)		1.9
21	13 (1/1600)		1.2
22	14		51.2

Table 5. **Specificity values for DIA-HBsAg kit obtained analyzing sera with interferent components from nonselective donors**

Samples	Number of samples	Number of positive results	Number of negative results	Specificity
Interfering components in blood sera:				99.4%
IgM/IgG to HCV	30	0	30	
IgG to HSV1/2	32	0	32	
IgM to HSV1/2	8	1	7	
IgM/ IgG to HSV1/2 IgM/IgG to CMV	16	0	16	
IgG to CMV	16	0	16	
IgG to CMV IgG to HSV1/2	24	0	24	
IgM to CMV	8	0	8	
IgM/ IgG to CMV IgG to HSV1/2	8	0	8	
IgM/ IgG to CMV	8	0	8	
Pregnant women's blood sera	24	0	24	
Total:	174	1	173	
Nonselective donors' blood sera	1177	1	1176	99.9%

Murex HBsAg 3.0, Roche COBAS. The high diagnostic ability of the kit was confirmed also by the results obtained for hepatitis B patients. The kit correctly distinguishes weakly positive sera of from negative ones. Testing 1177 sera of nonselective donors established the DIA-HBsAg kit specificity to be 99.9%. The qualitative parameters of the kit allow it to be widely used in specific diagnostics of hepatitis B and to detect both early and chronic stages of the disease, making donated blood safer.

REFERENCES

1. *Petruzziello A.* Epidemiology of hepatitis B virus (HBV) and hepatitis C virus (HCV) related hepatocellular carcinoma. *Open Virol. J.* 2018, 28 (12), 26–32.
2. Gepatit B. http://www.who.int/ru/news-room/fact-sheets//hepatitis-b (In Russian).
3. *Gong D. Y., Chen E. Q., Huang F. J., Leng X. H., Cheng X., Tang H.* Role and functional domain of hepatitis B virus X protein in regulating HBV transcription and replication in vitro and in vivo. *Viruses.* 2013, 5 (5), 1261–1271. https://doi.org/10.3390/v5051261
4. Global hepatitis report 2017. http://www.who.int/hepatitis/publications/global-hepatitis-report.2017/en/.
5. *Hirzel C., Pfister S., Gorgievski-Hrisoho M., Wandeler G., Zuercher S.* Performance of HBsAg point-of-care tests for detection of diagnostic escape-variants in clinical samples. *J. Clin. Virol.* 2015, 33 (5). https://doi.org/101016/j.jcv.201505.024
6. *Li M., Xi H., Wang Q., Hou F., Huo N., Zhang X., Li F., Xu X.* Kinetics of serum HBsAg in Chinese patients with chronic HBV infection with long-term adefovir dipivoxil treatment. *Chin. Med. J.* 2014, 127 (11), 2101–2104.
7. *Stasi S., Silvestri C., Berni R., Brunetto M.R., Zignego A.L., Orsini C., Milani S., Ricciardi L., De Luca A., Blanc P., Nencioni C., Aquilini D., Bartoloni A., Bresci G., Marchi S., Filipponi F., Colombatto P., Forte P., Galli A., Luchi S., Chigiotti S., Nerli A., Corti G., Sacco R., Carrai P., Ricchiuti A., Giusti M., Almi P., Cozzi A., Carloppi S., Laffi G., Voller F., Cipriani F.* Clinical epidemiology of chronic viral hepatitis B: A Tuscany real-word large-scale cohort study. *World J. Hepatol.* 2018, 10 (5), 409–416. https://doi.org/10.4254/wjh.v10.i5.409
8. *Shil N., Rahman A., Sultana N., Yasmin F.* Markers of hepatitis viruses by ELISA among healthy blood donors. *Mymensingh. Med. J.* 2015, 24 (4), 776–779.
9. Hepatitis B and C Testing Guide, World Health Organization, 2017. http://apps.who.int//iris/ bitstream/ handle/10665/260130/9789244549988-rus.pdf. (In Russian).
10. *Hon J., Ren J., Song L., Zhao F., Liang P.* Analytical performance of three diagnostic reagents for HBsAg on an automatic ELISA analyzer. *J. Clin. Lab. Anal.* 2018, 32 (1). https://doi.org/10.1002/jcla.22159.
11. *Mostovich L. A., Bezuglova L. V., Jaroslavceva O. A., Faranosova O. N., Netesova I. G.* HBsAg serovariants and the evolution of tests to identify it. http://www.fadlab.ru/.../mostovich-la-serovarianty-hbsag-22-okt-2015-khmao.pd. (In Russian).

ДІАГНОСТИЧНА ХАРАКТЕРИСТИКА ELISA ТЕСТ-СИСТЕМИ ДЛЯ ВИЗНАЧЕННЯ ПОВЕРХНЕВОГО АНТИГЕНУ ВІРУСУ ГЕПАТИТУ В

О. К. Киселькова[1], *Л. А. Ганова*[2], *О. М. Чумак*[1], *Т. Ю. Трохимчук*[1], *В. Г. Сердюк*[1], *М. Я. Співак*[1, 2]

[1]ПрАТ «НВК «Діапроф-Мед»», Київ, Україна
[2]Інститут мікробіології і вірусології ім. Д. К. Заболотного НАН України, Київ

E-mail: ekiselova26@ukr.net

Метою роботи було визначити діагностичну здатність імуноензимної тест-системи DIA-HBsAg (НВК «Діапроф-Мед»), в якій принцип аналізу засновано на біотинстрептавідиновій ампліфікації специфічного сигналу. Діагностикум виявляє 2-й Міжнародний стандарт HBsAg, субтип adw2, генотип A (NIBSC, code: 00/588) в концентрації 0,006 МО/мл, стандарт HBsAg Capricorn субтипу ad та ay (USA) — 0,006 нг/мл і 0,004 нг/мл відповідно.

Під час дослідження панелі сироваток РНА 106 M (BBI), 14 зразків якої містять низькі концентрації HBsAg, тест-система виявила його у всіх позитивних сироватках з високим співвідношенням ОГ/cut off —11,9–40,7.

За результатами аналізу панелі сироваток РНА 206 (BBI) з різними концентраціями HBsAg діагностична здатність тест-системи не поступалася її закордонним аналогам — Roche COBAS і Murex HBsAg 3.0.

Діагностикум коректно розділяв слабопозитивні зразки верифікаційної панелі VHA 601 (BBI) — ОГ/cut off 21,0–40,7 від негативного (ОГ/cut off — 0,4).

У процесі дослідження 174 сироваток крові з кросреактивними компонентами на гепатит В отримано один хибнопозитивний результат під час аналізу 1 зразка з 8 досліджених, які містили IgM до HSV1/2. Специфічність тест-системи за результатами аналізу 1177 донорів становила 99,9%.

Ключові слова: імуноензивна тест-система, діагностика, гепатит В, аналітична і діагностична чутливість, специфічність.

ДИАГНОСТИЧЕСКАЯ ХАРАКТЕРИСТИКА ELISA ТЕСТ-СИСТЕМЫ ДЛЯ ОПРЕДЕЛЕНИЯ ПОВЕРХНОСТНОГО АНТИГЕНА ВИРУСА ГЕПАТИТА В

Е. К. Киселева[1], *Л. А. Ганова*[2], *Е. Н. Чумак*[1], *Т. Ю. Трохимчук*[1], *В. Г. Сердюк*[1], *Н. Я. Спивак*[1, 2]

[1]ЧАО «НПК «Диапроф-Мед»», Киев, Украина
[2]Институт микробиологии и вирусологии им. Д. К. Заболотного НАН Украины, Киев

E-mail: ekiselova26@ukr.net

Целью работы было определение диагностической способности иммуноэнзимной тест-системы DIA-HBsAg (НПК «Диапроф-Мед»), в которой принцип анализа основан на биотинстрептавидиновой амплификации специфического сигнала. Диагностикум выявляет 2-й Международный стандарт HBsAg, субтип adw2, генотип A (NIBSC, code: 00/588) в концентрации 0,006 МЕ/мл, стандарт HBsAg Capricorn (USA) субтипы ad и ay — 0,006 нг/мл и 0,004 нг/мл соответственно.

При исследовании панели сывороток РНА 106 M (BBI), 14 образцов которой содержат низкие концентрации HBsAg, тест-система выявила его во всех положительных сыворотках с высоким соотношением ОП/cut off — 11,9–40,7.

По результатам анализа панели сывороток РНА 206 (BBI) с различными концентрациями HBsAg диагностическая способность тест-системы не уступала ее зарубежным аналогам — Roche COBAS и Murex HBsAg 3.0.

Диагностикум корректно разделял слабоположительные образцы верификационной панели VHA 601 (BBI) — ОП/cut off 21,0–40,7 от отрицательного (ОП/cut off — 0,4).

При исследовании 174 сывороток крови с кросс-реактивными компонентами на гепатит В получен один ложноположительный результат при анализе 1 образца из 8 исследованных, которые содержали IgM к HSV1/2. Специфичность тест-системы по результатам анализа 1177 доноров составила 99,9%.

Ключевые слова: иммуноэнзимная тест-система, диагностика, гепатит В, аналитическая и диагностическая чувствительность, специфичность.